U.S. FOOD & DRUG ADMINISTRATION

Investigations Operations Manual 2024



Office of Regulatory Affairs
Office of Operations

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Investigations Operations Manual 2024



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Foreword 2024

We are excited to bring you the 2024 *Investigations Operations Manual* (IOM). The IOM is the primary operational reference for FDA employees who perform field investigational activities in support of the agency's public health mission. Accordingly, it directs the conduct of all fundamental field investigational activities. Adherence to this manual is paramount to assure quality, consistency, and efficiency in field operations.

Other FDA manuals and field instruction supplement, but do not supersede, the information in this manual. We recognize this manual will not address all situations encountered in the performance of field activities. In such cases, your management must be informed and concur with any significant departures from the IOM.

The 2024 version of the IOM contains important changes which clarify or present new information and procedures. As with each new edition of the IOM, please take time to review sections of the manual for changes which may apply to your work. Additions to the IOM are highlighted in light gray.

The IOM is also posted on ORA's Internet Website https://www.fda.gov/inspections-compliance-enforcementand-criminal-investigations/inspection-references/investigations-operations-manual, with all graphics included.

In 2023, the IOM Refresh Project continued its cover to cover, all-inclusive review of the IOM to ensure the manual presents information in a clear and useful manner for field and operational staff. Elizabeth Miller, Dan Solis, and I, as the Executive Sponsors for the IOM Refresh Project, are particularly proud of the effort and engagements of the team to implement these most recent updates. The 2024 IOM includes the update to two of the IOM's core chapters: Chapter 5 – Inspections and Chapter 6 – Imports. Chapter 5 was reorganized to provide a General Section that is applicable to all programs and program specific sections, including a section on combination products. Chapter 6 is better organized and now contains all information related to imports for exports and inspections of food importers from the Foreign Supplier Verification Program.

The IOM is published in hard copy annually, though updates to the IOM will continue to be performed periodically during the year to the online version. The online IOM version serves as ORA's official document of record.

ORA leadership is committed to continuously improving the quality and usefulness of the IOM. Suggestions for the 2025 edition of the IOM including recommended changes, deletions, and additions to the IOM may be sent via e-mail to IOM@FDA.HHS.GOV. Suggestions are accepted from within the agency, our state and local partners, industry, and consumers. All changes are reviewed by the IOM Committee, which is composed of a cross-functional group consisting of representatives from each commodity area in addition to imports, recalls, and policy.

As the professionals across ORA continue to advance our mission every day, I am reminded how grateful I am to be a part of this dedicated and incredibly talented group of people. As we look forward to the potential of a new field organization, we can further focus our expert capabilities on the core frontline operations that protect public health - Inspections, Investigations, and Imports.

Thank you for your continued exceptional work and commitment to protecting and promoting the health and well-being of the American people. It is an honor serving with you.



Michael C. Rogers, MS
Associate Commissioner for Regulatory Affairs
U.S. Food and Drug Administration, Office of Regulatory Affairs

NOTE: This manual is reference material for investigators and other FDA personnel. The document does not bind FDA and does not confer any rights, privileges, benefits or immunities for or on any person(s).

Vision

Public health is protected, promoted, and advanced.

Mission

Protect consumers/patients and enhance public health by ensuring timely access to safe, quality FDA-regulated products.

Ultimate Outcome

Protect consumers and patients from injury or illness from FDA-regulated products while ensuring timely access to safe and quality products.

Core Values

ORA's core values define the organization's "character" and inform its actions and decisions.

Accountability
Commitment to Public Health
Communication
Inclusion, Diversity, Equity, and Accessibility
Integrity and Respect
Quality

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Note: *Certain links in this chapter are only available to FDA employees via the FDA Intranet site and cannot be accessed by individuals outside the FDA internal network. Requests for information can be made through the Freedom of Information Act (FOIA) process described in IOM Section 8.1.3.*

S.1 - Purpose

The purpose of this chapter is to give you the basic knowledge and skills to anticipate, recognize, evaluate, and apply control strategies to eliminate or minimize hazardous conditions and unsafe practices encountered during field investigations and inspections.

A *hazard* is defined as any source of, or the potential for, injury, damage, harm, adverse health effects, or death. Hazards include any substance, material, activity, or process that has the potential to cause harm or injury.

Workplace hazards are classified into various categories. Hazard categories addressed in this chapter include traumatic injury, biological/chemical/ergonomic/physical agents, and radiation.

Due to the unlimited variability of potential safety situations, it is not feasible to describe in the Investigations Operations Manual (IOM) what to do in each and every instance. The decision of what to do in each individual circumstance rests with you and your program/division management.

Personal Safety will not be discussed in detail in this chapter. The Personal Safety section below will currently continue to reference IOM Chap 5.3.1.1 until further notice.

S.2 - Unacceptable Risk

Most environments in which ORA conducts investigations or inspections contain identifiable risks. This chapter discusses many hazards found in regulated industries and describes approaches to protect ORA employees by reducing risks to acceptable levels. However, special consideration must be given when unacceptable risks are present. This section is intended as a framework to help investigators and their supervisors decide whether it is too unsafe to continue an investigation. It is critical to focus on plausible risks to investigators' wellbeing, and not to base these decisions entirely on regulations or definitions.

First and foremost: If you suspect that conditions in your work environment may harm you, take immediate and reasonable steps to avoid those conditions. If the decision may impact completion of your assignment, let your supervisor know right away.

While it is not possible to cover every possible situation in a single guidance document, some situations that should always be considered as unacceptable risks include:

- If you doubt your ability to perform an activity safely, e.g., walking on a layer of ice.
- If you feel there is a reasonable chance of a non-trivial injury or illness, e.g., close proximity to unguarded machinery, or exposure to an infectious disease.
- If you suspect that you might be exposed to a hazardous chemical above an established occupational exposure limit such as an OSHA Permissible Exposure Limit (PEL).

"Reasonable" steps will depend on the situation. While it would certainly be reasonable to avoid using an unstable flight of stairs, it probably would not be reasonable to end the investigation and leave the

premises because of them. Encountering pervasive hazards throughout a firm, or a single hazard with life-threatening implications (e.g., plausible risk of a serious chemical release or an explosion), would likely make leaving the premises a reasonable step. If in doubt, move to a safe location and contact your supervisor for guidance.

Take a similar approach to situations or conditions that make it difficult to complete your assignment but might not present a plausible risk of injury. Some investigations may occur in environments that are hard to tolerate due to physical discomfort, irritating materials, or similar conditions. If you follow the advice in this chapter for dealing with factors like temperature extremes or eye irritants, and still have difficulty tolerating the environment, move to a better location and contact your supervisor.

ORA's Office of Safety is available for consultation. Investigators and their supervisors can reach out to their supporting Industrial Hygienists or the Office of Safety leadership team.

S.2.1 - C.O.V.E.R. (Control, Observe, Vary, Exit, Report)

A tool that you can use to maintain safety awareness generally, and in instances where a safety or health hazard puts you at unreasonable risk of death or serious injury or illness, is to remember the mnemonic C.O.V.E.R.: Control, Observe, Vary, Exit, and Report.

S.2.1.1 - Control

First, psychologically and physically CONTROL your environment as much as possible.

- Maintain awareness of your surroundings as you perform inspectional activities. Always remain cognizant or conscious, of what is going on around you.
- Exhibit and maintain a professional attitude, driven by the reason that you are there, with a specific mission or task to accomplish.
- Carry yourself in a confident and professional manner--one that commands respect and cooperation.

S.2.1.2 - Observe

Carefully OBSERVE the environment and those within it during inspectional activities.

- Assess the exterior and interior environmental factors to identify potential hazards and/or dangers, and to locate escape routes and exit points.
- Consider behaviors of firm employees, such as threats, aggressiveness, awkward behaviors, and movements, etc.
- Look closely for weapons, anything that someone could potentially use as a weapon, or other physical hazards that may present safety concerns.

S.2.1.3 - Vary

VARY your tactics, techniques, or approaches based on what you know, observe, and experience. Review the firm's establishment inspection file and pay special attention to anything that causes you to be concerned about your safety (including such examples as a questionable geographic location, or noted questionable/suspicious firm behaviors, animals, etc.). Note existing personal safety flags in the firm file. Adjust your approach as warranted.

S.2.1.4 - Exit

Have an EXIT strategy in mind before you enter the establishment. Locate escape routes and exit points ideally before, or as you enter, the establishment.

S.2.1.5 - Report

REPORT the status and progress of your interviews, inspections, and other contacts.

- Tell your supervisor about any problems, threats, and safety concerns immediately.
- Generate a Personal Safety Alert (PSA) when warranted.

S.3 - Personal Safety

Personal safety entails protecting the physical and mental safety, health, and welfare of FDA employees. It also involves active engagement on your part and a general recognition and avoidance of possible harmful situations, or persons, in your surroundings. Basically, personal safety allows you to conduct or support field activities in a safe and effective manner. ORA managers should ensure that their employees have the resources and training they need to conduct their work safely, ***and*** that their employees keep abreast of and follow safety procedures.

First and foremost, if during inspectional activities, you determine there is the possibility of a threat to your personal safety or if you are assaulted (either physically, or put in fear by threats of physical/verbal violence), you should:

- Immediately disengage.
- Exit the premises.
- Get to safety.
- Contact the police as necessary.
- Get medical attention if needed.
- Call your supervisor.

ORA considers the safety of all staff who meet with regulated industry to be of utmost importance. Personal safety concerns can be further defined as those risk factors and circumstances that you should be aware of which constitute a possible threat or compromise to your safety while conducting an inspection. These include, but are not limited to:

- Situations in which another party initiates an assault (including both physical and verbal assaults) upon you or your colleagues; displays force (including the show or use of weapons, aggressive animals, or other similar tactics); or otherwise communicates resistance towards you or the work you are engaged in.
- Firms with a known or suspected history of potential violence, either agency-documented (via an inspection report, memo, PSA/flag, or other resource) or suspected (via reports from media, other federal agencies, law enforcement, neighbors, etc.).
- Situations of heightened security or vulnerability due to political, social, and economic factors or unrest, etc.
- Work assignments that involve Office of Criminal Investigations (OCI) and/or other federal agencies, as they tend to constitute more complex, potentially multi-jurisdictional activities.
- Firms associated with suspected illegal/criminal activities, tampering incidents, or any other suspicious activities, occurring both on-- and off-site.
- Work assignments that warrant visits to any private or remotely located residences.
- PSA-flagged firms or firms associated with prior personal safety plans.

- Work sites located in questionable or potentially unsafe surroundings (remote areas and/or high crime areas, etc.).
- Situations in which specific personal protective safety equipment is warranted.
- Situations in which a particular inspection may be medically contraindicated for some FDA personnel.

When these and similar conditions are noted prior to inspectional activities, you should discuss the situation with your supervisor. When these conditions are encountered without prior knowledge during inspectional activities, follow IOM sections S.2 and S.3 of this chapter to immediately mitigate any hazards and then notify your management as soon as you are able.

If the inspectional activity is deemed a personal safety risk, your supervisor can assist in assembling a team to create a Personal Safety Plan (PSP) prior to performing the assigned work**. The PSP should be cleared and approved prior to the start of any inspectional activities.** See IOM Chapter 5 for Personal Safety Plan information.

If a PSP is established, your supervisor will contact the local police/law enforcement to notify them of the situation and the potential hazards, as well as to brief them on the approval or resolution of the PSP. Your supervisor can also request assistance from the Federal Protective Service (1-877-437-7411) or contact OCI headquarters for additional assistance (301-294-4030). While OCI does not normally provide physical security in such cases, they will assist in threat evaluation based on specific facts provided and available criminal databases. OCI can also make contacts, on your behalf, with local police and federal agencies, based on their previous established liaisons (United States Marshals, Federal Bureau of Investigation (FBI), etc.).

Tips to maximize your personal safety:

- Prepare for your inspectional activities with safety in mind and attempt to anticipate any issues.
- Formulate an exit/backup plan.
- Don’t make yourself vulnerable by being distracted, disorganized, or inattentive/negligent.
- Move with confidence, focus, intention, purpose, and assertiveness.
- Pay attention to your surroundings and the people around you.
- Trust yourself and your instincts and avoid anything, anyone, or any situation that does not feel safe.
- Immediately report suspicious activity to your supervisor.

S.3.1 - Uniform Use

Uniform use, particularly by FDA Imports and PHS, has been a long-standing issue regarding personal safety. There are times when uniforms can potentially contribute to the perception of FDA as a threat and may create more volatile situations, especially during activities with certain commodities (tobacco, produce, raw milk….) or types of inspections (license revocations, outbreaks, injunctions…).

Uniformed, and therefore identified, regulatory personnel could possibly become targets while performing their duties. If you determine that there might be a personal safety hazard to wear your uniform in certain locations, situations or during specific activities, consult with your management immediately. Be sure to provide facts and details to support your concern(s).

Refer to IOM 5.3.1.1 - Personal Safety for additional personal safety concerns and information.

S.3.2 - Personal Safety Alerts (PSA)

During your review of eNSpect/Field Management Services (FMS), you should determine if any personal safety concerns exist. Prior to the start of your inspection, previously noted concerns will be flagged in the Firm field within eNSpect/FMS. Online Search and Retrieval System (OSAR) also prompts you to check the firm's files for a PSA Memo, which, if in existence, provides an explanation of why a firm was flagged. PSA Memos are filed on the left-hand side of the establishment file jacket and printed in eye-catching color so to be easily recognized. If the PSA indicates a firm has any documented associations with, or history of, personal safety threats, you should discuss these details with your supervisor and evaluate whether a PSP is warranted, prior to the start of the inspection.

Refer to this chapter, Field Alert 16 and IOM Chapter 5 if you encounter any personal safety issues—including, a threat to your personal safety, a need for specific Personal Protective Equipment (PPE), or circumstances posing medical contraindication risks (for example, staff with penicillin allergy potentially exposed to penicillin). First and foremost, take immediate steps to mitigate any hazards or threats. Once you are safe, including being potentially moved to another location, and after discussion with management, you should check the PSA flag field box associated with the firm in eNSpect/FMS so as to alert other investigators of the experienced threats to safety.

In eNSpect, the person creating an assignment can add PSA information on the Firm page by checking the flag box and utilizing the additional text box. This field is editable any time after the assignment has been created. This PSA tab will be selected when a firm, or inspection site, is affiliated with a potential hazard, including any of the following:

- A history of physical, verbal, or other types of threats or assaults; or other forms of physical resistance.
- A need for specific PPE, including respirators.
- The presence of medical risks, including those affecting specific investigator populations, such as women of child-bearing years who may be exposed to drugs known to be potentially hazardous to them; or individuals with allergies to peanuts, penicillin, or other products who may incidentally encounter those products or ingredients on site as part of their work.

When a personal safety concern is encountered, a PSA should be documented in the Endorsement text and in a Memo to the File. The Memo should be titled "Memo To File - Personal Safety Alert" and includes factual information to support the alert. Such details will also serve as critical background information for colleagues and future investigators who will also be consulting eNSpect for safety issues. As with other evidence, ensure the memo is factual when documenting PSA details, as it could later be used for legal purposes/proceedings and may result in a court case.

In addition, the Memo should:

- Be filed in the official establishment file jacket, with copies sent to all resident posts and import program divisions who may interact with the relevant firm.
- Be filed on the opposite side of the folder from all other documents and printed on eye-catching colored paper to be noticeably visible to the next investigator.
- Be retained and maintained at the program division office.

- Be sent to orahqcsosafety@fda.hhs.gov.

The supervisor and/or other program division management will be responsible for evaluating the need for any corrective actions to be taken by the firm, or individual, to remove or stop the potentially dangerous situation, circumstance, or condition. Follow-up inspections at the facility should continue to document the status of the ongoing safety situation, including its cessation. If the safety situation ceases or is resolved (by new management, dismissal of an employee, or removal of penicillin in a facility, etc.), the PSA should then be end dated as per IOM S.3.1.1.3 from eNSpect/FMS with required explanation.

To view PSA details in eNSpect:

1. Select “New Assignment”, then.
2. Select “Firm”.
3. Enter the applicable FDA Establishment Identifier (FEI) and click “Look Up.” If a PSA exists and is active, it will be indicated to the right of the firm’s name.
4. Select the “Details” button to display PSA details, and
5. select “View/Update” to display the reason, or basis, for the PSA.

Additionally, an internal Online Reporting Analysis Decision Support System (ORADSS) report, FIR055 Personal Safety Alert for a Firm by Home District (located in ORADSS under the Firms report folder), provides comprehensive, sortable information on PSAs (any relevant threats, PPE specifications, etc.) associated with PSA-flagged firms, including information on alert type, reason for the alert, and other remarks. This report should be used prior to field activities to prepare for personal safety situations. The report is searchable by FEI, district, state, country, and/or program area.

Refer to IOM Section 5.2 and 5.3.1.1 for more information about the PSA.

S.3.2.1 - Steps to creating a PSA

Detailed instructions with examples on how to create and edit PSAs can be found in the current eNSpect user manual at eNSpect Help References. When first accessing a firm page, the active PSA will appear as ‘No’ by default when no FEI is present. Once the FEI is added, you will see an option to add or edit the PSA. After operation creation, PSAs are editable.

S.3.3 - Personal Safety Training

S.3.3.1 - MP118 *Interviewing Skills and Personal Safety Reports*

Geared towards new FDA investigators and analysts, this instructor-led course provides participants the ability to successfully plan an on-site regulatory inspection while maintaining personal safety.

S.3.3.2 - MP8001S: ORA Personal Safety and Inspections Refresher 8 Part Training Series

This course chronicles the history of how ORA became involved in providing meaningful, interactive training to keep our Investigators and Analysts safer during inspections. This multi video series course describes the difficulties faced by Investigators and analysts during inspections and identifies tools that can be used to gain additional knowledge about firms prior to inspection that could help keep staff safer. How to create a Personal Safety plan is defined during this video series and necessary elements required in the plan are explained in detail. Also provided are basic evasive

tactics to use if necessary to escape from a physical altercation. Though open to all FDA, the target audience is ORA employees who conduct inspections, those who supervise inspectional employees, Compliance Officers, DCBs, DIBs and HQ staff involved in approval process of Personal Safety Plans or scheduling of ORA inspections. This training applies to all commodities and program areas.

S.4 - Employer/Employee Safety Responsibilities

Safety in all ORA work environments is foundational to our public health mission. The OSH Act requires employers to comply with hazard-specific safety and health standards. In addition, pursuant to Section 5(a)(1) of the OSH Act, employers shall provide their employees with a workplace free from recognized hazards likely to cause death or serious physical harm.

Safety is the responsibility of FDA employees, supervisors, and management. The agency will not allow employees or supervisors to disregard established or otherwise reasonable safety precautions and thereby place themselves, and/or their fellow employees, and/or the agency's facilities, at risk.

The FDA strives to provide a safe, healthy, and injury-free work environment for employees and promote a positive safety culture in which all employees value safety and behave in ways that prioritize their own safety, as well as the safety of their colleagues, and others around them.

You have a responsibility for your own safety and an obligation to observe established health and safety rules and precautions as a measure of protection for yourself and others. You will not engage in willful misconduct that causes or will likely cause the FDA to be in violation of any rule, regulation, order, permit, or license issued by a regulatory authority.

You are required to become familiar with and observe health- and safety-related policies, procedures, and guidelines. If provided with safety equipment, PPE, or any other devices and procedures necessary for your protection, you will use such equipment and procedures as directed. Respirator use should include consultation with your supervisor, in conjunction with the ORA Safety Office.

While performing assigned work, be alert to the presence of potentially unsafe or unhealthy conditions. When such conditions are observed, it is your right and responsibility to report them. Determine if these conditions warrant disclosure to OSHA. In the case of imminent danger situations, after first ensuring your own safety, alert your management immediately. In such situations, you should C.O.V.E.R. when you have a reasonable belief that, under the circumstances, the task or area poses an imminent danger.

S.4.1 - Safety Incident Reporting

The Office of Laboratory Safety (OLS) and the ORS Safety Workplace Incident Reporting site require the reporting of all work-related incidents, injuries, near misses, and property damage through the portal for Occupational Safety and Health (pOSH+). (A near miss is defined as an event in which no property is damaged, and no personal injury or exposure sustained, but where—given a slight shift in time or position—damage, injury, and/or exposure could have easily occurred. An example: A workplace shelf collapses and narrowly misses striking an employee.) The process of reporting any workplace incidents in the pOSH+ ensures incident investigation, mitigation, and corrective actions are completed with the intent to prevent future occurrences.

ORA employees can use the portal to directly submit workplace incident reports to their supervisor and the ORA safety team for further investigation. Incident reporting in pOSH+ can be done through use of a desktop icon or from any FDA mobile device. Incidents of property damage, without employee injury, may only require reporting through pOSH+. Your supervisor will automatically be notified via pOSH+ email. Your supervisor will then visit pOSH+ to review your submission before the incident is investigated by your Center/Office Occupational Safety and Health Officer (OSHO). If you visit an FDA Occupational Health Clinic as a result of an incident, the clinician will submit the report on your behalf to your Center/Office OSHO and you will not need to enter a report via pOSH+.

Additional incident reporting may also be required through the Employees' Compensation Operations and Management Portal (ECOMP). The support Industrial Hygienist (IH) for your program or division is available to provide support and additional information for incident reporting. Users can report these four types of safety-related incidents/events:

- *Injury, Illness, or Potential Exposure*, which is defined as an occupational event resulting in bodily injury (for example, due to a slip, trip, or fall), illness, or a potential exposure (for example, of chemical, biological, or radiological origin) to an individual.
- *Property Damage*, which is defined as an unplanned, undesired event that resulted in FDA property damage *without* perceived injury or exposure.
- *Near Miss*, which is defined as an event wherein no property was damaged, and no personal injury sustained, but where—given a slight shift in time or position—damage and/or injury could have easily occurred, as defined by OSHA.
- *Event of Concern*, which is defined as a safety concern or non-compliance event.

OLS has developed a SharePoint page for implementation of pOSH+ that includes frequently asked questions, resources, and training videos to assist employees, supervisors, and safety personnel in reporting and investigating workplace incidents. Information submitted through this portal will assist the FDA in the development of recommendations and corrective actions to improve safety.

Reference the following resources for incident reporting:

- ORA "Quick Steps" Employee's Guide to Incident Reporting (Exhibit S-1)
- ORA "Quick Steps" Supervisor's Guide to Incident Reporting (Exhibit S-2)

In addition, be alert to any problems associated with defective or misused equipment, or supplies, and their possible impacts on yourself and others. Contact your supervisor and/or the headquarters contacts listed in the applicable compliance program as necessary for assessment. The home division of the manufacturer should be notified of firm product misuse, so it may be brought to the manufacturer's attention for consideration of precautionary labeling or redesign of the product. Your pOSH+ report should fully document these problems, to include the hazard and/or defect observed, and whether or not user actions could be a contributing factor. Documentation should present sufficient data, such as photos and diagrams, to supplement a narrative describing the situation, as well as the collection of samples if applicable.

S.5 - Following Firm Safety Requirements

You should always follow any applicable and appropriate safety requirements set by firm, unless otherwise instructed by your supervisor or management (for instance, employee concerns or pre-

existing safety issues). A firm's safety requirements should also not hinder your ability to perform your duties. If you should experience doubt, confusion, or concerns regarding any safety requirement, seek clarification from the firm if possible. If you still have concerns, contact the FDA ORA Safety Program.

When conducting activities in facilities requiring the use of PPE, the following guidance should be provided by the firm's management:

- Information about the specific hazards present - including symptoms of exposure that may be encountered.
- Information regarding the potential levels and/or concentrations of stated hazards present.

The firm's management should be able to provide you with documentation showing how hazards were determined, what the expected exposures are, and how they relate to the OSHA Permissible Exposure Limit (PEL). Such documentation should also offer information about the PPE that will protect you against a hazardous exposure. If you have any doubts about the hazards or doubts about the effectiveness of the equipment recommended or provided to protect against them, **do not** enter these areas. The Safety Liaison for your program or division, or the ORA Safety Office, will be able to help you evaluate the information provided to you and will furnish information regarding the hazard, as well as the recommended PPE.

If you do not have the specific PPE recommended by the firm's management, request the needed equipment from your division. In some cases, the firm may be willing to provide the necessary PPE; however, if respiratory protection is required, you should comply with ORA's Respiratory Protection Program. You should *only* use respirators provided by FDA, unless your Division's IH, or the National Safety Office, has approved the use of other devices. *It is ultimately your responsibility to ensure that you do not expose yourself to any hazard.*

S.6 – Safety Risk Assessment Frameworks

ORA's Safety Office uses a risk-based approach to assessing, classifying, and mitigating occupational hazards, relying on risk assessments to help determine if procedures and/or protective measures are adequate.

Using, ORA Safety staff can apply a basic procedure for risk-based criteria and make a risk assessment.

Contact the ORA Safety program for any hazard questions, concerns, or classifications guidance. Note that when consulting with ORA's Safety Office for assistance with occupational hazards encountered, you may be asked to supply information that will be used to perform a risk assessment so that you can receive the most appropriate guidance on how to proceed.

S.7 - Additional Safety Information

S.7.1 - FDA/ORA Safety Programs

S.7.1.1 - FDA ORA Safety Program

The ORA Safety Office develops safety policy, training, and information for all ORA employees. ORA industrial hygienists work with ORA programs at all levels to develop the best possible safety guidance. Site topics include dangerous goods, hazard assessments, hazard communication

resources, hazardous waste management, radiation/laser safety, respiratory protection resources, safety training, safety labels, and workplace incident reporting.

S.7.1.1.1 - Industrial Hygiene (IH) Contact List

The ORA Safety Office, part of the Office of Regulatory Science (ORS), has a staff of IHs stationed at most of ORA's laboratories. The IHs serve as points of contact and subject matter experts for safety issues throughout ORA. Each IH covers one or more districts and provides safety support to all ORA staff located within their assigned districts' geographic boundaries. Many IHs also provide focused support to one or more ORA programs.

S.7.1.1.2 - ORA Safety Office FAQs

Frequently asked questions addressed by the ORA Safety Office cover topics including, general safety, employee protection, radiation safety, opioid sampling and analysis, laboratory environmental management, shipping of dangerous goods, and shipping of hand sanitizer.

S.7.1.1.3 - ORS Safety Hazard Assessments Grab & Go's

Grab and Go documents are Hazard Assessment documents, organized by program, that provide essential safety information for ORA field investigators and lab analysts. They provide one-page overviews of safety requirements for specific tasks. Investigators and analysts should review the documents relevant to their tasks to ensure awareness of safety requirements.
Each document includes:

- An overview of hazards.
- Required personal protective equipment.
- Respirator guidance.
- Training requirements.
- Other relevant topics, e.g., radiation safety or medical surveillance requirements.

S.7.1.1.4 - Office of Security and Emergency Management (OSEM)

OSEM protects FDA's personnel, facilities, and information from threats and ensures that FDA is prepared to manage emergencies and incidents, including those involving FDA-regulated products.

S.7.1.2 - Occupational Safety and Health (OSH) Program

The OSH Program strives to improve occupational safety and health through training, communication, and the implementation of initiatives that will achieve measurable results. This site offers the following resources, including, but not limited to:

- Hazard exposure self-assessment tools.
- Safety training.
- Safety and health information.
- Safety manuals.
- Preparedness resources.

S.7.2 - Emergency Response/Incident Command

You may be assigned to perform activities in which an Incident Command Structure (ICS) has been implemented. These situations may involve hazards posing a threat to human health and/or the environment. Examples of incidents that would be expected to have an active ICS structure include disease/illness outbreaks, special or national security events, chemical spills/hazardous waste sites, and natural disaster situations.

The Incident Management Team (IMT) will be responsible for tactical operations, to include performing investigations/inspections, collecting samples, and/or detaining or destroying contaminated product, and executing any other safety related functions in accordance with the Incident Action Plan (IAP) and safety plans, if appropriate.

If you are involved in a situation operating under an ICS, IMT or Incident Management Group (IMG), your reporting structure exists through that command staff; you shall follow the ICS management guidance or guidance provided by the ICS/IMT/IMG.

There is always the potential that unprotected personnel will not be permitted into hazardous zones for safety reasons. If the event has sufficient safety concerns to warrant a safety officer, safety consultations will be made in conjunction with that individual, through the ICS/IMT/IMG structure. If no safety officer is assigned, safety consultations will be conducted with your IH contacts, in conjunction with the ICS/IMT/IMG structure.

Also reference IOM 8.1.5.8 for information on FDA investigations in the aftermath of disasters.

S.7.2.1 - Office of Emergency Management (OEM)

The Office of Emergency Management (OEM) serves as the FDA focal point for coordinating emergency response activities involving FDA-regulated products. The office coordinates intra-agency and inter-agency activities related to crisis management and emergency preparedness and response, including the planning, conduct, and evaluation of emergency scenario tabletop/simulation exercises. OEM develops, manages, and coordinates incident management plans, policies, and programs for the FDA to ensure that an agency structure exists to respond rapidly and effectively to all hazards. OEM provides strategic direction and oversight of the FDA's adoption of the National Incident Management System (NIMS), including all aspects of the development of plans, procedures, and training programs in support of the ICS.

S.7.2.2 - Office of Emergency Operations (OEO)

The Office of Emergency Operations (OEO) serves as the FDA's central emergency coordination point with FDA headquarters, centers, and field offices. The OEO leads the following activities:

- Provides interagency coordination and response to adverse events, foodborne illnesses, injuries, product tampering, and man-made and natural disasters.
- Assists in the development of emergency operations plans and incident-specific annexes, and the design, implementation, and presentation of associated training and exercise programs.
- Represents the agency at federal, state, local, and foreign government meetings and workgroups on emergency preparedness and response.
- Provides a nationwide, 24-hour, seven-days-a-week emergency response system.
- Monitors Consumer Complaints on a National level, looking at what is received by ORA, Centers, and external sources.

S.7.2.3 - Additional Emergency-related Sites

- Coordinated Outbreak Response and Evaluation (CORE)
  Through CORE, the FDA combines expertise in medicine, public health, and science to coordinate its efforts to find, stop, and prevent foodborne illness outbreaks.

- ORA Emergency Response Coordinator (ERC) Site
  ERCs are dedicated to emergency response activities, exercises, training, and collaborations with federal, state, and local partners. ERCs are active in emergency response activities, engaged in all facets of emergency preparedness and response, and provide enhanced response capabilities for FDA/ORA. ERCs train and support the implementation of the ICS filling vital Command positions at HQ and in the field. ERCs provide support to State Rapid Response Teams (RRTs), as well as CORE.
- Continuity of Operations Plan (COOP)
  Continuity of Operations (COOP) is the initiative that ensures federal government departments and agencies can continue operations of their essential functions under a broad range of circumstances, including all-hazard emergencies, as well as natural, man-made, and technological threats, and national security emergencies.
- FEMA Preparedness (Ready.gov)
  Ready is a national public service campaign designed to educate and empower the American people to prepare for, respond to, and mitigate emergencies, including natural and man-made disasters. The goal of the campaign is to promote preparedness through public involvement.
- OSPOP's Emergency Preparedness Collaboration Site
  The purpose of the OSPOP Emergency Preparedness Collaboration site is to provide a platform where the FDA can share information about emergency preparedness and associated topics.

S.7.3 - Occupational Safety and Health Administration (OSHA)

With the Occupational Safety and Health Act of 1970, Congress created the Occupational Safety and Health Administration (OSHA) to ensure safe and healthful working conditions for workers by setting and enforcing standards, and by providing training, outreach, education, and assistance.

S.7.3.1 - OSHA Memorandum of Understanding (MOU)

FDA maintains a domestic MOU with OSHA to facilitate information sharing with respect to matters affecting the occupational safety and health of workers, and the safety and security of our nation's food supply in facilities where food is produced, processed, or held. The pertinent substance of MOU 225-11-0007 is that the FDA and OSHA will share relevant information with each other. If FDA and/or OSHA, in their investigations of facilities where food is produced, processed, or held, has reason to believe that a potential violation of an FDA/OSHA standard is present, the agency noting the potential violation(s) will provide this information to the other agency. This may include observations made directly by agency personnel, information provided to OSHA by a state participating in the OSHA State Plan program, as well as information received from other parties, including workers.

S.7.3.2 - OSHA Severe Violator Enforcement Program (SVEP)

Additionally, while the vast majority of employers want to protect their employees, there are others who continue to expose workers to very serious dangers even after receiving citations for hazards causing serious injuries, illnesses, and deaths. On June 18, 2010, OSHA instituted the SVEP to more effectively focus enforcement efforts on recalcitrant employers who demonstrate indifference to the health and safety of their employees through willful, repeated, or failure-to-abate violations of

the OSH Act. You have the option, prior to going on an inspection, to review the OSHA-maintained and publicly available SVEP Log detailing the names, locations, and citations of employers in the program. The link to the document can also be found on the OSHA Enforcement page in the Policy and Guidance section. OSHA updates the log at the beginning of every quarter.

S.7.4 - Other Safety Agencies

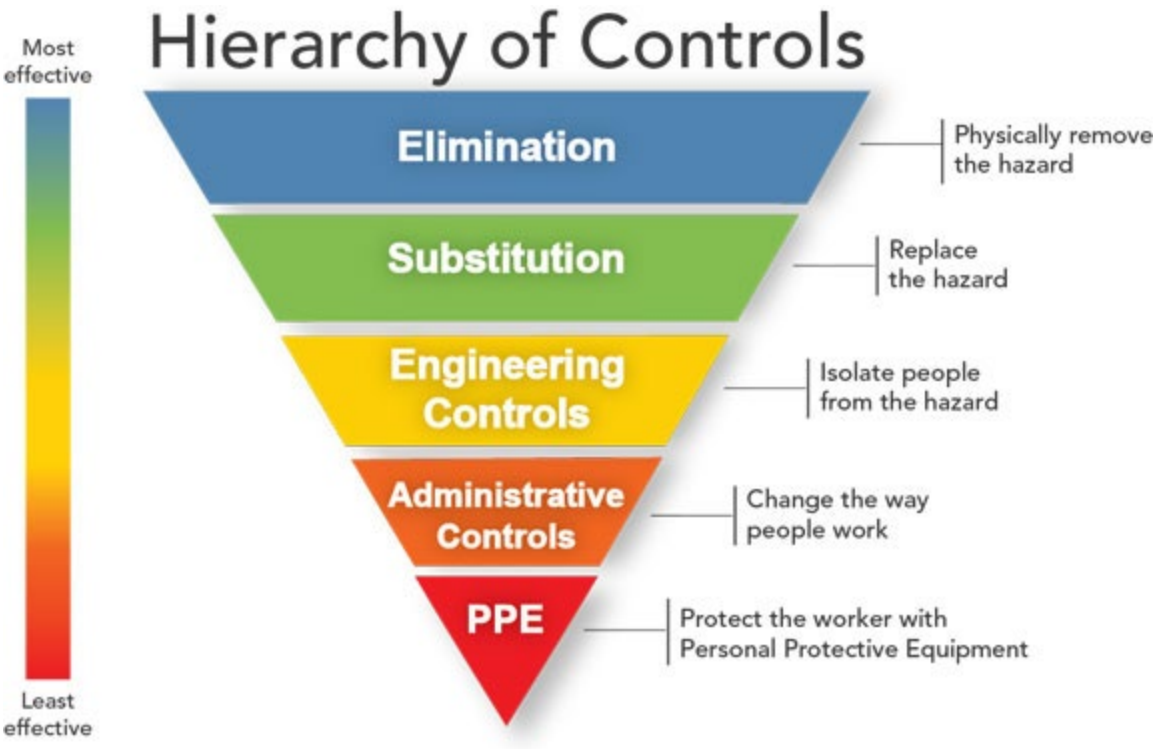
After first checking with ORA's Safety program, you can consult the following federal agencies for additional sources of workplace safety information:

- U.S. Environmental Protection Agency (EPA)
- Occupational Safety and Health Administration (OSHA)
  - All OSHA Publications
  - OSHA Fact Sheets
- The National Institute for Occupational Safety and Health (NIOSH)
  NIOSH is part of the U.S. Centers for Disease Control and Prevention, in the U.S. Department of Health and Human Services. NIOSH is a research agency focused on the study of worker safety and health and developing new knowledge in the field of occupational safety and health.
  - NIOSH Fact Sheets and Publications
  - NIOSH Emergency Response Safety and Health Database
  - NIOSH Workplace Safety and Health Topics
  - NIOSH Pocket Guide to Chemical Hazards
  - NIOSH Pocket Guide to Chemical Hazards Mobile Application

S.8 - Hierarchy of Controls

Although most investigations are conducted at sites FDA does not control, you are still able to take positive steps to mitigate hazards to which you might be exposed. The following information is provided to help you recognize effective mitigation options, and to approach occupational hazards using the same frameworks as the ORA Office of Safety's Industrial Hygienists (IHs).

The Hierarchy of Controls model ranks hazard control strategies from most to least effective in preventing injuries and illnesses. Although you typically will not be able to implement higher level controls such as eliminating hazardous machinery or reformulating products to remove hazardous chemicals, the overall philosophy can be helpful for comparing your feasible options. For example, requesting that the firm restrain an aggressive farm dog behind a barrier (an engineering control) will be more effective than trying to remain aware of the dog's activities, and observing a hazardous chemical process from a safe location (another engineering control) will be more effective than wearing PPE while standing close to the process.



The idea behind this hierarchy is that the control methods at the top of graphic are consistently more effective and protective than those at the bottom. Control methods are as follows:

- Elimination and Substitution are usually limited to the design phase of a facility or process. Although you won't be able to apply these to a firm's facility, they are relevant to hazards of supplies and equipment you use during investigations. For example, a box cutter may be substituted for a pocketknife when opening packaged materials.
- Engineering controls either create a physical barrier between you and the hazard, or they physically remove a hazard before it can affect you. Classic examples are guards over pinch points on machinery, or exhaust ventilation to remove hazardous gases and vapors before they mix with the room air. Although you won't be able to implement these at an investigation site in most cases, it's important to recognize any existing engineering controls that are in use and not to interfere with their operation.
- Administrative controls are an approach to limiting chemical exposure by reducing the length of time you are exposed, rather than reducing the amount of the chemical you are exposed to. Administrative controls rely on mathematical calculations of the total exposure and should not be relied on without concurrence from the ORA Office of Safety.
- Work Practice controls (not shown in the graphic above) are changes you make to the way you work, such as maintaining awareness of nearby hazards or attempting to use safe lifting practices. These are the least effective means of mitigating hazards, as the hazardous conditions are still present, and you are depending on your own vigilance for protection.
- PPE is an essential part of the overall investigation safety practices, but it should be viewed as a last line of defense in case higher-level controls are not completely effective.

S.8.1 – General Protective and Preventive Measures

Generally, the level of protection utilized during the inspection should be appropriate to the level of risk of exposure, and based on factors, such as, type of hazard present, potential exposure, the processes in which the hazards are being manipulated, and the potential outcome (injury) from exposure to the hazard. If exposure to hazards is a concern, or you feel at risk, exit to a safe area. Then contact your supervisor, or ORA Safety Office personnel, for additional guidance before proceeding any further.

General protective and preventive measures and guidance includes:

1. Determine if the firm has established safety precautions and procedures and follow them if adequate.
2. If there are signs of tampering or counterfeiting with the product being examined or inspected, consult your IH contact and your supervisor for any additional safety precautions needed. Based on the situation, protection could consist of work gloves worn over surgical gloves, full face respirator with appropriate cartridges, disposable coveralls, and work boots. If the situation changes, evolves, or escalates, exit and report to your supervisor.
3. As much as possible, do not touch. This means equipment, materials, reagents, animals, etc.
4. Wear protective clothing. Evaluate the needs for gowns, caps, masks, gloves, and shoe coverings, etc. and wear them where necessary. Protective clothing worn in a work area where a virus or spore-bearing microorganism is handled should not be worn into a work area for another product. As much as possible and with firm consent, leave all *used* protective clothing at the firm for proper disposal. Otherwise, consult with your IH and be prepared to transport the used PPE yourself.
5. Wash hands thoroughly after leaving each work area.
6. If the firm is processing viruses or other potentially infectious biological agents during the inspection, determine if it is advisable to enter the work areas. Chances of infection through aerosols are reduced when there is no active processing.
7. Vaccines are available for your protection against some organisms (e.g., *Rubella*). For information on inoculations and physical examinations, refer to FDA Occupational Health Services (OHS).

S.9 - PPE

PPE is protective clothing and equipment designed to reduce exposure to hazards and/or harm caused by hazards, prior to an exposure. You should identify and evaluate all hazards prior to selecting PPE. Ensure you have the proper training to use the needed PPE, and that the PPE is rated to protect you against the identified hazards.

Ideally, the primary means of protection from workplace hazards include avoiding hazards, remaining behind a barrier, or relying on engineering systems (such as exhaust ventilation) to physically separate from the hazard. However, due to the nature of ORA's investigative activities and the industries we regulate, there may be situations in which physical separation from hazards is not possible. In those situations, PPE is used as a barrier between you and the hazard. Numerous types of PPE are available, depending on work conditions and the part of the body that might be susceptible to a hazard. It is advisable to remember that a hazard is still present when relying on PPE for protection; the PPE provides a margin of safety from it.

Prior to any potentially hazardous situation, consult with your Industrial Hygienist (IH) Contact(s) if you are unsure as to the necessity for and/or adequacy of PPE. If you encounter situations in which you are not sure about the effectiveness of PPE, contact your supervisor and consult with your IH for guidance. If in any doubt about your safety, leave the area until all your concerns have been resolved. Also see Personal Protective Equipment - Overview OSHA and Personal Protective Equipment – OSHA.

Another aspect of safety/PPE is what clothing you wear during an inspection. Safety considerations, weather, type of work, hazards of the work, and many other factors will have an impact on what type of clothing is optimal for each situation you encounter. In addition to specific, situation-appropriate PPE, general clothing considerations/guidance are as follows:

- Be aware of drawstrings (for example, on hooded sweatshirts), ties, scarves, and other hanging, potentially entangling components of clothing and shoes (for example, shoelaces), as they can get caught up in rotating parts and on objects/equipment.
- Be aware of jewelry. Loose, protruding, or dangling jewelry poses safety risks when working around moving parts and machinery. As a note, OSHA prohibits conductive jewelry around live current since it can lead to an arc flash or blast, severe burns, the ignition of clothing, or electrocution. Metal jewelry also poses risks when in proximity to chemicals and has the potential to cause reactions. As jewelry can also harbor bacteria that cause food-borne illness, it is generally not recommended in food-handling facilities.
- Tie back long hair and use hairnets/hats to prevent entanglement. OSHA states that hair shall be "securely fastened" into a knot or bun without protruding pieces.
- Do not carry notebooks, credentials, pens, etc., in the outer pockets of your inspectional uniform because they could fall into equipment.
- Glasses, keys, and ID badges dangling from cords or chains can be hazardous; instead, use breakaway safety cords or lanyards.
- Wear clothing that fully covers the body, including arms and legs.
- Wear shoes that cover the entire foot, provide a stable platform, and have rubber or similar slip-resistant soles. Also, wear socks that cover the ankle.

S.9.1 - Eye and Face

Eye and face protection consists of safety glasses, face shields, and other specialized protective equipment. Safety glasses should be worn in environments where projective hazards exist, such as near grinding machinery. Face shields should be worn in environments where splash hazards to the eyes or face exist, such as near corrosive chemical dipping tanks. Specialized eye and face protection may be needed when working near processes involving electrical arcs and other sources of radiation. Consult with your supervisor and/or your IH Contact(s) if you encounter these situations. When selecting and purchasing general eye and face protection, ensure they meet American National Standards Institute ANSI/ISEA Z87.1-2020: Current Standard for Safety Glasses for impact resistance. For specialized eye and face protection needs and questions, consult with your IH Contact(s).

S.9.2 - Head

Head protection consists of hardhats and other specialized headwear. Hardhats should be worn in areas with overhead hazards, and specialized hardhats should be worn in areas where overhead hazards may present an electrical hazard. Specialized headwear may be needed when working in extreme

temperatures (hot or cold) or in situations where side impacts to the head are likely. Consult with your supervisor and/or IH Contact(s) if you encounter these situations. When selecting and purchasing hardhats, ensure they meet ANSI Z89.1 - Industrial Head Protection, Standard for Industrial Head Protection. ANSI Z89.1 - Industrial Head Protection, Standard for Industrial Head Protection. For specialized head protection needs and questions, consult with your IH Contact(s).

S.9.3 - Foot

Foot protection consists of crush-resistant boots/shoes, chemical-resistant boots/shoes, and other specialized foot coverings. Crush-resistant boots/shoes should be worn in environments where crushing hazards may impact the feet, such as in warehouses. Chemical-resistant boots/shoes should be worn in environments where hazardous chemicals may encounter the feet or lower legs. Specialized foot coverings maybe needed when working in extreme temperatures, in deep mud or snow. Consult with your supervisor and/or your local IH Contact(s) if you encounter these situations. When selecting and purchasing crush-resistant boots/shoes, ensure they meet ASTM International standard 2413-18. When selecting and purchasing chemical-resistant boots/shoes, ensure that they are compatible for use in protecting against the specific chemicals of concern in the environment. For specialized foot protection needs and questions, consult with your local IH Contact(s).

S.9.4 - General Body

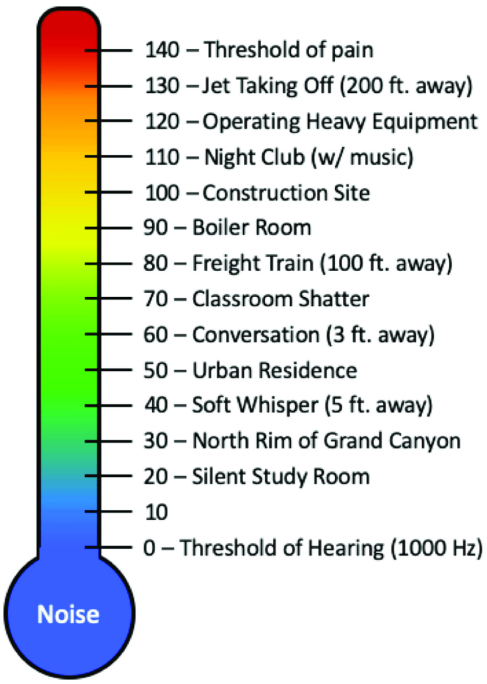
Body protection consists of protective clothing and suits. Protective clothing and suits should fit properly and provide protection against the hazard. An example of protective clothing is the use of cold weather clothing while working inside a freezer. Consult with your local IH liaison when selecting and purchasing protective clothing and suits needed to protect against hazards, which include but are not limited to, chemicals, fire, electricity, and other specific hazards. The protective clothing should fit you and be appropriate for the environmental conditions in which you are working. Note that protective clothing can be hazardous to the wearer if improperly fitted and/or not appropriate to the working or environmental conditions.

S.9.5 - Hands

Hand protection consists mainly of gloves. Gloves should fit properly and provide protection against the hazard. An example is the use of chemically compatible gloves when handling chemicals. When selecting and purchasing gloves, ensure they meet ANSI/ISEA 105-2016 standards for protection against cuts, punctures, abrasion, chemicals, heat, and/or vibration as applicable. Use appropriate gloves to avoid slivers and/or splinters when handling rough wooden cases or similar items. Use protective gloves when handling hot or cold items. Examples in which hand protection` would be warranted include working around steam pipes, or when handling frozen products or working in freezers. Use the appropriate, protective gloves when handling lead ingots containing radioactive materials to avoid hand contamination. If you are handling solvents, wear gloves that are impermeable to the solvent. Consult with your supervisor and/or your IH Contact(s) if you encounter situations in which you are unsure about which gloves to select for the task, or are unsure if the gloves made available to you provide adequate protection.

S.9.6 - Hearing

Hearing protection devices consist of ear plugs and/or earmuffs. Hearing protection should be used when ambient noise exceeds 85 decibels (dB), or when impulse noise (for example, a hammer strike) exceeds 140 dB. Noise levels are typically above 85 dB when face-to-face communication becomes difficult without shouting, and above 140 dB, when it is approximately as loud as a gunshot or explosive firework.



Noise Exposure Limits

	NIOSH	OSHA
Exposure Time	*dB SPL*	*dB SPL*
8 hrs	85	85
4 hrs	88	90
2 hrs	91	95
1 hr	94	100
30 min	97	105
15 min	100	110
7.5 min	103	115
3.75 min	106	120
> 2 min	109	-
> 1 min	111	-

NIOSH The National Institute for Occupational Safety and Health
OSHA Occupational Safety and Health Administration
dB SPL Decibel sound pressure level

When selecting and purchasing hearing protection devices, ensure they are EPA-rated and will reduce noise exposure to below 85 dB.

The NIOSH Sound Level Meter App is one tool available to the public to download on mobile iOS devices that measures sound levels and provides noise exposure parameters to help reduce occupational, noise-induced hearing loss.

Consult with your IH Contact(s) if you are unsure if hearing protection provided to you is adequate.

S.9.7 - Respiratory

Refer to the ORA Respiratory Protection Program (RPP) (SOP-000449).

The purpose of the RPP is to establish uniform responsibilities and procedures in accordance with OSHA Respiratory Protection Standard (29 CFR 1910.134) and FDA's Respirator Protection Plan for the appropriate selection, use, and care of respiratory protection equipment issued to ORA employees. ORA employees frequently perform work at worksites that are not under the control of FDA and may be exposed to physical, chemical, biological, and radiological inhalation hazards. When elimination, substitution or engineering controls are not feasible for protection against inhalation hazards, ORA employees will use administrative controls to limit the duration of exposure. Respirators will be used in conjunction with administrative controls to minimize exposure.

The ORA RPP addresses topics such as contacts, training, hazard assessment, respirator selection and respirator procurement.

Note that, per OSHA, respiratory hazards can exist in various forms: They may be gases, vapors, dusts, mists, fumes, smoke, sprays, and fog. Some of these substances can cause illness and/or death if inhaled. Certain respiratory hazards act quickly, like carbon monoxide - an invisible, odorless gas - which can make you unconscious or kill you within minutes. Other respiratory hazards can take years to make you sick, like asbestos, which can cause lung cancer years, or even decades, after you've breathed it in. More examples of respiratory hazards include, but are not limited to:

- Dusts, such as those found when adding dry ingredients to a mixture.
- Metal fumes, from welding, cutting, and smelting of metals.
- Solvent vapors, from spray coatings, adhesives, paints, strippers, and cleaning solvents.
- Infectious agents, such as tuberculosis bacteria in healthcare settings.
- Chemical hazards, such as chlorine gas and anhydrous ammonia in chemical processing and use operations.
- Sensitizing vapors or dusts, such as isocyanates, certain epoxies, and beryllium.
- Oxygen deficiency, which might be found in confined spaces.
- Pharmaceuticals during the production of prescription drugs.

The following sources, sites, and situations have been identified as having the potential for respiratory hazards:

- Feed, drug, and tobacco plants.
- Fumigation or storage facilities where treated grain or produce is encountered--including trucks, vessels, railroad cars, and fumigation chambers.
- Facilities using ozone (or where ozone is produced as a byproduct of the manufacturing operation), methyl bromide, phosphine, or sulfuryl fluoride.
- Facilities where sterilizers utilize ethylene oxide gas (EO).
- Grain elevators or other grain storage facilities, which may present asphyxiation hazards, toxic decomposition gases, or pathological toxins such as aflatoxin.
- Spice grinders and repackers that potentially produce airborne respiratory irritants such as pepper.
- Any rodent-infested areas.
- Poultry houses, which generate exposure to particulates, chemicals, and possible infectious agents.
- Ammonia, which is still used in some facilities as a refrigerant and should be considered a potential hazard.

Respiratory Protection Resources can be found on the ORA Safety SharePoint site. OSHA's Respiratory Protection - Overview also provides general guidance and resources.

S.9.8 – Marine/Water/Flotation

Employees working over or near water, where the danger of drowning exists, should consider U.S. Coast Guard-approved life jackets or buoyant work vests. Personal flotation devices (PFDs) mitigate harm

when there is a chance of falling into water such as working near unguarded edges, boarding, or leaving small boats, or working from scaffolds or staging. Lifesaving equipment such as life ring buoys with ropes and ladders should be available when working from floats, barges, or vessels.

When working in and around water on an open boat where water temperatures are below 70°F, reference Cold Stress - Cold Water Immersion | NIOSH | CDC. Also consult your IH Liaison.

S.9.9 - Common PPE

Common PPE to consider having on hand or to carry with you during inspections--not including specific inspection types warranting specialized PPE, such as egg, drug, Low Acid Canned Food (LACF), and others--include:

- Hard Hat
- Safety Shoes
- Hearing Protection
- Gloves
- Eye Protection
- Protective clothing, including coveralls, lab coats, reflective coats, freezer coats, rubber, or vinyl aprons, and disposable paper-like coveralls

Always plan in advance for any PPE that may be required for a particular location or situation.

You may have an option to utilize PPE provided by a firm. Firms may request that you use PPE they provide in conjunction with their safety programs and practices. If possible, attempt to determine if the provided PPE is adequate, or at least comparable to your FDA-supplied PPE and is compliant with recognized standards. Evaluate the provided PPE for cleanliness and sanitary status (particularly eye and head protection). If you feel that the firm's PPE is inadequate, do not enter and contact your supervisor or IH for next steps.

Additional non-PPE items that can be utilized in conjunction with your common PPE, include, but are not limited to, hair/beard nets, hand sanitizers, shoe covers, and face masks. Some of these items may be required by the inspected firm.

S.9.10 - PPE on/off sequence

Below is a generalized sequence for putting on and taking off PPE. The type of PPE used will vary based on the level of precautions required, such as standard and contact, droplet, or airborne infection isolation precautions. Note that the procedure for putting on and removing PPE should be tailored to the specific type of PPE and situation encountered. Follow the firm's procedures when required. If there are questions or concerns about a firm's procedure, consult with your supervisor or IH Contact(s).

Donning PPE (Putting on) as applicable	Doffing PPE (Taking off)
1. Perform hand hygiene.	1. Remove shoe covers/shoes.
2. Put on shoes/shoe covers.	2. Remove lab coat.
3. Put on lab coat.	3. Remove gloves.
4. Put on mask/respirator.	4. Perform hand hygiene.
5. Put on eye protection.	5. Remove eye protection.
6. Put on gloves.	6. Remove mask/respirator.

	7. Perform hand hygiene.

The CDC Sequence for Donning and Removing Personal Protective Equipment pdf provides options for safely donning (putting on) and doffing (removing) PPE.

Doffing techniques are particularly critical to mitigate self-contamination. There are a variety of ways to safely remove PPE without contaminating your clothing, skin, or mucous membranes with potentially infectious materials. For example, in instances when using a respirator: Remove all PPE before exiting, except the respirator. Remove the respirator after leaving and closing the door. See CDC sequence document for this and other doffing options.

S.9.11 - Maintenance and Care of PPE

- Note any expiration dates and/or manufacturer's maintenance schedules (including recommended replacement periods and shelf lives) as applicable.
- Always inspect PPE for damage prior to donning (putting on) and after doffing (removing).
- Clean and disinfect, if applicable, PPE before storing it.
- Dispose of and replace damaged PPE as necessary and whenever signs of integrity damage are apparent.
- Properly store PPE and avoid conditions that could potentially damage it, such as excessive heat, light, moisture, and humidity.
- Do not store or use PPE in close proximity to chemical or biological hazards.
- Plan to replace PPE on regular intervals even if no apparent signs of degradation are present.

S.9.12 - Purchasing protective equipment

ORA will provide required PPE for its employees. Employees can request safety shoes and/or prescription safety glasses by submitting completed request forms to their Supervisory Administrator Management Specialists (SAMs). ANSI-certified prescription glasses can be purchased from a vendor of your choice and convenience. ORA will pay pre-defined allotments for regular lenses/bifocal lenses for prescription safety glasses and for safety shoes. The cost of eye exams is not reimbursable. Employees are responsible for costs exceeding allowed allotments. Please refer to SOP-000123, Prescription Safety Eyewear and Safety Footwear, for further information and to access request forms A and B for safety glasses or shoes.

S.10 - ORA Safety Office

The ORA Safety Office develops safety policy, training, and information for all ORA employees. ORA industrial hygienists work with ORA programs at all levels to develop the best possible safety guidance.

S.10.1 ORA Safety Contacts

- Email ORASafetyOffice@fda.hhs.gov
- IH Contact List

S.11 - Resources

S.11.1 - Respiratory Protection Resources

S.11.2 - QMiS

QMiS is the repository for ORA's internal procedural documents and quality reports, including documents on safety, standard operating procedures, work instructions, templates, checklists, transmittal notifications, and reports--all organized by component and document type. Safety related QMiS content includes, but is not limited to:

SOP-000449	ORA Respiratory Protection Program
SOP-000923	Screening Packages for Radioactive Contamination
SOP-000927	Radiation Dosimetry Program
TRNMAT-000013	WEAC Personal Protective Equipment (PPE) 2020
WEAC-TMPL.222	Certification of Hazard Assessment Form for PPE Use
SOP-000178	ORA Shipping
ORA.006	ORA Radiation Safety Manual

S.12 - Special Safety Situations

S.12.1 - Fire/Explosion Hazards

Fire and explosion hazards may be a significant concern at many firms. The conditions leading to these hazards will usually exist beyond your control. Your safety will depend on your situational awareness and prompt action in the event that an emergency arises.

Most firms will be required by state or local authorities to maintain fire detection, alarm, and suppression systems. These will usually be similar to the systems you are familiar with from your FDA duty station, including alarm pull stations, smoke detectors, and sprinklers. If a firm has properly installed and maintained systems, the likelihood of a fire developing before you can evacuate is low. Asking the firm's management or an escorting employee what to do in the event of an alarm should be sufficient precaution in most cases.

Firms with very large quantities of flammable chemicals may be required by OSHA to operate under a Process Safety Management (PSM) plan. A PSM plan will contain detailed precautions for detecting chemical releases and notifying occupants of the need to evacuate. If you suspect the firm may need to operate under a PSM plan, discuss the alarms and immediate actions you should take with the firm's management.

If you have doubts about the adequacy of fire detection, alarms, and suppression systems, or if you are concerned that the firm does not have adequate plans for a quick evacuation, be alert for signs of increased fire risk. An exhaustive list of fire hazards in different industries is beyond the scope of the IOM, but some general principles apply universally.

Housekeeping practices can be a good indicator of fire risk. Accumulated dust and debris can potentially be ignited or contribute fuel to a fire, and disorderly or haphazard storage of materials and equipment can obstruct egress routes. Accumulations of grease on surfaces near cooking appliances can increase the risk of fire. Haphazardly stored materials are usually easier to ignite than the same materials stored in neat, managed stacks.

Electrical systems are a common ignition source for industrial fires. While it is not possible to assess a facility's electrical systems at a glance, if you notice any evidence of damaged or improvised wiring, exposed components or conductors, or heat-damaged building materials, you should consider the area to be a fire hazard.

Firms, depending on their types of operations, can be potential sources of explosion hazards. The National Electrical Code (NEC) defines hazardous locations as those areas "where fire or explosion hazards may exist due to flammable gases or vapors, flammable liquids, combustible dust, or ignitable fibers or "flyings".

FLAMMABLE LIQUIDS, GASES OR VAPORS	Acetylene, hydrogen, butadiene, ethylene oxide, propylene oxide, acrolein, ethylene, cyclopropane, ethyl ether, acetone, ammonia, benzene, butane, ethanol, gasoline, hexane, methane, methanol, methane, naphtha, natural gas, propane, and toluene
COMBUSTIBLE DUSTS	Combustible metal dusts: aluminum, commercial alloys, and magnesium Combustible carbonaceous dusts: carbon black, charcoal, coal, and coke dusts Other combustible dusts: Chemicals, flour, grain, plastic, and wood

MORE EXAMPLES OF POTENTIAL COMBUSTIBLE DUST MATERIALS (OSHA)		
AGRICULTURAL	**CARBONACEOUS**	**METALS**
Cellulose	Charcoal	Aluminum
Corn	Coal	Iron
Egg white	Lampblack	Magnesium
Fertilizer	Lignite	Titanium
Flour	Soot	Zirconium
Powdered milk	**OTHERS**	Zinc
Soy flour	Biosolids	**PLASTIC**
Spices	Dyes	Epoxy resin
Starch	Pharmaceuticals	Melamine
Sugar	Rubber	Phenolic resin
Tobacco	Soap	Polyethylene
Wood flour	Sulfur	Polypropylene

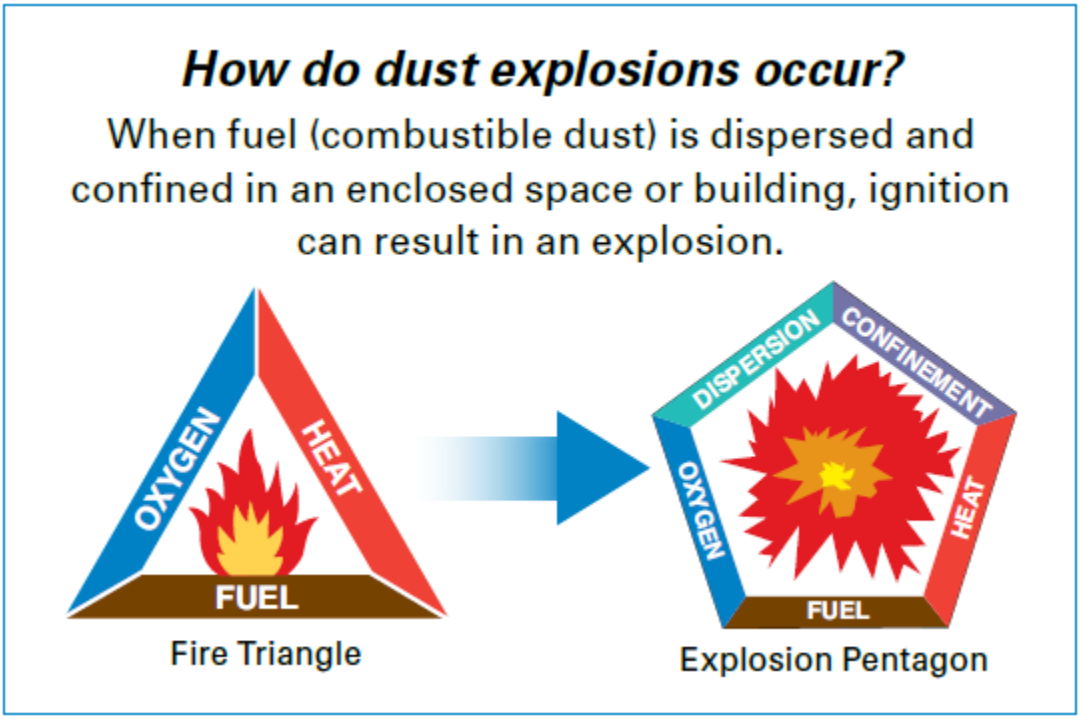
OSHA resources on combustible dust include:

- Combustible Dust Explosions Fact Sheet
- Combustible Dust: Protecting Workers from Combustible Dust Explosion Hazards Fact Sheet

Per OSHA, five elements, as indicated below, are necessary to initiate a dust explosion, or what is often referred to as the "Dust Explosion Pentagon."

- Combustible dust (fuel)
- Ignition source (heat)
- Oxygen in air (oxidizer)
- Dispersion of dust particles in sufficient quantity and concentration
- Confinement of the dust cloud

The first three elements are those needed for a fire and comprise what is commonly known as the "fire triangle." Dispersion of dust particles in sufficient quantity and concentration can cause rapid combustion known as a deflagration. If the event is confined by an enclosure such as a building, room, vessel, or process equipment, the resulting pressure rise may cause an explosion. Note that if one of the five elements is missing, a dust explosion cannot occur.



Precautions for Firefighters to Prevent Dust Explosions - OSHA

An initial (primary) explosion in processing equipment or in an area where fugitive dust has accumulated may dislodge more accumulated dust into the air or damage a containment system (such as a duct, vessel, or collector). As a result, if ignited, the additional dust dispersed into the air may cause one or more secondary explosions. These can be far more destructive than a primary explosion due to the increased quantity and concentration of dispersed combustible dust. Many deaths in past incidents, as well as other damage, have been caused by secondary explosions.

S.12.2 - Portable/Personal Electronic Devices (PEDs)

PEDs, including your mobile telephone, and their chargers, can provide potential ignition sources in explosion hazardous atmospheres. They can create electrical sparks, hot surfaces, electrostatic discharges, and other potential ignition sources via their batteries, motor brushes, pushbuttons, and/or damage caused by impact or related electromagnetic properties. Ignition can occur when the device is being used normally, while the device is being charged, or if the device is or has been damaged.

Examples of PEDs include mobile telephones, laptop computers, tablets, cameras, power tools, fitness monitors, watches/smart watches, calculators, temperature data loggers, car key fobs, flashlights, headlamps, gas monitors, testing equipment, medical devices, and defibrillators.

Equipment can be designed or modified for safe operation in hazardous locations. There are two general approaches for safe operation. One known as intrinsic safety, or non-incendive safety, limits the energy present in a device, so that it is insufficient to ignite a hazardous atmosphere under most conditions. This includes both low power levels and low stored energy. The second approach, explosion-proof or flame-proof equipment, is specifically constructed so that it will not ignite in a hazardous atmosphere, including in the presence of any sparks or explosions. Standards have been developed that identify what equipment may be used in hazardous locations. The suitability of equipment for specific hazardous areas must be tested by a Nationally Recognized Testing Laboratory, such as UL, FM Global, CSA Group, or Intertek (ETL).

Note that in the presence of known flammable vapors, OSHA stipulates to use *only* explosion-proof, self-contained temporary and portable lights (to include flashlights and headlamps) that have been approved for hazardous conditions by a nationally recognized testing laboratory (NRTL). OSHA defines such hazardous, flammable conditions as those in which the atmosphere is determined to contain a concentration of flammable vapors that are at, or above, 10 percent of the lower explosive limit (LEL), as specified in 29 CFR part 1915, subparts B and C.

Consult with your supervisor and/or your IH Contact(s) concerning PED/portable lighting usage and/or safety.

S.12.3 - Lithium Batteries

Per OSHA, small and wearable electronic devices used in workplaces (for example, body cameras) rely on a power source that stores a high amount of energy in a small space, in what is often referred to as high energy density. Lithium cells provide sustained power and often have the capability to recharge. When designed, manufactured, and used properly, lithium batteries are a safe, high energy density power source for devices.

While lithium batteries are normally safe, they may cause injury if they possess design defects, are made of low-quality materials, are assembled incorrectly, are used or recharged improperly, or are damaged. Lithium batteries are generally safe and unlikely to fail-- however, when lithium batteries do fail to operate safely or are damaged, they may present a fire and/or explosion hazard. Damage from improper use, storage, or charging may also cause lithium batteries to fail.

OSHA Preventing Fire and/or Explosion Injury from Small and Wearable Lithium Battery Powered Devices discusses the specifics of lithium battery-powered devices and their use in hazardous atmospheres.

S.12.4 - Confined Spaces

Referencing Confined Spaces - Overview OSHA: Many workplaces contain areas that are considered "confined spaces" because they are not necessarily, or optimally, designed for people, and only large enough for workers to enter and perform certain jobs. A confined space also has limited or restricted means for entry or exit and is not designed for continuous occupancy. Confined spaces include, but are not limited to tanks, vessels, silos, storage bins, hoppers, vaults, pits, manholes, tunnels, equipment housings, ductwork, pipelines, etc.

OSHA uses the term "permit-required confined space" (permit space) to describe a confined space that has one or more of the following characteristics: contains or has the potential to contain a hazardous atmosphere; contains material that has the potential to engulf an entrant; has walls that converge inward, or floors that slope downward and taper into a smaller area, which could trap or asphyxiate an entrant; or contains any other recognized safety or health hazard, such as unguarded machinery, exposed live wires, or heat stress. Confined spaces shall be identified by the firm who shall then inform potentially exposed parties of the existence and location of such spaces and their hazards.

Confined Spaces - Standards OSHA addresses specific OSHA standards for general industry, maritime, and construction and highlights OSHA standards and documents related to confined spaces.

Confined spaces may be encountered in virtually any occupation; therefore, their recognition is the first step in preventing fatalities. Since deaths in confined spaces often occur because the atmosphere is oxygen-deficient, toxic, or combustible, confined spaces that contain or have the potential to contain a serious atmospheric hazard should be classified as *permit-required* confined spaces and should be tested prior to entry and continually monitored. The references at Confined Spaces - Hazards and Solutions OSHA aid in recognizing and evaluating hazards and possible solutions related to confined spaces.

The following is a partial list of examples work areas that are considered to be confined spaces: ship cargo holds, import/shipping containers, walk-in freezers, walk-in refrigerators, and walk-in autoclaves.

Suggested behaviors and actions when encountering potentially confined spaces and situations:

1. Prior to entering a closed area, ascertain if it has been fumigated and, if so, has the space been aired out sufficiently. Do not enter if you are uncertain of either condition.
2. When sampling or inspecting at rendering plants or fishmeal plants, be alert to possible hydrogen sulfide accumulations in dump pits and other areas. These fumes can be deadly.
3. Be alert and take proper safety precautions in plants, silos, bins, pits, and any closed areas where semi-solid buttermilk or other liquid dairy products, silage, or other bulk products are stored. If not properly stored, improperly handled, or in a state of decomposition, certain products can produce dangerous amounts of carbon dioxide, or other gases, or may deplete the oxygen supply in these areas.
4. When transporting dry ice or packages containing dry ice in your car, have some external ventilation.

5. When sampling from the top of a grain elevator, do not jump down, stand on, or walk across the top of grain. There may be a cavity caused by crusted grain which could break and result in you being buried in grain or being in an atmosphere of fumigating gas.
6. Be alert when entering storage areas having controlled atmospheres, for example, where oxygen has been replaced by carbon dioxide to prolong fruit storage, or sulfur dioxide added for preservation purposes, etc. These areas should be aerated and deemed safe by the firm prior to your entering.
7. Contact your supervisor or IH Contact(s) if you require guidance to determine what hazards or DOT regulations may be applicable to a substance when it's being transported.
8. Be aware that such spaces may not open from the inside and verify that an escape is possible.

S.12.5 - Thermal Processing/Retorts

Canning retorts are considered confined spaces and are to be regarded as hazardous.

DO NOT ENTER RETORTS OF ANY KIND UNDER ANY CIRCUMSTANCES.

Should an inspectional need arise where entering a retort becomes necessary, notify your management who will then notify the Program Liaison IH and CFSAN Office of Food Safety's Division of Food Processing Science and Technology. Such inspectional activity occurs on an as-needed, mission-critical basis ONLY. Retorts should *never* be entered routinely.

There is the potential to request an employee of the firm to enter the retort on behalf of the agency, with an FDA camera and/or equipment and take measurements or photos. Note that such a request is not routine; it is completely voluntary, done at the firm's discretion, and subject to refusal.

Note that all applicable FDA inspectional forms have been adjusted to eliminate any need for entering retorts.

S.12.6 Altered/Oxygen-Deficient Atmosphere Environments

FDA-regulated products are often manufactured and stored using processes that require altered atmospheric conditions. Examples include fumigation treatment of food storage areas with pesticides, fruit, and vegetable ripening rooms, import containers, truck trailers, railroad cars, and device or drug processing spaces. Hazards commonly associated with altered atmosphere environments include asphyxiation, fires, explosions, and toxic effects. The substance or combinations of substances used to alter the atmosphere determine the specific hazards created. Substances commonly used to alter atmospheres include nitrogen gas, ozone gas, and fumigants (such as ethylene oxide).

When interviewing staff at a firm that uses altered atmospheres for processing, gather the following information and documents before proceeding with your inspection:

- Safety Data Sheets (SDS) for all substances used to alter the atmosphere.
- Safety controls used to prevent altered atmosphere exposure and associated hazards.
- Processes used by the firm to alter the atmosphere.
- Processes by which the firm returns the atmosphere to normal, safe conditions after altering it for a process.
- Processes by which the firm verifies that the atmosphere is in a normal, safe condition after being altered.

- Emergency procedures if someone enters the altered atmosphere environment, or the atmosphere is altered while an individual is in a processing space.

Once the above information has been gathered and you have determined that a risk assessment is needed, contact your supervision who can then contact your IH liaison before proceeding with any inspectional activities in the affected space(s). Note that altered atmosphere environments are commonly associated with confined spaces. Be sure to follow all applicable safety precautions if confined spaces are encountered.

S.12.6.1 - Ammonia

Ammonia is a colorless gas with a distinct odor. It can pose a health hazard because it is corrosive to skin, eyes, and lungs. Exposure to 300 parts per million (ppm) is immediately dangerous to life and health. Ammonia is also flammable at concentrations of approximately 15% to 28% by volume in air. When mixed with lubricating oils, its flammable concentration range is increased. It can explode if released in an enclosed space with a source of ignition present, or if a vessel containing anhydrous ammonia is exposed to fire. Ammonia spills and releases pose a significant threat to workers from skin contact, inhalation, and fire and explosion.

Anhydrous ammonia is widely used as a refrigerant in many industrial facilities, including:

- Meat, poultry, and fish processing facilities
- Dairy and ice cream plants
- Wineries and breweries
- Fruit juice, vegetable juice, and soft drink processing facilities
- Cold storage warehouses
- Other food processing facilities
- Petrochemical facilities

While refrigeration systems are closed systems, ammonia release could occur during receiving, storage, or due to leaks. Follow facility safety protocols and in the event of an ammonia leak or discharge, immediately evacuate the facility. When conducting field operations due to recalls or potential adulteration of product from ammonia, do not enter the facility until, or unless, it has been deemed safe to do so. Some inspections may require you to enroll in a Respiratory Protection Program for your safety. For example, all investigators conducting egg farm inspections or investigations should be medically cleared, fit-tested and trained in the proper use and limitations of the issued respirator. You need to determine as much as possible if a chemical hazard, such as ammonia, is present at the facility prior to arriving or conducting field work, as applicable. If ammonia is identified as a potential hazard, firm management should be asked whether ammonia levels are regularly monitored. During egg inspections, for example, you should have your respirator with cartridges with you in the event a chemical hazard arises. The hazard of ammonia may also need to be considered during other production environments, such as in cheese ripening or aging rooms.

Consult your supervisor or the Safety Liaison for your program or division regarding any inspectional safety concerns.

S.12.6.2 - Fumigants and Fumigation

The use of chemical fumigants for the control of insect infestation can result in hazardous exposures to those involved in the handling of both fumigants and fumigated products, like those associated

with controlling insects in grains. Fumigants can include pesticides, insecticides, and hazardous preservatives. Controlled atmosphere storage of certain food products is also a form of fumigation where, in a controlled atmosphere, most of the air in an enclosed storage area, or packaging, is replaced with a gas such as carbon dioxide.

Fumigant toxic effects can include permanent central nervous system damage, heart and vascular disease, lung edema, and cancer.

The increased use of fumigants and increases in the handling of fumigated products, coupled with the insidious nature of these toxicants, makes it imperative that you take special care during your inspection with respect to fumigated areas and products.

Substances used as fumigants and their usual physical state when applied for that purpose:

Fumigant and Chemical Structure	**Physical State of Fumigant as it is Applied**
Acrylonitrile (CH_2=CHCN)	Liquid
Aluminum phosphide (AlP)	Solid
Anhydrous ammonia (NH^3)	Liquid (gas)
Calcium cyanide (Ca $(CN)_2$)	Solid (gas)
Carbon disulfide (CS_2)	Liquid
Carbon tetrachloride (CCl_4)	Liquid
Chloroform ($CHCl_3$)	Liquid
Chloropicrin (CCl_3NO_2)	Liquid
Cyanogen bromide (BrCN)	Liquid
Cyanogen chloride (ClCN)	Gas
1,3-Dichloropropene (CHCl=$CHCH_2Cl$)	Liquid
Ethylene dichloride (CH_2ClCH_2Cl)	Liquid
Ethylene oxide (CH_2 - CH_2)	Gas
Hydrogen cyanide (HCN)	Liquid (gas)
Magnesium phosphide (Mg3P2)	Solid
Methylbromide (CH3Br)	Gas
Methylene chloride (CH2Cl2)	Liquid
Naphthalene ($C_{10}H_8$)	Solid
Para-dichlorobenzene ($C_6H_4Cl_2$)	Solid
Phosphine (PH3)	Gas
Propylene dichloride ($CH_2ClCHClCH_2$)	Liquid

Fumigant and Chemical Structure	Physical State of Fumigant as it is Applied
Propylene oxide (CH_2 - CH-CH_3)	Gas
Sulfur dioxide (SO2)	Gas
Sulfuryl fluoride (SO2F2)	Gas
1,1,1-trichloroethane (CH_3CCl_3)	Liquid

Source: American National Standard for respiratory protection during fumigation, ANSI Z88.3-1983
Notes: Aluminum and magnesium phosphide are solid substances that react with moisture to produce phosphine gas. At high concentrations, phosphine is spontaneously combustible. Calcium cyanide, a solid, reacts with acids to produce HCN, a gas.
Signs shall be clearly posted by the firm in instances where fumigants, pesticides, or hazardous preservatives have created a hazardous atmosphere. These signs shall note the danger and specific chemical hazards, as well as provide appropriate information and precautions, including instructions for the emergency treatment of employees affected by any chemicals in use. In the case of containerized shipments of fumigated products, the contents of the container shall be aerated by opening the container doors *for a period of 48 hours after the completion of fumigation*. When products are inside or within shipping cases having polyethylene or similar bag liners, the aeration period shall be *72 hours*. The firm should be able to provide written warranty stating that the appropriate aeration period has been met.

S.12.6.2.1 - Fumigant Use by Regulated Firms

Further references for fumigant use include the 40 CFR 171.2(a)(8) promulgated by the EPA and the Agricultural Marketing Service Fumigation Handbook.
Fumigants present a potential respiratory hazard when used in regulated establishments subject to inspection which include, but are not limited to, fumigation or storage facilities where raw agricultural commodities (RACs) are encountered, including trucks, vessels, railroad cars, shipping containers and fumigation chambers.
Do not enter any structure or conveyance or sample any product that is being treated with the fumigants including, specifically, methyl bromide, phosphine or sulfuryl fluoride. If a sampling area is suspected of having been fumigated with a fumigant and has not been cleared according to EPA requirements, contact your local IH for guidance as to how to ensure that the area is safe to enter. *Do not enter the area until it is appropriately aerated and tested.*
Areas and/or products being treated with fumigants are required by the EPA to be placarded, and the placards not to be removed until the treatment is complete (a process usually taking from 12 hours to 4 or more days) and the areas and/or products are clear of fumigant gases (with, specifically, phosphine at <0.3 ppm and methyl bromide at <1 ppm).
Although there should be no occasion where you should encounter hazardous fumigant concentrations, it is advisable to be fully aware of the symptoms of exposure to fumigants. Note that, in any situation where exposure to fumigants is unknown/questionable and/or there is moderate to high exposure, you should seek medical attention immediately.
Using phosphine as an example:

1) Symptoms of exposure to phosphine include:

a) Slight or mild poisoning, which may lead to feelings of fatigue, ringing in the ears, nausea, pressure in the chest, and uneasiness. All symptoms typically dissipate when the person is removed to fresh air.
b) Moderate exposure, which may lead to general fatigue, nausea, gastrointestinal symptoms accompanied by vomiting, stomachache, diarrhea, disturbance of equilibrium, strong pains in the chest, and difficulty breathing.
c) Exposure to very high concentrations, which rapidly causes strong difficulty in breathing, bluish-purple skin color, difficulty in walking or reaching, subnormal blood oxygen content, unconsciousness, and death. Death can be immediate or may be delayed until several days later.

2) Treatment:
a) The EPA-approved label contains information regarding practical treatment regimes. If any of the symptoms previously described are experienced, a physician should be contacted immediately.
b) To expedite proper treatment, it is advisable to have a copy of the EPA-approved label available for the physician. Generally, the most up-to-date information regarding medical treatment for exposure is available from the fumigant manufacturer. The EPA approved label contains the manufacturer or distributor name, address, and phone number.

S.12.6.2.2 - Fumigants related to Sampling

When collecting samples that may contain live insects, it may be necessary to fumigate and/or preserve the sample.

As soon as possible, freeze any sample containing, or suspected to contain, live insects—as long as freezing will not change or damage the product, or break the container. If freezing is inappropriate for maintaining the integrity of the sample, fumigation may be carried out using air-tight containers (such as a mason-type jar with inner ring, or a polypropylene container with air-tight lid), with sufficient fumigant to kill the insect infestation.

Moth crystals, containing paradichlorobenzene (PDB), are an alternative fumigant. Do not use mothballs or moth flakes containing naphtha or naphthalene. Do not use moth crystals in or near plastics, particularly Styrofoam and other polystyrenes as crazing or melting may occur. Crazing is the phenomenon that produces a network of fine cracks on the surface of a material, for example in a glaze layer. Crazing frequently precedes fracture in some glassy thermoplastic polymers. Other alternative fumigants include liquid household ammonia or ethyl acetate--either of which can be used by dampening on a cotton ball and placing in an appropriate container; or by cutting small portions of commercial pesticide strips and placing in container. Contact your servicing laboratory for guidance on alternative fumigants.

Follow safety precautions when fumigating and/or preserving samples. Guidance is as follows:

1. Whenever possible, freeze the sample. If freezing is not practical, contact your servicing laboratory for alternative fumigants and preservatives.
2. When fumigants or preservatives are used, exercise care to limit your exposure to these chemicals. Minimize transfer and exposure time. Avoid getting chemicals on hands or clothing. DO NOT MIX CHEMICALS. Contact your ORA Safety staff for the appropriate precautions necessary with these chemicals.

3. Safety Data Sheets (SDS) for each of these chemicals should be available at each duty site (for example at, division offices and resident posts), and can also be obtained from the chemical manufacturer. These sheets list the hazards involved with these chemicals and precautions to take for their use. You should read and follow the instructions in the SDS prior to using the chemical. As for shipping, if a measured amount of chemical fumigant or preservative is present, and considered a regulated hazardous material, follow the guidance and properly ship the item. Again, if you have any questions regarding safety, or shipping concerns, contact ORA Safety.
4. Carry all alcohols, fumigants, and other hazardous liquids in approved safety containers.
5. Ensure DOT regulations and guidance, and International Air Transport Association (IATA) guidelines are followed when mailing or shipping samples containing fumigants or preservatives. Exceptions for small quantities are listed in 49 CFR 173.4.
6. The sample identification data on your packaging, the FDA-525 and C/R, must always identify the fumigant and method of fumigation, and/or preservative used.
7. SDSs for each chemical fumigant or preservative used must be enclosed with the shipped sample. Read and follow all instructions and precautions listed on the SDS.

Additional information on fumigants for preservation can be found at

- USDA Collecting And Preserving Insects And Mites: Techniques And Tools
- Paradichlorobenzene General Fact Sheet (orst.edu)
- Naphthalene General Fact Sheet (orst.edu)

S.12.6.2.3 - Procedures for Fumigation

Place a small amount of fumigant, in an airtight container. Separate the fumigant from the sample with a piece of paper, paper napkin, or unscented facial tissue. Put specimen or product into container and seal tightly. Do not reopen container unless absolutely necessary. If possible, use a glass container with a lined screw lid. A mason-type jar with inner ring is also acceptable.

S.12.6.2.4 - Exceptions to Fumigation

When submitting samples or exhibits to show live infestation, do not fumigate. Consult with your supervisor or your servicing laboratory PRIOR to sending or bringing a live infestation into the laboratory to permit preparation for proper handling and storage. Do not fumigate sample when submitting samples for pesticide residue analysis.

S.12.6.2.5 - Preservation Liquids

Insects may be killed and preserved in 70% ethyl alcohol, or a 1:1 mixture of 70% ethyl alcohol and glycerin (may be labeled glycerol). These chemicals can be obtained from your servicing laboratory. Do not collect rodents or animal tissues unless specifically instructed. Ensure all vials or bottles of preservation liquids are tightly sealed to avoid leakage. Identification labels may be placed in containers but must be written in India ink or 2H pencil only. Keep all preservation liquids away from excessive heat or open flame.

Identify the preservative used on FDA 525, C/R, and on sample container. Enclose a copy of the SDS with the shipped sample. Follow DOT and IATA guidelines when shipping or mailing samples with preservatives, as stated under fumigants.

S.12.6.3 - Ethylene Oxide (EtO)

EtO is a highly flammable, colorless gas at temperatures above 51.3 ºF (10.7 ºC) that smells like ether (sweet, fruity, pungent) at toxic levels (above 500ppm). EtO is found in the production of

solvents, antifreeze, textiles, detergents, adhesives, polyurethane foam, and pharmaceuticals. Smaller amounts are present in fumigants, sterilants for spices and cosmetics, as well as during hospital sterilization of surgical equipment. Per Ethylene Oxide - Overview OSHA, EtO is produced in large volumes and is primarily used as an intermediate in the production of several industrial chemicals, the most notable of which is ethylene glycol. It is also used as a fumigant in certain agricultural products and as a sterilant for medical equipment and supplies. Unfortunately, EtO possesses several physical and health hazards that merit special attention. EtO is both flammable and highly reactive. Acute exposures to EtO gas may result in respiratory irritation and lung injury, headache, nausea, vomiting, diarrhea, shortness of breath, and cyanosis. Chronic exposure has been associated with the occurrence of cancer, reproductive effects, mutagenic changes, neurotoxicity, and sensitization.

Unmonitored and inadequate ventilation will allow EtO buildup of extremely high concentrations, especially in facilities using malfunctioning or leaking equipment. Door gaskets, valves, and threaded fittings are typical areas where leaks have been observed. Additionally, exhaust vents from the sterilizer and the sterilizer room should not be located near air conditioning intake vents or vented directly into work areas. If the odor of EtO is detected, ventilation and containment are evidently inadequate. Leave the area and report the situation to your supervisor for further inspectional guidance. Special EtO monitoring equipment is available upon request from the Office of Regulatory Science.

OSHA standard regulating employee exposure to EtO is presently 1 ppm, over an 8-hour day. You should avoid all unnecessary and preventable exposure to it. Adhere to any procedures the firm has established for protection of personnel from overexposure to EtO. Where improper venting procedures or defective equipment are observed, take adequate precautions, for example, do not enter potentially hazardous areas, and/or wear protective clothing and a respirator. 29 CFR 1910.134 contains basic requirements for proper selection, use, cleaning, and maintenance of respirators.

Ethylene Oxide - Hazard Recognition OSHA consolidates references that aid in recognizing and evaluating ethylene oxide hazards.

S.12.6.4 - Nitrogen

Nitrogen gas may be used during product packaging and manufacturing in both food and pharmaceutical operations to preserve freshness, prevent microbial growth, and enhance quality by preventing the negative impacts of oxygen exposure. Nitrogen flushing is popular for use in food packaging because it displaces oxygen, thereby maintaining a long shelf life and preventing spoilage. Liquid nitrogen may be used to freeze or cool products during production, and for other processes including grinding, mixing, and coating. Food firms may use liquid nitrogen in the production of a variety of foods, such as meat, poultry, seafood, fruits, vegetables, baked goods, beverages, and prepackaged meals. Laboratories requiring specific environments will utilize nitrogen to reduce oxygen levels, humidity, and temperature for sensitive procedures and equipment.

Nitrogen is odorless, colorless, and tasteless--attributes accounting for its increased risks in the absence of appropriate monitoring. Hazards of nitrogen may include asphyxiation and frostbite. While refrigeration systems are closed systems, nitrogen release can occur during receiving, storage,

or in instances of leaks. When liquid nitrogen is exposed to the air during leaks, it will evaporate, changing from a liquid to an oxygen-depleting gas.

Follow facility safety protocols, and in the event of a nitrogen leak or discharge, immediately evacuate the facility. When conducting field operations due to recalls or potential adulteration of product from nitrogen, do not enter the facility until, or unless, it has been deemed safe to do so. Consult your supervisor or the safety liaison for your program or division regarding any inspectional safety concerns.

S.12.6.5 - Ozone

Ozone is used in many industries during food production, for example, in produce, meat, seafood, and water/beverage production; for sanitization purposes; and as a disinfecting agent. Ozone gas may be colorless, or appear blue, and has a pungent odor. Exposure to ozone may cause headaches, coughing, dry throat, shortness in breath, a heavy feeling in the chest, and fluid in the lungs. Respiratory protection may be needed if entering an area with a high concentration of ozone.

S.12.7 - Lockout/Tagout (LOTO)

The absence of an appropriate Lockout/Tagout (LOTO) method consistently ranks as one of OSHA's most frequently cited violations, with the agency citing an average of 120 fatalities and 50,000 injuries each year that could otherwise be prevented by instituting/using an LOTO program.

LOTO is used across industries as a safe method of operating, or working on, hazardous equipment. Employees servicing or maintaining machines or equipment may be exposed to serious physical harm or death if power sources and access/exits to the machinery are not properly controlled. Machine-related injuries or fatalities can occur during maintenance and servicing tasks when workers are exposed to an uncontrolled release of energy, including during equipment startup, or if faced with an inability to exit, due to confined spaces or other factors.

LOTO involves the adoption and implementation of practices and procedures to shut down equipment, isolate it from its energy source(s), and prevent the release of potentially hazardous energy while maintenance and servicing activities are being performed. LOTO use can apply to any source of electric, mechanical, hydraulic, pneumatic, chemical, thermal, or other energy, which, if not controlled, could create a hazard. Firms have the flexibility to develop LOTO programs that are suitable for their respective facilities.

The following are definitions for Lockout (LO) and Tagout (TO), respectively:

- LO is a positive means, such as a key or combination-type lock (with a chain as necessary), to hold an energy-isolating device in a safe position and prevent energizing a machine or piece of equipment.
- TO involves a prominent warning device, such as a tag and a means of attachment, which can be securely fastened to an energy-isolating device, according to established procedure. The TO device shows that the energy-isolating device and the equipment being controlled may not be operated until the warning device is removed by the authorized employee who placed the TO device on the energy-isolating device.

LOTO ensures that no one can unlock and reenergize a piece of equipment while you are in the vicinity of, or in process of inspecting, equipment. LOTO procedures are required if the equipment can expose you to the unexpected startup or release of stored energy that could cause injury. For FDA, and especially ORA staff, the standard definition of LOTO is expanded well past the "control of hazardous energy" to encompass additional potentially harmful situations. Such additional LOTO-related situations include instances when:

- You are inspecting machines or equipment on which the guards or other safety devices have been removed or bypassed, whether intentionally or accidentally, during cleaning or maintenance.
- Parts or portions of your body are exposed to, or could potentially come within, the danger zone associated with the equipment, such as its point of operation. Also known as the "working area", the danger zone is any place in or about a machine or piece of equipment where an employee may be struck by or caught between moving parts, caught between moving and stationary objects or parts of the machine, caught between the material and a moving part of the machine, burned by hot surfaces, or exposed to electric shock.
- You need to inspect equipment with entrapment hazards that include walk-in freezers/coolers, grain silos, tractor/semi-trailers, import shipping containers, among others.

S.12.8 – Reproductive Hazards and Pregnant Employees

Where you work, how you work, and what you work with can affect your reproductive health and/or your family's health. OSHA notes that "exposure to reproductive hazards is an increasing health concern." From the Preamble to NIOSH's National Occupational Research Agenda (NORA) Statement on Reproductive Hazards: "While more than 1,000 workplace chemicals have shown reproductive effects in animals, most have not been studied in humans. In addition, most of the 4 million other chemical mixtures in commercial use remain untested. Physical and biological agents that may affect fertility and pregnancy outcomes are practically unstudied. The inadequacy of current knowledge coupled with the ever-growing variety of workplace exposures pose a potentially serious public health problem." Three-quarters of women of reproductive age are in the workforce. Over half of the children born in the United States are born to working mothers. See OSHA articles The Effects of Workplace Hazards on Female Reproductive Health and The Effects of Workplace Hazards on Male Reproductive Health for more information.

Reproductive hazards are substances or agents that may affect the reproductive health of women or men or the ability of couples to have healthy children. Hazards may be chemical, physical, or biological. Examples of reproductive hazards are lead (chemical), radiation (physical) and certain viruses (biological). You may be exposed to reproductive hazards by breathing them in (inhalation), by contact with skin (dermal) and by swallowing them (ingestion). Potential health effects include infertility, miscarriage, birth defects and developmental disorders in children. You can expose your family to these hazards by bringing them home from the workplace, for example, on your skin, hair, clothes, shoes, tools, or car. It is important to prevent these exposures by the use of workplace engineering controls, proper work practices and good hygiene.

NIOSH also provides information resources on pregnancy and reproductive health hazards associated with workplaces.

Per NIOSH, pregnancy can affect your safety as a worker. If you are pregnant, discuss possible job hazards with your physician, supervision, and your ORA safety office as soon as possible. Many pregnant women are able to adjust their job duties temporarily or take extra steps to protect themselves. By law, you have the right to receive information on hazards in your workplace and to receive training on how to stay safe. See Legal Rights of Pregnant Workers under Federal Law | U.S. Equal Employment Opportunity Commission (eeoc.gov) for more information on pregnancy in the workplace.

Pregnant employees should take special note that any and all current occupational exposure limits, including those established by OSHA, are set based upon studies of nonpregnant adults. In other words, what is considered safe for you, may *not* be safe for your fetus. Although many employees choose to safely continue their jobs throughout pregnancy, pregnancy can sometimes affect worker safety.

If you are pregnant and working, consider the following physiological attributes and/or changes experienced during pregnancy that may be in conflict with your usual workplace activities or demands:

- Changes in your metabolism can increase how quickly you absorb some chemicals, including some potentially hazardous metals.
- Because of physical changes, the PPE that you wore correctly before pregnancy may no longer fit properly. This includes lab coats and respirators. Consider refitting and/or acquiring new PPE as appropriate. Reference Personal protective equipment use while pregnant.
- Changes in your immune system, lung capacity, and even ligaments can alter your risk of injury or illness due to some workplace hazards.
- A fetus might be more vulnerable to some chemicals because of its rapid growth and development, particularly early in pregnancy when its organs are developing.

Consult with your physician, your supervisor and/or your IH Contact(s) for further information about any reproductive workplace-related health and pregnancy concerns you may have.

S.13 - Biological Hazards

Biological hazards may be present during various field investigation and inspection operations. Whether you find yourself working in agricultural fields, animal facilities, processing plants, drug, and clinical settings, or import operations, you should be cognizant of potential biological hazards and understand the appropriate steps needed to mitigate the risks of hazardous exposures. Biological hazards, also known as *biohazards*, are substances of biological origin that pose a health risk or threat to living organisms.

Possible sources of biological hazards vary widely and may include animal and animal products, blood and other bodily fluids, and biological waste streams from various processing facilities. Having a better understanding of potential biological hazards--through knowledge, appropriate planning, awareness of safety practices and preventative medical treatments available (for example, vaccines) can minimize the incidence of occupational exposures. Biological hazards may be present while performing work tasks; but, regardless of the source, appropriate safety measures can mitigate the risks and limit exposure. Appropriate PPE (gloves, N-95 masks, Tyvek protective clothing or coverings, and goggles) can mitigate exposure to biological hazards in the environment and are indicated based on the level of hazards present and the likely routes of contamination during work activities. Although a comprehensive list of

biological hazards is not possible, potential biological hazards and their sources will be addressed in the following sections.

S.13.1 - Microorganisms

Microorganisms are a large diverse group of microscopic organisms present in the environment. Only a small percentage of the total microorganism population are considered pathogenic, or disease-producing, with the capability to infect and negatively impact humans, animals, and plants. Along with the capability of producing disease directly, some microorganisms or agents cause additional harm by producing secondary products or toxins.

S.13.2 - Viruses

Viruses are small infective agents made up of a collection of genetic code (RNA or DNA) that replicate or multiply within living host cells. Viruses do not have the capability of replicating on their own but use the host cell components to reproduce. Antibiotics are not effective against viral disease. Available antiviral medications or vaccines are used to reduce, treat, and manage viral disease. Some examples of viral diseases include Human Immunodeficiency Virus (HIV), measles, and COVID-19.

S.13.3 - Bacteria

Bacteria are single celled organisms found everywhere on the planet with only a small contingent that are pathogenic or capable of causing disease. Bacteria are classified by their basic shape: sphere, rod, comma, spiral or corkscrew. Replication of bacteria occurs by binary fission or division with one cell dividing into two identical daughter cells. Antibiotics can be effective on specific bacteria, but antibiotic resistance may develop over time or under specific conditions. Some bacteria can form dormant structures called spores or endospores as a survival mechanism during unfavorable conditions. Spores can be very resistant to destruction methods.

S.13.4 - Fungi

Fungi, such as yeasts and molds, are organisms that feed on other organic matter to survive. Fungi are similar to plants but are separate as they do not contain chlorophyll and have unique cell wall and membrane components. As a group, fungi are very diverse and include molds, yeast, mildews, rusts, smuts, and mushrooms. Reproduction of fungi occurs by fragmentation, budding, or the production of spores. Some fungi are beneficial and essential to food processes, including for beer, wine, bread, and some cheeses. Other fungi can cause harm directly, or by producing a secondary metabolite that can be detrimental such as mycotoxins. Mycotoxins, like aflatoxins, are naturally produced, secondary metabolites of certain molds capable of causing disease. They can be found on grains, nuts, spices, and other food sources.

S.13.5 - Parasites

Parasites are organisms that live on or within another organism, called the host, often harming it. Parasites depend on its host for survival. They can be microscopic (like protozoa) or macroscopic (like helminths, or worms and ectoparasites). They can be transmitted through fecal oral route (like protozoa and helminths) and affect the gut of the host, by attaching to or burrowing into skin (including ectoparasites like mites and lice) or transmitted through insect bites (like protozoa such as plasmodium). Food can become contaminated with parasites resulting from the use of contaminated water or

improper food handling, and cause infection in consumers who unwittingly ingest such contaminated foods. Outdoor environments (including farms, surface water zones and areas, and animal production areas) are the most likely sources of parasites. Proper hygiene and PPE can mitigate risks of transmission.

S.13.6 - Prions

Although not a microorganism or living thing, a prion is a protein capable of causing normal proteins in the brain to fold abnormally and clump together. These misfolded proteins cause disease by damaging the central nervous system and brain tissue. Prion diseases, also known as transmissible spongiform encephalopathies (TSEs), impact both humans and animals and can potentially be spread by infected animal products, although the nature of the prion transmission is still not well understood. TSEs are progressive neurodegenerative brain disorders, have long incubation periods, progress rapidly once symptoms develop and are always fatal. Bovine spongiform encephalopathy (BSE) is a degenerative neurological disorder caused by prions that damages the central nervous system of cattle and is an example of a transmissible spongiform encephalopathies (TSEs).

S.13.7 - Biological Allergens

Biological allergies can result from exposure to certain plants or animal proteins. Some plants can produce allergens that cause skin dermatitis, rhinitis, or asthma as a result of exposure pathways of direct contact, ingestion, or inhalation. Protein allergies from exposure to animal urine, feces, hair, saliva, and dander can also cause allergic reactions in sensitized people.

S.13.8 - Biological Toxins

Biological toxins are hazardous substances produced by microorganisms, animals, insects, and plants that can cause harm upon exposure. Depending on the toxin, and amount and route of exposure, health effects can range from minor to severe. Toxins may be a secondary product produced by a microorganism, such as Clostridium botulinum toxin, or mycotoxins from molds found on such crops and food sources as corn and legumes.

S.13.9 - Routes of Infection/Intoxification

The routes of infection and intoxication are listed below:

- Inhalation can lead to infection/intoxification via the respiratory tract, when a person inhales aerosols, dust, mists, or vapors containing biological hazards.
- Direct contact can lead to infection/intoxification through contact with broken skin or eyes (mucous membranes).
- Ingestion can lead to infection via the digestive tract from consuming drinks or food (including chewing gum and tobacco) in work areas where hazardous chemicals are present. Poor hygienic practices, such as not washing hands after exiting a work area, can also result in the unintended ingestion of contaminants when eating, drinking, smoking, or applying makeup.
- Intoxification occurs when live bacterial cells are ingested which then produce toxins in the body.

Adverse health effects will not occur unless infectious or toxic substances enter the body. Common routes of entry include inhalation, skin absorption and ingestion; however, entry can occur by more than one route. For some pathogens, the symptoms of disease vary based on routes of contamination.

S.13.10 - Sources of Biological Hazards

S.13.10.1 - Animals and Animal Origin Products

Animal biological hazards may be encountered during various field investigation and inspection operations, including inspections of animal origin products, inspections of farms and outdoor areas, and/or inspections that have pest infestation issues.

Animals, including insects, can be a source of transmission of biological hazards. Animals have the potential to be the direct source of a pathogen, or vector, that transmits the pathogen. When around animals, you should take the time and care to understand the possible biological hazards that might be present from the animal, or its skin, feces, urine, etc.

Animal origin products, including foods, may also transmit the same hazards as the originating animal; hence the same caution should be taken when handling or manipulating animal origin products. Examples of such products include feed, milk, and imported bush meat, as well as potentially hazardous handling situations, such as thyroid-processing inspections. The appropriate PPE, based on the anticipated hazards of the animal or animal products, should be worn based on the exposure risk of the operations involved (see PPE section). When inspecting animal or animal origin products, the firm's safety procedures are to be followed to mitigate exposure risk and contamination. If the firm safety measures do not seem adequate for the situation, have a discussion with your supervisor and the program IH.

S.13.10.2 - Rodent-Infested Areas - Hantavirus

Hantaviruses are a group of viruses primarily spread by rodents that can cause disease in humans. Hantavirus can be spread to humans through aerosolization of virus shed in rodent feces, urine, saliva, and, less frequently, from an infected animal bite.

If inspecting crawlspaces, sheds, or warehouses, there is the potential for you to encounter biological hazards associated with rodents and other small animals. Although the exposure risk is low in most cases, evaluation of the potential exposure and risk should be taken along with any precautions, like use of PPE, needed when entering these areas.

When encountering known or suspected rodent-infested areas, the following protective and preventive measures should be implemented:

- Avoid direct contact with rodents dead or alive. Limit your exposure to rodent feces, urine, etc.
- Avoid, as much as possible, moving items around in dusty areas to limit the aerosolization of particulates when inspecting crawlspaces, sheds, or warehouses, and when performing necessary field exams and during breakdown of dusty pallets. If aerosolization of particulates is unavoidable, wear appropriate PPE.
- Wear appropriate PPE for the associated risk, which may include gloves, coveralls, eye protection, and a respirator, depending on the potential hazards and risks.
- Use good hygiene practices. Avoid touching your face, mouth, or eyes with potentially contaminated gloves. After removing gloves, wash hands with soap and water thoroughly.

- Follow any specific guidance issued by federal, state, or local health departments on hantavirus in the area or locality in which you are working.

S.13.10.3 - Poultry Houses

You may be exposed to biological hazards when entering poultry houses such as zoonotic diseases including Salmonellosis, Campylobacteriosis, Chlamydiosis, Tuberculosis, Newcastle Disease, and Avian Influenza that may be present in the facility. Influenza and tetanus vaccinations are recommended for these inspections. Additionally, appropriate PPE is necessary to prevent personal exposure to potential biological hazards when entering these types of facilities. PPE is also used for biosecurity measures, and to prevent the transference of biological hazards between houses and locations. PPE for poultry and egg houses typically includes Tyvek coveralls, boot covers, eye protection, gloves, hair nets, and a respirator, but be sure to follow specific program guidance. Other safety hazards can also be associated with poultry and egg houses (see the physical hazard and chemical hazard safety sections).

S.13.10.4 - Animal Feed

The Bovine Spongiform Encephalopathy (BSE) inspection and feed testing program investigators have the potential to encounter BSE-infected products during animal feed truck inspections and product sampling. Appropriate PPE for such tasks includes gloves and a respirator, which should be worn if there is potential for the animal feed particulate to become aerosolized, or airborne, during inspection and sampling operations.

S.13.10.5 - Sub-human Primate and Animal Testing Facility Hazards

During inspections or investigations of sub-human primate facilities (for example, Good Laboratory Practice (GLP) inspections, non-clinical laboratory testing facilities, animal holding facilities, etc.), do *not* enter rooms housing any sub-human primates. Monkeys housed in these facilities have the potential to carry Herpes-B Virus (also known as B virus, Simian B Virus, Herpes B, herpesvirus simiae, herpesvirus B, monkey B virus or monkey virus). B virus infection can lead to severe brain damage or death if you do not get treatment immediately. Be sure to follow the firm's safety protocols, including recommended use of any PPE.

During inspections of this type, you are not to enter any rooms which hold or house sub-human primates. Bioresearch monitoring (BIMO) inspection information should be obtained from firm personnel interviews and record evaluations. Review of study records is to be completed *outside* of the primate housing areas. Information on animal room activities is to be obtained through firm personnel interviews.

In addition to your IH, consult the references below for animal exposure situations:

- OSH Animal Safety
- Occupational Health and Safety in the Care and Use of Nonhuman Primates
- Occupational Health and Safety in the Care and Use of Research Animals

S.13.10.6 - Plants and Plant Products

S.13.10.6.1 - Psyllium

Psyllium is a type of soluble dietary fiber that can generate an allergic reaction in some sensitive individuals. Psyllium production facilities may require additional safety measures prior to entering their facilities. Allergen pretesting may be needed, including a radioimmune assay (RAST) blood test, prior to entry. Follow the safety guidance for the manufacturing facility and according to the relevant ORA Safety Grab and Go document.

S.13.10.7 – Human Biologics (Blood, Tissue, Plasma and Other Bodily Fluids)

Blood banks and plasma inspections pose the potential for exposure to blood and other bodily fluids. Investigators should be cautious and take suitable precautions to prevent infection in firms such as tissue and blood banks or other places where they may be subject to contact with infectious substances. Blood and tissues should be considered potentially infectious and capable of transmitting disease, including HIV and hepatitis. Follow all PPE protocol and precautions as determined by the risk evaluation for the job task.

Bloodborne Pathogens (BBP) are infectious microorganisms carried in blood and Other Potentially Infectious Materials (OPIM) that when transmitted from an infected individual can cause disease.

Exposure to BBP can occur across a variety of situations, with exposure potentially occurring through sharps, including needle sticks, via broken skin and also mucous membranes. The pathogens of primary concern are hepatitis B (HBV), hepatitis C (HCV), and HIV that causes acquired immunodeficiency syndrome (AIDS). Other bloodborne pathogens exist too and are covered by the OSHA Bloodborne Pathogen (BBP) Standard. The OLS and OHS provide a Bloodborne Pathogen Exposure Control Plan (BBPECP), with an HBV vaccine available to individuals who work with, or who may be potentially exposed to BBPs on the job. The FDA Bloodborne Pathogens Exposure Control Plan is for employees who may encounter blood (human or animal) or Other Potentially Infectious Materials (OPIM). The plan complies with OSHA's Bloodborne Pathogens Standard and is designed to guide workers on how to identify and minimize risks associated with exposure to bloodborne pathogens or OPIM.

S.13.10.8 - Biohazardous Waste

Waste streams have the potential to be contaminated with biological hazards. Biohazardous waste or infectious waste shall be treated in accordance with federal, state, and local regulations, and be handled and disposed of properly. Disposal of biohazardous waste is often conducted through a regulated waste vendor or contract service. Biohazardous waste types you may encounter during investigations, include sharps, infectious waste, and solid waste, all of which has the potential to transmit disease.

S.13.10.9 - Processing Facilities

Various facility processes have the potential to increase the generation of aerosols-- including filling, blending, grinding, spinning, pressurized rinsing, extruding, and spraying—all of which can increase the risk of transmission of biological hazards by inhalation and/or distribution of potential hazards through exposed contact surfaces.

An increase in biological hazards can occur during the processing of raw animal products, the processing of toxin-producing organisms themselves **(**mycotoxin on corn), or processing that propagates or use a biological hazard (vaccine manufacturers).

Although food can be contaminated with pathogens indirectly by contaminated water, animal intrusion, or improper food handling, levels are not expected to be high enough to present a high risk of transmission during sample collection at food processing plants. Additional information on hazards associated with foods can be found in Potential Hazards for Foods and Processes**.**

Processing and manufacturing facilities typically have safety controls and procedures in place to mitigate exposure to the possible hazards during production, including biological hazards. Follow IOM protocol and discuss facility safety measures with firm personnel *prior* to visiting the site when possible, or when on location. You should follow the firm's procedures for mitigating exposure risks during an inspection, to include any administrative, engineering, or PPE controls. PPE may include gloves, face shields, eye protection, coveralls, booties, and appropriate respirators for the specific hazards.

S.13.10.9.1 - Precautions - Blood and Plasma Inspections

Be alert around blood banks or blood-processing operations to the possible dangers of infectious agents.

Keep in mind the following:

1. Do not handle lab instruments, blood samples, containers, or reagents in blood bank labs unless *absolutely necessary*. Wear lab coats with long sleeves. Disposable lab coats that are impervious to blood are an optimal choice. Upon completion, such coats should be left in the laboratory area to be disposed of at the facility.
2. Do not smoke, drink, eat, or meet in blood banks, or in testing areas for Hepatitis B Surface Antigen (HBsAg), HIV, or any other infectious agents.
3. Do consider blood samples, antigens, and antigen testing kits, and other associated HIV-, HBsAg-, and other test reagents as potentially infectious.
4. Do consider the possibility of aerosol contamination if there is spilling or splashing of test reagents or blood samples.
5. Use care when placing inspectional or personal equipment in any lab or testing areas. Wash hands thoroughly after these inspections. *Hepatitis can be transmitted by hand to mouth.*
6. Use disposable gloves. Spills may be adequately addressed by wiping with a 5% sodium hypochlorite solution, and/or solutions such as Wescodyne or Betadine. Autoclaving is the preferred method (121 degrees C for 60 minutes) for sterilizing reagents, samples, and equipment. Note: When accidental spills or similar incidents occur in your presence, you are *not* required to participate in cleaning or disposing of materials. These activities are the firm's responsibility.
7. Use scrupulous adherence to standard/universal personal hygiene practices at all times in the blood bank, and in the testing areas for HBsAg, HIV, and other infectious agents.

S.14 - Chemical Hazards

The following basic information and steps can assist you in recognizing hazardous chemicals, thus enabling you to anticipate potential exposures, and follow preventive measures and practices when preparing for and during site visits. Research any prior inspection histories (file jacket, OSAR, FACTS…) and the type of trade or commodity to be inspected to gain knowledge about the type of chemicals you may encounter in establishment you will be visiting. You may also consult with your supervisor and the program's IH Contact(s) for guidance. In addition, while on site, you should also have access to and the opportunity to review information on chemicals that are present, including SDSs and labeling systems.

The following paragraphs provide an overview of the health and physical hazards posed by some chemicals, as well as reliable sources of information that can be used as reference:

Hazardous chemicals are substances that have the potential to cause harm to human or animal health, the environment, or are capable of damaging property. Chemical hazards can be present and in facilities of the industries that we regulate. Chemical hazards can be in solid, liquid, or gas form. Some are safer than others; but to some workers, who are more sensitive to chemicals, even common forms can cause illness, skin irritation, or breathing problems. You can even experience chemical exposures without direct handling of substances or products. Chemicals can be toxic, corrosive, flammable, and/or combustible. As such, they can pose health risks to workers and become hazards if inhaled, ingested, or absorbed through the skin. Chemical hazards can cause acute harm, such as burns, irritation, and vomiting--or create chronic, long-term health issues, such as asthma, liver damage, and cancer. Identifying potential and actual hazards and taking proper precautions to minimize the hazard(s) and protect yourself is key to avoiding any health problems or complications.

Employers in the United States are required by law to assess the hazards posed by the chemicals present in their workplaces and to implement measures to protect personnel from exposure to those hazardous chemicals. However, some unforeseen incidents, such as equipment failures, or accidental spills or releases may occur, thus increasing the possibility of exposures. While some chemicals have evident warning properties, such as a pungent odor at low or harmless concentrations that helps facilitate their detection, others have no detectable warning properties at all and require monitoring instruments to detect and measure their concentrations in air to determine if levels are safe. Awareness of the properties and hazards posed by chemicals present aid personnel in taking appropriate action to stay safe while performing tasks at different worksites.

Due to the nature of ORA's field investigations and the industries we regulate, there may be situations in which you may or may not anticipate, or be aware of chemical hazards, until you are in the field. The following information provides a guide to some common chemical hazards but is *not* all inclusive. It is recommended that you conduct a brief chemical hazard assessment with the regulated firm upon your arrival to ensure your personal safety. This may be as simple as asking the firm representative, during the opening discussion, if there are any known chemical hazards within the facility. Firm management is often aware of the chemical hazards that exist at their facility and will have safety guidelines and procedures that you will be expected to follow. If you determine that there is a chemical hazard, and you are unsure, or concerned, about the effectiveness of the firm's control of the hazard or your ability to minimize your exposure to the hazard through the use of physical separation and/or PPE, contact

your supervisor and consult with your Program's IH Contact(s) for guidance. If in any doubt about your safety, you should leave the area until all of your concerns have been resolved.

For any known chemical hazards that you identify prior to going out to conduct the inspection (based on your knowledge of the regulated commodity, pre-inspectional web searches, previous Establishment Inspection Report, etc.), be sure to also look through the available "Grab and Go Safety Guidance" tools that have been developed and/or posted on the ORA Safety SharePoint page available to all ORA employees.

S.14.1 - Chemical Hazard Basics

S.14.1.1 - Routes of entry for Chemical hazards

In order to cause health problems, chemicals must enter your body. There are three main "routes of exposure," or ways by which a chemical can enter your body. Common routes of entry include inhalation, skin absorption, and ingestion; however, entry can occur by more than one route.

- Inhalation happens when absorption occurs through the respiratory tract.
- Direct contact happens when absorption or injections occur through the skin, mucous membranes, or eyes.
- Ingestion happens when absorption occurs through the digestive tract.

S.14.1.1.1 - Inhalation

Through inhalation of vapors, fumes, mists, aerosols, or dusts, the breathed chemical enters the bloodstream though the lungs. Once in the bloodstream, chemicals may then be carried throughout the body and affect other organs.

S.14.1.1.2 - Skin Absorption

Skin (or dermal) absorption is another route of entry that may cause localized effects, such as irritation or damage of the tissue in direct contact with the hazardous chemical. Absorption can also lead to other responses, such as sensitization and systemic effects. If chemical sensitization occurs, subsequent skin exposures to that chemical may lead to allergic reactions in the skin or even at sites remote from the skin, such as the respiratory tract.

S.14.1.1.3 Ingestion

Another route of exposure is ingestion (or oral), which may happen when drinking or eating food, or notably, chewing gum or tobacco in work areas where hazardous chemicals are present. Poor hygienic practices can also contribute to chemical ingestion exposure.

S.14.2 Chemical Health Hazards

The following table from OSHA's Hazard Communication - Guidance For Hazard Determination further identifies chemical hazard categories:

CHEMICAL PHYSICAL HAZARDS		
Fire Hazards	***Reactive Hazards***	***Explosion Hazards***
Combustible liquid Flammable liquid Flammable aerosol Flammable gas	Organic peroxide Unstable (reactive) Water-reactive	Compressed gas Explosive

Flammable solid Oxidizer Pyrophoric		
CHEMICAL HEALTH HAZARDS		
Systemic Effects Carcinogen Toxic agent Highly toxic agent Corrosive Irritant Sensitizer	***Target Organ Effects*** Hepatotoxin Nephrotoxin Neurotoxin Blood/hematopoietic toxin Respiratory toxin Reproductive toxin Cutaneous hazard Eye hazard	
OTHER IMPORTANT CHEMICAL HEALTH HAZARDS		
Cardiovascular toxicity Gastrointestinal toxicity Immunotoxicity Skeletal/muscular effects Connective tissue effects Endocrine system toxicity Sensory organ toxicity (sight, hearing, taste)		

S.14.2.1 – Toxicity

Toxic chemicals may enter the body through any route of exposure and cause significant health effects at different levels.

- **Acute toxicity.** Substances with high acute toxicity may be fatal or cause damage to target organs (organ in the body that is most affected by the specific chemical, drug, bacteria, or other substance) as a result of a single exposure, or exposures of short duration. Examples of substances with high acute toxicity include hydrogen cyanide and hydrogen sulfide.
- **Reproductive toxicity**. Chemicals that cause adverse effects on any aspect of human reproduction, including the impairment of male or female reproductive organs, fertility, and fetal development.
- **Specific target organ toxicity** (can occur via single or repeated/prolonged exposure). Chemicals that can significantly impair the function of a target organ system after either a single or repeated exposure. Effects may be reversible, or irreversible, and can be immediate or delayed.

S.14.2.2 - Corrosives / Irritants (Skin, Eye, Respiratory)

Corrosive substances have the ability to cause visible destruction or irreversible alterations in living tissues by chemical action at the site of contact. Irritants can generate reversible damage upon contact, affecting skin, eyes, and respiratory tract.

S.14.2.3 - Sensitization (Skin, Respiratory)

A sensitizer is a chemical that causes a substantial proportion of exposed people or animals to develop an allergic reaction in normal tissue after repeated exposure to the chemical.

S.14.2.4 - Germ Cell Mutagenicity

Mutagens are chemicals that can modify the genetic material in the nucleus of cells in ways that allow the changes to be transmitted during cell division. Some mutations may result in cell death or the transmission of a genetic defect to other cells in the same tissue.

S.14.2.5 - Carcinogenicity

Carcinogens are substances capable of inducing or causing cancer or malignant tumor development, typically after repeated or chronic exposure. Carcinogens may cause no immediate harmful effects and may only become evident after a long latency period. Many factors influence the development of cancer, including the carcinogenic potency of the substance, the level and duration of exposure, and individual susceptibility to the carcinogenic action of the substance.

Entities, including the National Toxicology Program (NTP) and the International Agency for Research on Cancer (IARC) classify carcinogens after an extensive scientific review process. OSHA, NTP, and IARC all provide lists of specific substances identified as carcinogens.

In addition to chemicals, infectious agents--such as viruses, toxins, and physical agents, such as X-rays and ultraviolet radiation--may be classified as carcinogens.

S.14.2.6 - Aspiration Hazards

Aspiration hazards are substances that have the potential to enter the trachea and lower respiratory system through the oral or nasal cavity during inspiration, or breathing, in causing asphyxiation, injury, or other negative health effects. The hazard relates to the possibility of lung damage after swallowing the product. There are different categories of aspiration hazards, ranked according to their level of toxicity. Essential oils sometimes have an aspiration toxicity hazard, which is common for low-viscosity hydrocarbon substances.

S.14.2.7 - Simple Asphyxiants

Simple asphyxiants are inert gases or vapors that can displace oxygen in ambient air when they become too concentrated. Inhaling ambient air with an oxygen level below 19.5% will cause inadequate oxygen supply to blood and organs within minutes after the exposure. Depending on the severity of the oxygen deficiency, the exposed person may experience symptoms including impaired attention, thinking or coordination; fatigue; nausea; vomiting; lethargy; loss of consciousness; and death. Symptoms may appear suddenly, and damage caused by lack of oxygen may be irreversible.

Some examples of simple asphyxiants include nitrogen, helium, neon, argon, krypton, xenon, methane, and ethane. Since these colorless and odorless gases offer no detectable warning properties, oxygen monitors are often used to verify oxygen levels in processes involving the use of these substances.

Another type of asphyxiant, chemical asphyxiants, can cause suffocation by either preventing the uptake of oxygen in the blood, or by preventing the normal oxygen transfer from the blood to the

tissues or within the cell itself. Examples of these chemical asphyxiants include hydrogen cyanide and carbon monoxide.

Oxygen levels can also be consumed/reduced/displaced by rusting metals, ripening fruits, the drying of paints and coatings, combustion, and bacterial activities.

S.14.3 - Chemical Physical Hazards

OSHA states that a chemical is a physical hazard if it is likely to burn or support fire; may explode or release high pressures that can inflict bodily injury; or can spontaneously react on its own, or when exposed to water. OSHA Appendix B to 1910.1200 lists the physical hazards and definitions that will be discussed in this section. Appendix B also contains more detailed information on each physical hazard, if needed.

S.14.3.1 - Corrosive to Metals

A chemical that is corrosive to metals is a chemical that will materially damage or destroy metals by causing a chemical reaction.

S.14.3.2 - Explosives

An explosive substance (or mixture) is a solid or liquid that is, in and of itself, capable (by chemical reaction) of producing gas at such a temperature and pressure, and at such a speed as to cause damage to its surroundings. Pyrotechnic substances are included in this category even when they do not involve gases. A pyrotechnic substance (or mixture) is designed to produce an effect by heat, light, sound, gas, or smoke--or a combination of these as the result of non-detonative, self-sustaining, exothermic chemical reactions.

If you suspect a chemical could be potentially shock-sensitive and/or explosive, do not move the container in which it is found or held. Movement of containers containing potentially unstable chemicals could cause an explosion due to shock, heat, and friction sensitivity. Furthermore, be on the lookout for the following warning signs associated with potentially unstable chemicals that could lead to an explosion: deterioration of the chemical's container, crystal growth on the inside or outside of the chemical's container, and/or discoloration of the chemical itself.

S.14.3.3 - Flammables and Combustibles

Flammable and combustible materials come in many forms, including gas, liquid, solid, and aerosol. These types of materials are associated with two main hazards: fires and explosions.

- **Flammable Gases** are flammable in air at 68°F and at a standard pressure of 101.3 kPa (14.7 psi).
- **Flammable Liquids** have a flash point of not more than 199.4°F. Substances and mixtures of this hazard class are assigned to one of four hazard categories based on their specific flash point.
- **Flammable Solids** are readily combustible or may cause or contribute to fire through friction.
- **Flammable Aerosols** are aerosols that contain any component classified as flammable according to the criteria for flammable liquids, flammable gases, or flammable solids.

- **Readily Combustible Solids** are powdered, granular, or pasty substances that are dangerous as they can be easily ignited if exposed to an ignition source--such as a burning match--and the flames will spread rapidly.

S.14.3.4 - Self-reactive Chemicals

Self-reactive chemicals are inherently unstable and susceptible to rapid decomposition, and/or can react alone in a violent, uncontrolled manner. This definition excludes chemicals classified as explosives, organic peroxides, oxidizing liquids, or oxidizing solids. They are thermally unstable liquids, or solids, liable to undergo a strongly exothermic thermal decomposition, even in the absence of oxygen (air).

S.14.3.5 - Pyrophoric (liquids or solids)

Pyrophoric liquids or solids are liable to ignite within five minutes after coming into contact with air, even if present in small quantities.

S.14.3.6 - Self-heating substances

A self-heating chemical is a solid or liquid chemical--other than a pyrophoric liquid or solid-- which, by reaction with air and without energy supply, is liable to self-heat. This chemical type differs from a pyrophoric liquid or solid in that it will ignite only when in large amounts (kilograms) and after long periods of time (hours or days). Self-heating of a substance or mixture is a process in which the gradual reaction of that substance, or mixture with oxygen (in air), generates heat.

S.14.3.7 - Water-reactive materials

Water-reactive materials emit flammable gases when in contact with water. They are solid or liquid chemicals which, by interaction with water, are liable to become spontaneously flammable, or to give off flammable gases in dangerous quantities.

S.14.3.8 - Oxidizers (liquid, solid or gas)

Oxidizers are chemicals or materials that have the ability to oxidize other substances, or, technically speaking, accept another substance’s oxygen electrons. Oxidizers pose a safety concern due to their potential to promote and enhance fires. Fires need fuel, oxygen, and ignition sources. Oxidizers supply the oxygen, and, as a result, can facilitate burning or make fires burn hotter and longer.

Special precautions should be taken around oxidizers in which visible crystalline growth or discoloration of the chemical is observed or noted. Common oxidizing agents include:

- Oxygen
- Ozone
- Hydrogen peroxide and other inorganic peroxides, Fenton's reagent
- Fluorine, chlorine, and other halogens
- Nitric acid and nitrate compounds such as potassium nitrate, the oxidizer in black powder
- Potassium chlorate
- Sulfuric acid
- Peroxydisulfuric acid
- Peroxymonosulfuric acid

- Hypochlorite, chlorite, chlorate, perchlorate, and other analogous halogen compounds like household bleach
- Hexavalent chromium compounds such as chromic and dichromic acids and chromium trioxide, pyridinium chlorochromate (PCC), and chromate/dichromate compounds such as Sodium dichromat
- Permanganate compounds such as potassium permanganate
- Sodium perborate
- Nitrous oxide, Nitrogen dioxide/Dinitrogen tetroxide
- Sodium bismuthate
- Cerium (IV) compounds such as ceric ammonium nitrate and ceric sulfate
- Lead dioxide

S.14.3.9 - Gases Under pressure

Gases under pressure are gases that are contained in a receptacle at a pressure not less than 200 kPa (29 psi) or are gases that are liquefied or refrigerated. This covers four types of gases, or gaseous mixtures, to address the effects of sudden release of pressure or freezing which may result in serious damage to people, property, or the environment, independent of other hazards the gases may pose. The four types of gases under pressure are compressed gases, liquefied gases, refrigerated liquified gases, and dissolved gases.

S.14.3.10 - Organic Peroxides

An organic peroxide is any organic (or carbon-containing) compound having two oxygen atoms joined together (-O-O-). Organic peroxides are thermally unstable chemicals that may undergo exothermic self-accelerating decomposition. In addition, they may have one or more of the following properties:

- Be liable to explosive decomposition.
- Burn rapidly.
- Be sensitive to impact or friction.
- React dangerously with other substances.

Given their instability, organic peroxides can rapidly decompose, leading to flammable vapors that can easily catch fire and burn intensely. This is due to the peroxides providing both the fuel and oxygen needed for the fire. Some chemicals become explosive peroxides during storage, further enhanced in their explosiveness by exposure to light and heat. Others become more dangerous as they are concentrated.

The plastics and rubber industries are the largest users of organic peroxides. They are used as accelerators, catalysts, hardeners, activators, and more.

S.14.4 - Additional Chemical Hazard Information/Resources

OSHA's Hazard Communication Standards webpage highlights OSHA standards, preambles to final rules (background to final rules), directives (instructions for compliance officers), and standard interpretations (official letters of interpretation of the standards) related to hazard communication including:

General Industry (29 CFR 1910)

- 1910 Subpart Z, Toxic and hazardous substances
  - 1910.1200, Hazard communication
    - Appendix A, Health Hazard Criteria

  - Appendix B, Physical Criteria
  - Appendix C, Allocation Of Label Elements
  - Appendix D, Safety Data Sheets
  - Appendix E, Definition of "Trade Secret"
  - Appendix F, Guidance for Hazard Classifications Re: Carcinogenicity
- 1910.1201, Retention of DOT markings, placards, and labels

OSHA's HAZARD COMMUNICATION: Hazard Classification Guidance for Manufacturers, Importers, and Employers provides guidance on the processes involved and identifies considerations in the conduct of hazard classifications. Guidance on the allocation of the hazard communication label elements is provided in the OSHA Brief on Labels and Pictograms, located on the Hazard Communication webpage. Under the *Hazard Communication Standard* (29CFR1910.1200) established by OSHA, chemical manufacturers and importers are required to perform hazard classifications on the chemicals they produce or import. That information is available in SDS, formerly known as MSDSs, that employers are required to have readily available for review for each one of the chemicals present at their worksites. In general, SDSs provides information on the hazards of the product--including the physical and chemical properties, toxicology, handling and storage guidance, exposure controls, recommended PPE, first aid, firefighting and accidental release measures and any other applicable information. SDSs have sixteen sections; **carefully review sections 2 and 4** as the substance's hazards and first aid measures are listed under these two sections. SDSs can also easily be located online.

Labels and pictograms also aid in communicating chemical hazards information to personnel sharing the work environment.

The OSHA Occupational Chemical Database is OSHA's one-stop shop for occupational chemical information. It compiles information from several government agencies and organizations. Information available on the pages includes:

- Chemical identification and physical properties.
- Exposure limits.
- Sampling information.
- Additional resources.

S.14.4.1 - Chemical Labeling

When evaluating chemical hazards, review the chemical SDSs and any precautionary labeling. When conducting inspections of firms using chemicals, like pesticides, ask to review the SDSs for the products involved to determine what, if any, safety precautions you should take. This could include the use of respirators or other safety equipment.

Sometimes, products encountered during field activities fall under alternate labeling requirements than cited references. For example, pesticides, food additives, and food and drug/cosmetic ingredients, and their facilities, may use specific databases for confidentiality reasons. **Regardless of any alternate labeling systems, the hazard information should always be disclosed to you.**

Terminology and standards may vary by country or region. If there is any confusion, contact your supervisor before entering potentially hazardous areas. If safety procedures at a foreign firm are inadequate for your protection, take precautions based on your training and experience with domestic activities. If you have any doubts about your safety at a foreign worksite, you should

immediately move to a safe location, suspend the inspection as necessary, and contact your supervisor(s) for guidance.

Also review any precautionary labeling, such as Globally Harmonized System of Classification and Labeling of Chemicals (GHS), which is available. The primary purpose of GHS labels is to communicate chemical hazards to workers, or recipients, through signal words, pictograms, hazard statements, and precautionary statements.

OHSA maintains a section on its website with more in-depth information on GHS labeling and classification at: https://www.osha.gov/hazcom. The following, however, provides you with a basic description and pictogram of each of the nine GHS label chemical hazard classifications.



CORROSION

Health hazards: Skin Corrosion/Burns, Eye Damage, and other hazards.

Corrosives are highly reactive substances that cause obvious damage to living tissue. Corrosives can either directly destroy the tissue or indirectly by causing inflammation. They can also be corrosive to metals.



EXCLAMATION MARK

Health hazards: Irritant (skin and eye), Skin Sensitizer, Acute Toxicity (harmful), Narcotic Effects, Respiratory Tract Irritant, Hazardous to Ozone Layer (Non-Mandatory).

Chemicals or materials that can cause an immediate skin, eye or respiratory tract irritant, or narcotic



EXPLODING BOMB

Explosives, Self-Reactives, Organic Peroxides – Chemicals or materials that are highly unstable and at high risk of exploring even without exposure to air. A peroxide is a substance in which two oxygen atoms are linked together by a single covalent bond. This bond makes these peroxides capable of causing a severe fire or explosion hazard



FLAME

Flammables, Pyrophorics, Self-Heating, Emits Flammable Gas, Self-Reactives, Organic Peroxides - Chemicals or materials that can self-ignite when exposed to water or air, or which emit flammable gas. Pyrophoric refers to the property of a substance to ignite spontaneously upon exposure to air



FLAME OVER CIRCLE

Oxidizers - Chemicals or materials that have the ability to oxidize other substances, that is, they accept their oxygen electrons. As a result, these chemicals can facilitate burning or can make fires burn hotter and longer



GAS CYLINDER

Health hazards: Gas cylinders have numerous hazards ranging from direct or indirect exposure from the chemical gas itself, fire or explosion as the gas is under high pressure, and even trauma from improper handling such as sprains, strains, falls, bruises, or broken bones.

Gases Under Pressure – Chemical gases that are stored under pressure, such as ammonia or liquid nitrogen.



HEALTH HAZARD

Health hazards: Carcinogens are substances known to cause cancer. Mutagens are substances known to cause or increase the rate of changes to genes (sections of DNA in body's cells), these changes can be passed along as the cell replicates. Sensitizers are substances known to cause an allergic reaction in normal tissue upon exposure.

Carcinogen, Mutagenicity, Reproductive Toxicity, Respiratory Sensitizer, Target Organ Toxicity, Aspiration Toxicity – Chemicals or materials that cause damage over time (a chronic, long-term health hazard).



SKULL AND CROSSBONES

Health hazards: Acute Toxicity (fatal or toxic) - Chemicals or materials that have an immediate and sever toxic effect. Acute toxicity describes the adverse effects from a single exposure to a substance. These adverse effects can come from either oral (mouth) or dermal (skin) contact from a single dose of a substance, or multiple doses within a short period of time (24 hours), or inhalation exposure (4 hours)



ENVIRONMENT (NON-MANDATORY) Aquatic Toxicity - Chemicals or materials that are toxic to aquatic wildlife

S.14.4.1.1 - Resources related to Hazard Communication (HAZCOM)/chemical labeling

- OSHA Hazard Communication Publications
- OSHA Labels and Pictograms
- OSHA Hazard Communication Wallet Card
- 33 Hazard Classes | Postal Explorer (usps.com)
- US Department of Transportation Nine Classes of Hazardous Materials

S.14.5 – Special Chemical Hazards

**Please note that this list is provided for your awareness and does not include every chemical hazard that you may* encounter *while working in the field. Be prepared to assess the chemical hazards on-site, ask questions of firm management, and consult with your supervisor and your IH* Contact(s) *for guidance to determine if you need to take additional precautions to protect yourself.*

S.14.5.1 - Allergens/Hypersensitivities

Food allergies and food hypersensitivities occur when the body's immune system reacts to certain proteins in food. Food allergic reactions vary in severity from mild symptoms, including hives and lip swelling to severe, life-threatening symptoms, often called anaphylaxis, that may involve fatal respiratory problems and shock. In 2004, the U.S. Congress passed the Food Allergen Labeling and Consumer Protection Act (FALCPA), which identifies eight foods as major food allergens: milk, eggs, fish, shellfish, tree nuts, peanuts, wheat, and soy. On April 23, 2021, the Food Allergy Safety, Treatment, Education, and Research (FASTER) Act was signed into law, declaring sesame as the ninth major food allergen recognized by the United States. More than 160 foods have been identified to cause food allergies in sensitive individuals. There are also several food ingredients that cause nonallergic hypersensitivity reactions in sensitive individuals. These ingredients include, but are not limited to, gluten, colorings, and food additives.

If you or a team member has an allergy or hypersensitivity to the commodity, or something related to the processing of the commodity, to be inspected, remember that your personal safety comes first. Consult with your supervisor about the potential to reassign the inspectional work, or to discuss the appropriate precautions to be taken. When discussing appropriate precautions, consider consulting with the Safety Liaison for your program or office.

S.14.5.2 - Animal Food Ingredients

Most animal food manufacturing establishments are no more unsafe than most human food manufacturing establishments. Many of the relevant safety hazards are addressed in this section,

and include chemicals, allergens, fumigants, and confined spaces. Some feed manufacturers may have Type A medicated articles and/or concentrated minerals in their inventory to be used in manufacturing, so if you intend to sample or otherwise handle those materials, please read the label and observe any safe handling precautions.

If you are going to be conducting an inspection at a facility that manufactures Type A medicated articles, concentrated minerals (such as copper or selenium premix), or other specialty feed ingredients, it is helpful to know those substances in advance, so that you can be sure to have the appropriate PPE with you. You may need to wear a smock, dust mask, and gloves if you need to handle the materials (if you are sampling, for example). Feed manufacturing facilities may also be dusty, so if you are sensitive to dust, you may wish to wear a dust mask. Unless you are allergic to the chemicals present, a respirator should not be necessary, but if you think you would require one, consult with your supervisor and IH liaisons. Wash hands and other exposed skin when you are done.

Biosecurity is also important. Do not travel from an animal production facility or farm to a feed manufacturing facility on the same day, or in the same clothes or PPE, so as not to introduce hazards into any facility.

For any related questions or concerns, contact CVMAnimalFoodProgram@FDA.hhs.gov prior to conducting an inspection.

S.14.5.3 - Dry Ice- Transport and Use for Shipping Samples

Dry ice is potentially dangerous and requires caution in handling and shipping. Dry ice can cause cold burns and frostbite. Be sure to protect yourself by using the appropriate PPE, including safety goggles to protect your eyes from splashes; a face shield to protect sensitive tissues such as your mouth, nose, and other facial areas; and gloves to protect your hands (which should fit loosely so that they can be easily removed). When handling dry ice, also ensure that all other skin is covered with proper attire and that you wear closed toed shoes.

Dry ice can also contribute to an asphyxiation hazard. Dry ice should be stored and handled in well-ventilated areas. Dry ice should *not* be stored in sealed containers to prevent the risk of explosion. Do not handle with unprotected hands, transport in your car without adequate ventilation, or place inside tightly closed metal, plastic, or similar type containers that do not breathe. If it is necessary to use this type of container, adequately vent it to prevent pressure buildup. Do not use glass containers for packaging or storing dry ice. Again, make note that a failure to adequately vent a container containing dry ice may cause a dangerous pressure build-up, resulting in serious risks to sample integrity and the personal safety of all those handling the container).

When shipping frozen samples using dry ice, packages shall be identified in accordance with CFR 49, the International Air Transport Association (IATA) Dangerous Goods regulations and the UPS Dangerous Goods Agreement and Checklist. See IOM 4.7.3.5.1 when shipping packages containing dry ice.

Any FDA employee who ships items subject to Department of Transportation's (DOT) hazardous materials regulations must complete Shipping Dangerous Goods Safety Training.

S.14.5.4 - Opioids

Opioids are substances derived from the opioid poppy or manufactured synthetic analogues. When conducting opioid sampling, adequate safety precautions should be observed during the sampling process. **Do not handle opioids, including fentanyl and fentanyl analogues, without appropriate PPE,** which may include nitrile gloves, coveralls, goggles, and a respirator, depending on the situation and exposure risk. Possible routes of opioid exposure may include inhalation, ingestion, and dermal contact. Opioids have the potential to be inhaled in situations where drug samples are disturbed, and particles have become airborne. Avoid tasks that may aerosolize fentanyl or other opioids. Change gloves if they become contaminated. Avoid contact with eyes, mouth, nose, or unprotected skin with contaminated gloves. Wash hands with soap and water immediately after sampling, or as soon as feasible. **Do NOT use alcohol-based hand sanitizers to clean contaminated skin as these products could increase the drug absorption.**

Opioid overdose symptoms include respiratory distress with slow, shallow breathing, small constricted "pinpoint" pupils, confusion, drowsiness, nausea and vomiting, and loss of consciousness. The opioid antidote medication Naloxone (Narcan) nasal spray can reverse the effects of opioid overdose and restore normal breathing. Naloxone (Narcan) training is available for individuals at risk for exposure to opioids. Contact a supervisor or industrial hygienist for training information. Additional information can be found at Preventing Occupational Exposure to Fentanyl | NIOSH | CDC and Fentanyl: Incapacitating Agent | NIOSH | CDC (includes PPE recommendations).

*Special and similar safety considerations should also be made for firms responsible for penicillin antibiotics, dietary supplements, and CBD products.

S.15 - Physical and Radiation Hazards

Conditions at a firm may present a risk of injury to ORA investigators. This section covers situations or conditions that may cause traumatic injuries, and physical agents, such as noise and radiation (ionizing and non-ionizing), that may lead to certain occupational illnesses. It will focus on specific topics that you should be vigilant about before and during a site visit.

Physical hazards are factors within the environment that can harm the body. Physical hazards include activities or natural substances in a work environment that pose health risks. Extreme temperatures, poor air quality, and excessive noise and radiation can all harm workers, potentially causing respiratory problems, hearing loss, and cancer, among other problems. This category also includes traumatic injuries, which are the most common physical hazards. Physical hazards are present in most workplaces, at one time or another, and include unsafe conditions that can cause immediate and acute injury, illness, or death.

S.15.1 - Traumatic Injury Hazards/Industrial Injuries and Energy Related Illnesses

S.15.1.1 - General Environmental Conditions

The OSH Act requires employers to comply with hazard-specific safety and health standards. In addition, pursuant to Section 5(a)(1) of the OSH Act, employers shall provide their employees with a workplace free from recognized hazards likely to cause death or serious physical harm.

In some circumstances, **heat or cold stress** could be considered conditions that require training and other mitigation actions to be implemented. ORA Safety can be contacted if you have concerns regarding heat or cold stress. Temperature extremes can adversely impact the investigation process and put you at risk for heat or cold stress injuries. If you anticipate hot and/or humid conditions due to either the geographic location or the type of industry, attempt to staff the inspection team with members who are acclimated to similar conditions if possible. Inspections in potential heat stress conditions should be conducted by a team of two or more, with members observing each other for any signs of heat-related illnesses. If you anticipate significant exposure to cold conditions, prepare for the inspection by wearing suitably insulated clothing, or bringing appropriate PPE. In situations of extreme heat or cold, it may be necessary to plan work schedules to minimize the length of exposure. Information on temperature-related injuries and illnesses can be found on the ORA Safety SharePoint Online site.

Poor lighting can increase the risk of injury due to other causes, for example, by making it difficult to see tripping hazards. It may be possible in some cases to request a firm turn on additional lighting, or to wait for a time of day when natural lighting is better; but most likely the best solution will be using flashlights or other portable lighting.

Moving work surfaces, for example conveyor belts, can increase the likelihood of slip/trip/fall injuries or of striking/being struck by objects. Options for mitigating these increased risks may be limited. Supervisors should avoid assigning these inspections to individuals with medical conditions that may impair balance or equilibrium. Motion sickness may also be a concern. You should discuss potential working conditions with the firm and ask for the same advice that would be given to a new employee at the firm. FDA's Occupational Health Service (OHS) may be able to provide consultation and prescriptions to help deal with motion sickness for sensitive individuals.

S.15.1.2 - Slips, Trips and Falls

Fall hazards can be related to floor conditions, as well as elevated walking surfaces. Poor floor conditions can put you at risk for slipping or tripping. Slipping results from not having enough traction between footwear and the floor surface, while tripping results from either too much friction or uneven surfaces. Common slipping hazards in industrial facilities include ice, highly polished or worn floors, or fine powders on the floor. Under good lighting, any of these hazards are generally easy to spot, but it can be easy to overlook changes in floor conditions when moving from one area of a firm to another, especially in poor light conditions. For example, entering cold storage areas may put you at risk for slipping on icy or slushy floors. Similarly, tripping hazards due to slight changes in floor level are common where buildings have been added or extended over the years.

A fall from any height can cause injury, but federal safety regulations require protection at heights of 48 inches or more. The most common practice in industry is to install standard guard rails where a fall of 48 inches or more is possible, or where a shorter fall would result in exposure to a hazard below, such as landing on machinery. Standard guard rails in industrial facilities exist as they do in most other buildings, with a top rail that is roughly at waist height for most adults, and an intermediate rail halfway between the top rail and the floor. Avoid moving closely to ledges that are not guarded by a substantial rail, and remain at least far enough away that slipping, tripping, or being bumped or knocked into would not put you at the edge.

Some firms use personal fall restraint or fall arrest systems near unguarded ledges. Fall restraint systems use a belt or harness attached to a short lanyard, generally preventing workers from getting close enough to the edge to fall off. A fall arrest system uses a harness and shock-absorbing lanyard that will decelerate should a worker fall, bringing them to a stop before reaching the floor. Note that a successful fall arrest is still likely to result in injuries but reduces the chances of more significant ones. Fall restraint and arrest systems require careful fitting and significant training to use safely. **Do not use fall restraint or fall arrest systems provided by a firm.** If you are in a situation in which such a system seems to be the optimal, or only, option for completing an inspection, contact your supervisor and seek advice from your supporting Industrial Hygienist.

S.15.1.2.1 - Manlifts

A manlift is a device consisting of a power-driven, endless belt moving in one direction only, outfitted with steps or platforms and attached handholds, for the transportation of personnel from floor to floor.

Do not ride on a rotating belt, manlift style elevator at any time.

S.15.1.2.2 - Aerial Work Platforms

Many firms have aerial work platforms, mobile aerial devices, or bucket trucks to provide temporary access to elevated areas of a facility. The major causes of injuries and fatalities involving aerial lifts are falls, electrocutions, and collapses or tip-overs. Aerial devices include boom-supported aerial platforms, such as cherry pickers or bucket trucks, aerial ladders, and vertical towers. (Note that OSHA regulates scissor lifts as mobile scaffolds, not as aerial devices).

Do not operate or ride in firm aerial work platforms. Specific operational and safety training is required to utilize the equipment. If you are in a situation in which it appears necessary to use such a platform to complete an inspection, contact your supervisor and seek guidance from your supporting IH.

S.15.1.2.3 - Non-Permanent Scaffolding

A scaffold is an elevated, temporary work platform. There are two basic types of scaffolds:

- Supported scaffolds, which consist of one or more platforms supported by rigid, load-bearing members, such as poles, legs, frames, outriggers, etc.
- Suspended scaffolds, which are one or more platforms suspended by ropes or other nonrigid, overhead support.

Note that other types of equipment, principally scissor lifts and aerial lifts, can be regarded as other types of supported scaffolds.

Potential injuries associated with all scaffolds:

- Falls from elevation, due to lack of fall protection.
- Injuries due to collapse of the scaffold, caused by instability or overloading.
- Injury as a result of being struck by tools, work materials, or debris that have fallen from the scaffold.
- Electrocution, due to the proximity of the scaffold to overhead power lines.

Do not stand on non-permanent scaffolding at any time.

S.15.1.2.4 - Ladders

Per OSHA Fact Sheet on Fall Protection Standards: Falls from ladders account for 20 percent of all fatal and lost work-day injuries in general industry. In general, ladders must be capable of supporting their maximum intended load, while mobile ladder stands and platforms must be

capable of supporting four times their maximum intended load. **Each ladder must be inspected before initial use in a work shift to identify defects that could cause injury.**

Fixed Ladders – Fixed ladders are permanently attached to a structure, building, or equipment. These include individual-rung ladders, but not ship stairs, step bolts, or manhole steps. New OSHA rules have phased in a requirement for employers to have ladder safety or personal fall arrest systems for fixed ladders that extend more than 24 feet, phasing out the use of cages or wells for fall protection.

Portable Ladders – Portable ladders usually consist of side rails joined at intervals by steps, rungs, or cleats. They can be self-supporting or lean against a supporting structure. Firms must ensure that:

- Rungs and steps are slip-resistant.
- Portable ladders used on slippery surfaces are secured and stabilized.
- Portable ladders are not moved, shifted, or extended while a worker is on them.
- Top steps and caps of stepladders are not used as steps.
- Ladders are not fastened together to provide added length, unless designed for such use.
- Ladders are not placed on boxes, barrels, or other unstable bases to obtain added height.

If you find it unavoidable to use a ladder, follow OSHA Ladder Safety, including the following guidelines:

- Inspect the ladder being used/provided by the firm. If the ladder provided by the firm is not in good repair, ask the firm for another ladder.
- As available, read and follow any manufacturer's labels or markings on the ladder, including the maximum load rating.
- Do not use ladders that are damaged or in disrepair.
- Do not use makeshift ladders, or ladders that are positioned on top of boxes or unstable bases.
- Always maintain a three-point contact with the ladder when climbing.
- If possible, avoid carrying supplies or materials in your hands while climbing a ladder.
- Do not stand on the top rung unless it is designed for that purpose.
- If using a ladder, follow a 4:1 ratio for maintaining the proper angle of a ladder--that is, for every four feet of ladder height up to where the ladder rests on a surface, position the ladder base one foot away from the wall, with three feet extending beyond the upper landing surface.
- Do not overextend the ladder.
- Have someone hold the ladder while you are using it.
- If collecting samples while on a ladder, extreme care should be taken to not overreach, or lean too far beyond the center of the ladder and increase the risk of falling.

S.15.1.2.5 - Overhead Hazards

Overhead hazards are defined as hazards located above you that you may come in contact with or that can fall on you. They also include hazards associated with work activities that require you to do something above your head. Some overhead hazards include dropped objects, powerlines, and flying/fixed objects.

You should never walk under a suspended or elevated load. Avoid walking under powerlines if possible. Work conducted in areas with overhead hazards should be limited to only what is necessary. Proper head protection should be worn at all times.

S.15.1.2.6 - Machinery Hazards

You will encounter a variety of machinery types during your inspectional activities. Per OSHA, each piece of machinery has its own unique mechanical and nonmechanical hazards. Machines can cause severe injuries, such as amputations, fractures, lacerations, or crushing injuries. Machines can also cause minor injuries, such as bruises, abrasions, sprains, strains, burns, or cuts.

Examples of mechanical hazards that can hit, grab, or trap are:

- Hazardous motions.
- Points of operation.
- Pinch points and shear points.

There are different types of hazardous mechanical motions and actions:

- Hazardous motions such as rotating parts, reciprocating parts, or traversing parts.
- Hazardous actions such as cutting, punching, shearing, or bending.

Nonmechanical Hazards can also injure operators, or those nearby, and include flying chips, splashes, or sprays that are created when a machine is running.

Normal practice in industry is to enclose, or guard, any moving parts or pinch points on machinery that could strike, entrap, or otherwise injure workers. Typically, such practice is required for any point of operation hazards within seven feet of the floor or other walking surface. Do not assume the machine guarding meets an OSHA standard. Extreme care should be taken when working in or around moving parts of equipment.

S.15.1.3 - Energy Hazards

Energy sources, including electrical, mechanical, hydraulic, pneumatic, chemical, nuclear, thermal, gravitational, or other sources in machines and equipment, can be hazardous. Be aware of the potential for any of these types of energy hazards.

S.15.1.3.1- Thermal Energy

Thermal energy occurs when heat or cold is produced by mechanical devices (combustion and/or friction), electrical resistance, or chemical reactions (or changes of state like cryogenic materials). Boiling water is an example of thermal energy. Burns can occur due to both cold and hot forms of thermal energy, with the severity of the burn dependent on temperature and duration, or contact.

S.15.1.3.2 - Residual Energy

Residual or stored energy is energy within the system not being used, but when released, can cause severe injuries, even though equipment has been turned off or locked out.

S.15.1.3.3 - Electrical Energy

Electrical energy is the most commonly identified form of energy in workplaces. It can be available through power lines, induced, or stored, for example, in batteries or capacitors.

S.15.1.3.3.1 - Electrical Systems

Many inspectional activities are performed in poorly lit areas, or in older, poorly wired buildings. Be alert for low hanging wires, or bare, exposed, or worn wires, and broken or cracked electrical outlets.

When you are using portable power tools, etc., be extra cautious of the shock hazard. See Inspection Technical Guide # 22, Ground Fault Circuit Interrupter | FDA, regarding Ground Fault Circuit Interrupters. Use one if feasible.

S.15.1.4 - Powered Industrial Vehicles

S.15.1.4.1 - Forklifts

Forklifts are powerful vehicles commonly used for lifting and moving heavy loads. Some of the most common forklift accidents include overturns, being struck by a forklift, and falls from a forklift. *You are not to operate a forklift* as specialized training is required.

Accidents/injuries can be the result of forklifts and pedestrians traveling or moving in the same area. Forklift traffic should be separated from pedestrians wherever possible. Be aware of and stay within any floor markings, walkways, or aisles that delineate where you should be walking or that separate pedestrians from forklift and other vehicle traffic.

Additional forklift safety/vehicle reminders:

- Be aware that vehicles cannot stop suddenly. They are designed to stop slowly, to minimize load damage and maintain stability.
- Stand clear of vehicles in operation, including lifting and moving loads.
- Avoid a run-in. The driver's visibility may be limited due to blind spots.
- Be aware of the vehicle’s wide, rear-swing radius.
- Never pass under an elevated load.

S.15.1.4.2 - Moving Cranes

Moving cranes are used for lifting and moving heavy loads; but, unlike a forklift, the load is suspended overhead from a cable attached to the crane. Both the crane and the load attached can pose a serious hazard. Ensure you maintain a safe distance from the crane in the event that the crane/load tips or shifts.

S.15.1.4.3 - Mobile Elevated Work Platform (MEWP)

A MEWP, also known as a cherry picker, is a movable platform to help with high-level access tasks. Due to the heights involved, a serious fall or electrocution from a MEWP may be fatal. Due to the specialized training to operate this vehicle, consult with your supervisor and the ORA Safety Office before entering the basket of this type of vehicle.

S.15.1.4.4 - Semi Trucks

Semi-trucks and attached trailers have larger blind spots and require extra space to maneuver. Loading docks, where semi-trucks pickup or drop, are frequent locations of accidents due to these blind spots. As with any type of moving vehicle, maintain a safe distance from any moving semi-trucks.

You may be required to enter the trailer or take a sample from the top of the trailer. Prior to any activities inside or from the top of a trailer, ensure the truck is properly blocked in a way to prevent anyone from moving the truck while you are in or around it. Also ensure that you cannot be trapped or locked inside a trailer, via LOTO, or with the aid of another person.

Take frequent breaks if you are entering a trailer in hot weather.

If you take samples from the top of the semi-trailer, ensure proper safety precautions for climbing ladders. Never enter a trailer from the top.

S.15.2 - Radiation Hazards

Potential exposure to radiation can be found in nearly every ORA program because many FDA-regulated facilities use or manufacture radiation-emitting electronic products, including laser products, x-rays used in medical devices and blood banks, radioactive material used in positron emission tomography, and radiopharmaceuticals. Additionally, import and domestic inspectors may be asked to collect FDA-regulated products that possess potential radioactive contamination. Portable instrumentation used by ORA inspectors may also have an associated radiation hazard, including handheld or benchtop chemical analyzers.

Below is a brief overview of these hazards. For a full list of up-to-date radiation safety resources, including, but not limited to training requirements and contacts, visit ORA Radiation and Laser Safety Resources.

S.15.2.1 - Examinations with Non-Ionizing Radiation Hazards

Equipment that produces non-ionizing radiation can be found in nearly any inspection. Typical non-ionizing radiation encountered includes lasers, radiofrequency waves, microwaves, and ultraviolet light. Protective eyewear and other equipment for non-ionizing radiation must be provided by the manufacturer. If you see signs or placards indicating the presence of non-ionizing radiation hazards (for example, a sign marked “Laser Area”) do not enter the area unless provided with proper protective equipment.

If you believe there is a non-ionizing radiation hazard and you have *not* been given PPE by the firm, either do not enter the area, or tell a representative from the firm to power-off all equipment producing non-ionizing radiation hazards before continuing.

S.15.2.2 - Examinations with Ionizing Radiation Hazards

ORA strives to limit exposures to the Nuclear Regulatory Commission’s (NRC’s) public limit and considers 99% of the ORA inspectorate as non-radiation workers. ORA issues radiation dosimeters, radiation pagers, and radiation awareness summaries to employees engaged in the following activities or assignments:

- Operations involving an XRF analyzer.
- Import examinations. CBP also utilizes some radiation-based technologies to screen incoming shipments.
- Positron emission tomography inspections.
- Radiography x-ray inspections.
- Radiopharmaceutical inspections.

- Fluoroscopy inspections.
- Mammography inspections.
- Computed tomography inspections.
- Sterility facility inspections.
- Blood bank facility inspections.
- Imports/domestics (in cases of radiologically contaminated products).

Dosimeter Monitors are assigned to individuals by ORA Program Management, who are responsible for distributing and collecting dosimeters at the end of each wear period. For an updated list of dosimeter monitors, see the ORA Radiation and Laser Safety Resources SharePoint Site.
It is important to keep in mind that dosimeters only record radiation exposures, which can only be discovered after a potential radiation exposure event has occurred. Radiation Pagers, on the other hand, will warn an inspector of dangerous radiation while in the field, in-situ. If a Radiation Pager alarms, immediately leave the area. See Radiation Awareness for Dosimetry and Pager Users.
Upon inspecting a facility that contains ionizing radiation, ORA employees should expect to be given a firm-issued dosimeter, or other device, to measure radiation exposure. Per NRC and Agreement State regulations, visitors to facilities are considered members of the general public. If you do not receive any equipment from the firm, proceed with caution.

S.15.2.2.1 - When to stop examinations/collections due to Ionizing Radiation Hazards

If you encounter any of the following situations during an inspection, stop work immediately and contact your supervisor(s):

- Radiation levels above the general public limit (as alerted via pager alarms).
- The use of any uncontained, volatile, or loose radioactive material.
- Collection of radioactive samples that cause pager to alarm above public limit.
- Collection of radioactive samples that are powdery or volatile.

Individuals assigned to these duties are considered radiation workers. In addition to completing awareness training and carrying a dosimeter and pager, these individuals must complete hands-on classroom radiation safety and advanced equipment training approved by the ORA health physicist (HP).

S.15.2.3 - Radioactive Product Sampling

Sampling of potentially contaminated FDA-regulated products from all FDA programs could result in potential internal and external exposures to ionizing radiation. Safety equipment required for working around these products includes radiation dosimeters and radiation pagers. Sampling of volatile or powdery material containing radioactive particles requires special training. Air monitors or use of respirators may also be required. DOT and IATA regulations pertain to shipping radioactive samples. Contact Supporting IH and ORA HP for details at ORA Radiation and Laser Safety Resources SharePoint Site.

S.15.2.3.1 - Sampling Instrumentation with Radiation Hazards

The following handheld and benchtop instruments have been issued to ORA inspectors encountering radiation hazards:

- X-ray fluorescence Spectrometer for external ionizing radiation hazards.
- Ion Mobility Spectrometer for potential contamination hazards.
- Raman Spectrometer for laser hazards to the eyes.

S.15.3 - Animal Hazards

Inspections, particularly of farms and outdoor operations, have the potential to have animals and insects present.

As an investigator, you may encounter domesticated animals such as, dogs, cats, cattle, horses, chickens, sheep, etc., as well as wild animals, such as foxes, coyotes, badgers, wolverines, martens, rodents, spiders, and snakes, etc., during farm and outdoor operations. Be aware that any animal species can be dangerous, depending on circumstances. You may also experience infectious disease transmission from mosquitoes and ticks, small animal bites and swelling, or mild to severe allergic reactions from stinging insects.

Animal behavior can be unpredictable; you should remain constantly alert and watch for warning signs of animal aggressiveness and fear. These vary with animal breeds, but may include raised fur, flattened ears, twitching tails, or bared teeth. If a potentially hazardous encounter occurs, you should make no attempt at engaging with the animal and instead should vacate the area immediately and notify firm management as necessary.

Wear appropriate clothing for the situation. Wear long pants and sleeves, and boots taller than the ankle, as appropriate for the inspection and area. Use insect repellant. Stay out of tall grass and keep hands and feet out of areas you cannot directly see. If an encounter with an animal occurs in which you are injured, including a snake/spider/dog bite, seek emergency help immediately.

For snake bites, responding quickly is crucial. Immediately call for emergency medical attention. While waiting for emergency help to arrive, wash the area with soap and water if possible and apply a cold compress. Keep the bitten area lower than the heart and remove any constricting clothing and jewelry from the extremity as the area may swell. Note the time and location of the bite to report to emergency room personnel. Try to remain calm while waiting for help to arrive.

S.15.3.1 - Dog bites/attacks

If you are going to be conducting an inspection or investigation where you may encounter dogs--such as, but not limited to, the private residence of an individual, a shell egg producer, farm facility, or warehouse--you should exercise caution. If the inspection or investigation will be pre-announced, ask if there are farm or guard dogs on the property, and if so, whether they will be leashed or kenneled before your scheduled arrival. If the inspection will not be pre-announced, observe the area carefully prior to exiting your vehicle. Be aware of common places that dogs may hide, including under parked cars and hedges, or on porches. Upon exiting the vehicle, be aware of your surroundings to see if any noises from the vehicle, shutting doors, etc., have aroused the attention of a dog on the property. If an employee is present on the property, ask if any dogs are present. If you are entering a fenced-in area, rattle the gate before entering to alert animals to your presence and reduce chances of conflict. If you are bitten by a dog, seek medical care and report the incident to your supervisor. For additional information, refer to:

- ORA ORS Dog Encounters Grab and Go
- Dog bite prevention | American Veterinary Medical Association (avma.org)
- Dog Bite Prevention | ASPCA
- Dog Attack Information for All Mail Carriers (usps.com)

- Be Aware: Any Dog Can Bite - Postal Posts (uspsblog.com)
- 'Watch That Dog' explains basic protection and provides insight into the mannerisms of various types of dogs. This video from the Oregon OSHA Workplace Education and Training Grant Program https://osha.oregon.gov, tells how to protect yourself from possible attack and injury.

S.15.4 - Specific Industries

S.15.4.1 - Grain Handling Facilities

Grain storage structures, such as grain elevators and feed mills, can present life-threatening hazards. It is always preferable to inspect them or collect samples from the outside. If it is not possible to collect the samples from the outside, consult your supervisor prior to collection.

Before entering a grain storage structure, be sure to:

- Meet with the facility's operator to discuss hazards that may be present in the storage structure, including entrapment or engulfment in grain, asphyxiation, or the presence of toxic or flammable atmospheres, as well as procedures to be followed in the event of an emergency.
- Confirm that the operator will lock out any moving equipment within the storage structure, such as conveyors and augers, and will conduct atmospheric tests for oxygen, combustible gases, and toxic gases. Contact your supervisor for any questions.
- Refer to Man Lifts and Ladders for guidance. Do not use a man lift without supervisory approval.
- Make sure cross-rungs on ladders are safe.
- When stepping off of ladders or man lifts, be sure the floor is a true floor and not a bin covered with canvas, cardboard, or other temporary non-supportive cover.
- Never stand or walk across the surface of the material stored in a silo. The surface may only be a "thin crust" over a hollow space in the silo. Breakthrough the crust often causes death by engulfment of the material and subsequent asphyxiation.
- Make sure walkways between bins are sturdy.
- Use caution when sampling from high bins or tanks. Wet or icy conditions may prevail, so check these conditions.
- When brass grain bombs are used to collect bin samples, do not drop the bomb to the surface of the grain. This activity could cause sparks if the bomb hits the bottom or side of a bin. Instead, lower the bomb gently to the grain surface, then raise it four to five feet and let it fall to the grain surface to collect the sample. ***Do not use steel grain bombs***; use only brass bombs for sampling.
- Do not use flash units in dusty areas because of the possibility of explosion hazards. Any electrical devices used, including flashlights, cell phones, communication radios, and similar devices, should be explosion-proof.
- Do not enter a grain storage structure without appropriate PPE, or if you see that any grain is frozen or caked to the walls. Wear PPE during inspection and sampling, including for bump caps.

S.15.4.2 - Rail Safety

S.15.4.2.1 - Railyards

Railyards are dangerous areas. If there is a Safety Office at the yard, inquire about specific information concerning current hazards.

Maintain a safe distance from equipment in motion and cross tracks at right angles, whenever possible, without stepping on rails. Be aware of the pressure wave created as a train (or any moving vehicle) passes. This force can knock people down and into the path of subsequent cars.

S.15.4.2.2 - Railcars

When sampling railcars, make sure doors are propped open to avoid accidental closing if the car is bumped while you are in it. Display a **warning flag or similar device** to alert others that you are in the car. **Always have a railroad yardman or another FDA investigator present**. When entering the car, make sure the ladder is secure. On hot days, or after a car has been fumigated, it should be aired out prior to entering, preferably by opening both doors. Observe "No Smoking" in rail cars. Never crawl under railcars –walk around them. Avoid any cables between the railroad tracks. These are often used to move cars on sidings. A cable snapping taut can kill or maim.

S.15.4.3 Other Industries

Other inspected commodities that can pose **unique** safety challenges include, but are not limited to:

- Egg-producing facilities
- Compounding pharmacies
- Seafood
  - Vessels
- Produce farms
  - Irrigation canals
- Sprouts
  - Chlorine solutions
- ITS
  - Watering points
  - Airports
  - Cruise ships
- Imports/IMF
- Tissue/drug residues

With the above special situations, and others like them, be sure to consult any available compliance programs , assignments, commodity SMEs, InsideFDA.gov SharePoint sites, QMiS, as well as your IH liaison for safety considerations and precautions.

S.16 - Ergonomic

Per OSHA: Musculoskeletal disorders (MSDs) affect the muscles, nerves, blood vessels, ligaments and tendons. You can be exposed to risk factors at work, such as lifting heavy items, bending, reaching overhead, pushing, and pulling heavy loads, working in awkward body postures, and performing the same or similar tasks repetitively. Exposure to these known risk factors for MSDs increases your risk of injury. Ergonomics --- fitting a job to a person --- helps lessen muscle fatigue, discomfort, pain and

reduces the number and severity of work-related MSDs. Ergonomic risk factors are workplace situations that cause wear and tear on the body and can cause injury. These include repetition, awkward posture, forceful motion, stationary position, vibration, and extreme temperature. Exposure to multiple factors increases the risk of developing MSDs.

Ergonomic injuries occur when the type of work, body positions, and/or working conditions you must engage in put strain on the body. Symptoms, the strain on your body or the harm that these hazards pose aren't always immediately noticeable. Short-term exposure may result in "sore muscles" the next day or in the days following exposure, while long-term exposure can result in serious long-term illnesses. Poor ergonomics can lead to health issues for employees, such as cumulative trauma disorders, repetitive motion injuries, and musculoskeletal disorders. Often, ergonomic hazards arise due to poor or inadequate workplace design.

If needed, ORA Safety can provide advice on selecting tools and equipment that CSOs will use in the field as well as on work techniques to minimize the risk of musculoskeletal disorders. Consult with your supervisor and/or your IH Contact(s).

S.16.1 - Force

Tasks that require large amounts of force and/or large amounts of force relative to the affected body part increase the risk for ergonomic injury. Examples include forces on the lower back when lifting heavy objects and forces on the elbow while striking an object with a hammer. Examples of force-based hazards may include lifting/carrying/lowering/pushing/pulling heavy objects such as samples, sample supplies, or inspectional equipment.

When possible, reduce the amount of force on your body when performing tasks. Effective strategies include using proper tools and equipment, designing and/or planning work to avoid unnecessary forces on the body, and using safe work practices, such as team lifting of heavy and/or awkwardly shaped objects.

S.16.2 – Awkward, Same Posture/Improper Adjustments

Working in awkward body positions and/or with equipment not properly designed for the user increases the risk of ergonomic injury. Examples may include hunching over a workstation that is too short or using equipment that hasn't been adjusted to an individual's preference/size. Whenever possible ensure equipment and tools are properly adjusted to ensure user comfort and ergonomically sound positioning.

S.16.3 - Repetition

Tasks that require multiple repetitions put cumulative stress on the affected body parts, increasing the risk of ergonomic injury. Examples of tasks often done repetitively or for extended periods of time include collecting swab samples or using a mouse and keyboard. When possible, plan work to reduce the number of repetitions of a task you must complete, take frequent breaks, and avoid repeatedly performing tasks that require large amounts of force and/or awkward positions.

S.16.4 - Cold Temperatures

In combination with any one of the other risk factors, cold temperatures may also increase the potential for MSDs to develop. For example, many of the operations in food processing occur with a chilled product or in a cold environment.

S.16.5. - Vibration

Both whole body and hand-arm vibration can cause a number of health effects. Hand-arm vibration can damage small capillaries that supply nutrients and can make hand tools more difficult to control. Hand-arm vibration may cause a worker to lose feeling in the hands and arms resulting in increased force exertion to control hand-powered tools in much the same way gloves limit feeling in the hands. The effects of vibration can damage the body and greatly increase the force which must be exerted for a task.

S.16.5 - Special Ergonomic Situations

Inspectional and investigational tasks with an increased likelihood of exposure to ergonomic hazards include sampling and processing equipment inspections that could involve lifting, improper adjustments and repetition. Strategies for reducing the likelihood of ergonomic injury are listed below.

S.16.5.1 - Sampling

Sampling can involve repetitious motion in awkward positions, and the transportation of sampling supplies to and from a firm can require large amounts of force. When sampling, try to minimize time spent in awkward or uncomfortable positions, and switch roles with other members of the sampling team periodically to reduce bodily strain. Use containers and bags that are easy to lift, preferably with handles on them, to transport sampling supplies. If a bag or container is heavy, request help from another member of the sampling team.

S.16.5.2 - Processing Equipment Inspection

Inspecting processing equipment can require moving and or staying in awkward body positions for extended periods. When inspecting, use equipment such as cameras or mirrors, when possible, to visually inspect equipment without assuming an awkward position. If you must assume an awkward position, ensure you have your flashlight, camera, and/or other equipment necessary for evidence collection ready, to avoid remaining in the positions for longer than necessary.

S.17 - Employee and Traveler Health and Safety

S.17.1 - *FDA Occupational Health Services (OHS)*

FDA OHS has health units established for employees to receive occupationally related medical services. Each health unit provides access to on-site first aid and urgent care services; onsite clinical care, referral, and follow-up for work related injury and illness; immunizations; health risk appraisals; health screenings; health counseling; and health and wellness education. Services are provided by appointment only. To request OHS services **Outside the National Capital region**, send an email to occupationalhealthservices@fda.hhs.gov. Call 911 for medical emergencies.

S.17.2 - Immunizations

FDA provides operating field personnel with various immunizations for protection from infection or injury on the job. Utilize the following CDC sites, tools, and schedules to determine your immunization status:

- Adult Vaccination Home Page

- Adult Vaccine Assessment Tool
- Adult Immunization Schedule
- Vaccine Information for Adults

S.17.2.1 - Domestic Work

You may need vaccines based on your age, health conditions, job, lifestyle, or travel habits. Learn more about what other vaccines the CDC recommends for you and talk to your OHS about which vaccines are right for you.

S.17.2.2 - Foreign Travel

Reference the DTO Immunizations and Other Health-Related Topics site for information on immunizations and/or prophylactic medications for foreign travel.

Consult with your supervisor and trip planner, well in advance of planned foreign travel, as to specific requirements of the countries to be visited. *FDA employees are responsible for ensuring they have received recommended immunizations and/or prophylactic medications specific for their official travel destinations.* Immunizations and prophylactic medications are provided at no cost to employees that travel internationally as part of their official duties.

S.17.3 - Physical Examinations

There is no requirement for periodic physical examinations. Even so, it is your responsibility to adhere to good personal hygiene and health practices. If any firm management demands evidence of recent physical examination before permitting inspection, consult your supervisor. A mere request to examine your hands for sores, etc., is not unreasonable. However, do not accede to a physical examination.

S.17.4 - Traveler Health

S.17.4.1 - Domestic Travel

Refer to your division/supervision, DTO and CDC Travelers' Health-United States for domestic travel health issues.

S.17.4.2 - Foreign Travel

In addition to the immunization information above for foreign travel, the Division of Travel Operations (DTO) has captured materials and resources that serve as a supplement to the trip-specific communications that are sent to the foreign traveler. Be sure to visit the: Pre-Travel, During Travel, Post-Travel, Contact Information links below to find useful information that may assist you through all aspects of the foreign trip process.

The Foreign Travel Resources Page is a list of helpful resources for use when conducting foreign travel:

- Policy, Procedures and Guidelines
- Pre-Travel
- Health Information
- Commonly Used Terms Associated with Foreign Travel
- During Travel
- Post-Travel

All investigators conducting ORA foreign inspections shall take required courses and trainings prior to departure. You should contact your program office for information on these courses.

- The online training CT401 (https://fsitraining.state.gov/home/7480) was developed for staff who spend *90 days or less* outside of the country per year. The training remains good for six years.
- Staff who spend *90 days or more* outside the United States (including ORA foreign cadre staff), are required to attend and complete training CT650 (https://fsitraining.state.gov/FACT). All assigned overseas staff shall attend this intensive course. This training remains good for six years.

S.17.4.2.1 - Pre-Travel

If the CDC has issued a Travel Notice (Level 1: Watch, Level 2: Alert, Level 3: Warning) for your destination, make sure to discuss the notice with your supervisor/trip coordinator and during your health appointment.

S.17.4.2.2 - During Travel

This page details important information for the traveler while on official government travel.

S.17.4.2.2.1 - Medical Emergencies and/or Medical Assistance Abroad

In case of any emergency such as illness, injury or safety concerns, travelers should seek medical attention immediately. After treatment, contact your supervisor, trip coordinator (if unavailable, the coordinator's supervisor) or any other ORA contacts provided on the itinerary. Never postpone seeking medical attention if seriously ill or injured. Federal employees are covered by the Federal Employees' Compensation Act (FECA) while on government business abroad for work-related injury or illness. Review the Medical Emergencies and/or Medical Assistance Abroad page for additional information.

Before travelling internationally, FDA employees should check with their private medical insurance providers regarding what services and coverage they will have in case they become ill or injured in a foreign country. *FDA does not provide separate medical insurance or reimbursement for non-work-related medical treatment while on foreign travel.*

Commissioned Corps Officers in TDY/TAD OCONUS may seek medical care through use of the Tricare Overseas Program (TOP). For more information, call 1-888-777-8343 (from the U.S.), visit TOP site for country-specific contact information or access the website at TRICARE Overseas (tricare-overseas.com). Also see the MyCare Overseas™ Mobile App and Web-Based Portal, available via laptop or personal computer, providing easy-to-access services, such as checking your TRICARE Health Plan, verifying TRICARE covered services, finding a TOP Network Provider, and offering connections to 24/7 assistance to the local Near Patient Team (in specified locations), the Global First Call Desk, the Beneficiary Support Center (BSC), as well as Technical Support. There is also a self-service ChatBot feature that provides immediate answers to Frequently Asked Questions, and, if needed, a link to chat directly with the BSC. Reference the TRICARE Overseas Handbook for additional information.

After obtaining any necessary emergency treatment, use the Employees' Compensation Operations and Management Portal, ECOMP - U.S. Department of Labor (dol.gov), for completing required incident reports (OSHA-301) and worker's comp forms (CA-1 or CA-2). OSHA-301 shall be completed within seven days of injury or illness. CA-1/CA-2 shall be

completed within 30 days. If unable to access ECOMP website, or to complete forms, contact your trip coordinator, or your division representative within FDA Human Resources.

S.17.4.3 - Travel Health Kit

The CDC offers a plethora of traveler health information at CDC Travelers' Health and CDC Traveler Advice. At CDC Pack Smart, the CDC provides a checklist to prepare for your next trip. The website states that, particularly if travelling abroad, to make sure to bring items with you, since the quality of items bought overseas cannot be guaranteed. Not all of these items may be relevant to you and your travel plans. Additional travel tips include:

- Keep any needed routine prescription meds in your carry-on luggage and bring extra meds, if applicable, for possible travel delays. Bring copies of all prescriptions (meds, devices, glasses/contacts). Have letterhead letter from your health care provider for any controlled or injectable meds. Check with the relevant U.S. Embassy, prior to your departure, to ensure your meds are allowed in the country. Leave a copy of prescriptions at home with your designated contact person.
- Keep your health insurance card and contact information with you when abroad. Keep proof of yellow fever vaccination, too, if required.
- Keep your Emergency Contact Card with you, along with a list of local hospitals/clinics/emergency services. You should also carry with you the name of your local POC, and their address and phone number at the closest U.S. Embassy or Consulate.
- Additional items for consideration in your health kit include, inhalers, epinephrine auto-injectors, medical alert bracelets, special prescriptions for trip/travel (antibiotic for traveler's diarrhea, commercial suture/syringe kits for use by local physician, anti-altitude sickness meds, anti-malarial meds, etc.), over-the-counter meds (antacid, diarrhea meds, mild laxative, motion sickness, mild sedative, decongestant, pain and fever med, antihistamine, cough drops, saline nose spray, cough suppressant/expectorant, etc.), preventive items (hand sanitizer/wipes, insect repellant, permethrin, bed net, sunscreen, sunglasses, safety equipment, earplugs, etc.), first aid kits (first aid creams, wound bandages/blister care, elastic bandage wrap, eye drops, water purification tablets, oral rehydration salts, equipment-gloves, thermometer, scissors, swabs, tweezers, etc).

S.17.4.4 - General Precautions During Trip

The CDC states at The CDC Survival Guide to Safe and Healthy Travel that, whatever your reason for traveling, you should be prepared when it comes to your health—before, during, and after travel. Additionally,

- Practice personal security
  - Carry contact information for the nearest U.S. Embassy/Consulate.
  - Carry a photocopy of your passport and entry stamp/form.
- Note that motor vehicle crashes are the leading killer of healthy U.S. citizens in foreign countries.
- Follow safe eating and drinking practices.
- Prevent bug bites.
- Prepare for possible weather extremes.
- Avoid animal contact.

- Wash hands.
- Avoid sharing body fluids. If medical or dental care needed, make sure local clinic or hospital employs good medical hygiene.

Note also that, in the e-clearance form provided in your foreign travel process documents, you have a registered country clearance with the U.S. Embassy/Consulate in that location. Your country clearance will be obtained for you by the Passport Office. The e-clearance form includes contact information, health information, security threat, immigration/customs/quarantine, climate, and transport information. In "Contact Information" box on the form, you will see Embassy telephone numbers for business and after-hours. For any situation of physical or medical threat, you can contact the Embassy 24 hours/7 days a week.

S.17.4.5 - Additional travel resources

S.17.4.5.1 - Travel.State.Gov

At Travel.State.Gov, the U.S. Department of State's Bureau of Consular Affairs provides services that protect U.S. citizens and their interests abroad, ensure U.S. border security, facilitate the entry of legitimate travelers, and foster economic growth. Resources housed at this site include:

- Travel Advisories
- U.S. Citizens in an Emergency
  - If you are overseas and in need of emergency assistance contact the nearest U.S. embassy or consulate.
  - Call: From the U.S. and Canada: 1-888-407-4747. From overseas: +1 202-501-4444.

S.17.4.5.2 - CDC Travelers' Health

The CDC/Traveler's Health website is committed to updating the public with current and accurate information regarding COVID-19, COVID-19 related vaccines and medicines, along with other travel advice/recommendations, notices, and resources. You are encouraged to review this site frequently in advance of travel.

S.17.5 - Employee and Traveler Safety

S.17.5.1 - Employee Safety

See references to personal safety in this chapter and IOM Chapter 5.

S.17.5.2 - Traveler Safety Tips

- Conduct research into your destination(s).
- Keep travel plans private but check in with a trusted network often.
- Write down emergency information.
- Keep photocopies/scans/photos of important documents.
- Lock up your valuables.
- Don't draw attention to yourself.
- Don't share too much information with strangers.
- Stay "tethered" to your bags/equipment.
- Practice situational awareness; be aware of your surroundings.
- Avoid unsafe, "sketchy" vicinities.
- Don't advertise valuables.

- Use ATMs wisely.
- Trust your instincts.
- Do not bring anything with you that is irreplaceable if stolen.
- Drink alcohol responsibly.
- Choose safe foods and drinks when traveling per the CDC and consider the following suggestions:
  - Eat at popular places with long lines.
  - Try to watch how your food is prepared.
  - Pack translation cards to document your allergies.
  - Fully cooked, hot food is always the safest.
  - Only eat peelable fruit to avoid bacteria.
  - Avoid fresh salads and other raw foods.
  - Do not drink the tap water or use ice in developing countries.
  - Drinks from unopened, factory-sealed bottles or cans are best.

S.17.5.3 - Motor Vehicle Safety

Per the CDC/NIOSH Transportation Safety | Motor Vehicle Safety | CDC Injury Center, driving or riding in a vehicle as part of your job can add to your risk of injury. Motor vehicle crashes are a public health concern both in the United States and abroad. In the United States, motor vehicle crashes are a leading cause of death, and kill over 100 people every day. However, motor vehicle crash injuries and deaths are preventable. There are proven strategies that can help prevent these injuries and deaths. Whether you are a driver, passenger, cyclist, or pedestrian, you can take these steps to stay safe on the road:

- Make sure your vehicle works properly.
- Always use seat belts, obey speed limits, and keep a safe following distance.
- Stay focused on the driving task by avoiding distractions.
  - Don’t talk on hand-held cell phones or use other handheld devices. Avoid hands-free phones too – *any phone conversation can be a distraction*.
  - Don’t text.
  - Don’t adjust controls.
  - Don’t eat or drink.
  - Don’t drink alcohol and drive.
  - Don’t be distracted by passengers.
  - Keep your eyes on the road, and your hands on the steering wheel.
- Slow down when you get near intersections.
- Drive cautiously, especially when you see objects in or next to the road.
- Make sure you are well rested before you start driving.

Before operating a vehicle, check the following:

1. Tires, check for tread wear, inflation, etc.
2. Mirrors, for proper adjustment
3. Brakes for operability as much as possible
4. Windshield for visibility
5. Lights: headlight, turn signals and brake
6. Gasoline and oil gauges to determine levels

7. Spare, jack, lug wrench, first aid kit, flares, etc.

Note: Fire extinguishers are no longer required in vehicles.

When transporting materials of trade, or items that when shipped commercially would be regulated as hazardous materials/dangerous goods, it is strongly recommended to adhere to US DOT regulations, even though it may not in all instances be required. Ensure that all volatile solvents--either in the sample collection kit or contained in a sampled material--are properly packaged and sealed to prevent spills or leakage. Be especially aware of the hazards associated with transporting dry ice as a concentration of carbon dioxide gas can occur, potentially causing a dangerous over-pressurization, and/or a loss of oxygen, which can in turn, lead to hazards for users/handlers, such as feelings of drowsiness, or even an asphyxiation. Storing dry ice adequately, in a proper container, and transporting it in an adequately ventilated vehicle (windows cracked/down) reduces such risks.

S.17.5.3.1 - Global Road Safety

Per the CDC, whether you're on the road at home or abroad, you should know the risks and take steps to protect your health and safety both domestically and globally. When travelling by vehicle globally:

- Always use a seat belt on every trip, no matter how short--and no matter if you are seated in the front or the back of a vehicle.
- Always wear a helmet when driving or riding on motorcycles, motorbikes, or bicycles.
- Do not drive while impaired by alcohol or drugs, or with a driver who is impaired.
- Obey speed limits.
- Drive without distractions. For example, don't use a cell phone, or text, while driving.
- Be alert when crossing streets, especially in countries where motorists drive on the left side of the road.
- Ride only in marked/official taxis or ride share vehicles. Try to ride in taxis or ride share vehicles that have seat belts available in all seating positions.
- Avoid riding in overcrowded, overweight, or top-heavy buses or minivans.
- Check the Association for Safe International Road Travel (ASIRT) website for information about driving hazards and road safety risks, by country.
- For more information about road safety, overall safety, and security in every country of the world, visit the country information page on the U.S. Department of State website.
- Reference the CDC Health Information for International Travel (Yellow Book 2020). Chapter 8 – Travel by Air, Land & Sea – Road & Traffic Safety. 2020 Edition. Available at: https://wwwnc.cdc.gov/travel/yellowbook/2020/travel-by-air-land-sea/road-and-traffic-safety.

Exhibit S-1 - ORA "Quick Steps" Employee's Guide to Incident Reporting

In case of occupational injury or illness, employees have a right to obtain first aid or medical treatment. All work-related incidents, injuries, illnesses, near misses, or property damages must be reported. The following describes the steps employees should take to, first, acquire necessary first aid, and, secondly, the steps they should follow to report occupational injuries and illnesses:

1. If situation is severe, call 911 for immediate medical assistance. If the situation is not severe, report the incident to your supervisor and management. You may choose to visit an Occupational Health Clinic or a private physician.
2. Obtain the following forms from your supervisor, complete them, and provide them to the physician, at the clinic you are visiting for medical treatment:
    a. A completed and signed **Form CA-16**, "Authorization for Examination and/or Treatment." In instances in which emergency treatment is/was received, the CA-16 should be issued within 48 hours after treatment.
    b. A completed copy of **Form CA-17**, "Duty Status Report," so that the physician can document any work restrictions, if assigned.
    c. If you decide to be treated by a private physician, please take a copy of the American Medical Association Standard Billing Form (AMA) OWCP-1500 , along with the **Form CA-16**.

All work-related incidents, injuries, illnesses, near misses, or property damages must be reported using the following steps:

1. File the incident report as soon as possible in the employee Incident Portal, pOSH+ (within seven days from the date of incident). An employee step-by-step pOSH+ Incident Reporting Guide is available for help to complete the report. Additional employee resources can be found on the ORA Safety webpage. Complete all required fields denoted with a red asterisk*.
    a. Save your report as you complete each step.
    b. Submit your report once all information has been entered by clicking the submit field on the upper right-hand corner.
    c. Your supervisor will review and forward your report to ORA Safety, who will then review, investigate, and submit a completed report to pOSH+.
2. If you want to file a "Worker's Compensation Claim," you must register in ECOMP, file an OSHA 301 Injury and Illness Incident Report, and then, file either **Form CA-1** "Federal Employee's Notice of Traumatic Injury and Claim of Continuation of Pay/Compensation," or **Form CA-2** "Notice of Occupational Disease and Claim for Compensation."
    a. The **CA-1** must be filed along with medical documentation associated with the injury within **30 days** from the date of injury, to be eligible for continuation of pay (COP). COP and medical evidence supporting disability must be provided within **10 calendar days** after submitting the claim for COP.
    b. See procedures for accident reporting, medical surveillance programs, and worker compensation OWCP Employee's Guide at: Instructions for Injured Employees (fda.gov) Your supervisor will review the report in ECOMP. An ORA Safety IH will review, investigate, complete, and file the final OSHA 301 report in ECOMP.

Exhibit S-2 - ORA "Quick Steps" Supervisor's Guide to Incident Reporting

In case of occupational injury or illness, employees have a right to obtain first aid or medical treatment. All work-related incidents, injuries, illnesses, near misses, or property damages must be reported. Supervisors should consult the steps below for assisting an employee during an occupational injury and illness.

If an employee has sustained a work-related injury, please follow the steps outlined below:

1. Check on the employee to ascertain general status, condition, and/or need for assistance.
2. If situation is severe (for instance, employee is nonresponsive), call 911 for immediate medical assistance. If the situation is not severe, refer the employee to the Occupational Health Clinic, if available, and/or to a private physician, if needed. The employee may choose where they want to be treated.
3. Provide the following forms to an injured employee who is requesting to seek medical treatment:
    a. Completed and signed Form CA-16, "Authorization for Examination and/or Treatment", to the employee within four hours of the request for medical treatment and prior to seeking medical attention. You can obtain a copy of the CA-16 from your designated Industrial Hygienist. Refer to the Office of Workers' Compensation Programs Supervisors' Guide for additional guidance and exceptions on providing the CA-16.
        i. Form CA-16 *should not* be issued if more than a week has passed since the injury.
        ii. If you doubt whether the employee's condition is related to their employment, you should indicate this on Form CA-16 (item 6.B.2).
        iii. Form CA-16 should not be issued retroactively for treatment already received, except in the case of emergency treatment. In instances in which emergency treatment is/was received, the CA-16 should be issued within 48 hours after treatment.
    b. Completed Form CA-17, "Duty Status Report," with the employee's position description so that the physician can document any work restrictions, if assigned.

All work-related incidents, injuries, illnesses, near misses, or property damages must be reported using the following step(s):

1. Refer your employee to the Incident Portal, pOSH+ to file a report. An employee Getting Started in pOSH+ Guide is available to help complete the report. Visit the ORA Safety SharePoint for additional resources.
    a. Once the employee completes and submits the pOSH+ incident report, you will receive an email that the investigation is ready for your review.
    b. Review, sign, and submit the pOSH+ Incident Investigation as soon as possible. A supervisor's guide, How to Review an Incident Report Submitted by an Employee, is available.
2. If your employee wants to file a "Worker's Compensation Claim," refer them to ECOMP to register, file an OSHA 301 Injury and Illness Incident Report, and, either a **Form CA-1**, "Federal

Employee's Notice of Traumatic Injury and Claim of Continuation of Pay/Compensation," or *a* **Form CA-2**, "Notice of Occupational Disease and Claim for Compensation."

a. Inform your employee that the OSHA 301 Injury and Illness Incident Report must be filed within 7 days from the date of the injury, and that the Form CA-1 must be filed within 30 days from the date of injury to be eligible for continuation of pay (COP).
b. Once the employee completes and submits documents in ECOMP, you will receive an email that the incident paperwork is ready for your review.
c. Review the employee's OSHA 301 and CA-1/CA-2, if applicable. Complete the supervisory portion in ECOMP as soon as possible, but no later than 7 days. Supervisors will receive reminder emails from ECOMP if the portion that they are responsible for is not completed within 2 days.

3. ORA Safety will review, investigate, complete, and file the final pOSH+ and OSHA 301 reports in ECOMP.

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1.1 – Administration Notes

The FDA is a part of the Department of Health and Human Services (HHS). An appointed Commissioner who serves at the discretion of the President heads the agency. The FDA is a team of dedicated professionals working to protect and promote the health of the American people. The FDA's complete organization structures are available on FDA's Intranet website.

The Office of Regulatory Affairs (ORA) is responsible for the operational activities of FDA through the work of its headquarters and field staff across the continental United States and Puerto Rico. ORA inspects regulated products and manufacturers, conducts sample analyses of regulated products, and reviews imported products offered for entry into the United States. Resources for ORA employees can be found on the ORA site.

Accessible to all FDA employees, the InsideFDA and ORA intranet websites contain information about organizational structures for FDA/ORA. The ORA Organizational chart provides an overview of current ORA organization; information about specific offices within ORA can be found under the Office Tab on the ORA main SharePoint site. The FDA intranet site also contains the Employee Resources Hub that provides FDA employees with information such as new employee orientation, employment programs, human resources, facility services, trending topics, occupational safety and health services, and employee trainings. The Administrative Topic Hub covers resources for topics pertaining to acquisitions and grants, budget and finance, Continuity of Operation Plans (COOPs) and emergency planning, financial services, forms and office templates, furlough guidance, security, workforce management, and travel services.

1.2 – ORA Travel

All official travel must be authorized and approved with a valid travel authorization (TA) using FDA's Electronic Government Travel Service, ConcurGov. Typically, the travel authorization should be submitted at least 5 days in advance for review and approval. Travel itineraries listing where and how you can be reached should be provided to your supervisor since situations arise which necessitate contacting you while in travel status.

The FDA uses an Electronic Government Travel Services (ETS) as the Government Travel Service. The ETS is the Government-contracted, end-to-end travel management service that automates and consolidates the Federal travel process in a self-service Web-centric environment, covering all aspects of official travel, including travel planning, authorization, hotel and rental car reservations, ticketing, expense reimbursement, creating authorizations and vouchers (including local travel vouchers) and travel management reporting. In addition, the ETS will interface with the Unified Financial Management System (UFMS) for obligation and payment of travel vouchers. The system incorporates Federal Government travel policies which include the city pair airfare contract program and Federal Travel Regulations and is structured to require justification if you want to deviate from General Services Administration's (GSA) regulations. A policy has been established with the FDA so that your government-issued credit card will be your primary method of billing and payment when you book flights, make hotel reservations, or reserve a rental car.

Additional information can be obtained by contacting your Administrative Staff or visiting OFM's site.

The Fiscal Management Manual site provides policy, process, procedure, training, and additional materials for the FDA financial community.

Emergency travel can be approved, and the travel order prepared and authorized after the fact. "After the fact" TAs should be utilized on a very limited basis. The preparer should ensure that a detailed justification/explanation is provided and uploaded as an attachment in the TA to facilitate processing.

The Federal Travel Regulation (FTR) contained in 41 CFR 301, the Department of Health and Human Services (DHHS) Travel Manual, the FDA supplements to the DHHS 2012 Travel Manual and the Collective Bargaining Agreement (CBA) govern official travel. Article 42 of the National Treasury Employees Union (NTEU) CBA or Article IX of the American Federation of Government Employees (AFGE) CBA (depending on which union the bargaining unit employee is affiliated with) is intended to be read in conjunction with the FTR and the HHS Travel Manual. If there is a conflict between the HHS Travel Manual and the CBA, the CBA governs. Become familiar with these documents.

The HHS Travel Policy Manual is intended for use by HHS Employees, invitational travelers, consultants, and others authorized to travel on behalf of the Department. Please note that the words “employee” and “traveler” are the same for the purpose of this policy and in alignment with the FTR definition of “employee.”

The current HHS Travel Policy Manual provides users with the complete source of the Department’s management policies and procedures regarding travel and transportation procedures. Topics addressed in the Manual include, but are not limited to, Temporary Duty (TDY) Travel, Relocation Allowances, Interagency Personnel Agreements (IPAs) Travel and Transportation Expenses connected with the death of certain employees, and Acceptance of Payments of Travel Expenses from Non-Federal Sources (Sponsored Travel). All material contained in the Investigations Operations Manual (IOM) must be used in conjunction with, and subject to, federal travel regulations.

Job aids and SOPs are provided to guide users in how to prepare for travel with FDA. Additional travel information can be obtained from the ORA Office of Management’s Travel webpages, as well as the Office of Financial Management (OFM) Intranet home page.

1.2.1 - Government Contractor-Issued Travel Charge Card

The Government Travel Charge Card Program (GTCC) provides travelers with a safe, effective, convenient, and commercially available method to pay for expenses associated with official travel. Refer to the FDA Staff Manual Guide 2343.1 for additional information on policy governing the Agency-wide Travel Card Program and the procedures employees must follow for use of the card while on official travel.

Your Government Travel Card is a tool that assists you in the performance of your duties. The manner in which you use the travel card will reflect directly upon you as an employee and as an individual. With the privilege of a government travel card also come the responsibilities for its proper use. Use of the card does not relieve you of the responsibility to employ prudent travel practices and to observe rules and regulations governing travel for FDA, and as set forth in the FTR.

Travel charge cards are issued to employees to pay for all official travel and travel-related expenses. You must use the card only for authorized expenses incurred in connection with official travel orders, e.g., for lodging, transportation, baggage fees, parking, meals, etc. unless you have been granted an exemption. Exceptions can include expenses that are either relatively minor or inconvenient for credit card usage such as parking, local transportation, tips, phone calls, and certain expenses for which credit cards are not accepted. For more information on authorized exemptions, see the HHS Travel Manual, Chapter 9-00-10 C and D or go to the HHS Office of Finance web site for additional information on policy governing the Department-wide Travel Card Program and the procedures employees must follow for use of the card while performing official travel.

Personal use of the travel card or using the travel card to pay for someone else's travel expenses is prohibited. The use of the travel card for non-official expenses may result in disciplinary actions. Do not charge office supplies, training, conference registration fees, photocopies, postal services, or equipment on the travel card. Instead, use the purchase card or other acquisition vehicles to procure non-travel related services and products.

The only exception for use of the card not in connection with official travel applies to ATM withdrawals for purchase of samples.

Payments will include direct payment to the credit card company for expenses charged to the individual's official government travel credit card. Typically, the M&IE portion of per diem is reimbursed to the personal bank account, not the travel card. The HHS Travel Policy Manual states that the Government Issued travel card must be used for all travel related expenses including Per Diem and including M&IE. Concur defaults to reimbursing M&IE to the personal bank account. However, this can be changed during the TA and/or voucher creation stage to have the M&IE reimbursed to the Travel Card.

ATM cash advance is to be used only to cover anticipated out-of-pocket incidental travel expenses which generally cannot be charged directly to the card. Excessive ATM cash advances not commensurate with travel are Travel Card misuse. Therefore, direct charge of the Travel Card must be utilized in lieu of ATM Cash whenever and wherever possible for approved, travel related expenses. You will use your government-issued credit card to obtain a cash advance from an ATM machine, for official government business only. Ensure your Travel Authorization (TA) contains a statement that you are authorized to use an ATM to obtain cash advances and the maximum total amount authorized for your trip. ATM withdrawal for official travel is authorized based on 80% of your M&IE and estimated out of pocket expenses for the trip. Regardless of amounts indicated on your TA, ATM cash advances also may not exceed the weekly ATM withdrawal limit on your Travel Card account. This limit is established at the time that you apply for the travel card- based on a personal credit worthiness check. There are usually two fees associated with an ATM cash advance. The "Terminal Fee" assessed by the ATM terminal's owner/supplier and the "Cash Advance Fee" assessed by the bank. Currently, there are two formulas to calculate the reimbursable Cash Advance Fee using a 2.5% of the fee or a minimum of $3.00:

- Percentage – 2.5% multiplied by (Cash advance amount + ATM Terminal Fee).
- Minimum payment - $3 plus (Cash advance amount + ATM Terminal Fee).

The Cash Advance Fee is described in your credit card agreement. These amounts should be included on the Travel Authorization/Voucher along with receipts before reimbursement is made.

Additionally, there is also an international fee charged if cash advances are taken during foreign travel.

The government reimburses employees for authorized expenses. The employee is responsible for making payment to the bank; the cardholder is solely responsible for the timely payment of travel card bills and that account is delinquent if not paid within 30 days after the first statement date.

Read and understand the "HHS Traveler's Agreement for Government Contractor-Issued Travel Charge Card Users" before signing.

Immediately report a lost or stolen travel card to the bank and your Agency/Organization Program Coordinator (A/OPC) or travel coordinator.

If you do not have a government travel card and are required to travel, please contact your administrative officer about receiving a travel advance.

1.2.2 – U.S. General Services Administration (GSA) and Travel Management

GSA Federal Travel Regulations (FTR) summarizes the travel and relocation policy for all federal civilian employees and others authorized to travel at the government's expense. Federal employees and agencies may use the FTR as a reference to ensure official travel and relocation is conducted in a responsible and cost-effective manner.

Other important sites include:

- GSA Domestic Per Diem Lookup to assists travelers with finding Domestic Per Diem Rates.
- U.S. Department of State Foreign Per Diem Rates by Location to determine Foreign Per Diem Rates per location.
- GSA Airline City Pairs Search to assist travelers with finding the Airline City Pairs for the Current and Former Fiscal Year. For Domestic Travel, the traveler enters either the Departure City or three letter International Air Transport Association (IATA) code and the Arrival City or IATA code to find the Airline City Pair. For International Travel, the Departure and Arrival cities are required to query the Airline City Pair.

1.3 – Travelers' Health

Travelers' Health is a link to CDC's Travelers Health Section. The CDC/Traveler's Health website is committed to updating the public with current and accurate information regarding vaccines and medicines, along with travel advice/recommendations, notices, and resources. Investigators are encouraged to frequently review this site in advance of travel.

FDA Occupational Health Services has Health Units established for FDA employees to receive occupationally related medical services. Each health unit provides access to on-site first aid and urgent care services; onsite clinical care, referral, and follow-up for work related injury and illness; immunizations; health risk appraisals; health screenings; health counseling; and health and wellness education. Services are provided by appointment only. To request OHS services **Outside the National Capital region**, please send an email to occupationalhealthservices@fda.hhs.gov.

Also reference IOM Chap S for more traveler health and safety information.

1.4 – Division of Travel Operations

The ORA Office of Management's Division of Travel Operations (DTO) provides overall strategic leadership and guidance to ORA on all aspects of travel in accordance with established guidelines. DTO

works to advance the strategic goals and objectives related to travel policies and guidance in ORA and assures compliance with statutes, executive orders, and administrative directives.

To assist ORA travelers and travel preparers, DTO has created the Travel Resources SharePoint site intended to provide cumulative guidance to facilitate travel. The DTO site has information regarding domestic and foreign travel, gainsharing, travel tips & tricks, conference approvals, travel charge card information and travel processes & SOPs.

1.4.1 – Domestic Travel

1.4.1.1 – Domestic Travel Guide

ORA travelers preparing for domestic travel should use the Domestic Travel Guide to help walk them through the TA process. The Domestic Travel Guide – developed by the DTO Domestic Travel Branch - helps guide the traveler through what information and documents are needed to prepare travel authorizations and vouchers. Included in the guide are potential expenses to include on the TA, such as: Flights, Lodging, Lodging Tax, Hotel—Above Per Diem, First Bag Airline Fee, Taxi, Shuttle, Subway, etc., Tips/Gratuity, POV information, Airport Parking, Rental Car, Gasoline for Rental Vehicles, Tolls, ATM fees, Internet Expense, Conference Attendance and Laundry/Dry Cleaning.

The guide also includes information on payment methods, what and how to add comments for each expense and the supporting documentation needed for both TAs and Vouchers. Required information to include in the TA Trip Details section, how to identify states that are exempt from lodging tax (and what this means) as well as the types of travelers are also covered.

Additional information on domestic travel, including forms, frequently asked questions and tips on using ConcurGov are available on the DTO Domestic Travel site.

1.4.1.2 – Domestic Travel Contacts

DTO Travel Specialists: Travelers can reach out to their respective Travel Specialist (also called a Federal Agency Travel Administrator or FATA) as identified on the DTO Travel Specialists Contact Sheet with questions or for assistance.

Additional Contacts:

- OMEGA World Travel: 1-855-326-5411
- Citibank Customer Service: 1-800-790-7206
- Both OMEGA and Citibank are available 24 hours a day, 7 days a week. For any travel emergencies and concerns, contact your supervisor and OMEGA World Travel.

1.4.2– Foreign Travel

1.4.2.1 – Foreign Travel Information

International travel is important to achieving Departmental goals. However, such travel is typically very expensive and entails security concerns and other sensitivities. Therefore, managers must carefully monitor the frequency of the overseas travel performed by their employees and others authorized to travel for HHS. OpDiv/StaffDiv Heads must maintain proper delegations of authority to ensure they approve proposed official international travel only when it effectively and safely serves the goals of the Department.

When assigned to a foreign inspection, employees will be assigned a Trip Coordinator from DTO who will assist with coordinating the logistics of the trip, such as flights and lodging. The Trip Coordinator will provide the traveler with all pertinent information upon assignment on topics such as passports, visas, and immunization/health information. DTO has also captured materials and resources that serve as a supplement to the trip-specific communications that are sent to the foreign traveler on its Foreign Travel SharePoint site. Be sure to visit the: Pre-Travel, During Travel, Post-Travel, Contact Information, as well as the Resources section, to find links to useful information that may assist you through all aspects of the foreign travel process.

All Investigators conducting ORA foreign inspections must take required courses and trainings prior to departure. Investigators should contact their Program Office for information on these courses. See the DTO Foreign Travel Security Training Requirements site for more information.

DTO has also put together a timeline of the coordination process. While actual time for trip coordination will vary based on each trip's specifics, this timeline gives the traveler a good idea on what to expect during the coordination process. For foreign travel, be aware that there are differences in reporting requirements and reimbursable expenses. See the Guide to International Inspections and Travel, Chapter 2, Subchapter 215.2 – Reimbursable Expenses, for specifics.

1.4.2.2 – Foreign Travel Contacts

Travelers should always contact their DTO Trip Coordinator first. Before departure, travelers will also be provided a list of additional DTO contacts their travel itinerary for any questions they have during travel should their Trip Coordinator be unavailable.

Additional contacts that may be useful during foreign travel:

- **Office of Human and Animal Food Foreign HAF Operations**
- **Office of Medical Products and Tobacco Operations Contacts**
- **Office of Management Contacts**
- **Office of Regulatory Affairs Travel Specialists (FATA) Contacts**
- **Office of Security and Emergency Management**
- **Employee Resource Information Center (ERIC)**
- **Tricare Overseas Program (TOP):**1-888 777-8343
- **Concur Government Edition (CGE)**
- For Mailing Documents to the U.S.: UPS Int'l Service Center: 1-800-782-7892
- **FDA's Computer Security Incident Response Team** (Certain designated countries only): Report if you suspect lost, misplaced, or stolen equipment or if you believe there has been a personally identifiable information (PII) breach.
- **Disaster Evacuation Contact System (DECS)- Blue Card**: DECS provides management of the status of FDA personnel and their family members, information crucial in determining resource allocation for continued FDA mission execution during emergencies/disasters.
- **OMEGA World Travel**: Always attempt to contact the Trip Coordinator prior to contacting OMEGA at 855-326-5411
- **Citibank CitiManager**: 1-800-790-7206 or CCJAXL1HelpDesk@citi.com

1.4.3 – Per Diem and Subsistence Allowances

Per Diem is based on the actual cost of lodging, plus a set amount for "Meals and Incidental Expenses" (M&IE), not to exceed the maximum rate for the prescribed city or area. Subsistence is the cost of lodging, meals, tips, and the miscellaneous expenses you incur while in travel status. FDA Approving Officials, as well as FDA travelers, must follow the provisions of the FTR and HHS travel policy guidelines in authorizing, incurring, and approving per diem and subsistence expenses. Current per diem rates can be found on the General Services Administration's (GSA) website.

Per Diem commences when you depart your home, office, or other point of departure, and terminates when you return to your home, office, or other point. This applies whether you are traveling by auto or by common carrier. M&IE may apply where there is no overnight lodging. However, M&IE will not be allowed for periods of time less than twelve hours; your work time plus your total commute time must be greater than twelve hours for you to be eligible for M&IE.

The ConcurGov Program Support Center (PSC) has developed training and job aids to assist users with the most common travel processes in the online travel management system, ConcurGov. Each job aid includes simple step-by-step instructions for specific processes within the ConcurGov system. Topics include air travel, travel expense planning, the FedRooms program, booking travel, authorizations and vouchers, receipts, SmartPay and more.

The FTR requires traveling employees to exercise care in incurring expenses which includes claiming a federal exemption from payment of state and/or local taxes on lodging whenever this option is available. Not all states and localities offer tax exemption, and some locations do not specify a particular form. Please view GSA's tax-exempt state map to determine tax exemption status and forms by state.

For domestic travel if the hotel does not accept the tax-exempt form, report lodging taxes separate from lodging expenses and claim them on your travel voucher. Foreign travel taxes still remain a part of your lodging expenses.

Lodging expenses should be paid using your government-issued credit card, when possible, with direct payment to your government issued credit card (split disbursement) indicated on your travel voucher. It is your responsibility to pay the bill on time. The FDA will reimburse late charges on your bill only when you can show the late payment was due to late reimbursement of funds by the FDA.

Accurately record all of your expenditures; see IOM 1A.1.2 for information on recording expenses.

1.4.3.1 Per Diem Rates, Actual Expense Reimbursement, and Lodging

Section 5.1 of the HHS Travel Policy Manual provides guidance for HHS civilian employees, invitational travelers, and OpDiv/StaffDivs regarding allowable per diem and subsistence expenses for TDY travel. HHS employees are expected to travel on a lodgings-plus per diem basis. Under the lodgings-plus per diem method, a maximum per diem rate is established for lodging, plus M&IE, at a specific location.

Travelers or designated personnel must make lodging reservations using the ETS and/or contracted TMC. First consideration must be given to establishments that are contracted by GSA under the FedRooms program to ensure that travelers stay in fire-safe accommodations at a rate that is at or below per diem.

For Mandatory Statements Required on Travel Vouchers - See IOM Exhibit 1-1 Allowable Expenses Chart for allowable expenses, receipts required, etc.

1.4.3.2 Miscellaneous Expenses

Section 5.2 of the HHS Travel Policy Manual provides guidance for HHS employees and invitational travelers on reimbursable miscellaneous expenses incurred during official travel. Each type of miscellaneous expense will be reported as a separate line item on the travel voucher, indicating the amount and dates when incurred. Unless otherwise specified, receipts are required only when the individual expense is greater than $75.

Miscellaneous Expenses per the HHS Travel Policy Manual include:

- Hotel taxes: GSA does not include hotel taxes in the lodging rates that are issued as part of the per diem rates for the continental U.S. Hotel taxes are a miscellaneous expense item. Travelers are required to request exemption from state and local taxes where applicable. When the tax exempt option is available and used, the completed form is required to be attached to the traveler's voucher. Lodging taxes should not be claimed when the tax emption form is used.
- Business and Personal Telephone Calls: Refer to Staff Manual Guide 2343.2 to determine the maximum allowable reimbursement for telephone calls home. Also addresses Pre-Paid phone cards, Employee-Owned Personal Communication Devices, Internet Fees, Wireless access (internet fees), Airport/airplane internet fees.
- Laundry, Dry Cleaning, and Pressing of Clothing
- Baggage Fees
- ATM Fees/International Transaction fees for foreign withdrawals
- Trusted Traveler Programs and PreCheck (TM) Custom's and Border Protection's (CBP) Trusted Traveler Programs
- Emergency and Other Authorized Miscellaneous Expenses

1.4.3.3 - Special Travel Situations

See HHS Travel Policy Manual section 5.4 for guidance regarding special travel situations including the use of annual and compensatory leave.

1.4.4- Transportation Allowances/Expenses

1.4.4.1– Transportation Expenses

Section 4.1 of the HHS Travel Policy Manual provides guidance for FDA/HHS employees, invitational travelers, and OpDiv/StaffDivs regarding allowable transportation expenses for TDY travel. General Transportation Expenses topics include:

- Transportation Method and Routing
- Transportation Gratuities: Limited to 15% of the charge for service. If there is no service charge, the limit for tips is $5.
- Procuring Common Carrier Transportation
- Mandatory Use of Contract Fares and When Contract Fares May Not Be Used. Refer to Federal Travel Regulation (FTR) 301-10.107 and 301-10.108 for additional information.
- Use of Privately Owned Vehicles (POVs), Rental Cars, and Other Special Conveyances

1.4.4.2 -Authorization Of A Per Diem Allowance At The Official Station Or Within The Local Transportation (Formerly Local Travel) Area

Section 4.2 of the HHS Travel Policy Manual provides guidance regarding the authorization of a per diem allowance in conjunction with official business that takes place at the employee's official station or within the HHS defined local transportation (formerly local travel) area. It also applies to officers of the Commissioned Corps U.S. Public Health Service. Local transportation expenses do not require a no-cost travel order. Topics include:

- Criteria for Determining Allowable Local Travel Transportation Expenses
- Non-Reimbursable Local Travel Transportation Expenses
- Reimbursable Local Travel Transportation Expenses

1.4.5 - FURLOUGH GUIDANCE

1.4.5.1 - Ethics Rules During a Shutdown

As federal employees--furloughed or not—you are still governed by the provisions set forth in the Standards of Ethical Conduct as well as the Hatch Act and other federal laws.

Things to Know:

- When seeking outside employment, no prior approval is required if not intending to work for a prohibited source. If you're seeking outside employment with a prohibited source, you must receive prior written approval.
- If you are substantially involved in the acquisition/disposal of real estate at GSA, please see GSA Supplemental Standards of Ethical Conduct (5 C.F.R. 6701.104).
- You cannot receive compensation for teaching, speaking, or writing that relates to your official duties.
- You cannot represent another person before any federal agency, department or court except for yourself, spouse, parents, and children (18 U.S.C. 205).
- You cannot receive compensation from anyone else for their representational services before any federal agency, department, or court that is provided by another, including an employer (18 U.S.C. 203).
- You cannot use your official title to imply the government sanctions or endorses your personal activity.
- All gift rules still apply.
- The Hatch Act rules still apply. Visit the Hatch Act Update GSA InSite page for an overview and more information regarding the Hatch Act.
- Standards of Ethical Conduct for Employees of the Executive Branch, GSA Supplemental Standards of Ethical Conduct, as well as the conflict of interest statutes still apply.
- All media inquiries regarding your professional capacity, or GSA business, including speaking engagements, must be referred to the GSA Media Affairs team by emailing press@gsa.gov oryour Regional Public Affairs Officer if you're located in a regional office.

If you have any questions about your ethical obligations during the government shutdown, please contact GSA Ethics Law Staff at 202-501-0765 or your Regional Counsel. Find general furlough information in the OPM's Pay & Leave Furlough Guidance.

1.4.5.2 – Travel During A Lapse In Appropriations

Section 13 of the HHS Travel Policy Manual provides instructions and information concerning transportation and other expenses incident to travel in the event of a Lapse in Appropriations for HHS.

Travel in the event of a Lapse in Appropriations often involves unique or extraordinary travel scenarios for Federal employees and those traveling on behalf of HHS. However, all travel must be conducted in accordance with the FTR.

The policy guidance FAQs are intended to address those scenarios that occur most often, but it does not address every possible scenario.

Due to the fluid nature of a lapse in appropriations, visit the PCS website for the most recent information related to travel in the event of a lapse in appropriations.

During a lapse in appropriations, the Federal government may enact an Emergency Furlough. During an Emergency Furlough, the Office of Personnel Management (OPM) may issue guidance related to travel for employees impacted by an administrative furlough.

FDA Shutdown FAQs are contained in Exhibit 1-2; additional guidance may be found on OPM's Shutdown Furlough Guidance webpage.

1.5 – Vehicle Accidents

Immediate Action –

- Render first aid. If you are injured, obtain emergency treatment.
- Contact police.
- Report the accident to your supervisor as soon as possible.

1.5.1 – Government-Owned Vehicle (GOV)

Each GOV used for district operations should be furnished with a GSA Fleet Vehicle Packet (Exhibit 1-3) with a Fleet Vehicle Accident Kit-GSA 1627 (Exhibit 1-4). The US Government is self-insured and additional information can be found on the Fleet Vehicle Accident Kit.

1.5.1.1 – Information to be Obtained

- Description of vehicles involved, including license numbers
- Name, address and other pertinent information about drivers and owners of other vehicles; exchange state driver license information if possible
- Names, addresses, and signed statements of witnesses
- Names, official affiliation of investigating police officers
- Photographs of the scene and the damage
- Make no statements as to responsibility for the accident, except to your supervisor or investigating official.

1.5.1.2 – Reporting

Report the accident to the police after rendering emergency first aid to the injured. Telephone your supervisor and the chief of the motor pool from which the vehicle is assigned, unless your supervisor advises you the district will handle it. Report the accident to the GSA Accident Management Control Center (Accident Management Center (AMC) | GSA) Call (866) 400-0411, and select option 2.

- Complete the following forms and submit as required:
  - "Motor Vehicle Accident (Crash) Report" (SF-91) (A blank copy of this form should be kept in the glove compartment)
  - Copy of a traffic regulation or ordinance which was violated.
  - Results of any trial or disposition of summons if any arrests were made or charges referred.
  - "Claim for Damage, Injury, or Death" (SF-95) or other written notification of an incident accompanied by a claim. (SF-95 or statement constituting a claim must be date-stamped by the office initially receiving the claim to document the exact date the claim was received.) To be completed by claimant or non-government employee.
  - Investigation Reports and Policy Reports
  - "Statement of Witness" (SF-94)
  - Itemized receipt of payment for necessary repairs or two itemized written estimates of cost of repairs
  - Statement listing date of purchase, purchase price and salvage value where repair is not economical.
  - Photographs of damage and/or scene of accident if available
- File reports to comply with all local and state laws dealing with accident reporting. Keep copies of all reports made and attach them to the federal accident report.
- Check with your personal insurance carrier for their requirements.
- Immediately submit to your supervisor any notice, summons, legal paper, or claim, which may subsequently arise from the accident.
- Check with your supervisor or administrative staff to determine if additional reports or information are needed.
- Submit completed claims package electronically to the FDATortClaims@fda.hhs.gov e-mailbox or by inter-office mail or by the U.S. Post Office to the FDA Fleet Manager, Logistics and Transportation Management Branch, 10903 New Hampshire Ave, Bldg. 71, Room 2132, Silver Spring, MD 20993.

Tort claims must contain the completed SF-91 (Motor Vehicle Accident Report) and the -SF-95 (Claim for Damage, Injury, or Death). Notify the ORA Fleet Operations Manager of the accident via email at ORAFleetManager@fda.hhs.gov.

See also: FDA Fleet Vehicle Risk Management: Motor Vehicle Accidents/Incidents for additional information.

1.5.1.3 – Liability

The Federal Drivers Act (28 U.S.C. 2679(a)-(e)) was enacted to protect government drivers from personal liability while driving within the scope of their employment. This means you must be on official business to be covered. It relieves you from the burden of acquiring private automobile liability insurance for driving while on the job. The government's exclusive liability provided by this Act is predicated on its status as employer, without regard to whether the vehicle involved is government owned or privately owned.

The Military Personnel and Civilian Employees' Claim Act of 1964 allows for claims against FDA by employees, provided the loss or damage was within the scope of their employment and the employee (claimant) is free of negligence regarding those losses (See IOM 1.5.1.3.1). The Federal Tort Claims Act provides for claims generally coming from outside the Agency where the activities of the Agency or specific individual employees are negligent and cause death, injuries, or property loss or damage (See IOM 1.5.1.3.2).

Claims should be submitted through your Administrative Office electronically to the FDATortClaims@fda.hhs.gov email box via the Outlook mailbox or through regular mail to the FDA Fleet Manager, Logistics and Transportation Management Branch, 10993 New Hampshire Ave., White Oak Bldg. 71, Room 2132, Silver Spring, MD. 20993. The claim will be reviewed and forwarded to the Office of the General Counsel, (OGC) for determination. The claimant will be notified by the OGC.

1.5.1.3.1 – Military Personnel and Civilian Employees' Claim Act of 1964

Documentation and information are to be submitted as follows for military personnel and civilian employees' claims under the Military Personnel and Civilian Employees' Claim Act of 1964.

1.5.1.3.2 – Tort Claims

Tort Claims can be filed by any individual who states that they have suffered personal injury or property damage or loss resulting from the action of an FDA employee or Commissioned Officer who was acting within the scope of employment.

1.5.1.3.2.1 – Property Damage or Personal Injury

"Claim for Damage, Injury, or Death" (SF-95) or other written notification of an incident accompanied by a claim. (SF-95 or statement constituting a claim must be date-stamped by the office initially receiving the claim to document the exact date the claim was received.)

- Investigation Reports and Policy Reports
- "Statement of Witness" (SF-94)
- Itemized receipt of payment for necessary repairs or two itemized written estimates of cost of repairs
- Statement listing date of purchase, purchase price and salvage value where repair is not economical
- Photographs of damage and/or scene of accident if available

1.5.2 – Privately Owned Vehicle (POV)

The Federal Employees' Compensation Act (Workmen's Compensation) protects employees against losses due to personal injuries received while operating POVs on official business.

Under the Federal Driver's Act [28 U.S.C. 2679(a)-(e)], you are immune from any civil liability to other parties for property damage, personal injury, or death resulting from operation of a vehicle within the scope of your employment. This immunity applies whether the vehicle involved is a GOV or POV. The government would defend any such claim or suit and would pay any damage award to the injured party.

If an accident was caused by your negligent operation of a vehicle, and your vehicle is damaged, the cost of repairing your vehicle will not be paid for by the government. **You should look to your own private insurance carrier for reimbursement, payable under the terms of your own automobile insurance**

policy. You are protected from liability by the Federal Drivers Act. See IOM 1.5.1.3 for further information on this.

If the accident is determined not to have been caused by your negligence, the provisions of the Military Personnel and Civilian Employees' Claim Act of 1964 (31 U.S.C. 240-243) would be applicable. **Under this Act, you would be reimbursed for the deductible portion of the repair not covered by your own automobile insurance policy, up to a maximum of $250.00 deductible.** (You may also collect from the other party's insurance.) Form HHS-481, Employee Claim for Loss or Damage to Personal Property, should be obtained, completed, and submitted electronically to the FDATortClaims@fda.hhs.gov Outlook e-mailbox or through regular mail to the FDA Fleet Manager, Logistics and Transportation Management, 10993 New Hampshire Ave., White Oak Bldg. 71, Room 2132 Silver Spring, MD 20993 with evidence establishing that the use of a POV was authorized for official purposes and that the accident was not caused by your negligence.

Liability - see IOM 1.5.1.3.

Reporting - Report vehicle accidents as instructed in IOM 1.5.1.

1.5.3 – Rental Vehicle

1.5.3.1 – Reporting

Report the accident to the police after rendering emergency first aid to the injured. Telephone your supervisor as soon as possible. Follow IOM 1.5.1.1 to obtain the necessary information (e.g., description of vehicles involved, license plate numbers, pertinent information about drivers and owners of other vehicles, etc.)

Contact the car rental company to report the accident. Even if the damage to the rental vehicle appears to be minor, do **NOT** drive the rental vehicle from the scene unless you have contacted the rental car company and have obtained permission to do so.

- If the rental car company, other driver(s) involved, or other parties inquire about the requirements for filing a tort claim or personal property claim, provide them the "Claim for Damage, Injury, or Death" (SF-95). Provide the SF-95 to all customers (e.g., other drivers, their insurance company, rental car company) by following the Example Email Communication to Claimant Regarding Form SF-95 Submission (Exhibit 1-5). All claimants will return their SF-95 forms to you for submission with the tort claims package.
    - If possible, capture the date FS-95 forms are returned to you. If the form is returned via email, save a copy of the email, and submit a copy of the email with the claims package.
- In addition to SF-95 forms, the following documents (as applicable) must be included in the claims package:
    - "Motor Vehicle Accident (Crash) Report" (SF-91)
        - Note: Since the accident did not involve a GSA fleet vehicle, sections X1 through XIII will not be completed.
        - SF-91 must be reviewed and signed by your supervisor.
    - "Statement of Witness" (SF-94), if any, or equivalent written statement.
    - Two repair estimates for claimant's vehicle
    - Copy of claimant's receipts

    - Police Report
        - If you do not have a police report, you must explain why.
    - Pictures of damages to rental vehicle
    - Pictures of damages to claimant's vehicle
- Submit completed claims package electronically to the FDATortClaims@fda.hhs.gov e-mailbox or by inter-office mail or by the U.S. Post Office:
  FDA Fleet Manager, Logistics and Transportation Management Branch
  10903 New Hampshire Ave, Bldg. 71, Room 2132
  Silver Spring, MD 20993.

You will submit the claims package as described above even if you do not have SF-95 forms returned to you by the applicable claimants. Do not delay submission of the tort claims package. Explain which documents are not being submitted and why at the time the claims package is submitted to the Tort Claims Office. Missing documentation can be submitted as they become available (e.g., SF-95, police report)
Tort claims must contain the completed SF-91 (Motor Vehicle Accident Report) and the -SF-95 (Claim for Damage, Injury, or Death). Notify the ORA Fleet Operations Manager of the accident via email at ORAFleetManager@fda.hhs.gov.

1.6 – Transportation

Section 4.2.5 of the HHS Travel Policy Manual provides guidance for FDA/HHS employees, invitational travelers, and OpDiv/StaffDivs regarding modes of travel- public, private, government and rental.

Your agency must select the method most advantageous to the Government, when cost and other factors are considered. Under 5 U.S.C. 5733, travel must be by the most expeditious means of transportation practicable and commensurate with the nature and purpose of your duties. In addition, your agency must consider energy conservation, total cost to the Government (including costs of per diem, overtime, lost work time, and actual transportation costs), total distance traveled, number of points visited, and number of travelers".

1.6.1 – ORA Government-Owned Vehicle (GOV)

GOVs for district operations are furnished by the regional GSA motor pool office. GOV users should follow the district operating procedures in effect for the appropriate GSA motor pool. Each district has an assigned Fleet Operations Representative that can answer general GOV questions as needed.

Vehicle Operation - You are required to have a valid state, District of Columbia, or commonwealth operator's permit for the type of vehicle to be operated, and a valid DHHS identification document (i.e., Agency ID card, credentials, building pass, etc.).

Each district has working arrangements for the repair and maintenance of vehicles, either with GSA contractors or the GSA Fleet. It is your responsibility to adhere to those safety and maintenance checks. Do not operate cars known to be mechanically unsafe. Handle emergency repairs in travel status in accordance with your district and GSA motor pool procedures.

Purchase fuel and oil for your GOV with GSA Wright Express (WEX) Credit Cards. GSA WEX Credit Card receipts are to be turned into the GSA regional motor pool servicing your location. Follow your district procedure for submitting GSA WEX Credit Card receipts. Make emergency purchases with cash only

when the GSA WEX Credit Card is refused. You also have the option to contact GSA's Maintenance and Control Center (MCC) which provides GSA Fleet customers and vendors with one-stop service for mechanical repairs. The MCC provides authorization for repairs and services over $100, or for any tire and battery replacement, regardless of cost. Please consult your local Fleet Operations Representative and/or Fleet Vehicle Custodian and supervisor for specific instructions and guidance.

To contact the MCC, call 1-866-400-0411, and follow the menu options. The GSA Fleet Vehicle Assistance Card can be printed and carried with you for reference (Exhibit 1-6).

You are responsible for all traffic violations, including parking fines, you incur during the use and operation of a GOV. See Staff Manual Guide (SMG) 2173.1, Section Attachment D 1.H.

While traveling on official business, you may be reimbursed for parking fees or overnight storage charges. Provide for the safe and proper overnight storage of GOVs while you are in travel status and put the charges on your travel voucher. Receipts are required when available.

Bridge, ferry, and road tolls may be paid in cash. Put these charges on your travel voucher. Receipts are only required for amounts over $75.00.

FDA Fleet Vehicle Operator Training: Prerequisite for GOV operation

FDA Fleet Vehicle Operation: Use and Care of Government Vehicles

GSAFleet2Go
GSAFleet2Go is a mobile app for General Services Administration Fleet drivers to supply maintenance and repair, Fleets Service Representatives, preventive maintenance and recall reminders, accident reporting, and other relevant Fleet info.

1.6.1.1.1 – Care and Custody of U.S. Vehicles

GSA has issued instructions on the use and protection of U.S. Government vehicles, GSA WEX Credit Card, and car keys. The parts of these instructions applicable to you while the car is in your custody are:

- The car should be locked when parked in public areas, in private lots, or in open government parking areas.
- The vehicle operator is responsible for the keys and WEX card. They should be returned to the Fleet Operations Representative and/ or Fleet Vehicle Custodian's office or KeyTrak system (if installed) and secured in a locked environment daily/nightly. These items should be kept in a safe place in the office if the vehicle is stored at a location other than assigned FDA GOV storage.
- It is permissible to turn over a GOV to either parking lot attendants or valet parking attendants who must park the vehicles at locations where the drivers/operators are not permitted to park the vehicles themselves when no self-parking options are available. You must remove the WEX credit card from the GOV, keep it secure when handing the vehicle off to the valet or parking attendant, and keep it with you in a safe place.
- The credit card may only be used to purchase fuel and vehicle lubricants or other vehicle appropriate items listed on the back of the card for the vehicle identified, and not used for other vehicles.

- Before signing a service ticket, check for accuracy. Be sure the imprinted address is legible and write the vehicle mileage (odometer reading) on the ticket. Submit a copy or original to the Fleet Operations Representative or Fleet Vehicle Custodian for your appropriate district for monthly reporting requirements.
- Odometer readings can also be reported by using Get Odometer Reading at the Pump (GORP) when time to refuel a vehicle.
- Filling the government-owned vehicle with fuel is the responsibility of the authorized driver. Follow district guidelines for submitting fuel receipts.
- The use of tobacco products is prohibited in government-owned or commercial leased vehicles.
- In accordance with Executive Order 13513, "No Texting While Driving", federal employees shall not engage in text messaging (a) when driving GOV, or when driving POV while on official government business, or (b) when using electronic equipment supplied by the government.

Refer to the HHS Program Support Center Fleet Management Resources website for more information.

1.6.1.1.2 – Use of a GOV between Your Residence and Place of Employment

No FDA/ORA employee shall use a GOV for transportation between their home and place of employment without the expressed written approval of the Secretary of Health and Human Services. Requests for Home-To-Work Authority must be submitted in writing by the supervisor of requesting individual to the ORA Fleet Operations Manager. See also: Staff Manual Guide 2173.1 and FDA Fleet Vehicle Operation: Home-to-Work Policy for Use of Government Vehicles.

Vehicles assigned to or purchased or leased by FDA are intended for official business as authorized by Federal Management Regulation 102-34.220. FDA motor vehicles are not provided for the convenience of FDA employees.

Official business shall be interpreted strictly and shall not be construed to encompass the mingling of official business with non-official business. Official business is defined as those activities conducted during duty hours, which are considered an official part of the employee's assigned duties. Non-official business for which the use of Government owned or commercially leased/rented vehicles is illegal includes, but is not limited to such activities as:

- Attending to personal business
- Attendance at luncheons or other social engagements
- Pleasure trips; etc.

Any employee of the Federal Government who willfully uses or authorizes the use of any Government-owned or commercially leased/rented vehicle for other than official purposes shall be suspended from duty by the office concerned, without compensation for not less than 30 days and shall be suspended for a longer period or summarily removed from office if circumstances warrant.

Government vehicles should only be used when it is: (1) the least costly method of transportation available (considering the value of employee time and actual transportation costs) or (2) when no other practical method of transportation is available considering the mission to be performed; the location; and any equipment needed to be transported to support the mission.

The Daily Log of Government Vehicle (Form FDA-3369) must be maintained by all approved persons using a GOV, assuring that all items indicated on the form are completed for each trip. The DHHS now requires that each approved person taking a GOV home, must indicate the location of their residence in Column 10 on the FDA-3369.

The Daily Log must be kept for at least a period of three years and must be available for audit purposes. Please work with your Fleet Operations Representative and/or Fleet Vehicle Custodian to get the completed FDA-3369 forms uploaded to the appropriated vehicle on the Fleet Management Program (FMP) SharePoint site. If you need access to the site for uploading the form, please email the ORA Fleet Operations manager at: ORAFleetManager@fda.hhs.gov.

1.6.1.1.3 – Roadside Assistance for U. S. Vehicles

For situations that may require emergency towing, changing flat tires, or lock-out service, the following options are available:

- For roadside assistance from Monday through Friday from 7:00 AM to 8:00 PM ET, contact GSA Fleet MCC at 866-400-0411, choose option 1.
- For roadside assistance outside of the timeframe listed above, roadside assistance is offered by the manufacturers for vehicles under warranty. The contact for specific manufacturers can be found at GSA Roadside Assistance.

1.6.2 – Privately Owned Vehicle (POV), Rental Vehicle, and Other Special Conveyances

See HHS Travel Policy Manual section 4.1.10.

1.6.2.1 – Privately Owned Vehicle (POV)

On official business, you may use your POV instead of a GOV, if authorized. However, reimbursement for mileage will not exceed the cost of using a GOV. Mileage is payable to only one employee when two or more employees travel in the same vehicle on the same trip. The employee claiming reimbursement will list on the voucher the names of other passengers accompanying him or her. See current POV Mileage Reimbursement Rates.

You should carry a set of government accident reporting forms whenever you use your POV for official business. See IOM 1.5 for accident reporting requirements.

In general, the mileage allowance is in lieu of all expenses of operating your POV, except tolls. Unless otherwise authorized, reimbursement is limited to the cost of travel by common carrier. Standard highway guide mileage may be used in lieu of odometer readings for direct travel from one town to another. Explain any extra mileage on your travel voucher.

According to HHS Logistics Management Manual, HHS employees and contractors may use their POVs for official purposes when it is considered to be advantageous to HHS. Employees and contractors authorized to use POVs for official duties are entitled to reimbursement, per miles driven, based on GSA's annual rates.

Please Note - HHS employees and contractors who use POVs should inform their insurance companies that their vehicles are being used for official purposes. An HHS employee or contractor assumes full financial liability when using a POV for official purposes.

1.6.2.2 – Rental Vehicle

GSA and the Department of Defense (DOD) both provide employees with a nationwide commercial auto rental program. Agency policy dictates leasing the least expensive auto to satisfy the transportation requirements. If a rental vehicle is determined to be the most advantageous mode for travel, there must be specific written authorization or prior approval to obtain this service. See your Administrative Officer for additional information and necessary form to be uploaded into ETS.

When an employee is authorized in advance to hire a rental vehicle for official travel, the employee may use the rental vehicle for official purposes while at the TDY station, including travel to and from restaurants near the work site or hotel. Employees should be aware that the Government will deny liability for any loss or damage to a vehicle rented for official business purposes using a government travel charge card if that loss/damage arises from activities outside the scope of official business travel. Refer to the HHS Travel Policy Manual section 4.1.10.2 (Rental Vehicles) for more information rental car fuel, usage, default rental car size, responsibility for violations, etc.

Optional Collision Damage Insurance, known as CDW, will not be reimbursed for domestic travel. Participating rental companies have agreed to settle any claim for damages with the FDA. CDW is required for foreign travel and will be reimbursed. The government will not pay or reimburse you for Personal Accident Insurance (PAI) for domestic or foreign travel.

Travelers are required to adhere to the same rules and regulations covering government owned vehicles when using a rental car while on official business.

1.6.2.3 – Public Transportation

Public transport (also known as public transportation, public transit, or mass transit) is a system of transport for passengers by group travel systems available for use by the general public unlike private transport, typically managed on a schedule, operated on established routes, and charge a fee for each trip. Examples of public transport include city buses, trolleybuses, trams (or light rail) and passenger trains, rapid transit (metro/subway/underground, etc.) and ferries. Public transport between cities is mostly conducted by airlines, coaches, and intercity rail.

Public transportation should be used when practical between points where official business is being conducted and employees may be reimbursed for use of public transportation when using to conduct official government business.

1.6.2.4 – Bus

There are no government-preferred providers for bus service. If a traveler wishes to use bus as a means of common carrier transportation, it requires pre-authorization by the AO. Refer to the HHS Travel Policy Manual section 4.1.10.3 (Buses) for more information.

Shuttles/buses are an optional mode of transportation between sites when on TDY travel (e.g., between residence and carrier terminal, place of lodging and temporary work site, carrier terminal and place of lodging). Reimbursements for use of shuttles/buses in these instances will only be allowed when authorized on your TA. Use of a shuttle or bus for domestic local travel between sites (examples above) does not require supporting documentation to be uploaded in your TA. These transportation costs must be broken down into daily expenses. Receipts are mandatory if cost is over $75.00.

Per the HHS Travel Policy Manual section 4.1.3 (Transportation Gratuities), tips to a taxi, shuttle service, or courtesy transportation driver are limited to 15% of the charge for service. If there is no

service charge, the limit for tips is $5. Employees are expected to make maximum use of courtesy transportation (e.g., free airport/hotel shuttle service) in lieu of incurring charges for the same transportation. Transportation Gratuities should be listed as a miscellaneous expense on the Travel Voucher.

1.6.2.5 – Other and Special Conveyances for Transportation

Refer to the HHS Travel Policy Manual section 4.1.10.4 for more information on other types of conveyances such as public transportation (e.g. subway, train, ferry). TA and receipt requirements for public transportation between sites when on TDY travel are the same as described above for shuttles/buses (IOM 1.2.2.3).

1.6.2.6 – Authorization of and Reimbursement for the Use of Transportation Network Companies

In practice, employees shall consider courtesy shuttles, public transportation, multiple party transportation, and taxicabs before using a Transportation Network Company (TNC). Some fees particular to TNCs such as "surge" or "peak hour" fees shall not be reimbursed.

Refer to the HHS Travel Policy Manual section 4.1.10.5 and Understanding Transportation Network Companies for more information.

TA and receipt requirements for TNCs between sites when on TDY travel are the same as described above for shuttles/buses (IOM 1.2.2.3). See IOM 1.2.2.3 for more information on allowable transportation gratuities/tips.

1.6.2.7 – Taxi

Reimbursements for the use of taxicabs will only be allowed when authorized on your TA. Allowable tips are 15% of the reimbursable fare. Receipts are required for fares over $75.00.

You will be reimbursed for the usual cab and/or airport limousine fares plus tip from your home/office to the common carrier terminal on the day you depart on an official overnight trip, and upon your return. In lieu of cab, you may use your personal car at a mileage rate not to exceed the cab fare plus tip. See your administrative personnel for current mileage rates, the maximum allowable taxicab fares, and other pertinent details.

1.7 - Media Interactions During Inspections

The inspectional and investigational activities of the FDA receive extensive coverage in online/social, electronic, broadcast and print media. ORA field inspectional staff are occasionally requested by the media to comment or provide information on their individual inspectional activities. Such requests can include being interviewed and filmed during inspections, investigations, and sample collections. If media representatives contact you, be courteous and helpful, but refer all requests for information, interviews, and personal appearances to your supervisor. Those requests must be approved in advance and should be referred to ORApress@fda.hhs.gov for coordination with FDA's Office of Media Affairs.

Remember that you are always on the record, even during your initial contact with a reporter. Never tell a reporter you have to obtain clearance first; instead, obtain contact information, topic/questions and response timeframe for follow-up with the ORA Press Team. A request for information and a request for an interview should be treated the same way. When fielding a question(s) in person at an event or via the telephone if the person asking questions does not first identify themselves as a member of the news

media, it is ok for you to ask if they are a member of the news media. If they are not a member of the news media then follow existing protocol to direct people to the appropriate location at the FDA's website, www.fda.gov for the most up to date information on any topic.

The reason you should ask if the person is a member of the media is to ensure that any message shared with the public via a news organization is the latest vetted messages that have undergone close coordination with our scientific and policy experts at FDA headquarters.

Do not solicit media interviews or on-camera appearances. There may be occasions when management of a firm you are inspecting invites representatives from the news media to observe the inspectional process. Please see IOM 5.5.9.3 for instructions on how to appropriately handle such events.

1.7.1 – Media Resources

- ORA Media Engagement
- Mobile Support Instructions pdf (Exhibit 1-7)
- ORA Media Fact Sheet
- Media Tip Card (Exhibit 1-8)
- Media Preparedness Training
- ORA Media SharePoint Links
- Contact: ORApress@fda.hhs.gov
- Office of Media Affairs Contacts
- ORA Media Engagement Communications Toolbox

1.8 - Equipment

You are responsible for the proper acceptance, use, protection, and surrender of any Government property assigned to your custody or control; you may be held liable for violations of such responsibility when they result in losses to the Government. The Personal Property Management Program (PPMP) oversees the integrity, proper use, and safe guarding of equipment.

Per PPMP policy:

- Accept property only when properly assigned to you and do not remove any property without consent.
- Do not use, or permit any other person to use, FDA property for any purpose other than official use.
- Coordinate the disposition of all property through the PPMP or the Center/Office Accountable Property Officer (APO).
- An employee leaving any jurisdiction shall return any property or account for all personal property and other items for which personally responsible.
- Assure proper care of property entrusted to you (safe parking for vehicles, keeping inspectional and investigational equipment securely locked in the trunk of the car, not leaving valuable equipment in the car's trunk while the car is in for servicing, not leaving electronic equipment/computers in the trunk of the car for extended periods in extreme hot or cold weather conditions, storing all property in safe, secure areas…)

All FDA property related questions should be directed to your supervision who will then reach out to the Property Custodial Officer or the Center/Office's APO.

For lost or stolen equipment, immediately contact your supervisor, the FDA IT Security Operations Center, and your foreign travel trip planner as applicable if you suspect lost, misplaced, or stolen equipment (e.g., Blackberry, laptop, Ironkey, cell phone, etc.) that contains personally identifiable information (PII) such as a person's home address or social security number, or other sensitive non-public information. Using the IT Security Incident Checklist (Exhibit 1-10) as a guide, immediately contact the FDA Systems Management Center at:

- Email: FDA_Systems_Management_Center@fda.hhs.gov
- Toll Free Number: 855-5FDA-SMC (855-533-2762)

Additionally, a memorandum should be prepared detailing

- the circumstances surrounding the loss
- a full description of the article including FDA barcode/tag/serial number as available
- the comprehensive steps you took to recover the item(s)

In the case of theft, obtain a police report and provide a copy of the report within two days of the incident.

Follow your District procedures for any additional requirements.

Responsibilities for government property in your custody are also outlined in the Staff Manual Guide 2280.5.

1.8.1 - EQUIPMENT CARE/CALIBRATION

First-line maintenance rests with you as the custodian of the items entrusted to you. Generally, common sense and handling the equipment as if it belonged to you, should suffice, such as in equipment that requires little or no maintenance as such, other than dusting, replacing batteries and bulbs, making minor adjustments, properly packing in carrying cases, and proper protection as necessary.

Needed repairs, defects, or inoperative equipment, should be immediately reported to your supervisor. When in travel status, necessary minor repairs to equipment may be obtained locally, if possible, and reimbursement claimed on your travel voucher. Major repairs should be cleared through your supervisor.

You are responsible to assure equipment assigned to you is calibrated for accuracy prior to using in inspectional activities. This includes thermometers, pyrometers, balances, scales, stopwatches, etc.

Thermometers are used for evidence development during inspectional activities to enforce the Federal Food Drug and Cosmetic Act and other statutes in the specific ORA programs. Refer to SOP-000735 Thermometer Maintenance Procedure, in the Quality Management Information System (QMiS), for details.

Stopwatches may be calibrated using the atomic clock at the U.S. Naval Observatory in Washington D.C., using the commercial numbers at (202) 762-1401 or (202) 762-1069. Calibrate stopwatches at several different time intervals within the expected parameters of use. At least three runs should be made at each interval, then averaged for each interval and the correction factor, if any, entered on the record of calibration maintained with the watch. Calibration of your computer's internal clock can be obtained

from the same source. Information and software is also available on the U.S. Naval Observatory's Website. For more detailed stopwatch/timing devices calibration instructions, see the National Institute of Standards and Technology (NIST) procedure SOP 24.

1.8.2 – INFORMATION TECHNOLOGY (IT) DEVICES/EQUIPMENT

FDA's IT Hub provides FDA employees with the latest IT news, updates, and informational resources about technology services, programs, systems, and applications used agency wide.

1.8.2.1 - FDA Information Systems Security and Privacy Guide

Documents FDA control parameters and consolidates and aligns FDA IT Security Policies with requirements and standards. This document is an addendum to the Staff Manual Guide 3251.12 and establishes comprehensive IT security and privacy requirements for the FDA IT security program and information systems.

1.8.2.2 - FAQs

Refer to this site for information on telework, lost/stolen IT equipment, virtual meetings, etc.

1.8.2.3 - Mobile Devices Security Awareness

At FDA, a "Mobile Device" is an interactive mobile computing device, such as BlackBerry devices, laptops, and mobile phones with text capabilities. These devices can be used remotely and used both in and out of the Agency. If you have a mobile device for work or personal use, make sure to protect both the machine and the information it contains.

Examples of mobile devices include:

- Laptops, tablets, and iPads
- iPods and MP3 players
- Global Positioning System (GPS) satellite receivers
- BlackBerry devices
- Cell and smart phones
- PIV Card Readers
- Small (pocket-size) USB and FireWire (IEEE1394) hard drives
- USB flash drives (also known as thumb drives) and other removable memory devices (flash memory, SD cards)

Risks and Concerns with Mobile Devices:

- Mobile devices often have removable memory cards that create the potential for data leaks or loss.
- USB flash drives can be an immense source of data leakage. Thumb drives are easy to keep hidden because they are small. An employee with bad motives can easily slip one in and out of a facility, stealing Gigabytes of data.
- Centralized systems are not able to easily manage portable devices.
- Putting adequate safeguards in place to check what data is coming and going can be difficult.
- Mobile device breaches are often more difficult to detect than non-mobile breaches because users may not know about the loss for days or weeks.

• Social media applications and other applications can pull more information than intended. Personal information including your location, phone number, and address can be revealed. Be cautious and check the permissions of an application before it is installed.

Reporting an Incident: Report an incident to the FDA IT Security Operations Center if you suspect lost, misplaced, or stolen equipment (e.g., cell phones, laptops, badges, documents/paperwork, etc.) or if you believe there has been a Personally Identifiable Information (PII) Breach. Consult the FDA Reporting a Security Incident page for more information.

• Do NOT put FDA information on your personally owned mobile and portable devices.
• Keep an eye on your equipment at all times and report lost or stolen equipment by Reporting an Incident to the FDA Cybersecurity Operations Center immediately.
• Use FDA-approved mobile devices and media with encryption on FDA systems.
• Do not use personal flash drives or thumb drives in FDA equipment.
• FDA now offers a secure flash drive, called the IronKey.
• Do not place non-FDA-owned or authorized portable devices on FDA networks or sync to FDA PCs without prior written authorization from the FDA CISO. "It is against FDA Policy to connect any personal IT equipment (including laptops, printers, etc.) to the FDA network or to FDA equipment."

Only Agency approved mobile devices will be used with FDA data or the FDA network. All mobile devices shall be marked with appropriate FDA property tags.

Encryption is a process that transforms plain text or data using a mathematical formula/algorithm and a "key" making it unreadable to an outside party. Only those that have the "key" can decrypt the data. The more extensive the key, the harder it is to solve the encryption. Encrypt all sensitive information including the following:

• FDA information or data that is accessed remotely
• Messages containing sensitive information that are sent outside of FDA's network

The following MUST be encrypted:
• Laptops or other mobile devices with sensitive information
• Equipment that is transported and/or stored offsite

1.8.2.4 - Risks of Connecting Personal Devices to the FDA Network

Any personal or contractor-owned device that is connected to the network that is not authorized or does not meet government security standards is not allowed. Many types of personal devices could contain a vulnerability that could put the network at risk. Follow FDA/HHS policies and the HHS Rules of Behavior to help protect the FDA network. If you believe you may have accidentally connected a device to the network and/or feel malware has infected your computer, contact ERIC immediately. Note that if your office purchases a USB drive or other device that is not on the Master Approved Technologies (MAT) list, you should not connect this device to the network. You can locate the MAT list of approved software, hardware and devices at Request-IT.

1.8.2.5 - Traveling outside of the US with Government Furnished Equipment

1.8.2.5.1 - Use of Government Furnished Equipment (GFE) During Foreign Travel

Department of Health and Human Services (HHS) policy **strictly prohibits the use of government furnished equipment (GFE) on personal foreign travel/unofficial travel to all countries**.

FDA personnel should not take government furnished equipment on personal foreign travel unless an exception has been granted as outlined below. Due to the cybersecurity and counterintelligence risks that such activity poses to FDA systems, networks, and sensitive data, unauthorized telework sessions will be disconnected, and the individual's account disabled to prevent access to FDA network resources.

HHS allows Operating Divisions to grant exceptions to this policy on a case-by-case basis when legitimate, mission critical business requirements exist. Based on this policy, any FDA employee, contractor, or individual who wants to take their FDA computer, phone, or storage device to a foreign country while on personal travel must obtain approval prior to departing the United States. In order to obtain approval, the individual must first coordinate with their supervisory chain. The responsible Division Director may then submit a request with the legitimate business justification to the foreign travel team at foreigntravelbriefings@fda.hhs.gov for review and consideration for approval.

This policy does **not** apply to HHS personnel participating in official foreign travel on behalf of the FDA.

Before you bring FDA technology assets on international travel on behalf of the FDA, remember:

- If you do not need a laptop or iPhone, do not take it.
- Do not leave IT equipment unattended.
- Do not connect unauthorized IT equipment to your laptop or iPhone (i.e., thumb drives, hard drives, etc.).
- USB thumb drives are prone to malware infections. Rewritable discs (i.e., CD-RW, DVD-RW) and IronKeys are an excellent substitute to thumb drives.
- Loaner laptops and iPhones issued solely for international travel should NEVER be connected to the FDA network upon return.
- Return all FDA loaner IT equipment the next business day upon arriving back to the office.
- Contact IT-FOREIGNTRAVELSECURITY@FDA.HHS.GOVfor loaner equipment requests or questions.

Effective October 2017, all FDA Federal Employees and contractors traveling or planning to travel to China and its territories (i.e., Hong Kong) on official business must attend a counterintelligence awareness briefing prior to making travel arrangements. The U.S. Embassy will not approve an eCC until this requirement is met. This eCC represents official approval from the U.S. Embassy for U.S. government employees to enter the country. This briefing should be at the level of your security clearance (unclassified for Public Trust holders or classified for SECRET or TOP SECRET clearance holders). The briefing is good for one year.

Beginning April 2024, FDA has modernized Foreign Travel Security Operations and Support Services from manual email requests to ServiceNow to enhance customer service experience, improve equipment accountability, and ensure response timeliness.

To request foreign travel loaner equipment and/or counterintelligence awareness briefings in ServiceNow, please navigate to the Service Catalog, then choose Information Technology and select IT Security. Upon selecting one of these options, there will be a form to input travel

information. The request will be sent to the Foreign Travel Security Operations and Support Services Team for action.

For any questions or further assistance, please contact the Foreign Travel Security Operations and Support Services Team at: IT-FOREIGNTRAVELSECURITY@FDA.HHS.GOV .

Remember that you have no expectation of online privacy in most countries. For that reason, you should be aware of the following items, whether you are traveling for business or pleasure.

- Expect that transmission of information is being intercepted and read at any location where networks are controlled by another government. Foreign network providers can disable mobile device encryption and then turn it back on after information is intercepted. How to protect the data: Do not process or transmit sensitive information. Do not take FDA or personal technology assets (laptop, iPhone, cell phone, etc.) if you do not need them or connect to the FDA network via the virtual private network (VPN) or access FDA email (i.e., webmail or Outlook). Click here to view the FDA Information Systems Security & Privacy Guide (SMG 3251.12a) Appendix U: Mobile Equipment for Overseas Travel to Designated Countries.
- When overseas, foreign communication networks can intercept wireless device signals. Assume that all forms of communication with wireless devices are monitored and subject to compromise. Hacker software can be used to locate and connect to vulnerable Bluetooth-enabled cell phones, allowing address book information, photos, calendars, and SIM card details to be downloaded. Unauthorized long-distance phone calls could also be made using the hacked device. How to protect the data: Power off mobile devices when not in use and only use the Bluetooth function if absolutely necessary. (Do not use the Bluetooth function if traveling for business). Remove the battery from your mobile device and store it separately from the device.
- Anywhere facilities (i.e., hotel) are controlled by another government, you should expect tampering with unattended electronic devices. Hotel rooms and safes are accessible by hotel staff and possibly local authorities. How to protect the data: Avoid leaving electronic devices unattended in a hotel room. If that is not possible, remove the battery, and hard drive as accessible, and store separately from the device.
- Be aware that public Internet kiosks and cafes are breeding grounds for malicious software that can capture private information (passwords, bank account or credit card numbers, phone numbers, names, etc.). How to protect the data: Avoid connecting to public Wi-Fi hot spots and always use FDA provided systems and solutions using the Virtual Private Network (VPN) for remote access. Click here to view the FDA Information Systems Security & Privacy Guide (3251.12a) Appendix M: Remote Access.
- When passing through airport security, watch your laptop and other equipment until it enters airport scanners.
- Do not check a laptop with your baggage.

Immediately report any suspected tampering, unauthorized use, loss, or theft of any FDA asset to the SMC/Cybersecurity Operations at FDA_Systems_Management_Center@fda.hhs.gov or 855-533-2762 (24x7).

1.8.2.5.2 Foreign Travel FAQs

- Foreign Travel FAQs (pdf)

1.8.2.6 - Reporting an IT Security Incident

1.8.2.6.1 – Reporting IT Security Incident Checklist

- Reporting IT Security Incident Checklist (Exhibit 1-9)

1.8.2.6.1.1 Immediately contact

- Email: SMC@fda.hhs.gov
- Toll Free Number: 855-5FDA-SMC (855-533-2762)

1.8.2.7 - Employee Resource & Information Center (ERIC)

- Online: Submit your own ERIC ticket via the FDA Service Portal.
- By phone: 301-827-ERIC (3742) or toll-free 866-807-ERIC (3742)
- By email: ITCallCenter@fda.hhs.gov for IT-related issues OR ERIC@fda.hhs.gov for all other issues.

1.9 - OFFICIAL IDENTIFICATION

1.9.1 - Credentials/Badges

Guide 2280.3 provides instructions for the issuance and control of FDA Credentials and Badges including expiration, renewal, transfer, separation, and retirement. Contact your supervision and FDA-ORACredentials@fda.hhs.gov for additional information and questions.

1.9.1.1 - Policy, Authority

Official credentials are for issuance to investigators and inspectors who are regularly engaged in investigational and inspectional activities; however, on occasion they may also be issued to other FDA personnel when it is necessary for these employees to engage in inspectional activities which would require credentials. By virtue of their position, credentialed employees are recognized as authorized to perform the duties assigned.

Badges may only be issued to holders of FDA credentials to facilitate performance of their duties when it is determined that the possession of a badge would be advantageous. **Investigator badges shall not be used in routine operations.** They shall be used only in those situations where display of a badge is essential for rapid identification to indicate authoritative presence in order to facilitate FDA operations. Division Staff Manual Guide, FDA 2280.3, 5b, outlines situations in which use of the badge may be appropriate.

FDA official credentials and badges shall be used for OFFICIAL business only. They shall not be used as a means of personal identification or for personal purposes. Show your credentials to appropriate firm personnel during all non-undercover investigations, inspections, sample collections, recall effectiveness checks, etc.

Precautions against photocopying your credentials: although firm management may examine your credentials and record the number and your name, do not permit your credentials to be photocopied. Federal Law (Title 18, U.S.C. 701) prohibits photographing, counterfeiting, or misuse of official credentials. Credentials must not be shown over video during remote activities, such as a remote regulatory assessment. Do not permit a firm to take your fingerprints. Contact your SCSO for more information as necessary.

To apply for official credentials, you must complete FDA 2115 and submit it to ORA FDA-ORACredentials@fda.hhs.gov for processing. Please see your Administrative Officer for additional information.

1.9.1.2 - Renewal/expiration

Though issuing officials will notify credential and badge holders no later than 30 days prior to the expiration date that their credentials/badge will expire, check your credentials periodically, prior to performance of duties, to ensure they are not expired.

1.9.1.3 - Care of Credentials, Badges

FDA Official Credentials confer extensive inspectional authority on you. Exercise the utmost care of your badge and credentials. Carry them in a manner that will assure positive protection against loss. Do not carry them in the upper pockets of your clothing where they may fall out if you bend over. Carrying your credentials and badge in the glove compartment of your car or leaving them in the pocket of an unattended coat or jacket are invitations to loss or theft.

1.9.1.4 - Lost or Stolen Credentials, Badges

The procedure for reporting loss or theft of credentials and/or badge is in the Staff Manual Guide (SMG) 2280.3. Notify your supervisor immediately. Report the loss or theft to local law enforcement authorities (police department) and request a copy of the report including the police report identification number. Also report the loss or theft to the local (state) FBI field office so that the number of the credentials/badge can be entered into the National Crime Information Center (NCIC) system.

A written report containing the police report number and a statement that the local FBI field office was notified must be submitted to your supervisor and the issuing official. Replacement credentials will be issued at the discretion of the authorizing official.

1.9.2 - PIV

The FDA identification badge (PIV) is a multi-purpose badge that includes a magnetic strip (for card access) and a barcode (for employee identification programs). The purpose of your FDA PIV badge is to ensure that only authorized personnel gain access to FDA facilities. The badges are encoded to limit an individual's access to designated security areas. The FDA Badging PIV Card FAQs discusses PIV issues such as login, PIV pins, signing a document, remote networking, lost PIV and how to get PIV assistance.

1.10 - Business Cards

Business Cards are defined as cards of introduction bearing the name, address, phone number, fax number and e-mail address of active agency representatives. The distribution of business cards facilitates prompt and efficient communications by the persons and organizations with whom the Agency transacts business. The purpose of the business card is to further the Agency's statutory mission and therefore, the purchase constitutes a proper expenditure. Due to certain restrictions pertaining to the purchase of business cards, employees should consult with local management prior to purchasing such items, to ensure adherence to agency policy and procedures.

Resources:

ORA Memorandum on Ordering Business Cards

ORA Visual Identity Resource Center

1.11 - Ethics and Integrity

The Food and Drug Administration's ethics program is structured to provide advice and assistance to current and former employees in order to help ensure that decisions they make, and actions they take, are not, nor appear to be, tainted by any question of conflict of interest. The ethics laws and regulations were established to promote and strengthen the public's confidence in the integrity of the Federal government. The FDA ethics program, including prohibited financial interests, political activity, laws and regulations, gifts, conduct and outside activities, is available publicly at FDA.gov and internally through the ORA Office of Management Ethics and Integrity SharePoint site.

1.11.1 - Expected Conduct

As you work to advance the health and welfare of the public, seek to maintain the highest standards of ethical conduct. You are responsible for complying with the regulations, obtaining advice from your supervisor, personnel, or local administrative staff, and when required, obtaining advanced approval for certain outside activities.

FDA employees must be persons of unrivalled integrity and observe the highest standards of conduct. Because of FDA's special regulatory responsibility, its personnel must carry on the agency's business effectively, objectively, and without even the appearance of impropriety. Their actions must be unquestionable, and free of suspicion.

The Principles of Ethical Conduct were established by Executive Order 12674, modified by Executive Order 12731, as basic principles regarding the conduct of federal employees. It is important that federal employees observe these principles in order to promote confidence in the integrity of the federal government.

United States Code, Title 18 contains the criminal conflict of interest statutes applicable to employees in the executive branch of the government. Included in Title 18 is a prohibition against solicitation or receipt of bribes; a prohibition against acting as an agent or attorney before the government; post-employment restrictions; a prohibition against participating in matters affecting personal financial interest; and a prohibition against receiving supplementation of salary as compensation for government service.

Standards of Ethical Conduct for Employees of the Executive Branch
The Standards were developed by the Office of Government Ethics and set forth the basic obligation of public service. The standards contain regulations regarding matters such as conflicting financial interests, impartiality in performing official duties, and misuse of position.

HHS Supplemental Standards of Ethical Conduct
On February 3, 2005, The Department of Health and Human Services (HHS) amended the Supplemental Standards of Ethical Conduct (5 CFR 5501) and Supplemental Financial Disclosure Requirements section (5 CFR 5502), both effective on that date. On August 31, 2005, HHS published the Final Rule for both sections.

Department of Health and Human Services--Standards of Conduct
These regulations were superseded in 1992 by the Office of Government Ethics "Standards of Ethical Conduct for Employees of the Executive Branch." However, certain portions of the HHS Standards of Conduct remain applicable. This link contains the remaining relevant portions of 45 CFR Part 73.

You are the eyes and ears of FDA, and to most of the public you are their only contact with

FDA. Your actions may be the basis upon which they judge the entire FDA. The public

expects exemplary behavior and conduct from the government employee. This responsibility applies to both on the job and off the job activities. As you inspect or appraise individuals, you are, in turn, being evaluated. Both the industries FDA regulates and the public-at-large are keenly aware of, and are quick to report, what they consider improper actions by government employees.

You are expected to conduct yourself in a prudent manner, so that the work of the Agency is effectively accomplished. Your job is to gather and present the facts. Accuracy and objective observation are essential.

As a government official, your actions are under constant scrutiny. You must comply with the statutes and regulations listed above and epitomize integrity more broadly noting:

- Cameras/video/audio recording are everywhere.
- Integrity means doing the right thing even if no one is watching.
- In dealing with management and the public, your approach must be mature, dignified, authoritative and cordial.
- As a law enforcement officer, you must employ authority with discretion.
- Depend on tact, diplomacy, and persuasion to obtain the desired information.
- Be courteous and frank when calling attention to potentially violative practices and conditions.
- Be fair and responsive.
- Do not assume the role of a consultant.
- Do not be argumentative.
- Avoid replies that are likely to appear arbitrary or bureaucratic.
- Never recommend the products or services of a particular firm.
- Keep information obtained during inspections and investigations confidential.
- Avoid situations that may be or appear to be a conflict of interest.
- Your reports should be complete, concise, accurate and objective.
- Your personal habits must be above reproach.
- Look professional and effective in dress, grooming, and demeanor.
- Take pride in your work.
- Never use Government equipment/supplies for personal use.
- Never use public office for private gain.
- Never give preferential treatment to any person or organization.
- Never impede Government efficiency or economy.
- Maintain independence from outside influences and impartiality in performance of duties.
- Never make a Government decision outside of official channels.
- Never undermine the confidence of the public in the integrity of the Government

1.11.2 - Gifts

Gift means anything of monetary value (gratuity, favor, discount, entertainment, hospitality, loan, forbearance; includes services, training, transportation, local travel, lodging, meals). It DOES NOT include:

- modest items of food and non-alcoholic refreshments such as soft drinks, coffee and donuts offered other than for a meal

- greeting cards and items of little intrinsic value, such as plaques, certificates, and trophies, meant primarily for presentation
- loans and discount opportunities from financial institutions that are available to the general public
- rewards and prizes given to competitors in contests or events, including random drawings open to the public, unless the employee's entry into the contest is required as part of his official duties (e.g., attending a conference where attendees are all entered into a drawing)
- anything for which the Government pays, e.g., items purchased with Government funds
- any gift accepted by the Government, e.g., sponsored travel
- anything for which the employee pays market value; and
- Free attendance at an event provided by the sponsor of the event to an employee who is assigned to present information on behalf of the FDA, or an employee whose presence is deemed essential by the FDA to the presenting employee's participation, on any day when the employee is presenting

For additional information, click here.

Notwithstanding any of the exceptions provided above, an employee shall not:

- Accept a gift in return for being influenced
- Solicit or coerce the offering of a gift
- Accept gifts from the same or different sources on a basis so frequent that a reasonable person would be led to believe the employee is using his/her public office for private gain.

1.11.2.1 - Gifts Between Federal Employees

In general, FDA employees may not:

- Give a gift to an official superior (an employee, including but not limited to an immediate supervisor, whose official responsibilities include directing or evaluating the performance of the employee's official duties or those of any other official superior of the employee). This includes making a contribution toward a gift.
- Solicit a contribution from another employee for a gift to an official superior of either employee
- Accept a gift from subordinates in the employee's chain of command
- Accept a gift from a lower-paid, non-subordinate employee, unless there is a personal relationship that justifies the gift.

1.11.2.2 - Gifts From Outside Sources

If an FDA employee solicits or accepts a gift from an outside source that does business with or seeks official action from the employee or the employee's agency (a "prohibited source"), the public may be concerned that the donor will receive favored treatment as a result of the gift. Even if a gift is from a person or organization that has no official dealings with the employee's agency, accepting a gift offered because of the employee's official position may create an appearance of using public office for private gain. FDA employees may not solicit or accept gifts from a "prohibited source" or given because of the employee's official position, unless an exception applies, or the item is excluded from the definition of a gift.

1.11.2.3 - Gifts From Foreign Governments or International Organizations

As a Federal Government employee, you may not accept gifts from foreign governments or international organizations except as permitted under the Foreign Gifts and Decorations Act (FGDA),

5 U.S.C. 7342. The FGDA allows an employee to accept a gift with a market value of less than $415 from a foreign government or an international organization so long as the gift is intended as a souvenir or mark of courtesy. An international organization in this context refers to one which the US is not a member, such as the European Union (to clarify, a state-owned or operated company is NOT a foreign government for purposes of this statute). This statutory restriction extends to the spouse and dependents of the employee.

In the HHS General Administration Manual Chapter 20-25, Foreign Gifts and Decorations, the section on Gifts of Minimal Value states that, with specific exceptions, "an employee may not accept a gift of more than minimal value unless it appears that to refuse the gift would likely cause offense or embarrassment or otherwise adversely affect the foreign relations of the United States. If an employee accepts a tangible gift of more than minimal value, such a gift is deemed to have been accepted on behalf of the United States and, upon acceptance, becomes the property of the United States."

Procedures for appropriate disposition of such gifts are also included in the HHS Chapter. If you accept a gift from a foreign government or international organization on behalf of the U.S. Government, you must immediately contact an Ethics Specialist at the Ethics Hotline (240) 402-1111 or email FDAEthics_Advice@fda.hhs.gov when you return to the office.

1.11.3 - Attempted Bribery

Bribery is the practice of offering or soliciting something, such as money or a favor, to a person in a position of trust to influence that person's views or conduct. Occasionally, FDA employees experience bribery attempts.

Bribery or attempted bribery of a Federal Officer is a crime (18 U.S.C. 201). If you are offered money or anything else of value, pursue the following course of action:

- Attempt to obtain a clarification of the offer (e.g., Ask questions like, "What is this for?").
- Do not accept or refuse the offer. Appear to vacillate, and keep the door open for future contact.
- Calmly terminate the exchange.
- As soon as possible, prepare detailed notes concerning what transpired.
- Contact your supervisor as soon as possible. The Division should notify OCI/OIA immediately.

1.12 - QMiS

Quality Management Information System (QMiS) is the repository for ORA's internal procedural documents and quality reports. Standard operating procedures, work instructions, templates, checklists, transmittal notifications, and reports are organized by component and document type.

1.13- ORA Time Reporting

1.13.1 - eNSpect (also known as MARCS Field Client)

eNSpect is the first phase of the modernization of the FDA Field Accomplishments and Compliance Tracking System (FACTS) network. FACTS is still available and slowly over time more and more functionality will move into eNSpect. Currently, eNSpect supports multiple roles, components and functions and can be used online or offline. The bulk of the Investigator's work is performed in the Field Client.

1.13.2 - ORA Insight Time Reporting (ITR)

Insight Time Reporting (ITR) is an activity-based time reporting system that will enable ORA to report the work we do and identify the resources we need before we need them.

1.13.3 - ORA Activity Code structure

Insight Time Reporting (ITR) activity code structure which includes the activities and definitions that were specifically developed for ORA.

1.13.4- Field Accomplishments and Compliance Tracking System (FACTS)

An agency-wide information system that provides automated support for the daily activities conducted by the FDA ORA headquarters and field offices. FACTS provides a central data repository for workload management, sample collections, investigative operations, and compliance operations through inspections, reporting, and tracking.

Exhibits

1–1 Allowable Expenses Table

This Table lists allowable expense items and the requirements that must be met to assure reimbursement. Unless indicated, there are no special requirements for reimbursement. Please see your administrative staff or supervisor for additional information.

EXPENSE ITEM	Specific authorization or approval	Receipt	Justification on voucher for any amount
BAGGAGE 1. All fees pertaining to the first checked bag	Yes	Yes	
2. Additional charges relating to the second and subsequent bags may be reimbursed when the Agency determines those expenses are necessary and in the interest of the Government (See FTR 301-70.300)	Yes	Yes	Yes
3. Excess Baggage Charges for government property	Yes	Yes	Yes[1]
4. Service Charge for checking baggage by checking agent where such charges for checking baggage in baggage rooms, or station or air terminal	Yes	Yes	Yes
5. Storage Charges (e.g., when traveler stores baggage or equipment when such charges are result of official business.)	Yes	Yes	Yes[2]
6. Transfer Charges - when necessary for official travel (e.g., when changing between stations where free transportation is not issued by common carrier.) CAUTION: Where the traveler's plans are changed, he/she shall make sure that baggage has been checked beyond the point where he/she leaves the train is stopped or transferred. If baggage cannot be intercepted or transferred and is carried to original destination on unused portion of ticket, the traveler shall give full explanation of facts when submitting unused portion of ticket. Failure to do so will result in any excess cost being charged to traveler.	Yes	Yes	Yes
FEES OR TIPS 1. Tips – Allowable tips are 15% of the reimbursable fare.	Yes	Yes (over $75)	
2. Parking Fees - charges for parking automobiles	Yes	Yes (over $75)	
3. Porter - allowable only at transportation terminals for handling Government property carried by travelers. NOTE: Porter fees for personal property, briefcases, etc. are not allowed.			Yes[3]
4. Traveler Checks Money Orders Certified Checks Transaction Fees for use of Automated Teller Machines (ATMs) – Government contractor issued travel card	Yes Yes Yes Yes	Yes Yes Yes Yes	

5. Registration Fees – Attendance at local non-government sponsored meetings			
a. Payment of registration fee should be made via the Citibank government Purchase Card if the organization(s) will accept credit cards.	Yes	Yes	Yes
b. Citibank Convenience Checks	Yes	Yes	Yes
c. If the credit card cannot be used, and the organization accepts the purchase order, HHS-99 or SF-182 the organization may bill FDA directly.	Yes Yes	Yes Yes	Yes
Please see your Administrative Officer for additional information and guidance when requesting payment of registration fees.			
6. Exchange of Currency			
a. Allowed during foreign travel	Yes	Yes	
i. Fees for cashing U.S. Government checks or drafts reimbursing traveler for travel expenses only incurred in foreign countries.	Yes	Yes[4]	
ii. Commissions for conversion of currency in foreign countries	Yes	Yes	
iii. Costs of traveler's checks, money orders, certified checks purchased in connection with official travel. Costs may not exceed amount needed to cover reimbursable expenses.	Yes	Yes	
b. Not allowed: exchange fees for cashing checks or drafts issued in payment of salary.			
7. Special Expenses for Foreign Travel - Passports, visa fees, costs of photographs for passports and visas, costs of certificates of birth, health, identity, and of affidavits, and charges for inoculations not obtainable through a federal dispensary	Yes	Yes	
HIRE OF ROOM 1. Allowed when necessary to engage a room in a hotel or other place to transact official business	Yes	Yes	Yes[6]
2. Not allowed for personal use (cost included in subsistence allowance).			
PERSONAL SERVICES Stenographic and typing services, guides, interpreters, drivers of vehicles, etc.	Yes	Yes	Yes[5]
POSTAGE Postage necessary for official airmail, foreign, or parcel post mail; and for official registered and special delivery mail.	Yes	Yes	Yes[7]
POST OFFICE BOX RENTAL Where necessary for official airmail, foreign, or parcel post mail; and for official registered and special delivery mail.	Yes	Yes	Yes
PUBLIC TRANSPORTATION WHILE IN TRAVEL STATUS Public transportation fares are allowed from (or to) common carrier, or other terminals, to (or from) place of abode or place of business and between place of abode and place of business, or between places of business.	Yes	Yes (over $75)	Yes[8]
Public transportation fares between places where meals are taken, and places of business or places of lodging **are not** allowed, except where nature and location of work at temporary duty station is such that suitable meals cannot be procured there - allowance will be made for transportation to the nearest available place for such meals.			
TAXICABS WHEN USED LOCALLY WHILE IN TRAVEL STATUS Taxicabs are allowed from (or to) common carrier or other terminals, to (or from) place of abode or place of business and between place of abode and place of business, or between places of business where cheaper mode of transportation is not available or is impracticable to use.	Yes	Yes (over $75)	Yes[8]

Taxicabs are not allowed between places where meals are taken and places of business, except where nature and location of suitable meals cannot be procured there - allowance will be made for transportation to the nearest available place for such meals.	Yes	Yes (over $75)	Yes[8]
Limousine service plus taxicab tip rates between airport and limousine pick-up or discharge point	Yes	Yes (over $75)	
TELEPHONE CALLS / INTERNET CHARGES 1. Official Business – Charges for local and long-distance calls are allowed when made on official business		Yes[9, 10]	
2. Personal Calls – Employee traveling overnight within CONUS may be reimbursed for one brief telephone call per day to her/his residence in accordance with government-wide rules and regulations. Reimbursement is limited to actual expenses, not to exceed $5.00 times the number of consecutive nights of travel on official business; applicable only when the employee is authorized to be on travel for one or more consecutive nights; and conditioned upon the unavailability of government-provided long distance telephone systems and services (including government-issued telephone calling cards) during each day of travel on which expenses are incurred.		Yes	
a. OCONUS Travel may be reimbursed only for telephone call(s) home from a foreign country which have been authorized prior to the beginning of travel and are shown on the travel authorization. Permitted frequency and cost must be stated on the travel authorization and adhered to by the employee.			
3. Internet Charges – (Federal and Departmental policy requires specific written or electronic authorization when the use of internet services is required for official business.)	Yes	Yes (over $75)	
RECORDS Charges for copies of records furnished by State officials, such as Clerks of Courts, etc., when necessary for performance of official business		Yes	Yes[5]
SHIPMENTS (FREIGHT OR EXPRESS) - see IOM 4.7.5		Yes	Yes[12]
MISCELLANEOUS EXPENSES 1. Cash used in lieu of transportation request for passenger transportation and accommodations. 2. Purchase of emergency supplies. 3. Any other miscellaneous expenditure incurred by traveler in performance of official business, such as samples of drugs, cosmetics, etc., purchased by FDA inspectors and investigators.	Yes Yes Yes	Yes Yes Yes	Yes[5]
LAUNDRY EXPENSES Employees will be reimbursed for laundry, cleaning, and pressing expenses equal to the number of travel days multiplied by $5. a. For CONUS travel, employees must be on travel for four or more nights. b. Employees on OCONUS travel are not permitted to claim separate laundry expenses		Yes	

FOOTNOTES:

[1] Voucher must show weight of baggage and points between which moved.
[2] State that storage is solely on account of official business.
[3] State that porter fee was for handling Government property carried by traveler.
[4] Voucher shall show rate of conversion and commission charges.

[5] Voucher shall show date of service, quantity, unit, and unit price.
[6] In addition to information required in footnote #5, state necessity for hire of room.
[7] State that postage was used for official mail.
[8] State necessity for daily travel.
[9] For telegrams, faxes, cablegrams, and long-distance telephone calls, show points between which service was rendered, date, amount paid on each and "official business".
[10] For local telephone, calls show number of calls, rate per call, total amount expended each day, and "official business".
[11] When government Bill of Lading is not used, explain circumstances.
[12] Continental United States (CONUS) is defined as the 48 contiguous states and the District of Columbia.

1–2 FDA Furlough Shutdown FAQs

"What if I am on travel during a Lapse in Appropriations?"	If you are identified as a non-excepted employee who is to be placed in a furloughed status due to a lapse in appropriations while you are on TDY, you will need to arrange to return home within the next 24 hours or the first available flight. However, if your OpDiv/StaffDiv has identified you as an excepted employee, you may be eligible to stay in a TDY status. Please contact the TMC to make any necessary travel arrangements. Once Congress passes and the President signs a new appropriation or continuing resolution, accommodations for a return to TDY will be addressed on a case-by-case basis. HHS will only pay expenses for the time that it takes you to return to your official duty station. After that, you will be in a furloughed status and the agency will not pay for any additional expenses.
"Must agencies cover travel expenses during a furlough day, if an employee's travel status requires a stay that includes a furlough day?"	Yes, agencies must provide per diem or actual expenses to excepted employees whose travel status requires a stay that includes a furlough day. If you are identified as a non-excepted employee, you will need to arrange to return home with the next 24 hours or the first available flight. If excepted employees are authorized Per Diem (Lodging, Meals & Incidental Expenses) they are entitled to the full amount of Meals and Incidental Expenses or 75% on a travel day. If an excepted employee is on actual expenses, they can be placed on Actual Expenses for: up to 300% of Lodging, only up to 300% of M&IE, only up to 300% of both Lodging and M&IE. If an employee is on actual expenses, the employee is required to provide a receipt for all items, including meals. Without a valid receipt, the OpDiv/StaffDiv would not be responsible for reimbursement. It should be clearly stated that they are on actual expenses and that receipts are required for all expenses, even those that fall below the $75 threshold.
"Can I still use my Government Travel Card?"	The Government travel charge card may remain active during a lapse in appropriations, but only excepted employees should use them. You should contact the travel charge card vendor's customer service at the number on the back of the card should you experience problems with your card. In addition, you will not be able to submit your voucher until the Federal Government reopens for business. The Government will not reimburse you while there is a lapse in appropriations (more commonly referred to as a "shutdown"). As always, all charges on your government issued travel card are your responsibility.
"Can I stay at my TDY location while in a furloughed status?"	In general, the Department cannot obligate funds for TDY expenses or accept voluntary services in the absence of appropriations for non-excepted activities. By remaining on TDY, you are acting in an official capacity. Therefore, the general rule state above pertains: if you are identified as a non-excepted employee who is to be placed in a furloughed status due to a lapse in appropriations while you are on TDY, you will need to arrange to return home with the next 24 hours or the first available flight. If you are not an excepted employee that is currently on TDY, long term or not, and elect to stay at the TDY location, you need to be aware of the following: 1. Once you are furloughed you will no longer be covered under the Federal Employee's Compensation Act for workers compensation insurance; 2. You will not be reimbursed for per diem, including lodging, meals and incidental expenses (M&IE); you will be responsible for all costs incurred once you are in a furlough status; 3. If you are currently in long-term housing under a lease

	arrangement, your situation will be reviewed on a case-by-case basis, depending on when the next lease payment is due; and 4. During the furlough, no work is allowed to be performed as agencies may not permit voluntary performance of non- excepted services as covered in 31 U.S.C. 1342. a. These restrictions are enforced by criminal penalties. An officer or employee of the United States who knowingly and willfully violates the restrictions shall be fined not more than $5,000, imprisoned for not more than 2 years, or both. 31 U.S.C. 1350.
"Can I use the ETS?"	No, since you will not be on official Government travel, you cannot use the ETS; you will also not be able to: 1. Use the ETS to make travel authorizations or submit vouchers; 2. Use City Pair Fares for flights; 3. Use the Government Car Rental Agreement managed by the Defense Management Travel Office (DTMO); and 4. Use the FedRooms program; Hotels may choose to offer you a "government rate" but that is at the hotel's discretion.
"Can an employee use personal funds by travelers to complete the Agency's mission by attending an already planned conference?"	No. In attending a conference on behalf of the Department, you are acting in an official capacity. The Department cannot accept voluntary services in the absence of appropriations for non-excepted activities.
"Do relocation benefits stop during a Government shutdown?"	No, the monies for relocation come from already approved money and must be obligated up front for a relocation move, also referred to as a Permanent Change of Station (PCS). Each agency should have a plan in motion for those who may need assistance to include extensions to Temporary Quarters Subsistence Expenses (TQSE), etc.
"Do people who are in Temporary Quarters still receive benefits?"	As TQSE is reimbursed at the new PDS, there is no "old" PDS to recall the employee to. Since no permanent residence has been purchased yet, TQSE is the employee's only option. There is no case law that covers this issue; however, based upon the reasoning above, GSA legal is of the opinion that the expenses can still be incurred, particularly if the relocation monies have been obligated prior to beginning the move, but reimbursement cannot be made until the lapsed funds can be accessed again.
"Can the employee accept an offer during the shutdown period and therefore bind the government to the fee? Can contractors continue to order appraisals and inspections during the period the government has no money?"	First, there is no case law on this point. Thus, it is GSA legal' s contention that if the fair market value of the home was obligated when the contract with the Relocation Service Provider (RSP) was executed, and the amount is from a revolving fund or a fund that does not lapse under a furlough situation, then the offer can be accepted. However, if the fair market value of the home was not obligated, then there are no funds available to bind the Government, and the employee must wait until the applicable appropriation is passed to accept an offer. General rules regarding continuation of contractual arrangements should be followed. As for appraisals and inspections, these need to wait until the applicable appropriation is passed if the transactions are not covered by a revolving fund or a fund that does not lapse under a furlough situation.
"Can I proceed to start my enroute travel to an OCONUS foreign post during a government shut down?"	Per the State Department Regulation, staff policy office: "This is not to be treated any differently than a domestic move. All monies spent on relocation are monies already approved and pre obligated. In addition, the employee may present their credentials to the foreign country with no problems."

"What about other types of relocation allowances such as pre-departure, temporary quarters, and Household Goods (HHG)? Are these considered entitlements that should be obligated, and expenses incurred, or should these future relocation expenses be stopped and not obligated?"	If relocation has been approved and obligated prior to the shutdown, it may move forward. If it has not been approved and obligated prior to the shutdown, it cannot be started until after the budget is resolved. However, even if the funds have been obligated for a relocation, an agency should confirm with Human Resources if an employee should perform a House Hunting Trip (HHT) during the furloughed timeframe since an employee is normally in a "pay status" while on an HHT. It also applies for an enroute travel – they are in a pay status for the authorized number of days. Questions that may come in to play include "are the employees covered (insurance/disability) during those days if they travel and also furloughed." Check with your HR office for further guidance.

1-3 GSA Fleet Vehicle Packet

Maintenance and Accident Instructions:

GSA Fleet – Vehicle Assistance Centers Call 1 (866) 400-0411

Press 1 - Maintenance Control Center (MCC) – mechanical or tire problems
Press 2 - Accident Management Center (AMC) – accident body damage and glass
Press 3 - Fleet Service Card acceptance problem
Press 4 - Vendor with a payment problem

Fueling Instructions:

1. Using your Fleet Service Card, select Credit at the pump
2. Enter 6 Digit PIN
3. Enter odometer reading
4. Choose proper fuel. Use of mid-grade, premium or full-service fuel is prohibited.

These Require Prior MCC Approval

- Repairs over $100
- Replacement of:
  - Tires
  - Glass
  - Batteries



www.gsa.gov
March 2019
05-19-00532

Involved in an accident? See Accident Reporting Kit inside.

GSA

U.S. General Services Administration

GSA Fleet Vehicle Packet

Zone 1

Hartford, CT: (860) 240-3314
Baltimore, MD: (410) 406-2201
Hooksett, NH: (603) 666-7957
Buffalo, NY: (716) 551-4596
New York Metro Area: (732) 906-5605
Harrisburg, PA: (717) 770-4575
Philadelphia, PA: (215) 446-4832
Pittsburgh, PA: (412) 294-4001
San Juan, PR: (787) 749-4440
Franconia, VA: (703) 605-9350
Richmond, VA: (804) 279-6807
Chesapeake, VA: (757) 424-2389
Huntington, WV: (304) 529-5584

Zone 2

Alabama/Mississippi/
NW Florida: (850) 581-2036
Montgomery, AL: (334) 450-0796
Florida: (321) 213-6052
Georgia: (770) 435-7806
Fort Gordon, GA: (404) 215-8625
Chicago, IL: (630) 655-3464
Southern IL: (618) 622-5807
Indianapolis, IN: (312) 350-2286
Kentucky/Tennessee: (502) 909-3895
Livonia, MI: (313) 226-2391
Twin Cities, MN: (612) 725-4002
Jackson, MS: (601) 965-4192
North/South Carolina: (910) 436-2649
Camp Lejune, NC: (910) 451-2698
Cleveland, OH: (330) 342-0272
Dayton, OH: (937) 427-5639
Charleston, SC: (843) 727-4043
Fort Jackson, SC: (803) 751-7603
Nashville, TN: (615) 907-6208
Milwaukee, WI: (414) 769-5644

Zone 3

Little Rock, AR: (501) 324-5514
Denver, CO: (303) 236-7221
Baton Rouge, LA: (225) 757-7635
Kansas City, MO: (816) 823-3620
St. Louis, MO: (314) 263-3023
Helena, MT: (406) 449-5265
Bismarck, ND: (701) 250-4318
Albuquerque, NM: (505) 248-7347
Gallup, NM: (505) 863-9324
Los Alamos, NM: (505) 346-8601
Oklahoma City, OK: (405) 231-4436
Rapid City, SD: (605) 341-3842
El Paso, TX: (915) 772-1165
Houston, TX: (832) 397-8415
San Antonio, TX: (210) 306-2342
Dallas/Ft. Worth/
Ft. Hood, TX: (817) 850-8248
Utah: (801) 625-5020

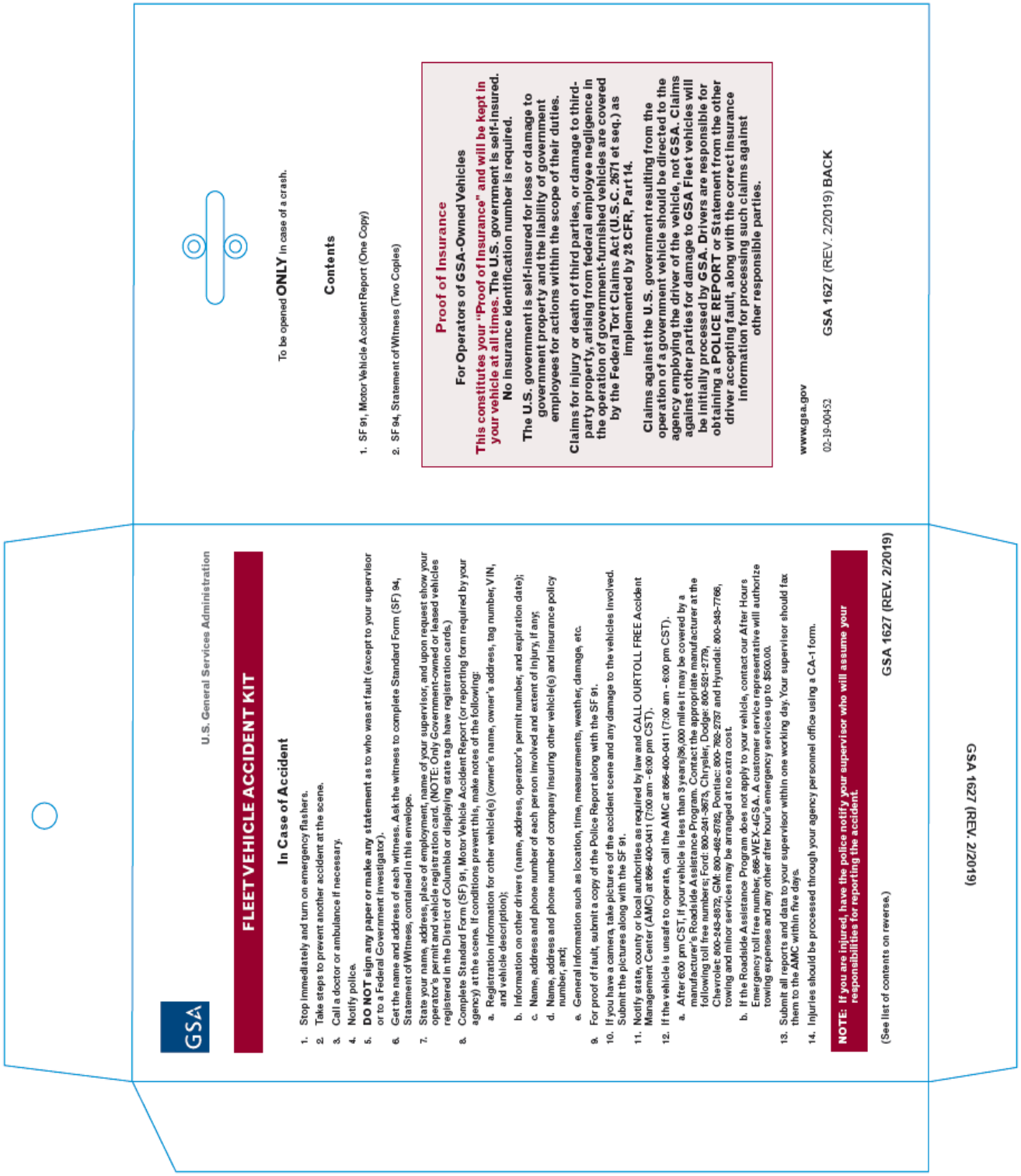
Zone 4: (415) 522-2858

Phoenix, AZ
Los Angeles, CA
San Diego, CA
San Francisco, CA
Honolulu, HI
Auburn, WA
Vancouver, WA

Visit www.gsa.gov/gsafleetfmcs for the most up to date contact information

Ask your FSR for information on the GSAFleet2Go App
Download the App on the Apple App Store or on Android's Google Play

1-4 Fleet Vehicle Accident Kit-GSA 1627



GSA

U.S. General Services Administration

FLEET VEHICLE ACCIDENT KIT

In Case of Accident

1. Stop immediately and turn on emergency flashers.
2. Take steps to prevent another accident at the scene.
3. Call a doctor or ambulance if necessary.
4. Notify police.
5. **DO NOT** sign any paper or make any statement as to who was at fault (except to your supervisor or to a Federal Government investigator).
6. Get the name and address of each witness. Ask the witness to complete Standard Form (SF) 94, Statement of Witness, contained in this envelope.
7. State your name, address, place of employment, name of your supervisor, and upon request show your operator's permit and vehicle registration card. (NOTE: Only Government-owned or leased vehicles registered in the District of Columbia or displaying state tags have registration cards.)
8. Complete Standard Form (SF) 91, Motor Vehicle Accident Report (or reporting form required by your agency) at the scene. If conditions prevent this, make notes of the following:
   a. Registration information for other vehicle(s) (owner's name, owner's address, tag number, VIN, and vehicle description);
   b. Information on other drivers (name, address, operator's permit number, and expiration date);
   c. Name, address and phone number of each person involved and extent of injury, if any;
   d. Name, address and phone number of company insuring other vehicle(s) and insurance policy number, and;
   e. General information such as location, time, measurements, weather, damage, etc.
9. For proof of fault, submit a copy of the Police Report along with the SF 91.
10. If you have a camera, take pictures of the accident scene and any damage to the vehicles involved. Submit the pictures along with the SF 91.
11. Notify state, county or local authorities as required by law and CALL OURTOLL FREE Accident Management Center (AMC) at 866-400-0411 (7:00 am - 6:00 pm CST).
12. If the vehicle is unsafe to operate, call the AMC at 866-400-0411 (7:00 am - 6:00 pm CST).
    a. After 6:00 pm CST, if your vehicle is less than 3 years/36,000 miles it may be covered by a manufacturer's Roadside Assistance Program. Contact the appropriate manufacturer at the following toll free numbers; Ford: 800-241-3673, Chrysler, Dodge: 800-521-2779, Chevrolet: 800-243-8872, GM: 800-462-8782, Pontiac: 800-762-2737 and Hyundai: 800-943-7766, towing and minor services may be arranged at no extra cost.
    b. If the Roadside Assistance Program does not apply to your vehicle, contact our After Hours Emergency toll free number, 866-WEX-4GSA. A customer service representative will authorize towing expenses and any other after hour's emergency services up to $500.00.
13. Submit all reports and data to your supervisor within one working day. Your supervisor should fax them to the AMC within five days.
14. Injuries should be processed through your agency personnel office using a CA-1 form.

NOTE: If you are injured, have the police notify your supervisor who will assume your responsibilities for reporting the accident.

(See list of contents on reverse.)

GSA 1627 (REV. 2/2019)

GSA 1627 (REV. 2/2019)

To be opened **ONLY** in case of a crash.

Contents

1. SF 91, Motor Vehicle Accident Report (One Copy)
2. SF 94, Statement of Witness (Two Copies)

Proof of Insurance

For Operators of GSA-Owned Vehicles

This constitutes your "Proof of Insurance" and will be kept in your vehicle at all times. The U.S. government is self-insured. No insurance identification number is required.

The U.S. government is self-insured for loss or damage to government property and the liability of government employees for actions within the scope of their duties.

Claims for injury or death of third parties, or damage to third-party property, arising from federal employee negligence in the operation of government-furnished vehicles are covered by the Federal Tort Claims Act (U.S.C. 2671 et seq.) as implemented by 28 CFR, Part 14.

Claims against the U.S. government resulting from the operation of a government vehicle should be directed to the agency employing the driver of the vehicle, not GSA. Claims against other parties for damage to GSA Fleet vehicles will be initially processed by GSA. Drivers are responsible for obtaining a POLICE REPORT or Statement from the other driver accepting fault, along with the correct insurance information for processing such claims against other responsible parties.

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02-19-00452 GSA 1627 (REV. 2/2019) BACK

1-5 Example Email Communication to Claimant Regarding Form SF95 Submission



Return Address

Date of Communication

Address of Recipient

Good Day,

Per our conversation, attached is a copy of the **SF-95 form**. This form is used to file a claim against the government for damage, injury, or death. As a result of the incident that occurred on XX/XX/XXXX, I am required to notify you of your right to file, if you should desire. If you chose to file a claim, complete the form, and please return the completed form to me via email for initial review and submission to the FDA Claims Liaison.

If you need additional information, please let me know.

Space for signature

Name and title of communication author

1-6 Fleet Vehicle Assistance Card



U.S. General Services Administration

GSA Fleet Vehicle Assistance Centers

Call 1 (866) 400-0411

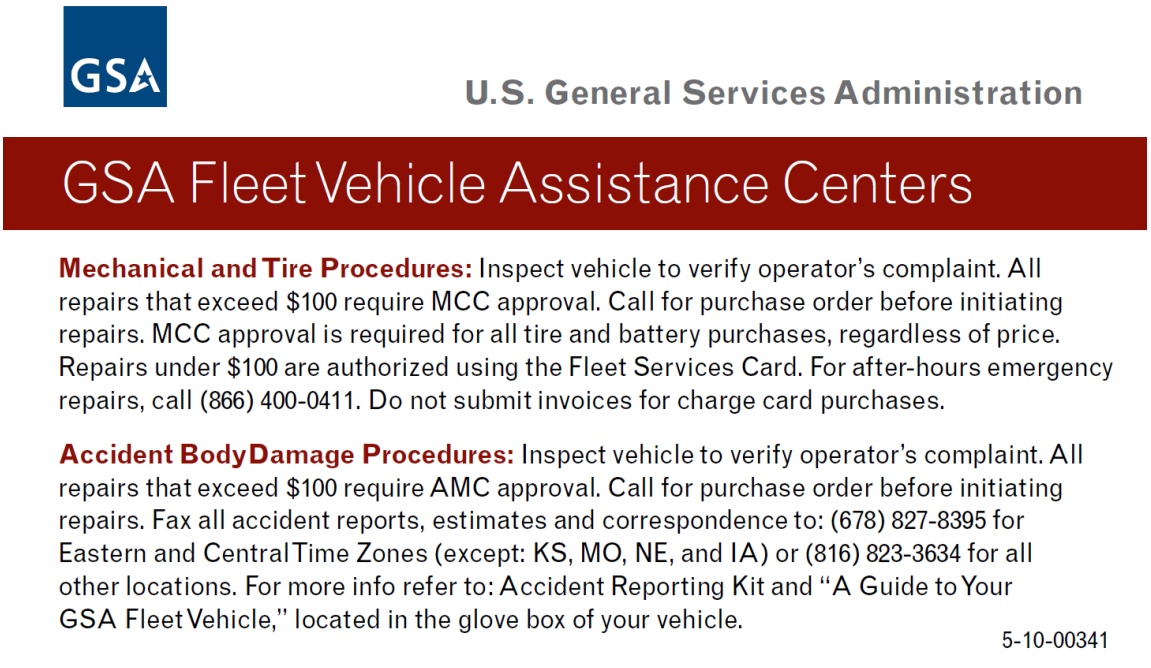
Press 1 – Maintenance Control Center (MCC)– mechanical and tire problems

Press 2 – Accident Management Center (AMC)– accident body damage

Press 3 – Fleet Service Card acceptance problem

Press 4 – Vendor with a payment problem

(3/10) (over)



U.S. General Services Administration

GSA Fleet Vehicle Assistance Centers

Mechanical and Tire Procedures: Inspect vehicle to verify operator's complaint. All repairs that exceed $100 require MCC approval. Call for purchase order before initiating repairs. MCC approval is required for all tire and battery purchases, regardless of price. Repairs under $100 are authorized using the Fleet Services Card. For after-hours emergency repairs, call (866) 400-0411. Do not submit invoices for charge card purchases.

Accident Body Damage Procedures: Inspect vehicle to verify operator's complaint. All repairs that exceed $100 require AMC approval. Call for purchase order before initiating repairs. Fax all accident reports, estimates and correspondence to: (678) 827-8395 for Eastern and Central Time Zones (except: KS, MO, NE, and IA) or (816) 823-3634 for all other locations. For more info refer to: Accident Reporting Kit and "A Guide to Your GSA Fleet Vehicle," located in the glove box of your vehicle.

5-10-00341

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1-7 ORA Mobile Media Support

FDA U.S. FOOD & DRUG ADMINISTRATION
OFFICE OF REGULATORY AFFAIRS
OFFICE OF COMMUNICATIONS AND PROJECT MANAGEMENT



MOBILE MEDIA SUPPORT

- Thank them for their interest!
- State that you would be more than happy to speak with them, but you need to refer them to the ORA Press Team
- Email address: ORAPress@fda.hhs.gov
- DO send a "Heads Up" email with the reporters **name, organization, nature of their inquiry & location of contact** to ORApress@fda.hhs.gov
- DON'T say, "No Comment"
- DO refer them ORApress@fda.hhs.gov
- REMINDER: not sure what to do re: a press or media inquiry? Contact ORAPress@fda.hhs.gov

1-8 Media Tip Card

Office of Regulatory Affairs

CAN WE TALK? A Guide to Dealing with the Media

The Division of Communications is here to assist you!

WHEN YOU ARE CONTACTED BY A REPORTER....



By phone or email:
forward the message to ORAPress@fda.hhs.gov.

At a conference or speaking event:
provide them with ORAPress@fda.hhs.gov for follow-up.

- We will work with the reporter to find out the deadline and focus of the request.
- When an interview is requested, we will coordinate with you and the Office of Media Affairs to set up the terms and scope of the interview.
- We will help prepare you for the interview by identifying key points you want to make during the interview and secure all required clearances.



NOTE: Never tell a reporter you have to obtain clearance first.

Suggested Response:
Let me get your contact information, your topic or questions, and deadline. I will have a member of the ORA Press Team follow-up with you to schedule time for us to talk.

WHEN YOU TAKE AN ACTION THAT MAY ATTRACT MEDIA ATTENTION

(e.g., establish guidance, exercise an enforcement)...

- We will work with you to determine whether a press announcement is appropriate and feasible.
- Please contact us as early as possible via email to ORAPress@fda.hhs.gov.

SOME HELPFUL TIPS

Before the interview

- Decide on the **3 or 4 most important aspects** of the action or topic and **make them the focus** of your comments.
- **Make your message concise** and easy to understand.
- **Use data or analogies**, when appropriate.

During the interview

- **Place** your topline messages and supporting points in front of you.
- If you are being filmed while seated, **sit up straight and lean slightly forward**. Avoid wearing white or clothing with busy prints or oversized jewelry that might distract the viewer.

Do's and Don'ts during the interview

- **DO** restate your primary message in several different ways during the interview. End with your most important point.
- **DO** mention our website www.fda.gov. Newspapers and other media organizations are increasingly interested in using graphics and referring readers to online content.
- **DO** take a moment if you feel you need time to think.
- **DO** redirect the conversation with a positive response if a reporter poses a question with a negative slant. For example, use phrases like: "On the contrary..." or "Not so; we strive..."
- **DO** avoid using jargon and acronyms. For example, refer to the "Office of Regulatory Affairs," not "ORA.".
- **DON'T** say "no comment." If you don't know or can't provide an answer, explain why. Direct the reporter back to ORA Press for help in providing follow-up information or resources.
- **DON'T** speculate if a reporter asks "What if...?" questions. One possible response is something like, "More work is needed within the scope of the FDA's mission."

Developed by ORA/Office of Communications and Project Management / Division of Communications - 7/2020

1-9 Reporting IT Security Incident Checklist

Please include the following pieces of information, so that we can quickly and efficiently respond:

Customer Information:

- Your full name
- Your FDA email address
- Your best immediate phone number contact
- A brief explanation of the circumstances
- When did the incident occur (Date, Time)?
- Location of the incident
- What country were/are you in?

Device Information:

- Type of device stolen (e.g., Laptop/Desktop/Iron Key/Storage Drive/RSA Token/Blackberry)
- FDA Asset Tag or Serial#
- Brand/Series/Model
- Encryption Type
- Sensitive Information or PII

Important:

- To request new equipment click here. The FDA SMC does not handle "IT Acquisition" requests.
- Please notify your center Property Custodial Officer (PCO) and/or Accountable Property Officer (APO) of this theft as soon as possible for a replacement. You can determine your center's PCO/APO by searching on http://inside.fda.gov.
- To learn how to report a suspected PII loss, click here.

Note: Security personnel will receive your email and respond to you immediately. **DO NOT** try to handle the security incident yourself; wait for a member of the security team to contact you and direct you.

Tips for Protecting FDA Equipment and Information:

- Lock your equipment at all times and do not leave your equipment unattended when outside of FDA facilities *(e.g., car, metro)*.
- Be alert and aware of your work environment. If you notice unknown individuals not wearing a badge, offer to escort them or report it to the FDA Security Command Center at (301) 796-2409.

CHAPTER 1A – NOTES, RECORDS, AND INFORMATION

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1A.1 – Regulatory Notes

1A.1.1 – Definition

Regulatory notes are the contemporaneous, sequential record of your daily investigatory efforts. They record your observations relevant to violations and active cases. They are the vital link between your findings and your subsequent testimony in court. Your regulatory notes are confidential because of the data they contain (e.g., information pertaining to open investigatory files, trade secrets, and personal information protected under the Privacy Act). Regulatory notes are government property and are releasable under the FOIA following FDA's procedures (See IOM 1A.3).

1A.1.2 –Difference between Regulatory Notes and Administrative Notes

Regulatory notes should not be confused with administrative notes. Administrative notes are purely administrative in nature and may include information related to travel, expenses, fiscal data, timekeeping, and documentation of meetings outside of regulatory operations. Regulatory notes should not contain purely administrative information, and they should not be maintained together. Administrative notes can be documented in a separate section of the same bound notebook where your regulatory notes are kept or in a separate administrative diary.

1A.1.3 – Use of Regulatory Notes

Accurate regulatory notes are to document evidence and to refresh your memory when reporting certain important details of a field operation, such as a sample collection, consumer complaint, inspection, or investigation. Regulatory notes are the source record upon which your reports will be prepared. Regulatory notes also support the principle of "presumption of regularity" (i.e., in the absence of clear evidence to the contrary, courts presume public officers properly discharge their official duties). Regulatory notes are useful to refute assertions by defendants, witnesses, or others. Regulatory notes also aid in defending lawsuits against FDA agents. This has been an issue of significance in several regulatory cases in the federal sector.

1A.1.4 – Quality Characteristics of Regulatory Notes

1A.1.4.1 – General Considerations

See IOM 1A.4 for English language requirement. Regulatory notes should be accurate, objective, factual, and free of personal feelings or conclusions. Regulatory notes should be made at the time of the event they represent. Regulatory notes are original, contemporaneous, sequential recordings of an activity, and may be handwritten in ink or electronically. (See IOM 1A.1.5 for information on what to do under rare circumstances when regulatory notes cannot be taken contemporaneously such as when entering a restricted environment.)

When using electronic notes, you should exercise good judgment when deciding if a change is contemporaneous, or if a change should be initialed and dated. For example, changes or backspacing to correct information as it is being written ordinarily would not need initialing and

dating if the changes were made contemporaneously with the activity being documented. However, if you are returning to the information to change it after it was initially recorded, you should initial and date the change. (See IOM 1A.1.4.3.1 for information on how to document corrections in your regulatory notes.)

1A.1.4.2 – Entries

Regulatory notes should contain sufficient detail to refresh an investigator's memory regarding field activities, such as inspections, investigations, consumer complaints, and sample collections. They should include descriptions of your activities during the operation and your findings, such as objectionable conditions observed, or details of a sample collection. If a checklist is used during an inspection, don't repeat that information in your regulatory notes and attach it to your EIR. The checklist should be handled as part of the notes. See also 5.7.1. Likewise, when relevant information is contained on an FDA form, or in an exhibit collected during an inspection, that information need not be repeated in your notes. The act of issuing the form, collection of the exhibit, your review of the record, etc., should be recorded in your regulatory notes.

Regulatory notes should contain the substance of all significant discussions with people contacted during the activity, (e.g., discussions of individual responsibility and refusals). When entering a direct quote in your regulatory notes, such as a statement against self-interest, it is important that the exact words be used to preserve the original intent of the individual and subject. Every quote of significance appearing in the final report should be in your regulatory notes since it is part of the source documents, which will support any regulatory or administrative action.

1A.1.4.3 – Format

You may choose to take your regulatory notes as handwritten notes (bound journal), electronic, or as a combination of the two. Follow your management's direction. Regulatory notes, whether written or electronic, are subject to audit at any time; must be available for review; and must, on demand, be surrendered to your supervisor or other authorized personnel. Advancing technology may increase the preservation options available. District policy should be followed regarding the preservation of all regulatory notes.

1A.1.4.3.1 – Handwritten Hardcopy Regulatory Notes

When taking handwritten regulatory notes, use a bound notebook. Bound notebooks provide continuity and integrity and prevent lost or misplaced pages. Loose-leaf and spiral bindings allow easy removal of pages, an invitation to vigorous and heated cross-examination on the witness stand. (See 1A.1.5 for information on situations where taking regulatory notes in your bound notebook may not be feasible.)

Do not erase, edit, or rewrite original notes. Do not leave excessive space between diary entries. Any additions, deletions, or corrections to handwritten regulatory notes should be identified by strike-through for deletions, brackets [] for additions, and by initialing and dating your changes.

The bound notebook in which your handwritten regulatory notes are kept should be identified with your name, telephone number, and address to facilitate their return if lost. To assist in the return of lost regulatory notes, include the following information in the bound notebooks inside cover, or as a placard affixed to the back cover:

This book is the property of the U.S. Government.
If found, drop in mailbox.
POSTMASTER: Postage guaranteed
Please return to: [Enter the appropriate district (or resident post's) mailing address here, including the zip code]

1A.1.4.3.2 – Electronic Regulatory Notes

You have the option of taking regulatory notes electronically as long as you can identify and attest that the electronic notes were taken by you, and you can ensure document integrity. Electronic regulatory notes (ERN) can be taken in eNSpect (preferred method), or outside of eNSpect, in software such as Microsoft OneNote or Word. You should contact your supervisor if you have questions on which software to use.

1A.1.4.3.2.1 – ERN Taken in eNSpect

eNSpect provides the capability to record and store electronic notes. This is ORA's preferred method for taking regulatory notes electronically. See https://fda.sharepoint.com/sites/ORA-OPOP/OISM/OISMExternal/Systems/eNSpect/SitePages/Home.aspx for the complete *User Guide and Frequently Asked Questions* section for additional information.

1A.1.4.3.2.2 – ERN Taken Outside of eNSpect

If using software/programs other than eNSpect, any additions, deletions, or corrections to regulatory notes should be identified by using strikethrough font for deletions, brackets [] for additions, and by initialing and dating your changes. Refer to 1A.1.4.1 – General Considerations. Notes should be stored in a method where they are preserved in a manner that ensures data integrity and are retrievable if needed, for example, uploaded into eNSpect or saved on electronic storage media. Adhere to agency directives and procedures to safeguard and file electronic notes. Regulatory notes taken outside of eNSpect can be printed. If printed, you should be able to attest to the fact that the notes are accurate, complete, and were taken contemporaneously. This includes electronically signing the ERN file before printing or applying handwritten initials and date to each printed page. If this procedure is used, the original electronic storage media, can be identified with the firm name, dates, and investigator's initials; placed in an FDA-525 envelope or equivalent; and then sealed with an Official Seal, FDA-415a. NOTE: See IOM 5.6.6.2.3 - Exhibits, for guidance on the identification and storage of electronic data. Regulatory notes are not exhibits to the EIR (See IOM 1A.1.6 for Retention of Regulatory Notes).

1A.1.4.3.3 – Switching between Handwritten and Electronic Regulatory Notes

At your management's discretion, you can switch between taking regulatory notes electronically and in your handwritten journal. However, it is important to document when switching between the two forms because your regulatory notes are meant to be recorded contemporaneously. When switching between the two formats during a single operation, make a note in both formats that you will be taking notes using the other format and why (e.g., "Entering production room floor to observe sanitation – notes to be taken via bound journal/handwritten. Will switch back to eNSpect ERN upon return to conference room."). Be sure to include the date and time at which you are switching. Repeat the same process each time you switch between formats. This practice ensures that there is no unaccounted-for gap in your regulatory notes for the same operation (e.g., inspection, investigation).

1A.1.5 – Recording Regulatory Notes in Restricted Environments

In rare circumstances, you may be unable to take regulatory notes using your notebook or electronic note-taking device because doing so might introduce contamination from your notebook into the environment (e.g., pharmaceutical clean rooms, egg-laying hen houses) or from the environment into your notebook (e.g., environmental sampling of manure pits during egg inspections, drug manufacturing areas where high-potency, cytotoxic, or β-lactam drugs are exposed). Additionally, if you use an electronic notetaking device, you may be unable to use it in environments that present an explosion hazard.

You should attempt to take contemporaneous notes in the most reasonable manner possible. Make a note in your official regulatory notes that you will be taking notes using another method and the reason (e.g., "Entering cleanroom to observe sterile operations – notes to be taken on sterile cleanroom paper provided by firm to prevent contamination"). If taking notes on unbound sheets of paper, please refer to supervisory guidance.

If you are unable to take notes in any manner, you should record your recollection of the events and/or observations in your regulatory notebook as soon as you are able to. Include the reason you could not contemporaneously take notes in your regulatory notebook and the time between the event and/or observations and the notes.

After the inspection, preserve the notes according to your division policy and in consultation with supervisor guidance.

1A.1.6 – Retention of Regulatory Notes

Identify your regulatory notes with your name and the inclusive dates they cover before they are turned over for storage (does not apply to ERN taken within eNSpect). Follow your district policy regarding the maintenance of regulatory notes.

Based on your district policy, regulatory notes may be kept by you, filed with the final report, or kept by the district in a separate, designated file.

If you leave the FDA, or are transferred from your district, identify any regulatory notes in your possession and turn them in to the district you are leaving. Districts are to retain regulatory notes as official records as outlined in the FDA Staff Manual Guide (see SMG 3291.1).

Regulatory notes prepared by center personnel during a field inspection/investigation are official records. Center personnel are to follow their center's policy regarding the retention of regulatory notes. In general, all regulatory notes should be maintained in the district or center where the original report is filed.

1A.2 - Records Management

A record as defined by the National Archives and Records Administration (NARA), the Federal agency that oversees all records management rules and regulations, includes all recorded information, regardless of form or characteristics, made or received by a Federal agency under Federal law or in connection with the transaction of public business and preserved or appropriate for preservation by that agency or its legitimate successor as evidence of the organization, functions, policies, decisions, procedures, operations, or other activities of the United States Government or because of the informational value of data in them." (44 U.S.C. 3301). Records must be retained until they are ready for disposition (instructions for managing records when not needed for agency business) and at what point they can be destroyed or transferred in accordance with their Record Schedule.

1A.2.1 – Types of Records

Different types of records require distinct maintenance and handling based on their record schedule and the type of record. This section describes the main records disposition categories.

1A.2.1.1 – Permanent Records

Records that contain historically significant materials, provide evidence of agency accomplishments, or document important events in national history, and as a result will be preserved by NARA.

1A.2.1.2 – Temporary Records

Records with a temporary disposition that will eventually be destroyed or deleted when all relevant business needs have expired.

1A.2.1.3 – Intermediary Records

Records of an intermediary nature, meaning that they are created or used in the process of creating a subsequent record. To qualify as an intermediary record, the record must also not be required to meet legal or fiscal obligations, or to initiate, sustain, evaluate, or provide evidence of decision-making.

1A.2.1.4 – Transitory Records

Records required only for a short time (generally less than 180 days) and are not required to meet legal or fiscal obligations, or to initiate, sustain, evaluate, or provide evidence of decision-making.

1A.2.2 – Records Retention

Per current FDA policy, records must be maintained for the duration of their retention period in accordance with their corresponding record schedule in the format that they are received. For example, paper and electronic records received from firms must be maintained in accordance with their retention periods even if they are scanned and/or uploaded into eNSpect. The official record is the original paper or electronic record received from the firm.

All records must be maintained for a certain amount of time and in a certain manner. See corresponding section of the IOM for specific information about how to handle many of the most common record types. Contact your local administrative and/or compliance branch for additional guidance about specific record retention policies including record schedules, maintenance, destruction, transfer, and storage.

Due to government-wide mandates to transition away from paper records, all records should be collected, created, stored, and distributed electronically to the fullest extent possible. Electronic records should not be printed for storage--electronic record management solutions should be pursued instead. Some situations, such as issuing FDA Forms (i.e., FDA-482, FDA-483, FDA-484) or Firm Correspondence (FMD-145), may require the creation of a physical record.

1A.2.3 – Additional Information about Records Management

Additional records management information can be found in the links below:

- Records Definitions: https://www.archives.gov/files/records-mgmt/rm-glossary-of-terms.pdf
- Transitory and Intermediary Record Guidance: https://www.archives.gov/files/records-mgmt/grs/grs05-2.pdf
- ORA Records SharePoint: Records Management - Home (sharepoint.com)
- FDA Records Control Schedules: https://www.archives.gov/records-mgmt/rcs/schedules/index.html?dir=/departments/department-of-health-and-human-services/rg-0088
- ORA Standard National File Plan: http://qmis.fda.gov:80/mc/index.cfm?initialRequest=http%3A%2F%2Fqmis.fda.gov%3A80%2Fmc%2Fmain%2Findex.cfm%3Fevent%3DshowFile%26ID%3DDMTEXEDZ3JEVRILSFG%26static%3Dfalse

1A.2.4 - Specific Records Investigators Handle and Create

Examples of records you will likely handle in your career as a CSO can be found in this section.

1A.2.4.1 - Regulatory Notes

See IOM 1A.1.

1A.2.4.2 - Administrative Notes

See IOM 1A.1.2.

1A.2.4.3 - E-mail

E-mails are official government records and are required to be retained appropriately. Most FDA employee emails are saved within outlook for seven years after employees depart the agency. This policy coincides with the HHS email policy and NARA GRS 6.1 record retention requirement for emails.

If any emails in your possession are associated with cases or are under legal hold, they may require longer than a seven-year retention. In such cases, an alternate electronic repository may be required to store the corresponding emails. For additional information or guidance, communicate with your local administrative branch and/or the compliance branch overseeing the case.
Capstone employee emails are saved permanently then transferred to NARA; however, this only applies to a small number of senior leaders.

See additional email policies:

- HHS email
- Policy: https://intranet.hhs.gov/policy/records-management-email#7.11
- NARA Email Record Schedule: https://www.archives.gov/files/records-mgmt/grs/grs06-1.pdf
- NARA file formats for permanent electronic records: https://www.archives.gov/records-mgmt/policy/transfer-guidance-tables.html
- Information about Capstone employee emails: https://www.archives.gov/records-mgmt/email-management/capstone-training-and-resources.html

1A.2.4.4 - Collection Reports and Lab Analytical Packages

Collection reports include documents collected from a firm and documents created by the FDA regarding the collection of a product, environmental, or documentary sample. Collection reports should remain intact and be stored at the home district of the firm where the sample was collected or the office from which any regulatory action would be executed.

Local district procedures should be followed for storing collection reports; however, in most cases physical collection reports of product and environmental samples should be stored separately from physical inspection records, while documentary samples should be stored with corresponding inspection records.

Lab analytical packages demonstrate laboratory results from a sample collection, and if physical records exist, they should be stored with their corresponding collection report at the home district of the firm where the sample was collected, or the office from which any regulatory action would be executed.

All efforts should be made to maintain Collection Reports and Lab Analytical Packages electronically such as in Compliance Management Systems (CMS).

1A.2.4.5 - Memoranda

Memoranda may include investigational or administrative subject matter and should be retained according to their content. Investigational memoranda should be stored at the home district of the firm visited or referenced in the memorandum and may include investigations, tracebacks, consumer complaints, Reportable Food Registry Responses, Out-Of-Business, etc. Administrative memoranda should be stored appropriately and may include topics such as Exceeding Travel Allowance, Internal Decision Memos, Other than Coach Class Travel accommodations, etc. All efforts should be made to maintain memoranda electronically, such as in CMS, eNSpect, or Enterprise Content Management System (ECMS).

1A.2.4.6 - Recall Audit Check Reports

The results of recall audit checks are reported on FDA Form 3177, "Recall Audit Check Report." See IOM Exhibit 7-3. Divisions have the option of completing the form FDA 3177 electronically or as a hard copy. The preferred method is electronically.

The form FDA 3177 will be routed through your supervisor to the recall coordinator at the division monitoring the recall, who will store the official signed form in the recall file. (IOM 7.3.2.4)

1A.2.4.7 - Consumer Complaints

Per SOP 000544, all consumer complaint records are stored electronically in CMS consumer complaint files. Hard copy files and documents provided by the complainant are stored in the district firm files.

If documents, records, or photographs are received from the complainant, the documentation is scanned into CMS and the hard copy documents are sent to the complainant receiving org for filing. See http://qmis.fda.gov/mc/index.cfm?initialRequest=http%3A%2F%2Fqmis.fda.gov%3A80%2Fmc%2Fmain%2Findex.cfm%3Fevent%3DshowFile%26ID%3D7QYTPC6FZFEZBO7GPP%26static%3Dfalse#/

1A.2.4.8 - Correspondence

Correspondence typically includes electronic or physical mail among FDA employees, or between FDA employees and the public or regulated industry.

If the correspondence is received from regulated industry in response to an FDA Form 483 or regulatory meeting, or is related to an inspection or investigation activity, then the correspondence should be filed in the Establishment File or Compliance File related to the activity. Physical correspondence should be stored in the home district of the associated firm. Electronic correspondence should be stored in the appropriate electronic repository per ORA or program policy.

Firm management should be requested to provide their inspection or investigation responses via program division email boxes as per program policy. Correspondence that is not associated with an inspection or investigation activity should be filed per ORA, local, or program policy. All efforts should be made to maintain correspondence electronically such as in CMS, eNSpect, ECMS, RES (Recall Enterprise System), or other electronic repository.

1A.2.4.9 - Attachments

Documents attached to the EIR not provided by the firm during the inspection and referred to in the EIR, may be referred to under the attachment heading.

See IOM 5.7.5 for additional information.

1A.2.4.10 - Exhibits

Exhibits are materials collected from the firm after the FDA Form 482 Notice of Inspection or FDA Form 482d Request for FSVP Records is issued and before the FDA Forms 483, 483a, or 4056 are issued or the inspection is closed out.

See IOM 5.7.4 for additional information on records obtained.

1A.2.4.11 - Additional Documents Collected during Inspection

Materials not used in an EIR do not need to be kept under an official file plan.
Hard copy documents collected from the firm that are not needed as exhibits should be destroyed in accordance with your program division or office policy, (i.e., shredded or placed in a designated shredder bin). If the inspection is ongoing, you may return such documents to the firm.
Electronic documents obtained on storage media containing exhibits should be handled per IOM 5.6.6.2. Documents not used in the EIR should not be deleted from storage media.

1A.2.4.12 - Photographs

The photographs included and described in the EIR are considered the official exhibit and are maintained in the eNSpect system. See IOM 5.6.7 for additional information on preserving photographic evidence.

1A.2.5 - Litigation Holds or Injunctions

There are circumstances where the FDA must maintain records beyond the Records Management requirements. These circumstances are generally related to legal cases pending with the agency. You may receive a notice that there is a litigation hold or injunction regarding destruction of records. This includes deletion of e-mails related to a particular matter. Read these notices carefully if you receive one.

1A.2.5.1 Litigation Holds

Litigation holds are holds placed on records. The request to hold records comes from the FDA OCC to ensure that records associated with an ongoing legal action are not destroyed. Records under litigation hold cannot be deleted or destroyed while the legal hold is active. If you are notified directly of a litigation hold on records in your possession, you should preserve those records until you are notified that the litigation hold is no longer active. For the purposes of supporting the preservation of ORA records under litigation hold, there is a consolidated list of known litigation holds and added it to the ORA Records Management SharePoint Site. (See link below for this list and additional guidance.)

1A.2.5.2 – Injunctions

Injunctions are legal actions with potentially extensive or indefinite time periods until completion or lifting of the injunction, especially in the case of permanent injunctions. Records that lead to the development of an injunction cannot be destroyed prior to the end of the injunction, and therefore, must be preserved in a similar manner as litigation holds. For the purposes of supporting the preservation of ORA records under injunction, there is a consolidated list of known injunctions on the ORA Records Management SharePoint Site. (See link below for this list and additional guidance.)

1A.2.5.3 – Additional Information

The litigation holds and injunctions lists linked below may not include all existing litigation holds or injunctions. If you are aware of any additional litigation holds or injunctions, you must preserve all associated records, regardless of their inclusion on these lists.

ORA Records Management SharePoint Site with litigation hold and injunction lists and additional relevant guidance can be found at: https://fda.sharepoint.com/sites/ORA-OM-Internal/ORARecManagement/SitePages/RM%20Legal%20Holds.aspx?csf=1&web=1&e=ej0cGs

1A.3 – Information Disclosure

Sharing of information, regardless of the manner, must comply with FOIA, other applicable laws such as the Privacy Act and FDA procedures. Do not disclose any non-public information (NPI) (written or verbal) obtained during FDA official duties, unless you are authorized to do so by ORA's Division of Information Disclosure Policy (DIDP). Do not release any originals or copies of reports, memos, regulatory notes, forms (e.g., FDA-483, 484, 464, etc.), confidential or trade secret information obtained by a firm, or similar investigational documents to anyone outside the agency without express concurrence and appropriate authorization of division or headquarters management, the Office of the Chief Counsel (OCC), or information disclosure personnel. Unauthorized disclosure of confidential commercial or financial information, trade secrets, or personal privacy information could be a civil or criminal violation and may carry legal or other consequences for the disclosing official.

NPI includes information exempt from public disclosure under FOIA (see also FDA regulations under 21 CFR Part 20 Subpart D - Exemptions), as well as any other information prohibited from public disclosure under federal law or regulation, including the Privacy Act and the Trade Secrets Act (See other CFR

disclosure references for an inexhaustive list). Examples of non-public information include confidential commercial information, trade secret information, pre-decisional FDA communications, investigative information, enforcement information, and personal privacy information. Confidential information in particular includes commercial or financial information "customarily kept private, or at least closely held," by the submitter. Submitted confidential information that FDA determines is exempt from public disclosure will be held in confidence by FDA unless required or authorized by regulation, statute, or court order.

Disclosure of non-public information must follow FDA regulations:

- 21 CFR 20.85 – other federal government departments or agencies
- 21 CFR 20.88 – state/local
- 21 CFR 20.89 – foreign
- 21 CFR Part 20 – Freedom of Information Act (FOIA)
- 21 CFR Part 21 – Privacy Act
- Other disclosure procedures found on the ORA Information Disclosure page

If non-public information is inadvertently disclosed, follow ORA's Addressing Inadvertent Disclosures SOP. Any information disclosure questions should be directed to DIDP at ORAinfoshare@fda.hhs.gov.

1A.3.1 – Subpoena

If you are served a subpoena (commanding your appearance in court) or a subpoena duces tecum, (commanding the production of any record or testimony, or the giving of information relating to official FDA matters), immediately advise your supervisor and ORA's Division of Information Disclosure (DIDP) (ORA OSPOP Testimony – Info Sharing Team) at ORAinfoshare@fda.hhs.gov. A testimony specialist will instruct you about the proper procedures and actions, so you are able to comply with the subpoena. (See 21 CFR § 20.1, § 20.2 and the Regulatory Procedures Manual (RPM) chapter 10-11, "Testimony; Production of Records; Certification of Records.")

1A.3.2 – Requests by the Public

See IOM 1A.1.4 regarding information requested by the public under FOIA. For procedures for sharing non-public information with federal, state, local, or foreign government officials, see IOM 1A.1.3.
If a complainant requests sample results, see IOM 8.1.3. For procedures on the release of EIRs to the establishment inspected, see Field Management Directive (FMD)-145. For procedures on the disclosure of analytical results to establishments pursuant to Section 704(d) of the FD&C Act [21 U.S.C. 374 (d)], see IOM 4.6.2.59 and FMD 147.

1A.3.3 – Sharing non-public information with other government officials

If you receive requests for non-public information from officials of other federal agencies or from state or local officials, contact your designated state liaison or DIDP at ORAinfoshare@fda.hhs.gov. If you receive requests for non-public information from foreign officials contact International Federal

Engagement at "ORA OP International & Federal Engagement Group"
oraopdiintlandfederalgroup@fda.hhs.gov.

Follow the current guidance:

- SMG 2830.3 Sharing Non-Public Information with Foreign Government Officials
- SMG 1410.65 Disclosure of Trade Secret Information to Foreign Governments
- SMG 1410.66 Delegation of Authority for Disclosure of Non-Public Information to Foreign Government Officials or Receipt of Non-Public Information from Foreign Government Officials
- MAN-000006 Regulatory Procedures Manual Chapter 3: Commissioning and Information Sharing (Specifically Section 3-6-4 Sharing Non-Public Information with Federal Government Officials and Section 3-6-3 Sharing Non-Public Information with State and Local Government Officials)

FDA's practice regarding requests for non-public information (NPI) from state government officials and agencies is governed by 21 CFR 20.88. All exchanges of confidential commercial or financial information with all state government officials must be authorized through DIDP and made pursuant to a written confidentiality agreement with the government official or officials seeking to access the non-public information.

Requests for NPI from foreign regulatory authorities are governed by 21 CFR 20.89. These confidentiality agreements are established and managed by the Office of Global Policy and Strategy and can be found on the confidentiality agreement webpage.

Requests for non-public information from other federal government departments and agencies are governed by 21 CFR 20.85. All exchanges of non-public information with federal government officials outside of DHHS must be authorized through DIDP pursuant to a written confidentiality arrangement with the government official.

For any questions regarding the sharing of non-public information with a state, local, or federal entity, please contact DIDP at ORAinfoshare@fda.hhs.gov.

1A.3.4 – Freedom of Information Act (FOIA)

The Public Information section of the Administrative Procedures Act, 5 U.S.C 552, more commonly known as the FOIA, adopts a general rule that, except where specifically exempt, all documents in government files shall be made available to the public. The regulations exempt certain information, such as personal privacy, deliberative process, open investigatory, as well as a company's trade secrets or confidential commercial or financial information.

You can find information about disclosure and confidentiality of information related to FDA records and documents in 21 CFR Parts 20 and 21, 21 CFR 71.15, 170.102, 312.130, 314.430, 514.11, 514.12, 601.50, 814.9, and within other documents and statutes as detailed on the ORA Information Disclosure page. In

addition to the FOIA, other acts such as the , PHS Act, and 18 U.S.C. 1905 also contain information relating to the confidentiality of information in government files. Note that special care should also be taken to protect the identity of confidential sources, see IOM 5.4.1.8.

All ORA staff must adhere to FDA's laws and procedures regarding the maintenance of confidentiality of non-public information.

1A.3.4.1 – Requests for Documents

If you receive requests for information, you may direct the requester to the FDA Electronic Reading Room (https://www.fda.gov/regulatory-information/freedom-information/electronic-reading-room). If answers cannot be found, the requester may be directed to submit a FOIA request at https://www.fda.gov/RegulatoryInformation/FOI/HowtoMakeaFOIARequest/ucm2007229.htm. If your office receives a request, forward an electronic copy of the request to the director of the Division of Freedom Information (DFOI).

1A.3.5 – Internal FDA Documents

FDA records that are intended for internal use only may contain information protected from disclosure to the public by a FOIA exemption. Examples include work plans, internal decision memos, internal federal agency emails, and attorney-client communication. Do not disclose such records without consultation from an information disclosure expert in DIDIP. If you receive requests for internal documents, or for parts of them, refer to IOM 1A.1.4 and IOM 1.10.2.5.

1A.4 – English Language Requirement

Records or Federal Records are defined in 44 U.S.C. 3301 as including “all recorded information, regardless of form or characteristics, made or received by a Federal agency under Federal law …” which includes regulatory notes, memoranda, inspection reports, emails, and official government forms e.g. SF-71, FDA-482-FDA-483, etc. made or received by an agency of the United States Government under Federal law or in connection with the transaction of public business and preserved or appropriate for preservation by that agency or its legitimate successor as evidence of the organization, functions, policies, decisions, procedures, operations or other activities of the Government or because of the informational value of the data in them (44 U.S.C. 3301). (See also § 1222.10 of this part for an explanation of this definition).

All official FDA documents generated during your routine duties shall be completed in English. This requirement is necessary to facilitate efficiency in the workplace. For instance, many of your work products used in support of FDA’s regulatory process are subject to review and auditing by your supervisor, utilized by your co-workers, and others, including the public, in that they are releasable under the Freedom of Information Act (FOIA). The agency does not have the resources to assure the accurate and timely English translation of documents written in a non- English language in order to facilitate their use in the conduct of official business. English is generally considered to be the common

language of the U.S.; therefore, it is necessary to standardize the language utilized in the production of official FDA documents.

Additionally, FDA imposes English only requirements on the public for information submitted to the agency. For example, 21 Code of Federal Regulations section 803.13(a) (English Reporting Requirement) states that all reports required in this part which are submitted in writing or electronic equivalent shall be submitted to FDA in English.

1A.5 – Full Name Requirement

Full name means the person's first name, middle initial, last name, and any appropriate suffixes (e.g., Jr. Sr.). If an establishment inspection report is associated with the operation, the fact that there is no middle initial should be explained in the Individual Responsibility and Persons Interviewed section of the report (see IOM 5.6.3).

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2.1 – Purpose

This chapter provides you with the statutory and regulatory frameworks and additional information related to your work. It summarizes authorities for inspections; sample collections; advisory, administrative, and judicial actions and discusses your distinct role in these activities. This chapter also includes information on certain regulatory submissions for FDA-regulated products. The Regulatory Procedures Manual (RPM) is the field reference containing specific internal procedures and other guidance related to the work of compliance officers. (You may want to review pertinent sections of the RPM while reading this chapter.)

2.2 – Statutory Authority

Various acts specify the authorities granted to the Secretary of the Department of Health and Human Services (DHHS). This authority is delegated to the commissioner of Food and Drugs, and certain authorities are delegated further by him or her. See Staff Manual Guides, Delegations of Authority, Volume II (1400) for more information.

2.2.1 – Federal Food, Drug, and Cosmetic (FD&C) Act

This act, as amended, and its regulations provide the basic authority for most operations. (Note: Section 2.5.11.1 of this chapter describes authority to detain products under the FD&C Act.)

2.2.1.1 – Selected Amendments to the FD&C Act

The amendments to the FD&C Act are summarized in RPM Chapter 2-2. (https://www.fda.gov/media/77516/download).

2.2.2 – Authority to Sample

Collecting samples is a critical part of the FDA's regulatory activities. Section 702 of the FD&C Act [21 U.S.C. 372(a)] gives the FDA authority to conduct investigations and collect samples. An FDA-482 Notice of Inspection is not always required for sample collections. However, if during a sample collection, you see a need to conduct an inspection and conduct activities, (e.g., examining storage conditions, reviewing records for compliance with laws and regulations, etc.), immediately issue an FDA-482 before continuing your activities. (See IOM 5.1.3.) Sampling authority for biological products that are also drugs is found in both the FD&C Act and the Public Health Service (PHS) Act.

Section 702(b) of the FD&C Act [21 USC 372(b)] requires the FDA to furnish, upon request, a portion of an official sample for examination or analysis to any person named on the label of an article, the owner thereof, or his attorney or agent.

In a precedent case, *United States v. 75 Cases, More or Less, Each Containing 24 Jars of Peanut Butter*, the U.S. Circuit Court of Appeals for the Fourth Circuit held that the taking of samples is authorized under section 702(b) of the FD&C Act [21 U.S.C. 372(b)], since this section *"clearly contemplates the taking of samples."* Sections 704(c) and 704(d) [21 USC 374(c) and 374(d)] also imply an authority to collect samples.

2.2.3 – Authority to Inspect

Section 704 of the FD&C Act [21 U.S.C. 374] provides the basic authority for establishment inspections. This authorizes you, upon presenting appropriate credentials and a written notice (FDA-482, Notice of Inspection), to enter and to inspect at reasonable times, within reasonable limits, and in a reasonable manner, establishments or vehicles being used to process, hold, or transport food, drugs, devices, tobacco products, or cosmetics, for introduction into or in interstate commerce. The statute does not define, in specific terms, the meaning of "reasonable." FDA's establishment inspection procedures maintain this authority extends to what is reasonably necessary to achieve the objective of the inspection.

2.2.3.1 – Food Inspections

Authority to inspect food facilities resides in the general inspectional authority of Section 704 of the FD&C Act [21 U.S.C. 374].

Section 306 of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 ("the Bioterrorism Act") (PL 107-188), created Section 414, “Maintenance and Inspection of Records” in the FD&C Act [21 U.S.C. 350c]. Under this authority, the Secretary may by regulation establish requirements for persons (excluding farms and restaurants) who manufacture, process, pack, transport, distribute, receive, hold, or import food to establish and maintain food records. These records identify the immediate previous sources and the immediate subsequent recipients of food.

In addition, Section 414(a)(1), "Records Inspection," and section 704(a)(1), "Factory Inspection," authorize the Secretary to access and copy all records related to an article of food if: (1) the Secretary has a reasonable belief that an article of food, and any other article of food that the Secretary reasonably believes is likely to be affected in a similar manner, is adulterated and presents a threat of *serious adverse health consequences or death to humans or animals* (SAHCODHA), and (2) the records are necessary to assist the Secretary in making such a determination.

Under Section 414(a)(2), FDA can also access and copy all records related to an article of food if the FDA believes that there is a reasonable probability that the use of, or exposure to, an article of food, and any other article of food that the FDA reasonably believes is likely to be affected in a similar manner, will cause SAHCODHA. The FDA may carry out its authority to inspect all records and other information described in Section 414 in a similar manner as FDA’s authority to perform inspections of facilities (i.e., upon presentation of appropriate credentials and a written notice at reasonable times, within reasonable limits, and a reasonable manner). FDA employees will not invoke this authority during inspections unless the requirements for record access under the Bioterrorism Act are satisfied. Further guidance is available at https://www.fda.gov/food/guidance-documents-regulatory-information-topic-food-and-dietary-supplements/food-defense-guidance-documents-regulatory-information.

The Infant Formula Act of 1980 added new authority to the FD&C Act. Section 412 of the FD&C Act [21 U.S.C. 350a] extends the definition of adulteration to include specific nutritional, quality, and good manufacturing control requirements. Section 412 also mandates a firm make available batch records, quality control records, nutrient test data and methodology, and similar documents for examination and copying. See 21 CFR 106.100 for regulations on infant formula records. Section 704(a)(3) of the FD&C Act [21 U.S.C. 374(a)(3)] gives investigators the right to examine and copy these records.

Section 361(a) of Part G of the PHS Act [42 U.S.C. 264(a)] authorizes the FDA to make and enforce regulations necessary to prevent the introduction, transmission, or spread of communicable diseases. FDA regulations at 21 CFR Part 1240, Control of Communicable Diseases, and 21 CFR Part 1250, Interstate Conveyance Sanitation, authorizes inspection, among other measures, to prevent the introduction, transmission, or spread of communicable diseases. This includes investigation of any disease outbreak (not just foodborne) aboard US-flagged vessels (see IOM 8.2.2.3). These regulations also cover the mandatory pasteurization for all milk in final package form intended for direct human consumption; the safety of molluscan shellfish; the sanitation of food service; and food, water, and sanitary facilities for interstate travelers on common carriers.

2.2.3.2 – Drug Inspections

In the case of drug inspections, FDA has explicit authority to address the delay, denial, limiting, or refusal of an inspection, under section 707 of the Food and Drug Administration Safety and Innovation Act (FDASIA), which created Section 501(j) of the FD&C Act [21 U.S.C. 351(j)]. Section 501(j) deems adulterated any drug that is manufactured in an establishment that delays, limits, denies, or refuses to permit entry or inspection. FDA has issued Guidance for Industry with examples of the types of conduct that the FDA considers to be in violation of section 501(j) of the FD&C Act. This guidance also specifies that under certain circumstances, delaying, denying, limiting, or refusing a request for records in advance of or in lieu of an inspection under Section 707 of FDASIA may also result in a manufacturer's drugs being deemed adulterated under the FD&C Act.

2.2.3.3 – Device Inspections

Section 704(a) of the FD&C Act [21 U.S.C. 374(a)] provides the general inspectional authority to inspect medical device manufacturers. The Medical Device Amendments of 1976 provide additional authority to inspect records, files, papers, processes, controls, and facilities to determine whether restricted devices are adulterated or misbranded. The amendments also provide FDA authority, under Section 704(e) [21 U.S.C. 374(e)], to inspect and copy records required under Section 519 or 520(g) of the FD&C Act [21 U.S.C. 360i or 360j(g)]. Section 501(j) of the FD&C Act [21 U.S.C. 351(j)], discussed above in 2.2.3.2 – Drug Inspections, also applies to devices, pursuant to the FDA Reauthorization Act (FDARA) of 2017. Section 704(h)(1) added additional requirements for investigators for inspections of device establishments. These requirements include: pre-announcing the inspection and communication; inspection timeframes; and communication during the inspection. See Guidance Document - Review and Update of Device Establishment Inspection Process and Standards.

2.2.3.4 – Electronic Product Radiation Controls (EPRC) - Examinations and Inspections

The authority for obtaining samples of radiation-emitting electronic products for testing is provided in Section 532(b)(4) of the FD&C Act [21 U.S.C. 360ii(b)(4)].

The authority to inspect factories, warehouses, and establishments wherein electronic products are manufactured or held is provided in Section 537(a) of the FD&C Act [21 U.S.C. 360nn(a)]. This authority is limited. The FDA must find "good cause" that methods, tests, or programs related to radiation safety (such as noncompliance with a standard) may be inadequate or unreliable. If there is no finding of "good cause," inspections must be voluntary unless another authority applies, such as Section 704(a) of the FD&C Act [21 U.S.C. 374(a)] for medical devices. The authority to inspect books, papers, records, and documents relevant to determining compliance with radiation standards is provided in Section 537(b) of the FD&C Act [21 U.S.C. 360nn(b)]. The Electronic Products Radiation Control (EPRC) prohibited acts and enforcement authorities are specified in Sections 538 and 539 of the FD&C Act [21 U.S.C. 360oo and 360pp].

2.2.3.5 – Biologics Inspections

Section 351 of the PHS Act [42 U.S.C. 262] contains provisions for the regulation of biological products. A biological product, as defined in Section 351(i) of the PHS Act [42 U.S.C. 262(i)], also meets the definition of a "drug" or a “device” in Section 201 of the FD&C Act [21 U.S.C. 321]. Section 704 of the FD&C Act [21 U.S.C. 374] and Section 351(c) of the PHS Act [42 U.S.C. 262(c)] authorize the agency to inspect establishments that manufacture biological products. Additionally, Section 510(h) of the FD&C Act [21 U.S.C. 360(h)] applies to biological product establishments because all biological products are also subject to regulation under the drug or device provisions of the FD&C Act. See 21 CFR Part 600, Subpart C for regulations on establishment inspections for biological products.

Section 361(a) of Part G of the PHS Act [42 U.S.C. 264(a)] authorizes inspection and other activities for the enforcement of 21 CFR Part 1270, Human Tissue Intended for Transplantation.

2.2.3.6 – Tobacco Inspections

The Family Smoking Prevention and Tobacco Control Act (Tobacco Control Act) of 2009 gives the agency broad authority to regulate the manufacturing, distribution, and marketing of tobacco products. The Tobacco Control Act added Section 905 to the FD&C Act [21 U.S.C. 387e]. Pursuant to Section 905(g) to the FD&C Act [21 U.S.C. 387e(g)], establishments registered under this section shall be subject to inspection under Section 704 of the FD&C Act [21 U.S.C. 374] or 905(h) of the FD&C Act [21 U.S.C. 387e(h)]. See 21 CFR 1107.58 (effective November 4, 2021) for regulations related to certain records that must be available for inspection and copying by duly designated officers or employees.

2.2.3.7 – Bioresearch Monitoring (BIMO) Inspections

Inspectional activities in the Bioresearch Monitoring (BIMO) program involve all product areas and centers. See IOM section 5.14 for BIMO establishment types. In general, the, basic authority for establishment inspections is found in Section 704 of the FD&C Act [21 U.S.C. 374]. Authority for BIMO inspections is detailed in section 704(a)(5) of the FD&C Act [21 U.S.C. 374(a)(5)].

FDA's BIMO program covers Good Laboratory Practices (GLP) (Nonclinical Laboratories) inspections, which includes inspection collaborations between FDA and Environmental Protection Agency (EPA) under the GLP program. As is described in CP 7348.808A, FDA may conduct data audits for EPA under authority delegated from EPA to review records under Sections 8 and 22 of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA; 7 U.S.C. 136 et seq.) and/or under Sections 9 and 11 of the Toxic Substances Control Act (TSCA; 15 U.S.C. 2601 et seq.). That understanding is described in an interagency agreement between FDA and EPA. BIMO investigators conducting data audits pursuant to EPA's authority will receive documentation of the delegation of authority from EPA in a "Letter of Entry."]

2.2.4 – Limitations

Section 704(a)(1) of the FD&C Act [21 U.S.C. 374] provides authority for FDA to conduct inspections of factories, warehouses, and establishments in which food, drugs, devices, tobacco products, or cosmetics are manufactured, processed, packed or held, and vehicles being used to transport or hold such food, drugs, devices, tobacco products, or cosmetics, and all pertinent equipment, finished and unfinished materials, containers, and labeling therein. This section does not include a provision to inspect records within those facilities, except for inspections of foods, prescription drugs, nonprescription drugs intended for human use, and restricted devices, or tobacco products, as stipulated in Section 704(a)(1)(B) [21 U.S.C. 374(a)(1)(B)], or inspections of infant formula described in Section 704(a)(3) of the FD&C Act [21 U.S.C. 374(a)(3)].

Keep in mind that several other sections of the act or of regulations also include provisions for inspections and copying of required records. For example, 505(k) provides authority to access and copy records required for new drug applications and abbreviated new drug applications; 512(k)(2) and 512(m)(5) of the FD&C Act [21 U.S.C. 360b(k)(2) and 360b(m)(5)] provide access and copying of records regarding new animal drug and medicated feed permits; HACCP regulations in 21 CFR 123 for fish and fishery products provide for access and copying of required records; and 920(c) provides access, with written notice, to records for investigating potential illicit trade, smuggling, or counterfeiting of tobacco products.

Some firms will allow access to files and other materials for which the FD&C Act does not give mandatory access but retain the right to later refuse. Firm management may propose the following alternatives:

- Inspections to obtain data from these files be made without issuing an FDA-482, Notice of Inspection. You cannot agree to this because the act requires the notice be issued before the inspection.
- When data is provided, you are advised in writing it is being given voluntarily. In this instance accept the written or oral statement and include it as part of the Establishment Inspection Report (EIR).

Firm management may also insist answers to specific questions be provided by the firm's legal department or other administrative officers. In some instances, management may request questions be submitted in writing. Only submit lists of questions if you are specifically instructed to do so by your supervisor.

2.2.5 - Remote Regulatory Assessments (RRAs)

Remote Regulatory Assessments (RRAs) are examinations of an FDA-regulated establishment and/or its records, conducted entirely remotely, to evaluate compliance with applicable FDA requirements. RRAs assist in protecting human and animal health, informing regulatory decisions, prioritizing regulatory activities, and verifying certain information submitted to the Agency. RRAs complement FDA's authority to conduct inspections under section 704(a)(1) of the FD&C Act and other applicable FDA authorities but are not themselves inspections.

Programs across FDA have differing remote regulatory authorities, making participation in RRAs by FDA-regulated establishments either mandatory or voluntary depending on the program and authority.

For more information about RRAs (both mandatory and voluntary RRAs), please refer to the RRA Staff Manual Guide (SMG 6001.1).

The RRA SMG serves as a reference document that includes but is not limited to RRA:

- Purpose, background, scope
- Responsibilities
- Procedures (e.g., selecting, planning, conducting, reporting)

Different programs across the FDA have more specific procedural information that can be accessed through the FDA Remote Regulatory Assessment (RRA) SharePoint Page. Please reach out to your specific program contact(s) as needed for more information.

2.2.6 – Other Acts

See IOM 2.2.10 and IOM 3.2.1.3 for special authorities involving detentions under the Federal Meat Inspection, Poultry Products Inspection, and Egg Products Inspection Acts.

See RPM Chapter 2-2 for selected amendments to the FD&C Act and RPM Chapter 2-3 for other laws. The laws listed below are not referenced in the RPM.

2.2.5.1 - Anabolic Steroids Control Act of 1990

The Anabolic Steroids Control Act amends the Controlled Substances Act by adding Anabolic Steroids to Schedule III of Section 202(c).

2.2.5.2 - Federal Caustic Poison Act

This is primarily a labeling act specifying warnings and precautionary statements required on labeling of certain household caustic preparations.

2.2.3.3 - Poison Prevention Packaging Act

This act provides for special packaging to protect children from serious personal injury or serious illness resulting from handling, using, or ingesting household substances.

2.3 - Evidence

Evidence is quite simply information. While you are out conducting inspections, collecting samples, or conducting other operations, you will be gathering and collecting information or evidence. Evidence is used in judicial cases to show the facts of a matter that is in dispute.

2.3.1 – JIVR (See IOM 4.4.3)

JIVR is an acronym that stands for jurisdiction, interstate commerce, violation(s), and responsibility. It is not a legal term but used within the agency to describe the elements for evidence needed for most charges used by FDA against person(s) as defined by FD&C Act section 201(e).

2.3.1.1 - Jurisdiction

Jurisdiction is the power, right, or authority to interpret and apply the law. Jurisdiction is not defined in the FD&C Act; however, FDA's jurisdiction over a subject (e.g., a product) is determined by acts that the FDA is charged to enforce. In the context of JIVR, jurisdiction is shorthand for evidence that the product is regulated by FDA based on the definitions found in Section 201 of the FD&C Act. See also What does FDA regulate? Exhibit 3-1 in the IOM describes the separation of jurisdiction for foods between FDA and the United States Department of Agriculture (USDA). Exhibit 2-1 contains the definitions of the various commodities and programs that the FDA regulates.

2.3.1.2 – Interstate Commerce

Interstate commerce is an interchange of goods or commodities between one state or territory and any place outside thereof, or commerce within the District of Columbia or within any other territory. Section 201(b) of the Act.

2.3.1.3 – Violation

A violation is an illegal condition (a condition that is contrary to a statute). The most common FD&C Act violations include adulteration and/or misbranding.

2.3.1.4 – Responsibility

Responsibility refers to those who are legally responsible for the violation and who could be named as defendants in a judicial action. There are two types of responsible persons: those who directly perform or cause a prohibited act (see Section 301 of the FD&C Act) and those who have the responsibility and authority either to prevent in the first instance, or promptly to correct, the violation as a result of their position (see U.S. v. Dotterweich and U.S. v. Park). Section 201(e) of the FD&C Act broadly defines the term “person" to include an individual, partnership, corporation, and association.

2.3.2 – Presumption of Regularity

The presumption of regularity is founded on the common-sense idea that courts should assume that government officials “have properly discharged their official duties.” United States v. Chem. Found., Inc., 272 U.S. 1, 15 (1926). The presumption began as a way of filling in minor evidentiary gaps, usually related to procedural or technical formalities. Historically, the same presumption of normality and regularity applied to private parties and corporate officers, as well as to government officials. For example, if a copy of a document with a corporate seal was filed, a court would presume it was an official corporate seal issued by an authorized party unless someone submitted evidence to the contrary. Today, consistent with its historical origins, the presumption serves as a “general working principle” that means courts will “insist on a meaningful evidentiary showing” before entertaining doubts about the integrity of official acts or documents. (National Archives & Records Admin. v. Favish, 541 U.S. 157, 174 (2004))

Presumption of regularity is demonstrated when you follow established procedures in the IOM and other guidance documents.

2.4- Advisory Actions and Other Notices of Violations

Prior Notice means that under most circumstances and consistent with its public protection responsibilities, the FDA will notify or advise persons of violations that appear to exist. In cases of violations of regulatory significance, failure to comply with this notice or advisement may result in the initiation of enforcement action. This affords individuals and firms an opportunity to voluntarily take appropriate and prompt corrective action.

When it is consistent with the public protection responsibilities of the agency, and depending on the nature of the violation, it is the FDA's practice to give individuals and firms an opportunity to take voluntary and prompt corrective action before it initiates an enforcement action.

The FDA is under no legal obligation to provide Prior Notice to individuals or firms before taking enforcement action, except in a few specifically defined areas.

Prior Notice, including exceptions to the practice, is discussed in RPM Chapter 10 - Other Procedures.

2.4.1 - Warning Letters

A Warning Letter is informal and advisory. It communicates the agency's position on a matter, but it does not commit FDA to taking enforcement action. For these reasons, FDA does not consider Warning Letters to be final agency action.

As stated in RPM Chapter 4, Warning Letters are issued to achieve voluntary compliance and to establish Prior Notice. The use of Warning Letters and Prior Notice are based on the expectation that most individuals and firms will voluntarily comply with the law.

The agency's position is that Warning Letters are issued only for violations of regulatory significance that may lead to enforcement action if not promptly and adequately corrected.

See Field Alert 40 (https://fda.sharepoint.com/sites/insideFDA-ORA/Shared Documents/Forms/AllItems.aspx?id=%2Fsites%2FinsideFDA-ORA%2FShared Documents%2FField Investigations%2FField Alerts%2FField Alert 40%2Epdf&parent=%2Fsites%2FinsideFDA-ORA%2FShared Documents%2FField Investigations%2FField Alerts) for information related to interstate commerce documents necessary for a Warning Letter.
There are instances when issuing a Warning Letter is not appropriate, and as previously stated, a Warning Letter is not a prerequisite to taking enforcement action. RPM Chapter 4 (Section 4.-1-1) describes in detail the situations in which the agency will take enforcement action without necessarily issuing a Warning Letter.

2.4.2 - Untitled Letters

An Untitled Letter cites violations that do not meet the threshold for regulatory significance for a Warning Letter. However, it still serves provides prior notice by advising the firm about these violations. Therefore, the format and content of an Untitled Letter should clearly distinguish it from a Warning Letter.

2.4.3 - Regulatory Meetings

A regulatory meeting is a meeting requested by FDA management, at its discretion, to inform responsible individuals or firms about products, practices, processes, or other activities that are in violation of the law. (See RPM Chapter 10.)

Regulatory meetings can be an effective enforcement tool to obtain prompt voluntary compliance and have been used successfully in a variety of different situations.

2.5 - Administrative Actions

Administrative actions are actions that the FDA may take without going through judicial review. The various acts that the FDA enforces provide authority for these actions and specific regulations further explained the regulations. (Chapter 5 of the RPM covers administrative actions in detail.)

2.5.1 - Section 305 Notice/Meeting

The Section 305 Notice is a statutory requirement of the FD&C Act. It provides a respondent with an opportunity to explain why they should not be prosecuted for the alleged violation. Response to the notice may be by letter, personal appearance, or attorney. ORA management must communicate with the local OCI office before pursuing any criminal matter (see RPM 6-5-1).

Under certain circumstances, the agency will refer prosecution (or for further investigation) without first providing the opportunity for presentation of views in accordance with Section 305 [See 21 CFR 7.84(a)(2) and (3)].

2.5.2 - Civil Money Penalties (CMP)

The Civil Money Penalties (CMPs) are monetary penalties that are assessed by the FDA for violations of the FD&C Act or the PHS Act. CMPs are authorized under the FD&C and PHS Acts.

2.5.3 – No-Tobacco-Sale Orders

A No-Tobacco-Sale Order (NTSO) may be pursued against retailers that have a total of five or more repeated violations of certain restrictions within 36 months. Retailers are prohibited from selling regulated tobacco products at the specified locations during the period of the NTSO.

2.5.4 – Disqualification of Clinical Investigators

The FDA may preclude a clinical investigator from receiving investigational drugs, biologics, or devices, and deem them ineligible to conduct any clinical investigation that supports an application for a research or marketing permit for products regulated by FDA. A clinical investigator can be disqualified if they have repeatedly, or deliberately, failed to comply with applicable regulatory requirements, or they have repeatedly, or deliberately, submitted false information to the sponsor or, if applicable, to the FDA, in any required report.

Subchapters 5-10 of the RPM, titled, “Disqualification of Clinical Investigators,” describes the process, including timeframes, for initiating disqualification proceedings – from completion of the inspection to issuance of the Notice of Initiation of Disqualification Proceedings and Opportunity to Explain (NIDPOE) to the clinical investigator.

Criteria for initiation of disqualification proceedings are included in the Compliance Program Guidance Manual (CPGM) 7348.811 for Bioresearch Monitoring: Clinical Investigators, Part V. B.

2.5.5 - Importer Debarment

Importer Debarment is an action taken by the FDA, on the basis of a criminal conviction or conduct, as identified in Sections 306 (b)(3)(A) or (B) of the act, to prohibit an individual, corporation, partnership, or association from:

- Submitting, or assisting in the submission of, certain drug applications or, in the case of individuals only, providing services in any capacity to the sponsor of an approved or pending drug application;
- Importing or offering for import an article of food into the United States;
- Importing or offering for import a drug article into the United States; or
- Being accredited to perform certain functions related to devices through programs administered by the FDA, by other government agencies, or by other qualified nongovernment organizations; and from carrying out activities under agreements with foreign countries to facilitate commerce in devices.

If you observe conduct, or receive an oral or written notice, indicating that a person is violating an active debarment order, please notify your supervisor so that appropriate action can be taken as prescribed in Staff Manual Guide (SMG) 7712 (https://www.fda.gov/media/80036/download). The current FDA debarment list is located on the following agency web page (check both the main list and the updates to the list for the most recent additions): https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/fda-debarment-list-drug-product-applications/fda-debarment-list-updates.

2.5.6 - Food Facility Suspension of Registration (Section 415(b))

The FDA can suspend registration of a facility if it determines that the food produced, processed, packed, received, or held at such facility poses a reasonable probability of serious adverse health consequences or death. A facility that is under suspension is prohibited from distributing food.

Section 415(b) of the FD&C Act, as amended by the Food Safety Modernization Act (FSMA) on January 4, 2011, provides that the FDA may suspend the registration of a food facility if the agency determines that food manufactured, processed, packed, received, or held by a registered facility has a reasonable probability of causing serious adverse health consequences or death to humans or animals. FDA may by order suspend the registration of a facility that:

- Created, caused, or was otherwise responsible for such reasonable probability; or
- Knew of, or had reason to know of, such reasonable probability; and packed, received, or held such food.

2.5.7 - Emergency Permit Control

The commissioner can issue an emergency permit for a temporary period as necessary to protect public health.

Section 404 of the FD&C Act [21 U.S.C. 344] provides for the issuance of temporary permits prescribing the conditions governing the manufacture, processing, or packing of any class of food by reason of

contamination with injurious microorganisms, where such contamination cannot be adequately determined after such articles have entered interstate commerce.

2.5.8 - Mandatory Recall

FDA's mandatory food recall authority was included in the FSMA. The authority allows the FDA to order a responsible party to recall an article of food wherein the FDA determines that there is a reasonable probability that the article of food (other than infant formula) is adulterated under Section 402 of the FD&C Act [21 U.S.C. § 342] or misbranded under Section 403(w) of the FD&C Act [21 U.S.C. § 343(w)] and that the use of or exposure to such article will cause SAHCODHA. Applicable evidence will be evaluated when determining whether there is reasonable probability the adulterated or misbranded food will cause SAHCODHA. See RPM 7-5-3 and Attachment J.

2.5.9 - License Revocation or Suspension

Biologics licenses issued under the PHS Act [42 U.S.C. 264] can be revoked or suspended. Revocation will cancel the firm's license, and without such license, the firm is no longer authorized to introduce, or deliver for introduction, biological products into interstate commerce. If biological products are believed to pose an immediate danger to public health, the Center for Biologics Evaluation and Research (CBER) can place a "suspension" on a biological firm's license. Suspension provides an immediate pause to the introduction, or delivery for introduction, of biological products into interstate commerce. A suspension summary action can be an initial step or an intermediate step to license revocation.

When the license relates to multiple locations, revocation may be limited to one or more of the locations if inspectional findings support that approach. The agency may consider revocation of a biologic license when any of the conditions specified in 21 CFR 601.5 exist. If conditions are met, the agency can either issue a Notice of Intent to Revoke, or Direct Revocation. The Notice of Intent to Revoke provides the license holder an opportunity to address or become compliant before the agency proceeds with the revocation. In cases where willful conduct is involved, the agency can directly revoke a firm's license without providing an opportunity to address compliance status prior to proceeding with the revocation.

Detailed information on these Administrative Actions can be found in Chapter 5 of the RPM in section 5-7.

2.5.10 - Orders of Retention, Recall, or Destruction and Cessation of Manufacturing Related to Human Cell, Tissue and Cellular and Tissue-Based Products (HCT/Ps)

An Order of Retention, Recall, or Destruction of Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/Ps) may be appropriate in situations where there are significant concerns regarding the source or violative nature of the HCT/P, the adequacy of the screening and/or testing, or a failure of the establishment to fulfill stated commitments to gain control over violative HCT/Ps. The agency may order the retention, recall, and/or destruction of the violative HCT/P; take possession of and/or destroy the

violative HCT/Ps; or order the establishment to cease manufacture until compliance with Part 1271 has been achieved.

Consumer safety officers (CSO) should contact their supervisor if there are significant concerns while an inspection is open and should not wait until the inspection has been completed. The CSO, in conjunction with their supervisor, should ensure that all documentation supporting the violative condition is collected.

An Order of Cessation of Manufacturing may be appropriate in situations where there are significant concerns regarding one or more steps in the manufacture of HCT/Ps, or a failure of the establishment to fulfill stated commitments to gain control over or to bring the areas of manufacturing into compliance with the applicable regulations. During the inspection, if it is determined that an Order of Cessation of Manufacturing is necessary to prevent a potential danger to health, the investigator should collect complete documentation of the violative conditions, including an inventory of products on the premises as of the last day of the inspection. Refer to RPM Subchapter 5-8 "Orders of Retention, Recall, Destruction and Cessation of Manufacturing Related to Human Cells, Tissue, and Cellular and Tissue-Based Products (HCT/Ps)," for procedural instructions for issuance of an order.

2.5.11 - Detention Powers and Criteria for Detention

Detention is an administrative action which protects the public by preventing movement in interstate or intrastate commerce of a food, device, drug, or tobacco product that an authorized FDA representative has reason to believe is adulterated or misbranded, while the agency institutes appropriate action (e.g., seizure or injunction). Import detention is covered separately in IOM Chapter 6 - Imports.

2.5.11.1 – Federal Food, Drug and Cosmetic Act (FD&C Act)

Section 304(g) of the FD&C Act provides the FDA with authority to detain foods, devices, drugs, or tobacco products believed to be adulterated or misbranded. The products may be detained for a reasonable period, not to exceed 20 days, unless extended to no more than 30 days as necessary to institute appropriate action (e.g., seizure or injunction). You should become familiar with this section and the regulations implementing this authority. See 21 CFR 800.55 and 21 CFR 1.980. At present time, the device regulations apply only to devices intended for human use. See FD&C Act section 304(g) [21 U.S.C. 334 (g)].

Section 304(h) of the FD&C Act provides the FDA with the authority to order the administrative detention of any article of food that is found during an inspection, examination, or investigation under the FD&C Act, if FDA has reason to believe that such article is adulterated or misbranded. Become familiar with this section of the FD&C Act and the implementing regulations in 21 CFR Part 1, Subpart K. The FDA's administrative detention authority applies to both food offered for import and food in domestic commerce. FDA's authority to administratively detain food under Section 304(h) is separate and distinct from FDA's authority to refuse admission of imported food under section 801[8](a).

The authority to detain drugs can be found in Section 304(g) of the FD&C Act. The primary criteria are:

- The article(s) meets the definition of drug in section 201(g)(1) of the FD&C Act.
- There is reason to believe the drug(s) are adulterated or misbranded.

Please see RPM Chapter 5, Section 5. Administrative Detention of Drugs for drug detention procedures.

2.5.11.2 – Products Regulated by USDA in Dual Jurisdiction Establishments

Foods regulated by the USDA (i.e., meat, poultry, and processed egg products) located at a dual-jurisdiction facility and meeting the jurisdictional requirements of Section 304 of the FD&C Act and believed to be adulterated or misbranded, can be detained under USDA authority.

2.5.11.2.1- Federal Meat Inspection Act

Federal Meat Inspection Act (FMIA) Sections 402 and 409(b) provide the FDA with the authority to detain meat products subject to the FMIA, found outside a USDA inspected plant, if the FDA has reason to believe the products are adulterated or misbranded under the FD&C Act. The detention may not exceed 20 days and the items detained shall not be moved by any person from the place of detention until released by the FDA representative.

2.5.11.2.2 - Poultry Products Inspection Act

Poultry Products Inspection Act (PPIA) Sections 19 and 24(b) provide the FDA with the authority to detain poultry products subject to the PPIA found outside a USDA inspected plant, if the FDA has reason to believe the products are adulterated or misbranded under the FD&C Act. Detention may not exceed 20 days and the items detained shall not be moved from the place of detention until released by the FDA representative.

2.5.11.2.3 - Egg Products Inspection Act

Egg Products Inspection Act (EPIA) Sections 19 and 23(d) provide the FDA with the authority to detain egg products subject to the EPIA, found outside an USDA inspected plant, if the FDA has reason to believe the products are in violation of the EPIA Act. Detention may not exceed (20 days and the items detained shall not be moved from the place of detention until released by the FDA representative.

2.6 - Procedural Steps for Execution of a Detention at a Firm

The procedures to be followed in both ordering and terminating a detention differ depending on the applicable authority and product. You must consult with your supervisor before detaining any food from a dual jurisdiction facility under Section 304 of the FD&C Act, or under the detention authorities in FMIA, PPIA, or EPIA. If upon consultation, you and your supervisor determine that a detention is the appropriate action, then you should initiate a request with them seeking approval from the affected district office. It's imperative that before detaining any food that you have the approval of the Division

Director in whose district the article of food is located, or from an official senior to the division director, prior to detaining any food under Section 304(h) of the FD&C Act. You must also have the approval of the Division Director or an official senior to the Division Director before detaining any device, drug, or tobacco product under Section 304(g). If prior written approval is not feasible, prior oral approval must be obtained and confirmed in writing as soon as possible.

2.6.1 - Detention Procedure

After assuring that the criteria for detention are met, immediately advise your supervisor of the situation.

The information you furnish be adequate to fully complete the following blocks appearing on Detention Order, FDA 2289: 2, 4, 5, 7, 8, 10, 11, 13, 15, 19, 20, 21, 22, 24 and 26. See Exhibit 2-2. See IOM 2.6.2.1.

2.6.1.1 - Considerations

If the article of food to be detained is in transit aboard a conveyance (e.g., railcar, truck, or ship), be aware that detention of food aboard a conveyance may impact other activities of commerce that are dependent upon the ongoing operation of the conveyance.

FDA may allow the detained food to be removed from the conveyance to a storage facility. However, consult with your supervisor on this matter because the determination of whether the food can be moved from the conveyance to another location should be made based on considerations about the nature of the contaminant, security, preservation of the food, and accessibility to the food during the period of detention.

For all detentions, follow the guidance in IOM Section 4.3.3 to determine when FDA may examine a package that is in the possession, control, or custody of a common carrier. Guidance on resealing a conveyance is also found in IOM section 4.3.3.3.

If your supervisor instructs you to detain the article, proceed as directed in IOM 2.6.2.3, and 2.6.2.4.

2.6.1.2 - Executing the Detention

When you have been authorized to place a detention, proceed as follows:

- If the article is a food, indicate the conditions that are to be maintained while the article is detained by checking the appropriate method in Block 28 on the Detention Order (Form FDA 2289). After a device, drug, or food is detained, it may not be moved, unless specific procedures are followed. Consult your supervisor for guidance.
    - For detention of food under section 304(h), determine the storage conditions required (e.g., refrigeration), and whether movement to another facility is necessary to either provide the storage conditions required or for security purposes. Consult your supervisor for guidance. Indicate conditions that are to be maintained while the article of food is detained in the “Remarks” section of the detention notice (Block #26). If

applicable, also indicate that the movement of the food to another facility during detention has been authorized in writing by the FDA Division Director or an FDA official senior to such director, pursuant to 21 CFR 1.380 and 1.381.
    - Maintain surveillance on detained products, including the in-transit products, during their transfer and after the products are placed in storage if possible.
    - Ensure the custodian (i.e., the person in possession of the article when detained) places or maintains the detained product under the proper storage conditions.
    - If neither of the above items are possible, you should then place product under detention and move it to a proper storage facility. Notify the custodian of the place of storage (use Block 16 on the FDA-2289) and advise your supervisor of the necessity for including this information in the letter to the custodian and/or owner of the article.
- Personally inform the immediate custodian, at the highest management level, that the article is under FDA detention. If the article is a device, inform the custodian that the record-keeping requirements of 21 CFR 800.55(k)40 are in effect. If the article is a drug, inform the custodian that the record-keeping requirements of 21CFR 1.980(k) are in effect.
- Prepare the Form FDA-2289, as instructed in IOM 2.7.2.3.1, and issue page 1, the original, to the custodian named. Point out the appeal rights of the owner of the article, which are listed on the back of page 1 of the FDA-2289, and the right to appeal, with or without requesting an informal hearing.
- Affix Detention Tags, FDA-2290, to the article in a manner to assure visibility. If necessary, a label other than the Detention Tag may be used to identify an article(s) of food that has been detained, provided the label includes all the information listed on the current FDA-2290.

2.6.2 - Detention Order (Form FDA 2289)

The Detention Order (Form FDA 2289) is a pre-numbered, five-part, snap-out form, constructed and arranged to serve as the Detention Order, as a report of the action and as a notice to the custodian of an opportunity for an informal hearing.

2.6.2.1 - Preparation of Detention Order Notice

Print or type the information in the appropriate blocks of the Form FDA 2289. The first page blocks--which must be filled for detentions of foods in accordance with 21 CFR 1.382 are those numbered 1, 3, 6, 9, 10, 11, 12, 15, 16, 17, and 18. In blocks 17 and 18, indicate the name and title of the person who approved the detention order, and the manner in which the approval was obtained. For devices or drugs, mark 24 and 26 as N/A. For meat, poultry, or egg products not being detained under the authority of section 304(h) of the FD&C Act, mark 17 and 18 as N/A. Complete block 2. Once page 1 is completed, signed, and issued to the custodian of the product, it becomes an official document, and the detention period begins.

Immediately complete the additional pages of the Form FDA 2289 (pages 2 through 5) and submit them to your supervisor, for processing the action. Blocks to be filled in on these pages are items 13, 14, and 19 through 28. These blocks should be completed as appropriate (e.g., if samples were collected) or according to the product being detained (e.g., device, drug, or food) if the pertinent information can be readily determined. See IOM Exhibit 2-2.

Specific instructions for completing the FDA 2289 are provided on the last pages of the form. Pages 2-5 of the form are identical and completion of these constitutes your report on the detention, unless directed otherwise by your supervisor. Promptly submit these pages to your supervisor when you return to the office. Use FDA Form 2289c to elaborate on items wherever necessary. List any recommendations you made to the custodian for special storage of the product, such as its need to be refrigerated, frozen, etc.

2.6.2.2 - Distribution of FDA-2289

Distribution of FDA-2289 - The five-part, snap-out form is distributed as follows:

- Page 1, original - Give to custodian and, if applicable, give a copy of page 1 to the owner of the product. Give the two-sided text page listing statutory references to the owner of the article.
- Page 2, 3, 4 - Turn in to your district immediately using the fastest means possible.
- Page 5 - Retain in your possession.

2.6.2.3 - Detention Tag FDA-2290

This tag is a warning and identification device intended to be affixed to the detained products. Reference:
https://fda.sharepoint.com/sites/insideFDA-Administrative/FDA%20Forms/Forms/AllItems.aspx?id=%2Fsites%2FinsideFDA%2DAdministrative%2FFDA%20Forms%2FFDA%2D2290%5F508%289%2E14%29%2Epdf&parent=%2Fsites%2FinsideFDA%2DAdministrative%2FFDA%20Forms

2.6.2.3.1 - Preparation

As soon as you have issued the Detention Notice, fill out Detention Tags FDA 2290, following the instructions below. The information on the 2289 should be copied onto the FDA 2290, but where there is not sufficient room, you may shorten or copy enough information to make it clear what is intended in the block. See IOM Exhibit 2-3.

2.6.2.3.2 - Use of Tag

Complete and affix tags so that they are visible on several sides of the lot being detained. Use sufficient tags to give adequate warning that the lot is under U.S. FDA Detention and must not be used, moved, or tampered with, in any manner.

Each tag has a self-locking pin, the point of which should be firmly inserted in an appropriate seam, border, flap, or other area of the container or product, and pulled sharply downward to engage the top curve of the pin. Do not simply lay tags on the articles. Secure them to the containers or products. If the locking pin cannot be used, tape or tie the tag firmly onto the container or item. If using the pdf version of the Detention Tag, use tape to affix the tag to the product. Print multiple copies so that you can affix tags in several locations as needed to clearly and fully identify the lot.

Advise the custodian that Detention Tags have been affixed, the reason for the detention, and that the merchandise may not be moved without written permission of the agency. In-process devices may be completed without permission. See 21 CFR 800.55(h)(2)[53] for instructions on devices. See 21 CFR 1.980(h)(2) for instructions on drugs. See 21 CFR 1.381(c) for detention of foods.

2.6.2.4 - Termination of Detention

When final action has been taken on the detention, you will be authorized to terminate the detention. This will occur when one of the following conditions has been met.

1. For articles of food under detention, the article of food has been destroyed under appropriate supervision.
2. For drugs or devices, the product has been brought into compliance or destroyed under appropriate supervision. For meat, poultry, or egg products detained under authority of the FMIA[55], PPIA[56], or EPIA[57], the product has been brought into compliance, denatured or destroyed under appropriate supervision.
3. For meat, poultry, and egg products detained under authority of the FMIA, PPIA, or EPIA, the USDA, state, county, or local authorities have accepted jurisdiction and control of the article.
4. For meat, poultry, and egg products detained under authority of the FMIA, PPIA, or EPIA, it has been determined there is no significant violation of the FD&C Act, or of the EPIA, whichever is applicable, and the USDA has been notified that the FDA intends to terminate the detention.
5. Twenty calendar days have expired (or, if an additional 10-calendar-day detention period has been ordered, 30 calendar days have expired), counting from the day and hour of detention of the product. In this circumstance, no action is necessary on the part of the district.
6. A seizure action under section 304(a) of the FD&C Act has been instituted in court, and the goods have been seized by the U.S. Marshals pursuant to a court-issued warrant; or injunction action under section 302 of the FD&C Act has been instituted in court.
7. The division director or the Office of Regulatory Affairs program directors order the termination.

2.6.2.4.1 - Removal of Detention Tags

As soon as you are authorized to terminate the detention, proceed to where the detained material is stored, then personally remove, and completely destroy all detention tags. Do not merely throw them in the trash.

2.6.2.4.2 - Issuance of Detention Termination Notice FDA 2291

Once you have removed all detention tags, inform the custodian that the article is no longer under detention. Immediately prepare a Detention Termination Notice by filling out blocks 1 through 12, and the bottom of the form to include name, title, and signature. Give the original (page 1) to the custodian. This action terminates the detention.

Complete the "Remarks" section to elaborate on pertinent information such as supervision, reconditioning, destruction accomplished, etc. The Detention Termination Notice, FDA 2291, together with Detention Notice, FDA 2289, will, unless instructed otherwise, constitute the complete report on the detention. See IOM Exhibit 2-4.
https://www.fda.gov/files/inspections,%20compliance,%20enforcement,%20and%20criminal%20investigations/published/Chapter-5---Administrative-Actions.pdf

2.6.3 - Sampling

When sampling is directed, official samples of articles involved in this type of operation are collected, prepared, and submitted in the same manner as any other regulatory samples. In the case of food detained under Section 304(h) of the FD&C Act[59], consult with your supervisor to determine whether the suspected contaminant in articles of food that have been detained makes it necessary to follow sampling procedures that may be different from those followed for routine regulatory samples.

2.6.4 - Supervision of Reconditioning, Denaturing, Or Destruction

Methods and procedures for reconditioning, denaturing, or destruction will be proposed to the division by the owner of the devices, drugs, or meat, poultry, or egg products. For food detained under Section 304(h) of the FD&C Act[60], destruction will likely be the only option, and it can only be done after the FDA approves in writing a request to modify the detention order. For all detentions, do not take any action on reconditioning, denaturing, or destruction unless you are authorized by your supervisor. Division officials will determine the adequacy of the proposed method. If satisfactory, you will be advised of the procedure and authorized to monitor the action.

When the operation is satisfactorily completed, and when authorized, terminate the detention as indicated in IOM 2.6.2.6.

The results of the reconditioning, denaturing, or destruction may be described in the "Remarks" section on the Detention Termination Notice, FDA 2291, if desired. See IOM Exhibit 2-4.

2.6.5 - Reporting

Except in unusual situations, or unless instructed otherwise by your supervisor, the Detention Order, Form FDA 2289, the Detention Order Termination, Form FDA 2291, and the Collection Report provide all information required to report the action from detention to termination.

2.7 - Denaturing

The purpose of denaturing is to prevent salvage or diversion of violative materials for human consumption. When products must be destroyed through a procedure other than incineration or direct entry into a landfill or compost operation, they are typically denatured using a chemical agent, rendering them undesirable to attempt to salvage or later sell for human consumption.

2.7.1 - Diversion to Animal Feed

The indiscriminate use of contaminated food for livestock may constitute a hazard to such livestock, as well as humans. Due to this concern, all diversion requests of this nature should be forwarded to the Center for Veterinary Medicine (CVM), Division of Compliance for review, to determine if the product may be converted to animal feed.

2.7.1.1 - Rodent or Bird Contaminated Foods

Diversion of rodent- or bird-contaminated foods for animal feed is authorized only when the contaminated product is treated by heat to destroy *Salmonella* organisms. In the case of wheat and other grains containing rodent excreta, a suitable heat process may be used, or the product is examined bacteriologically and proven not to contain *Salmonella*.

2.7.1.2 - Moldy Food

If processors insist on salvage of moldy grain or foods for animal feed use, it must be done under proper supervision, and provide for:

- Treatment by dry heating to destroy viable spoilage microorganisms (generally, this will result in grain having a toasted color and odor), and
- Evidence it does not contain mycotoxins, and
- Evidence, by animal feeding studies, the product is safe for animal use.

2.7.1.3 - Pesticide Contamination

Foods contaminated by pesticide residues should not be diverted to animal food use unless a determination is made that assures illegal residues will not be present in the food animal or their food products, (e.g., meat, milk, eggs).

2.7.2 - Decharacterization for Non-Food or Feed Purposes

Choose the method(s) by considering the type of the denaturant, the physical properties of the diverted material, and the ultimate use of the product.

2.7.3 - Reconditioning and Destruction

Sections 304 and 801 of the FD&C Act [21 U.S.C. 334 and 381] provide the legal basis for the reconditioning or destruction of goods under domestic seizure or import detention.

Reconditioning and destruction are the means whereby goods are brought into compliance with the law, or permanently disassociated from their intended use. Manpower may not be expended on supervision of reconditioning and destruction of goods except under administrative controls, detention, or emergency and disaster operations. See IOM 8.1.5.8 for operations in disasters.

FDA does not seek or condone the destruction of books or other publications. FDA policy and practice tries to be sensitive to the potential First Amendment issues associated with the regulation of books and

other printed materials that function as labeling of a product. See Compliance Policy Guide 140.100. In the context of judicial enforcement, disposition of any labeling subject to the court's jurisdiction is determined by the court. In a voluntary compliance situation, the disposition is the prerogative of the manufacturer, distributor, wholesaler, or retailer. Agency policy does not authorize field employees to director limit the options for disposition of violative labeling or other printed materials in such circumstances. Good judgment should always be exercised in such matters.

Section 536(b) of the FD&C Act [21 U.S.C. 360ii (b)] provides authority for electronic products to be reconditioned if FDA determines they can be brought into compliance with radiation performance standards. Therefore, reconditioning of radiation-emitting products must be approved by the Center for Devices and Radiological Health (CDRH), OHT8: Office of Radiological Health, prior to implementation to assure compliance with performance standards. If a foreign manufacturer conducts the reconditioning, the division should notify both the importer/consignee and the foreign manufacturer's agent of all FDA actions.

2.8 - Judicial Actions

2.8.1 - Information

An Information is a legal document filed in misdemeanor actions identifying the defendants and setting forth the charges. The Information is forwarded to the appropriate U.S. attorney, who then files the legal instruments. A trial date is set by the court. Ideally, trial preparation is a collaboration between representatives of the U.S. attorney's office, Office of the Chief Counsel (OCC), the division, and the involved FDA center.

2.8.2 - Grand Jury Proceedings

The Department of Justice (DOJ) must proceed by indictment in all felony cases. Evidence in possession of the government is presented to a grand jury that decides if it is sufficient to warrant prosecution. If the grand jury returns a "True Bill", and the defendant pleads not guilty at the arraignment, preparation for trial begins.

2.8.3 - Seizure

Seizure is a judicial civil action directed against specific offending goods, in which goods are "arrested." Authority for seizure is found in Section 304 of the FD&C Act. Originally designed to remove violative goods from consumer channels, it was intended primarily as a remedial step; however, this sanction often has a punitive and deterrent effect.

For more information on seizure actions consult RPM Chapter 6-1 “Seizures.”

2.8.3.1 – Division Recommendation

The division considers all evidence, including any establishment inspection, sample collection, and analytical results, as an inspection progresses. The Investigations Branch communicates with the

Compliance Branch during the inspection, and if the division determines a seizure is the best course of action, the compliance officer sets up a Preliminary Assessment Call (PA call). The investigator typically participates in the PA call and works closely with the compliance officer. If during the PA call there is consensus that a seizure action should be pursued, the process described in the RPM is initiated (See link above).

2.8.3.2 - Department of Justice

The Food and Drug Division of the HHS OCC reviews and forwards the seizure action to the U.S. attorney assigned to the judicial district in which the violative goods are located, through the seizing district. The U.S. attorney files a Complaint for Forfeiture addressed to the U.S. district court, setting forth the facts of the case and calling for the "arrest" of the goods. This complaint is filed with the appropriate district court.

2.8.3.3 - U.S. District Court

The court orders the arrest of the goods by issuing a motion and warrant to the U.S. Marshals Service, directing the seizure of the goods.

2.8.3.4 – Seizure of Goods by the Marshal and Investigator's Role

A Deputy U.S. Marshal (deputy marshal) seizes the goods, which then become the property of the court. You may be asked to assist in the seizure. If so, submit a memorandum to your division office covering this activity. This often includes documenting a detailed list of all product names, amount of each product seized, and location of each product. The investigator should work with the compliance officer prior to assisting the deputy marshal to determine the activities that must be documented.

2.8.3.5 - Claimant and Options

Any person who has an interest in the goods may appear as claimant or to step in to intervene and claim the goods.

2.8.3.6 - Abandonment

If no claimant appears within a specified time, (return date), then the U.S. attorney requests a Default Decree of Condemnation and Forfeiture, in which the court condemns the goods and directs the U.S. Marshals Service to destroy or otherwise dispose of the goods. Usually, the division assists in determining the method of disposal. You may be asked to help in the actual disposition. However, primary responsibility for disposition of seized lots following a default decree lies with the U.S. Marshals Service. Your role may include accompanying a deputy marshal to witness the operation. Although you are there in an advisory capacity, assist as needed to assure compliance with the court order. Promptly submit a written report of your observations upon completion of the operation. (See IOM 8.1.2.1 and 8.1.9.2)

2.8.3.7 – Proposed Actions to Come into Compliance from Claimant

A claimant may propose the goods be destroyed or reconditioned to bring them into compliance. After the FDA agrees to the method of reconditioning, the court issues a Decree of Condemnation permitting destruction or reconditioning under the supervision of the FDA, after a bond is posted. The investigator will typically observe the destruction and/or reconditioning as defined in the court order. If the reconditioning process does not appear to comply with the order, you should immediately advise the claimant and your supervisor. Submit a detailed report upon conclusion of the operation. In instances where the operation is prolonged, you should submit interim progress reports. Include the following information in your report of the operation:

- Identification of the case (sample number, court number, FDA number, product, and claimant).
- Description of the method of reconditioning or destruction. Collect pertinent written methods, labels, etc.
- Disposition of rejects; explanation for unaccounted goods.
- Findings of field examinations.
- Exhibits and samples collected. Do not pay for samples collected during reconditioning operations conducted under a consent decree.
- Expenses, including time spent in supervision and travel, mileage, per diem, and incidental expenses.

2.8.3.8 - Contested Seizure

A claimant may file an answer to the complaint and deny the allegations. The issues then go to trial. See Court Room Testimony section below (Reference section).

2.8.4 - Injunction

An injunction is a civil restraint issued by the court to prohibit violations of the FD&C Act. Injunction is designed to stem the flow of violative products in interstate commerce, and to correct the conditions in the establishment.

Injunction actions must be processed within strict time frames. Therefore, you may be requested to conduct an inspection to determine the current condition of a firm and to obtain specific information required for the injunction.

An injunction is ongoing. For more information on how to manage injunctions refer to RPM 6.2.

2.8.4.1 – Injunction Recommendation

The division considers all evidence, including inspections, samples, and analytical results. The Investigations Branch communicates with the Compliance Branch during the inspection, and if the division determines an injunction is the best course of action, the compliance officer sets up a Preliminary Assessment Call (PA call). The investigator typically participates in the PA call and works closely with the compliance officer. If during the PA call there is consensus that an injunction should be pursued, the process described in the RPM is initiated (See RPM 6-2-9).

2.8.4.2 - Temporary Restraining Order (TRO), Preliminary Injunction and Permanent Injunction

See RPM 6-2-3 for detailed definitions of these terms.

A temporary restraining order (TRO) is a court-enforced order entered to control an emergency situation. A TRO seeks immediate temporary relief. The TRO may be subject to a hearing prior to its expiration. Generally, a TRO lasts 10 days, but can be extended 10 days prior to hearing (a total of 20 days). If a hearing is held, the U.S. attorney presents evidence to support the injunction. This is not a courtroom trial described in 2.8.4.3.

A preliminary injunction may be issued by a judge based on a motion from the government requesting one prior to a trial. The judge may or may not grant a hearing depending on the actions of the defense.

A permanent injunction is a final decree from the court declaring actions that must be taken to correct the continuing violations. It may be entered by the court following a trial, hearing, or without a hearing, if no one contests the DOJ petition.

2.8.4.3 – Processing the Injunction

If the center(s) and OCC concur with the injunction recommendation, OCC sends a referral letter to the DOJ. If DOJ concurs, it will then issue a letter, containing a proposed consent decree, to the respective firm. If the firm signs the consent decree, the complaint is entered into the court. If the firm does not sign it, a trial begins in the U.S. court. (See Court Room Testimony section below.) If the court rules in favor of the government, a court-ordered injunction is filed. The terms of the injunction specify the steps to be taken to correct the violations at issue. See RPM 6.2.3 for details on the differences in the process and timeframes between a preliminary and permanent injunction. Unless there is a trial and the court rules in the firm's favor, or the case is withdrawn by the government, the outcome of an injunction case is either a court-ordered injunctive relief or a consent decree signed by the firm. In either case, the firm must comply with the terms of the court's order.

2.8.4.4 - Division Follow-up

It is the agency's responsibility to assure the terms of an injunction are met. This may include inspections to assure compliance. You must review the court order (injunction or consent decree) prior to inspection to assure that the firm is not only meeting the requirements of the regulations but is also meeting any additional requirements set forth by the court.

If during the inspection the investigator determines that the terms of the consent decree are not being followed, the supervisor and compliance officer should be notified immediately. Often the terms of the injunction require the firm to pay for the cost of supervision. If so, the investigator must document the hours spent inspecting at the firm, as well as any applicable costs related to

flights, mileage, lodging, and per diem, so that the compliance branch can appropriately charge the firm for the cost of supervision. (see RPM 6-2-14)

2.8.5 - Prosecution

Prosecution is a criminal sanction directed against a firm and/or responsible individuals. Prosecutions can be pursued at one of two levels: misdemeanor or felony and Misdemeanor prosecutions. A prosecution is punitive, with the view of punishing past behavior and obtaining future compliance.

2.8.6 - Court Room Testimony

If the seizure, injunction, or prosecution is contested, the case goes to trial. If required to testify, the investigator will work with the U.S. attorney and OCC to prepare.

2.8.6.1 - Courtroom Testimony

You may be called to testify in court before a judge, jury, or grand jury; or at a deposition before opposing counsel. Effective testimony is a result of quality investigative skills, the ability to prepare factual and informative investigative reports, and thorough preparation.

As a fact witness, you are required to testify from memory, but you are allowed to refer to notes, reports, and memoranda, as necessary to refresh your recollection. For this reason, and because they are available to opposing counsel; your notes, reports and the like must be accurate, organized, and complete.

There is little difference in giving testimony in court, in a deposition or before a grand jury. In a deposition, testimony is given upon interrogation by opposing counsel, under oath, and before a court reporter. Use guidance from your (the government's) attorney in preparing for a deposition. Once completed, the deposition is available to all persons interested in the case and is available for use at trial.

In a grand jury, testimony is given under oath to a group of jurors who determine whether sufficient evidence exists to charge an individual or party with a felony (See IOM 2.2.7.3).

2.8.6.2 - Testimony Preparation

Keep in mind you must have approval to testify. The authority to testify is found in 21 CFR 20.1. The following suggestions may be helpful in preparing to provide testimony in court, before a grand jury or at a deposition:

- Carefully and thoroughly review your notes, inspection reports, and all information about samples collected.
- Be neat in your personal appearance; dress conservatively in business attire and be well groomed.

- When you take the witness stand, sit erectly in your chair, look around the room to familiarize yourself with the court surroundings, but also try to assume a feeling of comfort and ease.
- Tell the truth. You are not there to convince, only to answer. If asked, do not hesitate to admit that you have discussed your testimony in advance with the U.S. attorney's office.
- Do not volunteer information. Do not interject comments that you have not been asked to make, as comments could be inadmissible and could result in a mistrial.
- Be sure you fully understand the question before you answer. If you don't understand the question, request clarification.
- Take your time. Give each question ample thought, as well as the time needed, to understand and formulate your answer.
- Do not answer questions too quickly. Give your attorney time to raise an objection in case it is a question you should not answer.
- Answer questions clearly and loudly enough so that everyone can hear you. Look at and address your remarks to the jury so that all jury members will be able to hear and understand you.
- Speak directly and authoritatively. Do not use ambiguous phrases such as, "I guess so, “or "I believe," etc.
- However, in instances where you genuinely lack the information or facts with which to answer, it is quite acceptable and advisable to reply, "I don't know."

If you are testifying virtually, you should also ensure that you have a plain, undistracting background and that your internet connection will be uninterrupted. Plan to test your internet connection and assure that the platform being used (e.g., Zoom, Teams, etc.) is installed and operating on your laptop before you connect for the testimony.

2.9 – Compliance Achievement for Voluntary Corrective Actions

The FDA uses a blend of industry voluntary corrections and regulatory actions to help achieve industry compliance. See FMD 86 and RPM 10-2.

A voluntary corrective action is defined as the observed voluntary repair, modification, or adjustment of a violative condition or product. For purposes of this definition, violative means the product or condition does not comply with the Acts FDA enforces or their associated regulations.

Voluntary destruction, in lieu of seizure of small lots of violative goods, shall be encouraged in instances where the proposed method is adequate. Supervision of voluntary segregation and denaturing of violative goods shall not be provided, except where it can be accomplished quickly and effectively, using minimal inspectional resources, and in a manner consistent with procedures outlined in this subchapter. The most extensive actions in this area usually occur in disaster situations. Follow instructions in IOM 8.1.5.8 Disaster/Emergency Response.

Do not engage in actual destruction, reconditioning, repair, modification, etc. of goods. This is the responsibility of the owner or dealer. You are a witness only. Samples of violative goods should be

collected prior to voluntary destruction if needed to support subsequent action against the responsible individuals. Take photographs where applicable. See IOM 5.7.6.1 and IOM 2.6.4, 2.6.4.1/2 for reporting requirements.

2.9.1 - Destruction

Before you supervise destruction, be sure management is aware the action is voluntary and that you are acting only as a witness. See IOM 2.6.4.

Personally witness all destructions, making certain destroyed goods are rendered totally unsalvageable for use as a food, drug, device, etc. Keep in mind your own personal as well as public safety. Exercise proper precautions in dealing with potentially dangerous substances and situations. Comply with local ordinances regarding the disposition of garbage and trash.
Note that certain products should not be disposed of in a conventional manner (e.g., sanitary landfill, flushing down the drain, etc.), especially if they contain chemicals that are banned (e.g., chloroform, methapyrilene, hexachlorophene, PCB, etc.), and have been classified by the EPA as hazardous and toxic substances. These products may require a special method of disposal by a licensed hazardous disposal facility. Any possible hazardous or toxic substance (carcinogen, mutagen, etc.) should not be disposed of without prior consultation by the firm with the EPA and/or the regulating state authority. Refer to 21 CFR Part 25 and the National Environmental Protection Act for guidance regarding the environmental impact of voluntary destructions.

2.9.1.1 - DEA Controlled Drugs

The FDA has a memorandum of understanding (MOU) with the Drug Enforcement Administration (DEA) (see MOU 225-15-11)). The FDA and DEA have a written policy to permit FDA representatives, in certain situations, to witness the destruction of DEA-controlled drugs. The procedures and instructions to follow when these drugs are destroyed are:

2.9.1.1.1 - DEA Approval

The FDA and the DEA have a mutual, written policy concerning witnessing the destruction of drugs under the distribution control of DEA. This policy dictates that FDA, upon receiving a request to witness such destruction, will advise the DEA regional office about the request and obtain approval for the action. If approval is requested by telephone and verbally approved, the approval should be reflected in writing for the record.

2.9.1.1.2 - Procedure

The necessity for FDA personnel to witness destruction of DEA-controlled drugs typically occurs in one of two situations:

- when you are already present at the firm in question, and you encounter DEA-controlled drugs, and you are requested to witness destruction; or
- when DEA-controlled drugs are to be destroyed at the same time the FDA is witnessing destruction of other drugs, not under DEA control.

If you are in a firm either conducting an inspection or witnessing destruction of drugs under FDA's distribution control, and the firm requests you to also witness destruction of DEA-

controlled drugs, do not commit yourself. Telephone your supervisor for instructions. You will be advised whether to proceed after your division communicates with DEA. In all other situations, refer the requester to DEA.
If the request to witness the destruction is approved, observe the destruction, and prepare DEA Form DEA 41. Instructions for completing it are included with the form.

2.9.2 - Reconditioning

The supervision of voluntary segregation of violative goods without the regulatory safeguards of seizure should be avoided. Voluntary segregation and destruction of violative lots should be encouraged; but under no circumstances should you supervise the voluntary segregation and salvage of unfit goods, regardless of the nature of the violation or the size of the lot. Be sure management is aware that the segregation is its responsibility. Collect samples where indicated, and/or advise the dealer or owner of their responsibilities under the law. If the dealer decides to voluntarily destroy any lot, refer them to the National Environmental Protection Act (NEPA). See IOM 2.6.2.

2.9.3 – Reporting Voluntary Correction

Report any voluntary correction of a problem unrelated to a division recommendation for regulatory action.

2.9.3.1 - Documenting Voluntary Destruction

Prior to supervising voluntary destruction, prepare a statement on the firm's letterhead, or on an FDA 463a Affidavit, providing the following information.

- Voluntary nature of the action, with you as a witness.
- Name of the product, including applicable code marks.
- Condition of the lot.
- Amount.
- Method of destruction.
- Signature of responsible individual.

2.9.4 - Compliance Achievement Reporting

Voluntary corrective actions should be described in the EIR and reported into the Compliance Achievement Reporting System (CARS) in the Field Accomplishments and Compliance Tracking System (FACTS) (Exhibit 5-15) per division standard operating procedures (SOP). Reportable items include:

- Voluntary destruction of any violative product by the person in possession of it.
- Destruction of violative products by a cooperating food or health official, where such product was discovered by and reported to such official by the FDA, or when those officials were doing work for the FDA under contract. Do not report formal condemnation by cooperating officials in the usual course of their independent work.
- Voluntary destruction of manufacturer's raw materials during an inspection.
- Capital Improvements such as significant improvements correcting a violative condition including, for example new equipment, rodent-proofing, etc. Typically, these corrections cannot

be verified during the inspection where they are observed and should be reported at follow-up inspections where actual improvement has been accomplished and is the result of a previous FDA observation. It should not be reported in CARS when it resulted from a seizure, injunction, or prosecution.

- Correction of GMP deficiencies when, during an inspection, the investigator observes that good manufacturing practice (GMP) deficiencies have been corrected since the previous inspection. These corrections are based on the previous FDA-483 and any communication following the previous inspection identifying significant deficiencies not listed in FDA-483. Corrections reported should be specific to observations made during inspections and reported when completed.
- Formula or label correction made based on a sample analysis, consumer complaint, etc.
- Additional employment of personnel for quality improvement or improved quality control.
- Initiation of an education and/or training program among employees or producers, or other general industry movement to improve conditions.

Do not report:

- Recalls, although voluntary, because they are already recorded elsewhere.
  Corrections that are not directly attributable to the efforts of the FDA, or to states under contract to the FDA.
- Corrections as a result of a seizure, injunction, or prosecution.
- *Medical Devices Only:* Use Form FDA 2473a to report corrections related to field compliance testing of diagnostic X-Ray equipment, as directed by the Compliance Program.

2.10 – Regulatory Submissions

This subchapter provides information on the procedures for obtaining information and filing applications with the agency. The filing and registration requirements are directed by the FD&C Act and its implementing regulations. They are filed, in most cases, by industry (e.g., drug registration, Low Acid Canned Food (LACF) registration and process filing, new drug applications, etc.).

Although these regulatory submissions are typically submitted to the various centers, it is important that you are introduced to these applications. Issues identified by the centers during the application review process can lead to follow-up assignments for ORA. In addition, while conducting a surveillance assignment, you may find that an establishment has not filed a regulatory application or is not following an application submission. The filing itself can provide information on what regulations are applicable to an establishment when the inspection is conducted.

Complete, accurate and up-to-date establishment registration and listing information is essential to promote safety. FDA relies on establishment registration and listing information for several key programs, including:

- Establishment inspections (foreign and domestic)
- Post market surveillance
- Counterterrorism
- Recalls
- Drug quality reports

- Adverse event reports
- Monitoring of drug shortages and availability
- Supply chain security
- Import admissibility decisions and export decisions
- Identification of products that are marketed without an approved application
- Establishment of user fees

2.10.1 – Human Foods

The FD&C Act was amended in 2002 requiring "any facility engaged in manufacturing, processing, packing, or holding food for consumption in the United States be registered with the Secretary." See 21 U.S. Code § 350d. For more information see the FDA/CFSAN website on food firm registration.

2.10.1.1 - Low Acid Canned Food (LACF) / Acidified Foods (AF) Food Canning Establishment (FCE) Registration

Food Canning Establishments (FCE) (foreign and domestic) engaged in the manufacturing of Low Acid Canned Food/Acidified Foods (LACF/AF) offering their products for interstate commerce within the United States are required by 21 CFR Parts 108, 113, and 114 to register their facility with the FDA. Registration details can be found on the FDA Website at Establishment Registration & Process Filing for Acidified and Low-Acid Canned Foods (LACF) | FDA.

2.10.1.2 - FCE Process Filing of LACF/AF Processors

Processors must submit scheduled process information for their LACF/AF products. Details can be found on the FDA website at Establishment Registration & Process Filing for Acidified and Low-Acid Canned Foods (LACF): Paper Submissions | FDA.

2.10.1.3 – Cosmetics

Cosmetics registration is voluntary. Details on registration for cosmetic establishments can be found on the FDA website at Voluntary Cosmetic Registration Program | FDA.

2.10.1.4 – Color Certification Program

Color additives are subject to FDA approval before use in many FDA-regulated products that come in contact with human or animal bodies for a significant period of time. FDA will also certify batches of color additives. Details about color certification can be found on the FDA website at Color Certification | FDA.

2.10.1.5 – Infant Formula

Prior to introducing or delivering for introduction a new infant formula into interstate commerce, persons responsible for manufacturing or distribution of it must register with the FDA. Details about registration can be found on the FDA website at Infant Formula Registration & Submissions | FDA.

2.10.1.6 - Interstate Certified Shellfish (Fresh and Frozen Oysters, Clams, and Mussels) Shippers

FDA maintains the Interstate Certified Shellfish Shippers List (ICSSL). The list includes firms that may ship molluscan shellfish in interstate commerce under the National Shellfish Sanitation Program (NSSP). Details about the listing and the program can be found on the FDA website at Interstate Certified Shellfish Shippers List | FDA.

2.10.1.7 - Interstate Milk Shippers (IMS)

FDA maintains the Interstate Milk Shippers List (IMSL). The list includes firms that may ship Grade A milk and milk products in interstate commerce under the National Milk Safety Program. Details about the listing and the program can be found on the FDA website at Interstate Milk Shippers List | FDA.

2.10.1.8 - Premarket Notification of New Dietary Ingredients.

Firms are required to notify FDA prior to using a new dietary ingredient not marketed before October 15, 1994. https://www.fda.gov/food/dietary-supplements-guidance-documents-regulatory-information/dietary-supplement-labeling-guide-chapter-vii-premarket-notification-new-dietary-ingredients

2.10.1.9 - Qualified Facility Attestation

A business that meets the definition of a "qualified facility" is subject to modified requirements of the preventive controls' rules. These modified requirements can be met by submitting a form to FDA, attesting to the business's status as a qualified facility and attesting that the facility is implementing preventive controls to address hazards associated with its food or is in compliance with non-Federal food safety laws and regulations. https://www.fda.gov/food/registration-food-facilities-and-other-submissions/qualified-facility-attestation

2.10.1.10 - Shell Egg Registration

Shell egg facilities are required to register with FDA.
https://www.fda.gov/food/registration-food-facilities-and-other-submissions/shell-egg-producer-registration

2.10.1.11 - Structure/Function Claim Notification for Dietary Supplements Electronic Submissions.

The Federal Food, Drug, and Cosmetic Act (the Act) requires that the manufacturer, packer, or distributor who wishes to market a dietary supplement notify FDA regarding the statement on the label or in the labeling of its product, pursuant to § 403(r)(6) of the Act.https://www.fda.gov/food/registration-food-facilities-and-other-submissions/structurefunction-claim-notification-dietary-supplements-electronic-submissions

2.10.2 – Human Drugs

The FD&C Act and its regulations require the filing of certain forms by firms that produce human drugs and drug-related products. The requirements and procedures for these are described below.

2.10.2.1 - Registration and Listing

Owners or operators of drug manufacturing establishments are required to register their establishments with the FDA. Registrants are also required to list each drug manufactured at their establishment(s) intended for commercial distribution and to submit updated drug listing information to the FDA twice each year, in June and in December, notifying FDA if this information has changed.

Registration and listing are required whether interstate commerce is involved or not.

- Drug Establishment Registration - The guidance document on electronic submissions for drug establishments' registrations and drug product listings is available at: https://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/guidances/ucm072339.pdf.
  General information and questions can be addressed by phone: 301-210-2840 or e-mail: eDRLS@fda.hhs.gov. See IOM Exhibit 5-12 for types for drug operations that require registration and listing.
- Outsourcing Facility Registration - The guidance documents on electronic submissions for outsourcing facilities' registration and drug product reporting is available at: https://www.fda.gov/media/87570/download and https://www.fda.gov/media/90173/download.
  General information and questions concerning outsourcing facilities' registrations and product reporting can be addressed by: Compounding@fda.hhs.gov.

21 CFR 207.69 defines the requirements for the official contact and the United States agent for registration and listing information.

Since many products and components are manufactured overseas, particular attention should be made to verify that the U.S. Agent as defined in 207.69(b) is correct and has the defined responsibilities such as when there is need to initiate product recalls or facilitate a foreign inspection.

207.69(b) U.S. Agent: Registrants of foreign establishments subject to this part must designate a single United States agent. The United States agent must reside or maintain a place of business in the United States and may not be a mailbox, answering machine or service, or other place where a person acting as the United States agent in not physically present. The United States agent is responsible for:

(1) Reviewing, disseminating, routing, and responding to all communications from the FDA including emergency communications;

(2) Responding to questions concerning those drugs that are imported or offered for import to the United States;

(3) Assisting the FDA in scheduling inspections; and

(4) If the FDA is unable to contact a foreign registrant directly or expeditiously, the agency may provide the information and/or documents to the United States agent.

2.10.2.2 - Investigational New Drug Application (IND)

An Investigational New Drug (IND) application must be submitted to the FDA by a drug sponsor before beginning tests of a new drug on humans. The IND contains the plan for the study and is supposed to give a complete picture of the drug, including its structural formula, animal test results, and manufacturing information. Detailed instructions for the submission of INDs can be found in 21 CFR Part 312.

Federal law requires that a drug be the subject of an approved marketing application before it is transported or distributed across state lines. Because a sponsor will probably want to ship the investigational drug to clinical investigators in many states, it must seek an exemption from that legal requirement. The IND is the means through which the sponsor technically obtains this exemption from the FDA.

More information on the IND Process.

2.10.2.3 - New Drug Application (NDA)

A New Drug Application is an application requesting FDA approval to market, in interstate commerce, a new drug for human use. The application must contain, among other things, data from clinical studies needed for FDA review from specific technical viewpoints, including chemistry, pharmacology, biopharmaceutics, statistics, anti-infectives, and microbiology. Detailed instructions for the submission of NDAs can be found in 21 CFR Part 314.

The goals of the NDA are to provide enough information to enable the FDA reviewer to reach the following key decisions:

- Whether the drug is safe and effective in its proposed use(s), and whether the benefits of the drug outweigh the risks.
- Whether the drug's proposed labels and labeling are appropriate, and what they should contain.
- Whether the methods used in manufacturing the drug and the controls used to maintain the drug's quality are adequate to preserve the drug's identity, strength, quality, and purity.
-

The documentation required in an NDA should be adequate enough to tell the drug's whole story, including its ingredients, the drug’s behavior in the body, the results of animal studies, the nature and results of clinical tests or studies, and information about the drug’s manufacturing, processing and packaging.

More information on New Drug Applications.

2.10.2.4 - Abbreviated New Drug Application (ANDA)

An Abbreviated New Drug Application (ANDA) contains data that is submitted to the FDA for the review and potential approval of a generic drug product. Once approved, an applicant may

manufacture and market the generic drug product to provide a safe, effective, lower-cost alternative to the brand-name drug it references.
ANDAs are for products with the same or very closely related active ingredients, dose form, strength, administration route, use, and labeling as a product already shown to be safe and effective. An ANDA includes all the information on chemistry and manufacturing controls found in a new drug application (NDA) but is not required to include data from studies in animals and humans. It must, however, contain evidence that the duplicate drug is bioequivalent to the previously approved drug. Information concerning the submission of ANDAs can be found in 21 CFR Part 320. For more information, visit ANDA.

2.10.3 – Animal Foods and Drugs

Requirements for registration and filing of various applications by firms that manufacture animal drugs, feeds, and other veterinary products are required by the FD&C Act.

2.10.3.1 - Registration and Listing

Owners or operators of all drug establishments, not exempt under Section 510(g) of the FD&C Act [21 U.S.C. 360 (g)] or Subpart D of 21 CFR 207, who engage in the manufacture, preparation, propagation, compounding, or processing of a drug or drugs, are required to register. Also, they must submit a list of every drug in commercial distribution; however, such listing information may instead be submitted by the parent, subsidiary, and/or affiliate company for all establishments when operations are conducted at more than one establishment, and there exists joint ownership and control among all the establishments. Owners and operators of establishments engaged in manufacture or processing of drug products must register and list their products.

The owner or operator of an establishment must register within five days after beginning of the operation and submit a list of every drug in commercial distribution at that time. Owners and operators of all establishments engaged in drug activities described in 21 CFR 207.3(a)(8) shall register annually. The guidance document on electronic submissions for drug establishment registration and drug product listing is available at: https://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/ucm072339.pdf.

For information on registered animal drug firms, contact CVM's Registration Monitor (HFV-212), 7519 Standish Place, Rockville, MD 20855, or 240-402-6816. You may make inquiries on the registration status of individual firms through CVM's Registration Monitor or through the Medicated Feed webpage at Medicated Feeds.

For information on animal drug listing, CVM maintains its own database for animal drug listing found at Animal Drugs @ FDA. You may also make inquiries for information via email at MedicatedFeedsTeamMail@fda.hhs.gov.

2.10.3.2 - Medicated Feed Mill License (FML)

An approved medicated feed mill license is required for facilities that manufacture feed using Category II, Type A medicated articles; liquid and free-choice medicated feed containing a Category II drug; or liquid and free-choice medicated feed containing a Category I drug that follow an approved proprietary formula and/or specifications.

Licensed mills are required to operate in compliance with current GMP described in 21 CFR 225 and must undergo a pre-approval inspection prior to licensure. Licensed mills must also register as drug establishments with FDA per 21 CFR 207. Registration is completed electronically each year between October 1 and December 31. Information on how to complete registration and check registration status can be found on CVM's Medicated Feeds webpage.

For general information and questions, an email can be sent to the Medicated Feeds Team at MedicatedFeedsTeamMail@fda.hhs.gov.

2.10.3.3 - New Animal Drug Application (NADA)

A new animal drug is defined, in part, as any drug intended for use in animals other than man--including any drug intended for use in animal feed but not including the animal feed--the composition of which is such that the drug is not generally recognized as safe and effective for the use under the conditions prescribed, recommended, or suggested in the labeling of the drug (21 U.S.C. Section 321(v)). Manufacturers of new animal drugs must complete a New Animal Drug Application (NADA) and receive approval prior to distribution.

New Animal Drug Applications must be submitted on a form FDA 356. The applications must be signed by the applicant or by an authorized attorney, agent, or official. The application must be filled out completely, in triplicate, and submitted to the address below.

FDA 356 which can be obtained from:

Food and Drug Administration
Center for Veterinary Medicine (HFV-12)
7500 Standish Place
Rockville, MD 20855

Completed NADAs should be mailed to:

Food and Drug Administration
Center for Veterinary Medicine (HFV-199)
7500 Standish Place
Rockville, MD 20855

General information or questions can be answered by calling 240-276-9300 or more information is available at NADA.

2.10.3.4 - Abbreviated New Animal Drug Application (ANADA)

The Generic Animal Drug and Patent Term Restoration Act amended the FD&C Act to provide for the approval of generic copies of previously approved animal drug products. The generic product may be approved by providing evidence that it contains the same active ingredients, in the same concentration, as the approved article, and is bioequivalent. The information is submitted to the FDA in the form of an Abbreviated New Animal Drug Application or ANADA.

An ANADA must be submitted to FDA on the form FDA 356V. The format and content of the application must be in accordance with the policies and procedures established by FDA's C VM. The application must be filled out completely in triplicate and submitted to the address below.

ANADA's may also use the form FDA 356 which can be obtained from:

Food and Drug Administration
Center for Veterinary Medicine (HFV-12)
7500 Standish Place
Rockville, MD 20855

Completed legible applications should be mailed to:

Food and Drug Administration
Center for Veterinary Medicine (HFV-199)
7500 Standish Place
Rockville, MD 20855

Assistance and additional information can be obtained by calling 240-402-5674. More information is available at ANADA.

2.10.4 – Medical Devices

The FD&C Act, its amendments, and the regulations promulgated under the Act, require the filing of certain forms and the submission of certain data by those involved in the production (and in some cases the use) of medical devices and radiological products. Within the CDRH, the Division of Industry and Consumer Education (DICE) has been charged with responsibility for providing information and assistance to industry in complying with these requirements. The general requirements are discussed below, as several issues are unique to CDRH submissions.

2.10.4.1 – Device Registration and Listing

Section 510 of the FD&C Act [21 U.S.C. 360] and 21 CFR 807 describe the establishment registration, device listing, and premarket notification requirements, and also specify conditions under which establishments are exempt from these requirements.

Manufacturers of finished devices (including device specification developers, reprocessors of single-use devices), repackers and relabelers, contract sterilizers, foreign exporters, and initial importers of medical devices, are required to register their establishments by submitting their registration and

listing information via the FDA Unified Registration and Listing System (FURLS)/Device Registration and Listing Module (DRLM). After initial submission, annual registration is accomplished by reviewing previously submitted registration and listing information via FURLS/DRLM. Component manufacturers are not required to register if the components are only sold to registered device establishments for assembly into finished devices. Registration and listing are required, however, if the component is labeled for a health care purpose and sold to medical or clinical users. Optical laboratories, clinical laboratories, dental laboratories, orthotic and prosthetic appliance assemblers, hearing aid dispensers, and others who, using previously manufactured devices, perform a service function for physicians, dentists, other licensed practitioners, or their patients, are exempt from establishment registration if they are located in the United States. X-ray assemblers are exempt from establishment registration. An exemption from registration does not exempt an establishment from inspection under Section 704 of the FD&C Act [21 U.S.C. 374].

Each establishment required to register, except initial importers of medical devices, must list their devices. Device listing and updates to listing information are accomplished via FURLS/DRLM.
All foreign manufacturers are required to notify the FDA of the name, address, telephone, and fax numbers, and e-mail address of their United States agent.

Medical device establishments are required to register and list, even if interstate commerce is not involved. Foreign establishments must register, list, and identify a United States agent prior to exporting to the United States. See IOM Exhibit 5-13 for the types of medical device operations that require registration and listing.

An establishment must initially register by paying the annual registration user fee and submitting their registration and listing information via FURLS/DRLM. Step-by-step instructions explaining how to pay the annual registration user fee, register an establishment, and list a device can be found on our website at https://www.fda.gov/medical-device/how-to-study-and-market-your-device/device-registration-and-listing.

General registration and listing information and questions about FURLS/DRLM can be addressed by sending an e-mail message to reglist@cdrh.fda.gov. Policy questions can be addressed by sending an email to device.reg@fda.hhs.gov.

2.10.4.2 - Premarket Notification - Section 510(k)

The Medical Device Amendments of 1976 require medical device manufacturers to notify the CDRH at least 90 days before commercially distributing a device. This is known as a “Premarket Notification”, or a 510(k) submission. Commercial distribution, for practical purposes, means the device is held for sale. These 510(k) requirements do not apply to Class I devices unless the device is intended for a use that is of substantial importance in preventing impairment of human health, or that presents a potential unreasonable risk of illness or injury. See Section 510(l) of the FD&C Act [21 U.S.C. 360(l)]

A manufacturer must submit a Premarket Notification to the FDA in any of the following situations:

- Introducing a device into commercial distribution, for the first time, when a predicate device exists.
- Introducing a new device or product line, for the first time, which may already be marketed by another firm.
- Introducing a device into commercial distribution when there is a modification to a previously cleared device that could significantly affect safety and/or effectiveness. Such changes or modifications may relate to design, material, chemical composition, energy source, manufacturing method, or intended use.
- Introducing a device into commercial distribution when the device exceeds the limitations of exemption per the .9 section of the associated regulation. (For example, 21 CFR 888.9 describes limitations of exemptions from Section 510(k) for Orthopedic Devices.)
-

These requirements do not apply to Custom Devices. A Custom Device is a device made exclusively for, and to meet the special needs of, an individual physician or health professional; or for use by an individual patient named in the order of a physician or dentist (such as specially designed orthopedic footwear). A "custom device" is not generally available in finished form for purchase and is not offered through labeling or advertising for commercial distribution.

Refer to IOM Exhibit 5-13 for the types of medical devices that require 510(k) submissions. The investigator should document, for CDRH review, failures to submit required 510(k)s.

2.10.4.3 - Premarket Approval

Class III devices are required to undergo Premarket Approval (PMA) in accordance with the provisions of Section 515 of the FD & C Act [21 U.S.C. 360e]. A PMA is initiated with the submission of an application to the FDA. Prior to approval of a PMA application, or a PMA supplemental, the FDA may inspect the applicant's facilities and records as pertinent to the PMA.

Compliance Program 7383.001 *Medical Device PMA Preapproval and PMA Postmarket Inspections* provides instructions to FDA field and CDRH staff for PMA preapproval, PMA postmarket inspections, and regulatory activities associated with PMAs.

Requests for PMA inspections will be made by CDRH Office of Regulatory Programs, DRP2: Division of Establishment Support, Regulatory Inspections and Audits Team. These assignments will require a comprehensive assessment of the firm’s quality management system for compliance with the appropriate regulations.

2.10.4.4 - Investigational Device Exemption/Humanitarian Device Exemption (IDE/HDE)

2.10.4.4.1 - Investigation Device Exemption (IDE)

The IDE regulation in 21 CFR 812 contains requirements for sponsors, Institutional Review Boards (IRBs), and clinical investigators. Additional requirements are found in 21 CFR 50, Informed Consent; and 21 CFR 56, IRB's. All sponsors of device clinical investigations must have an approved IDE, unless specifically exempted by the regulation. Sponsors who have an

approved IDE are exempt from requirements regarding labeling, registration and listing, premarket notification, performance standards, premarket approval, GMPs (except the design control provisions), banning of devices, restricted devices, and color additives.

Provisions for obtaining an IDE, and the sections of the regulations, with which sponsors, investigators, and IRBs must comply, differ according to the risks posed by the device. Sponsors of nonsignificant risk devices must obtain IRB approval and are subject to a limited number of provisions; sponsors of significant risk (See 21 CFR 812.3(m)) investigations are subject to the entire regulation.

There are investigations, described in 21 CFR 812.2(c), which are exempt from the IDE regulation. Exempted investigations apply to devices and diagnostics that meet the criteria in the regulation. These devices, however, are still subject to other regulatory requirements of the FD&C Act, such as labeling, premarket approval of Class III devices, and GMPs (as stated in the preamble to the IDE regulation).

A sponsor who knows a new device is not "substantially equivalent" to a pre-amendment device, or who is not sure if a device is "substantially equivalent" without conducting a clinical investigation, must obtain an approved IDE to conduct the clinical investigation. After collecting clinical data, a sponsor who desires to market a device must either submit a premarket notification (510k) or a premarket approval application to the FDA. A premarket notification may be submitted if the sponsor believes the data supports a finding of substantial equivalence. Certain radiation-emitting electronic devices that are investigational are also subject to radiological health regulations, as found in 21 CFR 1000 through 1050.

Transitional devices must have an approved IDE to be investigated. Sponsors, monitors, IRBs, investigators, and non-clinical toxicological laboratories will be covered under the BIMO Program. FDA has the authority to inspect and copy records relating to investigations. Records identifying patients by name will be copied only if there is reason to believe adequate informed consent was not obtained, or if investigator records are incomplete, false, or misleading.

2.10.4.4.2 – Humanitarian Device Exemption (HDE)

A Humanitarian Device Exemption (HDE) is a device approved under Section 520(m) of the FD&C Act [21 U.S.C. 360j(m)]. The HDE standard for approval is exempt from the requirement of establishing a reasonable assurance of effectiveness that would otherwise be required under Sections 514 and 515 of the FD&C Act but is not exempt from the requirement for a reasonable assurance of safety. FDA approval of an HDE application authorizes an applicant to market a humanitarian use device in accordance with approved labeling and indication(s) for use, subject to certain profit and use restrictions set forth in Section 520(m) of the FD&C Act. HDE approval for a device is initiated with the submission of an application to the FDA. Refer to IOM Section 2.9.2.4, Premarket Approval.

2.10.4.5 - Classification of Devices

All medical devices subject to the FD&C Act will be classified as either Class I, Class II, or Class III medical devices.

Manufacturers who have questions regarding the classification of a device can write CDRH under Section 513(g) of the FD&C Act [21 U.S.C. 360c (g)] and request a response regarding the status of the device.

2.10.4.5.1 - CLASS I

Class I - General Requirements- Devices for which general controls (i.e., the controls in Section 501, 502, 510, 516, 518, 519 and 520 of the FD&C Act [21 U.S.C. 351, 352, 360, 360f, 360h, 360i, and 360j]) provide reasonable assurance of safety and effectiveness.

2.10.4.5.2 - CLASS II

Class II - Special Control Requirements - Devices for which the general controls, by themselves, are insufficient to provide reasonable assurance of safety and effectiveness of the device, and for which there is sufficient information to promulgate special controls, necessary to provide such assurance.

2.10.4.5.3 – CLASS III

Class III – Premarket Approval Requirements – Devices which:

- Cannot be placed into Class I or II because insufficient information exists to provide assurance of safety and effectiveness, and cannot be placed into Class II because too little data exists to support the promulgation of special controls, and
- Are purported or represented to be for use in supporting or sustaining human life, or for a use that is of substantial importance in preventing impairment of human health, or
- Presents a potentially unreasonable risk of illness or injury.

Unless they are determined substantially equivalent to devices distributed prior to the 1976 Medical Device Amendments, devices proposed for marketing after May 28, 1976, fall automatically into Class III. Class III medical devices marketed before May 28, 1976, and the substantially equivalent devices marketed after that date, remain subject to the premarket notification requirements until required to have an approved PMA. Petitioners can request to have such devices reclassified into Class I or II. Transitional devices, those regulated as new drugs before May 28, 1976, are automatically assigned to Class III.

2.10.5 – Unique Device Identifier

The FDA established the UDI system to adequately identify medical devices sold in the United States, from manufacturing through distribution, under section 519(f) of the F D&C Act. Benefits of the UDI system include, but are not limited to, simplifying the integration of device use; providing for more rapid identification of medical devices with adverse events; providing for more rapid development of solutions to reported problems and efficient resolution of device recalls; and providing better focused and more effective FDA safety communications. In the UDI final rule (78 FR 58785), device labelers (typically manufacturers) are required to: 1) include a UDI, issued under an FDA-accredited issuing agency's UDI system, on device labels, device packages, and in some cases, directly marked on the device; and 2)

submit device information to the Global Unique Device Identification Database (GUDID). Access GUDID is a searchable database of device information (including, for instance, device identifier on the label, device name, premarket submission numbers) available to the public. The Unique Device Identifier System: Frequently Asked Questions, Vol. 1, provides guidance to industry and FDA staff, and provides clarification on key provisions of the UDI Rule.

2.10.6 – Biologics

The requirements for the registration and licensing of biological products fall under both the (PHS) and the FD&C Act.

2.10.6.1 - Registration and Listing

CBER provides industry with registration and listing forms, including Form FDA 2830, Blood Establishment Registration and Product Listing; and Form FDA 3356, *Establishment Registration and Listing for Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/Ps)*. Instructions for completing these documents are found on the reverse side of these forms along with establishment and product definitions. Registration forms are available through your district office, and through CBER's Office of Communication, Manufacturers Assistance and Technical Training Branch, and from its website. Registration and listing is required whether interstate commerce is involved or not. (See IOM 5.13.3)

For questions regarding a firm's registration, CSOs should refer to Document JA-000081, "OBPO Registration and Listing Inquiries." CSOs can refer industry questions to: Industry.Biologics@fda.hhs.gov. See also IOM 5.13.3.

2.10.6.1.1 - Human Blood and Blood Products

1. **Who must register** - Section 510 of the FD&C Act and 21 CFR 607 delineate the requirements and exemptions relating to the registration of establishments engaged in the collection, manufacturing, preparation, or processing of human blood or blood products. Registration and listing are required whether or not interstate commerce is involved. Fixed blood collection sites must register if they have supplies or equipment that requires quality controls or compliance with an expiration date, (e.g., copper sulfate, centrifuges, etc.), or is being used to store donor records. Temporary collection sites--to which all blood collection supplies are brought on the day of collection and are completely removed from the site at the end of the collecting period (except beds, tables, and chairs) -- and blood mobiles are not required to register. All military blood bank establishments are required to register. (MOU with Department of Defense [Federal Cooperative Agreements Manual] Regarding Licensure of Military Blood Banks.) Brokers who take physical possession of blood products, such as in storage, pooling, labeling, or distribution, are required to register. Blood establishments located outside of the United States that import or offer for import blood products into the United States are required to register with the FDA. They must also provide the name of the U.S. agent, the name of each importer, and the name of each who imports or offers for import these blood products.
2. **When to register** - Establishments must register within five days after beginning operations and must submit a list of blood products that they distribute commercially. They must register annually thereafter.

3. **How to register** - Owners or operators of blood establishments must register using the Form FDA 2830. Refer to Compliance Policy Guide (CPG) 230.110 for additional information on registration. These persons may complete and submit line or may submit a paper form.
4. **Where to mail completed paper forms** -
   Food and Drug Administration
   Center for Biologics Evaluation and Research
   Division of Blood Applications (HFM-370)
   1401 Rockville Pike, 200N
   Rockville, MD 20852-1448
5. **For general information and questions:**
   Phone: 301-827-3546
   Email: bloodregis@cber.fda.gov
   Mail:
   Food and Drug Administration
   Center for Biologics Evaluation and Research
   Document Control Center
   10903 New Hampshire Avenue, WO7, G112
   Silver Spring, MD 20993-0002

2.10.6.1.2 - Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/PS)

1. **Who must register** – Any establishment that manufactures HCT/Ps that are regulated solely under the authority of section 361 of the Public Health Service Act (42USC264) (the PHS Act) must register and list with CBER whether or not the HCT/P enters into interstate commerce (21 CFR 1271.1). Establishments that manufacture HCT/Ps regulated as drugs, devices and/or biological products under Section 351 of the PHS Act and/or the Federal Food, Drug and Cosmetic Act, must register and list with CBER following procedures in subpart B, 21 CFR 1271.21 thru 1271.37. Registration and listing are required if the establishment recovers, processes, stores, labels, packages, or distributes any human cell or tissue; or screens or tests the cell or tissue donor. Establishments exempted from registration are listed in 21 CFR 1271.15. Establishments that only have HCT/Ps under premarket review (IND/IDE/BLA/PMA) do not have to register and list until the HCT/P has been licensed, approved, or cleared by the FDA.
2. **When to register** - Establishments must register within five days after beginning operations and must submit a list of each HCT/P manufactured.
3. **How to register** - To register, a Form FDA 3356 must be completed.
4. **Where to mail completed forms** -
   Food and Drug Administration
   Center for Biologics Evaluation and Research
   Attention: Tissue Establishment Registration Coordinator
   10903 New Hampshire Avenue, WO7, G112
   Silver Spring, MD 20993-0002

   Or forms may be submitted by FAX according to form instructions.
   Alternatively, establishments may now submit the information electronically via the Electronic Human Cell and Tissue Establishment Registration (eHCTERs) page.

5. **For general information and questions:**
   Phone: 301-827-6176 (Tissue Establishment Registration Coordinator)
   Email: tissuereg@cber.fda.gov
   Mail:
   Food and Drug Administration
   Center for Biologics Evaluation and Research, HFM-775,
   1401 Rockville Pike, 200N,
   Rockville, MD 20852-1448

2.10.6.2 - Biologic License

Section 351 of the Public Health Service Act requires individuals or companies who manufacture biological products for introduction into interstate commerce to hold a license for the products. Biologics licenses are issued by CBER and the Center for Drug Evaluation and Research (CDER) (21 CFR 601.4).

Applicants must inform the FDA about each change in the product, production process, quality controls, equipment, facilities, responsible personnel, or labeling established in the approved license application (21 CFR 601.12).

Major changes require supplement submission and approval prior to distribution of products made using the change (21 CFR 601.12(b)). Certain changes require supplement submissions at least 30 days prior to distribution of the product made using the change, and other minor changes need only be described in an annual report (21 CFR 601.12(c) and (d)).
Where to send reports –

For licensed biological products regulated by CBER:
Food and Drug Administration
Center for Biologics Evaluation and Research
Document Control Center (HFM-99),
10903 New Hampshire Avenue, WO7, G112,
Silver Spring, MD 20993-0002

For licensed biological products regulated by CDER:
Food and Drug Administration
Center for Drug Evaluation and Research
Office of New Drugs (OND) (Specify OND Review Division)
5901-B Ammendale Road

2.10.7 – Tobacco

The FD&C Act and its amendment under the Family Smoking Prevention and Tobacco Control Act require manufacturers or importers of tobacco products to submit certain information to the FDA, including: Tobacco Health Documents, Establishment Registration and Product Listing, and Ingredient Listing. New tobacco products subject to further requirements include the following: any tobacco product that was not commercially marketed in the United States as of February 15, 2007 (including

those products in test markets); or any tobacco product that has been modified (including a change in design, or change to any component, any part, or any constituent, including a smoke constituent, or change in the content, delivery or form of nicotine, or any other additive or ingredient) t in which the modified product was commercially marketed in the United States after February 15, 2007. The general requirements for new tobacco products are discussed below. On March 15, 2022, the President signed legislation to amend the FD&C Act to extend FDA's jurisdiction to products "containing nicotine from any source," not just nicotine derived from tobacco. See Consolidated Appropriations Act, 2022, Public Law 117-103, Division P, Subtitle B. The changes to the law took effect April 14, 2022, thus FDA considers "tobacco products" to encompass both tobacco-derived nicotine and non-tobacco-derived nicotine products.

2.10.7.1 – Premarket Requirements

A Premarket Tobacco Product Application (PMTA) can be submitted by any person seeking an FDA marketing order for any new tobacco product, under Section 910(b) of the Federal Food, Drug, and Cosmetic (FD&C) Act. A PMTA must provide scientific data that demonstrates a tobacco product is appropriate for the protection of public health. To reach such a decision and to authorize marketing, the FDA considers (per Section 910(c)(4)), among other things:

- The risks and benefits to the population as a whole, including people who would use the proposed new tobacco product, as well as non-users
- Whether or not people who currently use any tobacco product would be more, or less likely, to stop using such products if the proposed new tobacco product were available
- Whether or not people who currently do not use any tobacco products would be more, or less, likely to begin using tobacco products if the new product were available
- The methods, facilities, and controls used to manufacture, process, and pack the new tobacco product

2.10.7.2 – Postmarket Requirements

Postmarket requirements oblige applicants to establish and maintain records and make reports that the FDA requires as necessary to determine, or facilitate a determination of, whether or not there may be grounds to withdraw or temporarily suspend a marketing granted order. Postmarket reporting requirements for all tobacco products that receive a marketing granted order are set forth in § 1114.41, and the FDA may require additional reporting under the terms of a marketing granted order.

2.10.7.3 – Substantially Equivalent

The term 'substantially equivalent' or 'substantial equivalence' means, with respect to a tobacco product being compared to the predicate tobacco product, that the Secretary, by order, has found that the tobacco product either a) has the same characteristics as the predicate tobacco product; or b) has different characteristics and the information submitted contains clinical data (if deemed necessary by the Secretary) demonstrating that it is not appropriate to regulate the product under this section because the product does not raise different questions of public health. (In subparagraph (a) above, the term 'characteristics' means the materials, ingredients, design, composition, heating source, or other features of a tobacco product.)

A tobacco product may not be found to be substantially equivalent to a predicate tobacco product that has been removed from the market at the initiative of the Secretary, or to a predicate tobacco product that has been determined by a judicial order to be misbranded or adulterated.
General information regarding industry submissions, or the process, can be found at: https://www.fda.gov/tobaccoproducts/compliance-enforcement-training/manufacturing.

2.11 – References

2.11.1 – Definitions involving Districts

Program Alignment created program specific divisions in which most field CSOs are assigned to work. However, geographical districts still exist, and references are made to them in assignments, correspondence, and various procedures described in this manual and used throughout the FDA. Geography-related terms are described below.

2.11.1.1 – Home District

Home district is the term used for the FDA district office that an establishment or firm is associated with. This is based upon the geographical area responsibilities of the district. Most often, the home district will be the office retaining original records associated with a firm, such as sample collection reports, analyst worksheets, establishment inspection reports, and correspondence. Check with your supervisor for your program division procedures for maintaining original records.

2.11.1.2 – Seizing District

Seizing district is the district in which a seizure was actually accomplished. The seizing district is not necessarily the collecting district, (as in the case of in-transit samples).

2.11.1.3 – Supervising District

Supervising district is the district that exercises supervision over reconditioning lots in connection with seizure actions.

2.11.2 – FDA/ORA Manual and Reports

The most used FDA and ORA manual and reports you may need to reference are linked below.

- Compliance policy guides,
- Compliance program guidance manuals,
- Enforcement reports,
- Field Managements directives,
- Guide to International Inspections and Travel
- Inspection Technical Guides
- International Cooperative Agreements
- Investigations Operations Manual
- Laboratory Manual
- Laboratory Information Bulletins

- Regulatory Procedures Manual
- Recalls and Safety Alerts
- Staff Manual Guides
- State and Federal Cooperative Agreements
- Federal Memorandums of Understandings

2.11.3 – Forms and Other Publications

The FDA Online Public Forms Catalog contains a list of FDA forms and the information necessary to order them.

Paper copies of the forms may be ordered electronically from the Program Support Center. To submit a forms request, or for other questions concerning FDA forms, see https://www.fda.gov/AboutFDA/ReportsManualsForms/Forms/ucm236184.htm.

The DHHS Program Support Center at 16071 Industrial Drive, Gaithersburg, MD 20877, also maintains a limited selection of FDA forms and publications. To inquire about printing, please contact the center at: pscpublishing@psc.hhs.gov.

FDA's intranet Electronic Forms Catalog is a repository of internal forms related to field operations. For example, you can find seals, affidavits, FDA-482, Notice of Inspection, and other forms that document activities related to investigations, inspections, and sample collection and analysis. Forms are organized alphabetically, as well as by form number.

2.11.4 – Regulatory References and the General Public

The public must make a request under the Freedom of Information Act (FOIA) in order to obtain certain FDA documents that require redaction. See IOM 1A.3.4 (FOIA) and IOM 1A.3.5 (internal FDA documents) for additional information on FOIA. For guidance for the public on how to file an FOIA request, see https://www.fda.gov/RegulatoryInformation/FOI/HowtoMakeaFOIARequest/default.htm.

Many FDA documents are available to the public without a FOIA request. To obtain forms, direct the public to the FDA Public Use Forms web page. The public can purchase paper editions of various agency manuals, such as the Food Code and Compliance Program Manuals, if ordered by National Technical Information Service (NTIS) item number from the NTIS. Instruct the person in search of a publication to first locate the NTIS item number by calling the NTIS sales department at 888-584-8332. Next, enter the NTIS item number in the search box at the NTIS website at www.ntis.gov, and follow directions on ordering the publication. For additional information on NTIS publications, refer the public to the following contact information:

National Technical Information Service
Technology Administration
U.S. Department of Commerce
Alexandria, VA 22312

Order Desk: 703-605-6050
customerservice@ntis.gov

2.11.5 – Laws Enforced by FDA

The Food and Drugs Act of 1906 was the first of more than 200 laws, constituting one of the world's most comprehensive and effective networks of public health and consumer protections. Details about the laws that the FDA enforces can be found on the web at Laws Enforced by FDA. Information about, and links to, the FD&C Act can be found at FD&C Act.

2.11.6 – Regulations

The Code of Federal Regulations (CFR) is a codification of the general and permanent rules published in the Federal Register by the executive departments and agencies of the federal government. The CFR is divided into 50 titles that represent broad areas subject to federal regulation. Each title is divided into chapters, which usually bear the name of the issuing agency. Each chapter is further subdivided into parts covering specific regulatory areas. For example, the specific regulation covering drug GMPs appears as "21 CFR 211", that is, Title 21, Part 211. Regulations enforced by the FDA are found in volumes 1-8 of Title 21, parts 1-1299. They are updated as of April 1 of each year. Both the Federal Register and the CFR must be used together to determine the latest version of a given rule.

2.11.7 - United States Code (U.S.C.)

“The United States Code is a consolidation and codification by subject matter of the general and permanent laws of the United States. It is prepared by the Office of the Law Revision Counsel of the United States House of Representatives.” U.S.C. Use FDA’s to obtain cross references for sections of the FD&C Act and the U.S.C.

2-1 - Definitions

The following definitions are from the Food, Drug and Cosmetic Act. Additional definitions can be found in 21 USC 321 (FD&C Act Definitions).

- The term “food” means (1) articles used for food or drink for man or other animals, (2) chewing gum, and (3) articles used for components of any such article.
- The term “drug” means (A) articles recognized in the official United States Pharmacopoeia,[1] official Homoeopathic Pharmacopoeia of the United States, or official National Formulary, or *any supplement to any of them; and (B) articles intended for use in the diagnosis, cure,* mitigation, treatment, or prevention of disease in man or other animals; and (C) articles (other than food) intended to affect the structure or any function of the body of man or other animals; and (D) articles intended for use as a component of any article specified in clause (A), (B), or (C). A food or dietary supplement for which a claim, subject to sections 343(r)(1)(B) and 343(r)(3) of this title or sections 343(r)(1)(B) and 343(r)(5)(D) of this title, is made in accordance with the requirements of section 343(r) of this title is not a drug solely because the label or the labeling contains such a claim. A food, dietary ingredient, or dietary supplement for which a truthful and not misleading statement is made in accordance with section 343(r)(6) of this title is not a drug under clause (C) solely because the label or the labeling contains such a statement.
- The term “device” (except when used in paragraph (n) of this section and in sections 331(i), 343(f), 352(c), and 362(c) of this title) means an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component, part, or accessory, which is—
  (A) recognized in the official National Formulary, or the United States Pharmacopeia, or any supplement to them,
  (B) intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals, or
  (C) intended to affect the structure or any function of the body of man or other animals, and which does not achieve its primary intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of its primary intended purposes. The term “device” does not include software functions excluded pursuant to section 360j(o) of this title.
- The term “cosmetic” means (1) articles intended to be rubbed, poured, sprinkled, or sprayed on, introduced into, or otherwise applied to the human body or any part thereof for cleansing, beautifying, promoting attractiveness, or altering the appearance, and (2) articles intended for use as a component of any such articles; except that such term shall not include soap.
- The term “raw agricultural commodity” means any food in its raw or natural state, including all fruits that are washed, colored, or otherwise treated in their unpeeled natural form prior to marketing.
- The term “food additive” means any substance the intended use of which results or may reasonably be expected to result, directly or indirectly, in its becoming a component or otherwise affecting the characteristics of any food (including any substance intended for use in producing, manufacturing, packing, processing, preparing, treating, packaging, transporting, or holding food; and including any source of radiation intended for any such use), if such substance is not generally recognized, among experts qualified by scientific training and experience to

evaluate its safety, as having been adequately shown through scientific procedures (or, in the case of a substance used in food prior to January 1, 1958, through either scientific procedures or experience based on common use in food) to be safe under the conditions of its intended use; except that such term does not include—

(1) a pesticide chemical residue in or on a raw agricultural commodity or processed food; or
(2) a pesticide chemical; or
(3) a color additive; or
(4) any substance used in accordance with a sanction or approval granted prior to September 6, 1958, pursuant to this chapter, the Poultry Products Inspection Act [21 U.S.C. 451 et seq.] or the Meat Inspection Act of March 4, 1907, as amended and extended [21 U.S.C. 601 et seq.];
(5) a new animal drug; or
(6) an ingredient described in paragraph (ff) in, or intended for use in, a dietary supplement.

- The term "color additive" means a material which—
  (A) is a dye, pigment, or other substance made by a process of synthesis or similar artifice, or extracted, isolated, or otherwise derived, with or without intermediate or final change of identity, from a vegetable, animal, mineral, or other source, and
  (B) when added or applied to a food, drug, or cosmetic, or to the human body or any part thereof, is capable (alone or through reaction with other substance) of imparting color thereto;

  except that such term does not include any material which the Secretary, by regulation, determines is used (or intended to be used) solely for a purpose or purposes other than coloring.
  - The term "color" includes black, white, and intermediate grays.
  - Nothing in subparagraph (1) of this paragraph shall be construed to apply to any pesticide chemical, soil or plant nutrient, or other agricultural chemical solely because of its effect in aiding, retarding, or otherwise affecting, directly or indirectly, the growth or other natural physiological processes of produce of the soil and thereby affecting its color, whether before or after harvest.

The term "animal feed", as used in paragraph (w) [2] of this section, in section 360b of this title, and in provisions of this chapter referring to such paragraph or section, means an article which is intended for use for food for animals other than man and which is intended for use as a substantial source of nutrients in the diet of the animal, and is not limited to a mixture intended to be the sole ration of the animal.

2-2 FDA 2289 - Detention Order

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DETENTION ORDER

1a. DIVISION ADDRESS

1b. PHONE NUMBER

1c. NAME OF DIVISION DIRECTOR

1d. EMAIL ADDRESS

1e. FAX NUMBER

2. NAME OF CUSTODIAN

TO:

3. DETENTION ORDER NUMBER

DO

4. TITLE OF CUSTODIAN

5. TELEPHONE NUMBER

6. DATE AND HOUR DETAINED

a.m.

p.m.

7. FIRM NAME

8. ADDRESS *(Street, City, State, ZIP Code)*

9. MAXIMUM DETENTION

DAYS

Pursuant to *(Check applicable Section(s))* ☐ Section 304(h) of the Federal Food, Drug and Cosmetic Act (FD&C Act), ☐ Section 304(g) of the FD&C Act, ☐ Sections 402 and 409b of the Federal Meat Inspection Act, ☐ Sections 19 and 24(b) of the Federal Poultry Inspection Act, and/or ☐ Sections 19 and 23(d) of the Federal Egg Products Inspection Act, the article(s) listed in blocks 10 - 12 below on this form must not be used, moved, altered or tampered with in any manner during the detention period without the written permission of an authorized representative of the Secretary of the U.S. Department of Health and Human Services, except that, pursuant to Section 304(g)(2)(B) of the FD&C Act, 1) a device may be moved and processed under 21 CFR 800.55(h)(2), and 2) a drug may be moved and processed under 21 CFR 1.980(h)(2). An article of food detained pursuant to Section 304(h) of the FD&C Act shall not be consumed, moved, altered or tampered with in any manner during the detention period, unless the detention order is first modified under 21 CFR 1.381(c).

10. NAME OF DETAINED ARTICLE(S)

11. SIZE OF DETAINED LOT

12. DETAINED ARTICLE(S) LABELED *(Include Master Carton Label)*

15. REASON FOR DETENTION

16. DETAINED ARTICLE(S) STORED AT *(Name, Address, ZIP Code)*

17. NAME AND TITLE OF PERSON WHO APPROVED THE DETENTION ORDER

18. APPROVAL OF DETENTION ORDER ☐ Written ☐ Verbal

20. STORAGE OF DETAINED ARTICLES *(Select appropriate – Per 21 CFR1.393(b)(7), the detained articles must be stored by only these methods.)*

☐ N/A ☐ Refrigerated at ____ * F ☐ Frozen ☐ Ambient ☐ Other *(For non-temperature related storage conditions; specify)*:

NAME OF FDA EMPLOYEE *(Type or print)*

TITLE *(FDA Employee)*

SIGNATURE *(FDA Employee)*

FORM FDA 2289 (01/22) **DETENTION ORDER** **1**

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■ See instructions following page 5 in this electronic form version.

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DETENTION ORDER

1a. DIVISION ADDRESS

1b. PHONE NUMBER

1c. NAME OF DIVISION DIRECTOR

1d. EMAIL ADDRESS

1e. FAX NUMBER

2. NAME OF CUSTODIAN

TO:

3. DETENTION ORDER NUMBER

DO

4. TITLE OF CUSTODIAN

5. TELEPHONE NUMBER

6. DATE AND HOUR DETAINED

a.m.

p.m.

7. FIRM NAME

8. ADDRESS *(Street, City, State, ZIP Code)*

9. MAXIMUM DETENTION

_____ DAYS

Pursuant to *(Check applicable Section(s))* ☐ Section 304(h) of the Federal Food, Drug and Cosmetic Act (FD&C Act),
☐ Section 304(g) of the FD&C Act, ☐ Sections 402 and 409b of the Federal Meat Inspection Act,
☐ Sections 19 and 24(b) of the Federal Poultry Inspection Act, and/or ☐ Sections 19 and 23(d) of the Federal Egg Products Inspection Act,
the article(s) listed in blocks 10 - 12 below on this form must not be used, moved, altered or tampered with in any manner during the detention period without the written permission of an authorized representative of the Secretary of the U.S. Department of Health and Human Services, except that, pursuant to Section 304(g)(2)(B) of the FD&C Act, 1) a device may be moved and processed under 21 CFR 800.55(h)(2), and 2) a drug may be moved and processed under 21 CFR 1.980(h)(2). An article of food detained pursuant to Section 304(h) of the FD&C Act shall not be consumed, moved, altered or tampered with in any manner during the detention period, unless the detention order is first modified under 21 CFR 1.381(c).

10. NAME OF DETAINED ARTICLE(S)

11. SIZE OF DETAINED LOT

12. DETAINED ARTICLE(S) LABELED *(Include Master Carton Label)*

13. APPROXIMATE VALUE OF LOT

14. SAMPLE NUMBER

15. REASON FOR DETENTION

16. DETAINED ARTICLE(S) STORED AT *(Name, Address, ZIP Code)*

17. NAME AND TITLE OF PERSON WHO APPROVED THE DETENTION ORDER

18. APPROVAL OF DETENTION ORDER ☐ Written ☐ Verbal

19. NAME AND ADDRESS OF ARTICLE(S) OWNER

20. NAME AND ADDRESS OF INITIAL SHIPPER OR SELLER

21. NAME AND ADDRESS OF SUBSEQUENT SHIPPERS OR SELLERS *(Continue in Remarks, if necessary)*

22. NAME OF CARRIERS

23. DATE LOT SHIPPED

24. NAME AND ADDRESS OF PACKING PLANT

25. DATE LOT RECEIVED

26. PACKING PLANT USDA NUMBER

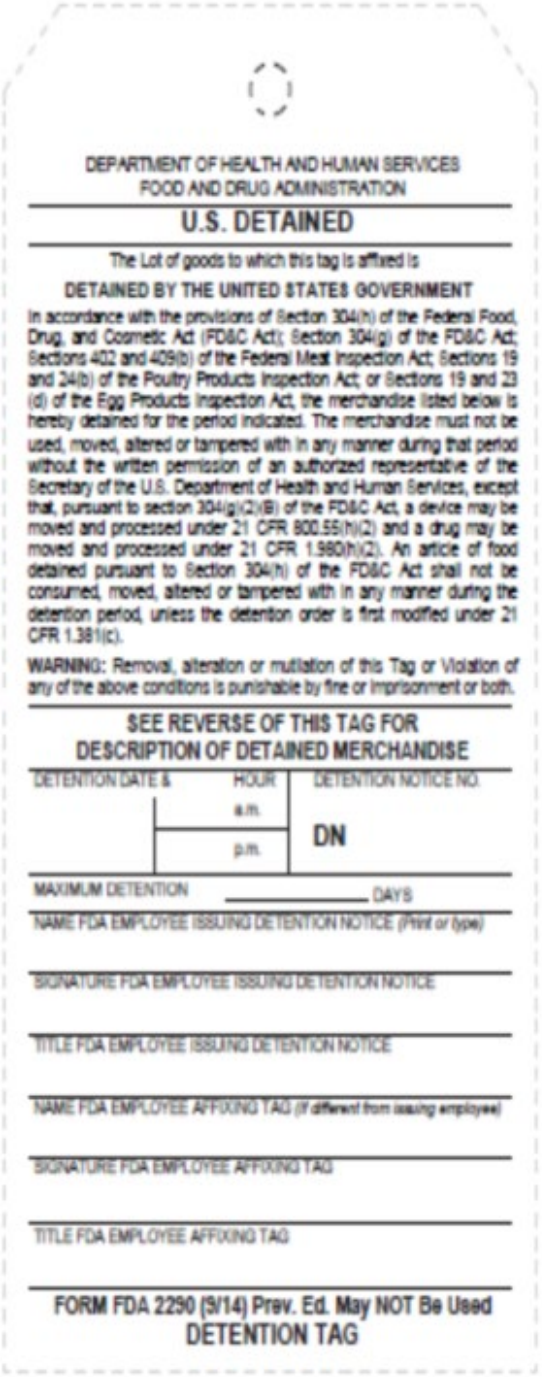
27. DESCRIPTION OF SAMPLE

28. STORAGE OF DETAINED ARTICLES *(Select appropriate – Per 21 CFR1.393(b)(7), the detained articles must be stored by only these methods.)*
☐ N/A ☐ Frozen ☐ Other *(For non-temperature related storage conditions; specify)*: _____
☐ Refrigerated at _____ ° F ☐ Ambient

NAME OF FDA EMPLOYEE *(Type or print)* | TITLE *(FDA Employee)* | SIGNATURE *(FDA Employee)*

FORM FDA 2289 (01/22) DETENTION ORDER 2

2-3 – FDA 2290 – Detention Tag



DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

U.S. DETAINED

The Lot of goods to which this tag is affixed is

DETAINED BY THE UNITED STATES GOVERNMENT

In accordance with the provisions of Section 304(h) of the Federal Food, Drug, and Cosmetic Act (FD&C Act); Section 304(g) of the FD&C Act; Sections 402 and 409(b) of the Federal Meat Inspection Act; Sections 19 and 24(b) of the Poultry Products Inspection Act; or Sections 19 and 23 (d) of the Egg Products Inspection Act, the merchandise listed below is hereby detained for the period indicated. The merchandise must not be used, moved, altered or tampered with in any manner during that period without the written permission of an authorized representative of the Secretary of the U.S. Department of Health and Human Services, except that, pursuant to section 304(g)(2)(B) of the FD&C Act, a device may be moved and processed under 21 CFR 800.55(h)(2) and a drug may be moved and processed under 21 CFR 1.980(h)(2). An article of food detained pursuant to Section 304(h) of the FD&C Act shall not be consumed, moved, altered or tampered with in any manner during the detention period, unless the detention order is first modified under 21 CFR 1.381(c).

WARNING: Removal, alteration or mutilation of this Tag or Violation of any of the above conditions is punishable by fine or imprisonment or both.

SEE REVERSE OF THIS TAG FOR DESCRIPTION OF DETAINED MERCHANDISE

DETENTION DATE &	HOUR	DETENTION NOTICE NO.
	a.m.	DN
	p.m.	

MAXIMUM DETENTION _____ DAYS

NAME FDA EMPLOYEE ISSUING DETENTION NOTICE *(Print or type)*

SIGNATURE FDA EMPLOYEE ISSUING DETENTION NOTICE

TITLE FDA EMPLOYEE ISSUING DETENTION NOTICE

NAME FDA EMPLOYEE AFFIXING TAG *(If different from issuing employee)*

SIGNATURE FDA EMPLOYEE AFFIXING TAG

TITLE FDA EMPLOYEE AFFIXING TAG

FORM FDA 2290 (3/14) Prev. Ed. May NOT Be Used
DETENTION TAG



U.S. DETAINED

NAME OF DETAINED ARTICLE

DETAINED ARTICLE LABELED

SIZE OF DETAINED LOT

SEE REVERSE

FORM FDA 2290 (3/14)

2-4 – FDA 2291- Detention Termination

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DETENTION TERMINATION NOTICE

1a. Division Address

1b. Phone Number

1c. Name of Division Director

TO: 2. NAME OF CUSTODIAN

3. DETENTION NOTICE NUMBER
DN

4. TITLE OF CUSTODIAN

5. DATE AND HOUR DETAINED
a.m.
p.m.

6. FIRM NAME

7. DATE AND HOUR DETENTION TERMINATED
a.m.
p.m.

8. ADDRESS (Street, city, and State)

9. ZIP CODE

The merchandise listed below which, pursuant to Sections 402 and 409(b) of the Federal Meat Inspection Act; Sections 19 and 24(b) of the Poultry Products Inspection Act; Sections 19 and 23(d) of the Egg Products Inspection Act; or Sections 304(g) or 304(h) of the Federal Food, Drug, and Cosmetic Act, was detained on the above date and bears the above detention number, is hereby released and the detention is terminated.

10. NAME OF DETAINED ARTICLE

11. SIZE OF DETAINED LOT

12. DETAINED ARTICLE LABELED (Include Master Carton Label)

NAME OF FDA EMPLOYEE (Type or print)

TITLE (FDA Employee)

SIGNATURE (FDA Employee)

FORM FDA 2291 (1/22) DETENTION TERMINATION NOTICE 1

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DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DETENTION TERMINATION NOTICE

1a. Division Address

1b. Phone Number

1c. Name of Division Director

TO:

2. NAME OF CUSTODIAN

3. DETENTION NOTICE NUMBER

DN

4. TITLE OF CUSTODIAN

5. DATE AND HOUR DETAINED

a.m.

p.m.

6. FIRM NAME

7. DATE AND HOUR DETENTION TERMINATED

a.m.

p.m.

8. ADDRESS (Street, city, and State)

9. ZIP CODE

The merchandise listed below which, pursuant to Sections 402 and 409(b) of the Federal Meat Inspection Act; Sections 19 and 24(b) of the Poultry Products Inspection Act; Sections 19 and 23(d) of the Egg Products Inspection Act; or Sections 304(g) or 304(h) of the Federal Food, Drug, and Cosmetic Act, was detained on the above date and bears the above detention number, is hereby released and the detention is terminated.

10. NAME OF DETAINED ARTICLE

11. SIZE OF DETAINED LOT

12. DETAINED ARTICLE LABELED (Include Master Carton Label)

REMARKS

NAME OF FDA EMPLOYEE (Type or print)

TITLE (FDA Employee)

SIGNATURE (FDA Employee)

FORM FDA 2291 (1/22) DETENTION TERMINATION NOTICE 2

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SUBCHAPTER 3.1 - COOPERATIVE EFFORTS

3.1.1 - POLICY

The scope of consumer protection is extended by cooperative efforts of federal, state, local, territorial, and tribal agencies, and international cooperation. Procedures to appropriately share responsibilities and cooperate with our consumer protection partners are essential.

Procedures to appropriately share responsibilities to cooperate with our consumer protection partners are essential.

Federal, state, local, territorial, and tribal cooperation shall be fostered whenever possible. The Agency issues the IOM as well as other FDA manuals to international regulators and conformity assessment bodies, and state, local, territorial, and tribal inspectors. FDA fosters cooperation through correspondence, FDA testimony, press releases, reprints from the Federal Register, and distribution of all pertinent policy and regulations issued by FDA which have significance in other regulatory jurisdictions. The Agency may share FDA's non-public information as long as the sharing complies with the Agency's confidentiality laws and procedures.

Districts, headquarters' offices, and resident post personnel in particular, should maintain liaison with federal, state, local territorial, and tribal officials.

Follow District policy regarding contacts with appropriate federal, state, local, territorial, and tribal officials to exchange information, coordinate operations, and arrange joint inspections. If an assignment calls for joint work with state, local, territorial, or tribal inspectors, make every effort to accomplish this work. See IOM 3.3.1. When you travel internationally, follow policy established in the "GUIDE TO INTERNATIONAL INSPECTIONS AND TRAVEL."

3.1.2 - LAWS, CODES, AGENCIES

Many states have enacted the basic Uniform Food, Drug, and Cosmetic Bill, and others have adopted at least a part of the Uniform Bill. The provisions of these laws are very similar to the 1938 provisions of the Federal Food, Drug, and Cosmetic Act. A few states have enacted the Pesticide Food and Color Additives or Kefauver-Harris type amendments. See IOM 3.3.3.

Most states without the Uniform FD&C Act, have laws based on the 1906 Food and Drug Act. Most larger cities have their own ordinances and regulations. A portion of the food supply of the United States is consumed within the state in which it is produced, and is therefore, not directly under the jurisdiction of the Federal Food, Drug and Cosmetic Act as amended. Thus, the various state and local agencies are solely responsible for policing this supply.

The departments of the executive branch of the federal government operate under the laws and regulations which they are specifically responsible for enforcing. Since responsibilities may overlap and be duplicated, operating agreements and liaison between agencies is essential for smooth and efficient governmental operation. Section 702(c) of the FD&C Act [21 U.S.C. 372(c)] recognizes this by providing that the records of any department in the executive branch shall be open to inspection by authorized DHHS personnel.

District management is responsible for maintaining official liaison between FDA and other federal agencies. However, for day-by-day operations, personal contact between various operating federal investigators, inspectors, and agents is desirable and encouraged.

3.1.2.1 - Agreements and Memoranda of Understanding (MOU)

It is FDA's policy to enter into MOUs with other entities in situations in which there are a need to define lines of authority or responsibility, or to clarify cooperative procedures (see SMG 2820.1). FDA and various agencies often enter into formal or informal agreements, and/or understandings to improve consumer protection through more effective use of collective resources and to eliminate duplication of activities. These agreements and understands specify areas of primary responsibility.

Prior to disclosing FDA's information, ensure that the Agreement and MOU contain confidentiality provisions that comply with FDA's information disclosure laws and

procedures (e.g., sharing with the public (FOI), federal government officials 21 CFR 20.85, state/local 21 CFR 20.88, foreign 21 CFR 20.89). Contact ORA Office of Partnerships at OP.Feedback@fda.hhs.gov when encountering an MOU for the first time, drafting an MOU, or for clarification of disclosure.

A complete listing (domestic, academia and non-profit) is publicly available on the FDA **MOUs page**

3.1.3 - OTHER GOVERNMENT INSPECTION

General procedures regarding cooperation with other federal, state, and local officials are furnished below.

During establishment inspections determine the specific type of inspection service and inspecting units, such as the name of the federal, state, county, or city health agency or department. Obtain the name and title of the inspectional official, and general method of operation. IOM 5.8.9.1 discusses coverage of grade A Dairy Plants.

3.1.3.1 - Federal

Compulsory Continuous Inspection - Do not inspect firms, or that portion of a plant, under compulsory, continuous inspection under United States Department of Agriculture's (USDA) Meat Inspection Act, Poultry Products Inspection Act, or Egg Products Inspection Act, except on specific instructions from your supervisor or assignment document.

Ingredients or manufacturing processes common to both USDA and FDA regulated products should be inspected by FDA. See IOM 3.2.1.3 for FDA/USDA Agreements in specific areas.

Provide routine FDA coverage of such firms as breweries and wineries, which may be intermittently inspected on a compulsory basis by the U.S. Treasury Department, U.S. Public Health Service, or other agencies.

Voluntary - All products inspected under the voluntary inspection service of the Agriculture Marketing Service (AMS), USDA, and the National Marine Fisheries Service (NMFS), US Department of Commerce, are subject to FDA jurisdiction and are usually given routine coverage; however, formal written Agreements or a MOU between FDA and other agencies are often executed and may govern the agreeing agencies' operations on these types of inspected plants.

3.1.3.2 - Discussion with Federal Inspector

If you are assigned to cover a federally inspected plant which is under either compulsory or voluntary inspection, check to see if an Agreement or a MOU exists between FDA and the agency involved to determine the obligations of both agencies. When you arrive at the firm:

1. Identify yourself to the inspector(s) and invite him/her to accompany you on the inspection but do not insist on their participation.
2. At the conclusion of the inspection, offer to discuss your observations and provide the in-plant inspector with a copy of your Inspectional Observations (FDA 483).

3.1.3.3 - State and Local

State and local officials usually have extensive regulatory authority over firms in their area regardless of the interstate movement or origin of the food products involved. Joint FDA-State or local inspections are occasionally conducted. These are usually arranged by district administrative or supervisory personnel. See IOM 3.3.1.

SUBCHAPTER 3.2 - FEDERAL AGENCY INTERACTION

This subchapter deals with the interaction of the FDA with other federal agencies. This interaction will be discussed below. Each agency with which FDA has agreements or an MOU is listed separately. Information regarding MOUs and other interactions are discussed as appropriate. Information about the complete MOU or agreement can be found in the appropriate Cooperative Agreements Manual. Listings of all Liaison Officers are included below.

3.2.1 - U. S. DEPARTMENT OF AGRICULTURE (USDA)

See IOM 3.1.3 for procedures to be followed when making inspections of firms under USDA inspection or subject to inspection by USDA.

3.2.1.1 - Foods Rejected by USDA

All procurement and processing contracts administered by USDA for edible food products require compliance with FDA regulations. The USDA routinely reports to the FDA its findings on lots of flour, cereal, or other products which have been rejected for acceptance into USDA-sponsored programs, based on FDA guidelines. This notification of rejection is routinely furnished to the involved District office. When a District office receives such notification, it will determine appropriate follow-up by evaluating the reason for rejection, current priority assignments, and workload.

Samples should not be routinely collected from the USDA rejected material. If a follow-up inspection is made the District will then determine the need for samples or additional action.

3.2.1.2 - USDA Complaints

Whenever a complaint is received involving any meat-containing product, including such items as soups, combination infant foods, frozen dinners, etc., evaluate the

need to contact USDA. Most products containing red meat or poultry are regulated by USDA. The exceptions include:

1. Products containing meat from game animals, such as venison, rabbits, etc.
2. Meat-flavored instant noodles
3. The product "pork and beans" which contain only a small amount of pork fat and for historic reasons is regulated by FDA.

Determine from the consumer whether there is a round "shield" on the label with the USDA establishment number. Alternatively, the establishment number may be identified in the lot number. Red meat products under USDA jurisdiction will often contain the abbreviation "EST" followed by a one to four-digit number; poultry products under USDA jurisdiction will contain the letter "P" followed by a number.

FDA reports suspected outbreaks to USDA and CDC. In addition, FDA and CDC have an agreement that FDA will be immediately advised whenever CDC ships botulism antitoxin anywhere in the United States or its possessions. See IOM 3.2.4.3 regarding interaction with CDC.

USDA and FDA have an agreement whereby FDA informs a designated USDA Compliance and Evaluation Area Office about any foodborne disease where a meat or poultry product is suspected. Conversely, USDA will alert the FDA District office on suspected products subject to FDA jurisdiction. In order for your District to alert USDA promptly, check with your supervisor immediately if meat or poultry products are involved in an outbreak you are investigating, or which comes to your attention.

3.2.1.3 - USDA Acts

The following USDA Acts under which FDA has been delegated detention authorities for products subject to USDA inspection are:

1. Federal Meat Inspection Act (FMIA) see IOM 2.7.1.2.2
2. Poultry Products Inspection Act PPIA see IOM 2.7.1.2.3

3. Egg Products Inspection Act (EPIA) see IOM 2.7.1.2.4

See IOM 2.7.1 for additional information. See IOM Exhibit 3-1 for a chart depicting jurisdictional lines for products regulated by FDA and USDA.

3.2.1.4 - FDA-USDA Agreements & MOUs

MOUs and Agreements with USDA and its various units will be listed and, in some cases, described below. This first subsection covers MOUs with the USDA, USDA/other agency, and FDA. The following subsections provide information about MOUs with other USDA units.

MOU with:

1. US Department of Commerce and USDA Concerning Inspection of Industrial Fishery Products Intended for Animal 315 Feed Use (225-75-7001).
2. USDA, NIH Regarding Importation of Biological Specimens under US/USSR Scientific Exchange Agreement (225-74-1010).
3. USDA and DHHS Regarding General War Food Inspection (225-75-8004).

4. USDA Concerning the trade facilitation of milk and milk products exported from the United States (225-20-017).

3.2.1.5 - Agricultural Marketing Service (AMS)/ USDA (MOUs)

MOU with:

1. AMS Concerning the Inspection and Grading of Food Products (225-72-2009).
   This MOU has extensive separation of duties between AMS and FDA.
   Both agencies agree to maintain a close working relationship, in the field as well as headquarters. Both agencies will work with industry toward greater efficiency connected with improvement of coding methods. Each agency will designate a central contact point to which communications dealing with this agreement or other issues may be referred to for attention.
   The FDA Liaison Officer is the Director, Office of Compliance, Center for Food Safety and Applied Nutrition, HFS-600 (240-402-1364).
   The USDA Liaison Officer is the Chief of Technologies Services Branch, Science Division, AMS (202-690-4025).
2. AMS Regarding the Egg Products Inspection Act. FDA has exclusive jurisdiction over restaurants, institutions, food manufacturing plants, and other similar establishments, that break and serve eggs or use them in their products (225-75-4003).
   AMS shall notify FDA whenever it has reason to believe that shell eggs or egg products have been shipped in commerce in violation of the act to a receiver for which FDA has exclusive jurisdiction, and notify FDA when applications are made to import shell eggs into the U.S. FDA will notify AMS so that they can check on the seller of any restricted eggs when it is determined that more restricted eggs than are allowed in U.S. Consumer Grade B. are encountered. FDA will also notify AMS of any unwholesome egg products it encounters, including imported shell eggs which contain restricted eggs not in accordance with USDA regulations and labeling requirements.
   The FDA Liaison Officer is the Director, Office of Emergency Operations, HFA-615, (866-300-4374).
   The FDA Liaison Officer for imported shell eggs is the Branch Chief, Import Product Adulteration Branch, Division of Enforcement, Office of Compliance, Center for Food Safety and Applied Nutrition, HFS-606 (1-888-723-3366).
   The USDA Liaison Officer is the Deputy Administrator, Poultry Program, Agricultural Marketing Service (202-720-4476).
3. AMS Concerning Imported Dates and Date Material (225-72-2001).

FDA inspects samples and examines imported dates and date products intended for processing to determine whether they are in compliance with the statute.

AMS, upon request, will provide FDA with a copy of each examination report which will contain information such as that in the FDA Technical Bulletin Number 5, Microanalytical Procedures Manual.

The FDA Liaison Officer is the Director, Division of Natural Products, Microanalytical Branch, Center for Food Safety and Applied Nutrition, HFS-315 (240-402-1990).

The USDA Liaison Officer is the Chief, Processed Products Branch, Fruit and Vegetable Division, Agricultural Marketing Service (202-720-4693).

4. AMS Concerning Cooperative Efforts for Inspection, Sampling, and Examination of Imported Raisins (225-73-2007).

   AMS evaluates raisins for grade condition requirements and at the time and place of entry all lots of imported raisins. Upon completion of the examination, AMS promptly notifies the appropriate FDA District Office of any lots found not to meet minimum acceptance criteria because of insect infestation, filth, etc., and any questionable cases regarding the laboratory examination results. At the end of the season, the AMS provides FDA with a copy of each examination report.

   FDA accepts, unless it notifies USDA to the contrary, AMS findings on any lot of raisins sampled and inspected by them. FDA will detain any lots of raisins rejected by USDA because they contain insect infestation, etc. See the cooperative agreement manual for details of responsibilities.

   The FDA Liaison Officer is the Director, Division of Natural Products, Microanalytical Branch, Center for Food Safety and Applied Nutrition, HFS-315 (240-402-1990).

   The USDA Liaison Officer is the Chief, Processed Products Branch, Fruit and Vegetable Division, Agricultural Marketing Service (202-720-4693).

5. AMS Regarding Aflatoxin Testing Program for In-Shell Brazil Nuts (225-96-2002).

   Importers of Brazil Nuts voluntarily offer for USDA inspections before introducing them into U.S. commerce. USDA is responsible for sampling and testing each lot for aflatoxin in accordance with procedures prescribed by FDA and for issuing an analysis certificate for each lot. The Agricultural Marketing Service (AMS) will forward a copy of each certificate to the appropriate FDA District office. FDA accepts the certificate and then allows entry of the lots into U.S. commerce provided the aflatoxin level does not exceed the current action level prescribed by FDA.

   The FDA Liaison Officer is the Director, Office of Compliance, Center for Food Safety and Applied Nutrition, HFS-600 (240-402-1364).

   The USDA Liaison Officer is the Chief of Technologies Services Branch, Science Division, AMS (202-690-4025).

6. AMS Concerning Aflatoxin in Peanuts (225-96-2001).

   AMS will use FDA administrative guidelines on objective samples to certify peanuts, recognizing that GMPs remove significant quantities of unfit peanuts and that levels of aflatoxin are reduced by heating. USDA will provide FDA with a copy of the analytical certificate and identification of the applicant on each lot found to exceed 25 ppb of aflatoxin and the analysis certificate on any lot on request. FDA will routinely confirm chemical assays in finished product at 20 ppb by bioassay procedures.

   FDA will not formally object to the offering of lots of peanuts to processors where certificates show levels of aflatoxin above 25 ppb but will examine finished products from such lots. Such lots of raw peanuts may be subject to appropriate action in cases where there is lack of assurance that the finished product will comply with current standards.

   The FDA Liaison Officer is the Director, Office of Compliance, Center for Food Safety and Applied Nutrition, HFS-600 (240-402-1364).

   The USDA Liaison Officer is the Chief of Technologies Services Branch, Science Division, AMS (202-690-4025).

7. AMS and FSIS and EPA re: Regulatory Activities Concerning Residues of Drugs, Pesticides, and Environmental Contaminants in Foods (225-85-8910). Parts of this MOU are discussed below. Information about the complete MOU can be found in the appropriate Cooperative Agreements Manual. The contact offices are as follows:

   The FDA Liaison Office is the Director, Division of Natural Products, Microanalytical Branch, Center for Food Safety and Applied Nutrition, HFS-315 (240-402-1990).

   The USDA Liaison Office is the Administrator, Food Safety and Inspection Service (202-720-7025).

   The EPA Liaison Office is the Office of Pesticide Programs, (703-305-7090), or Health Effects Division, (703-305-7351).

8. AMS Concerning Salmonella Inspection and Sampling Coverage of Dry Milk Plants (225-75-4002).

   Parts of this MOU are discussed below. Information about the complete MOU can be found in the appropriate Cooperative Agreements Manual.

   USDA has two types of voluntary inspection programs: Plant Inspection Program for USDA Approved for Grading Services, and their Resident Inspection and Grading Program.

   Plant Inspection Program (PIP). Under the PIP, dry milk plants are surveyed for approval every three months. This includes a salmonella surveillance testing of the plant's product and environmental material. Product inspection and grading is provided on request and dry milk products produced under this program are eligible to bear the USDA shield.

   FDA will accept the AMS Salmonella Surveillance Program results on such plants and the finished dry milk products after shipment from those plants will not be sampled by FDA for Salmonella examinations. This does not preclude FDA sampling dry milk at manufacturing plants using dry milk as an ingredient as a follow-up to consumer complaints, or where the dry milk may have become contaminated or adulterated after leaving the dry milk manufacturer's control. Neither will it preclude FDA inspections of any plant for problems other than Salmonella whether or not such plant produces dry milk products under USDA

inspection, or the sampling of their products, including dry milk products, for problems other than Salmonella.
The FDA Liaison Office is the Director, Office of Emergency Operations, HFA-615, (866-300-4374).
The USDA Liaison Office is the Chief, Grading Branch, Dairy Division, Agricultural Marketing Service, (202-720-3171) or Chief, Standardization Branch, (202-720-7473).

3.2.1.6 - Animal Plant Health Inspection Service/USDA (APHIS)

MOU with APHIS Concerning Mutual Responsibilities for Regulating Biological Products (225-82-7000).

Referral and exchange information for purposes of investigation and appropriate legal action. To coordinate investigations and enforcement actions and to avoid duplication of effort, FDA and USDA agree to provide each other with any information which may be germane to either agency's enforcement functions. Information regarding pending investigations and enforcement actions shall be provided to the liaison officers noted below on a regular basis.

The FDA Liaison Office is the Director, Office of Surveillance and Compliance, Center for Veterinary Medicine, HFV-200, (240-453-6830).

The USDA Liaison Office is the Director, Center for Veterinary Biologics, Animal and Plant Health Inspection Service, (301-734-8245).

APHIS and NIH Regarding the Care and Welfare of Laboratory Animals.

3.2.1.7 - Federal Grain Inspection Service/ USDA (FGIS)

MOU with FGIS Concerning Inspection of Grain, Rice, Pulses, and Food Products (225-80-2000).

During an FDA inspection of any facility that processes, packs, or holds agricultural products, the investigator and or inspector will request that the FGIS inspector or licensee stationed at a facility accompany him/her during the inspection.

The inspector/investigator will request from FGIS any information concerning quality determinations of specific lots of products against which FDA has taken or may take action.

FDA will notify FGIS of any details concerning serious objectionable conditions found by FDA to exist in processing plants, packing plants, grain elevators, or any other facility where FGIS provides official services.

General matters involving this agreement may be referred to the agencies' liaison officers.

The FDA Liaison Office is the Director, Office of Plant and Dairy Foods and Beverages, Center for Food Safety and Applied Nutrition, HFS-300, (240-402-1488) or Director, Division of Programs and Enforcement Policy, Center for Food Safety and Applied Nutrition, HFS-305, (240-402-1988).

The USDA Liaison Office is the Director, Field Management Division, Federal Grain Inspection Service, Grain Inspection, Packers, and Stockyards Administration (202-720-0228).

3.2.1.8 - Food Safety and Inspection Service/USDA (FSIS)

1. FSIS Pertaining to Class I and Class II Recalls of Food Products that Contain Poultry and/or Meat Products that have been Manufactured in a FSIS Inspected Establishment (225-75-4072).
   FDA and FSIS agree that they will keep the customary records and make those related to the operation of this agreement available to the other agency. Both agencies will furnish reports of the progress of the work and such other reports as may be mutually agreed upon from time to time between cooperating parties.
   The FDA Liaison Officer is the Director, Office of Emergency Operations, HFA-615, (866-300-3474). The USDA Liaison Officer is the Director, Emergency Planning Office, Food Safety and Inspection Service (301-504-2121)
2. FSIS Concerning Inspection of Food Manufacturing Firms FDA investigators will attempt to contact any on-site FSIS inspectors when they arrive at a plant, invite them to participate in the inspection and discuss with or report any adverse findings involving meat and poultry products to that inspector prior to leaving the premises (225-99-2001).
   When report findings are classified "indicated" FDA will provide FSIS with a copy when the plant is also inspected by FSIS.
   If the FDA investigator has found unsanitary conditions or otherwise adulterated products, the appropriate FSIS office should be informed by telephone unless the FDA investigator has already reported his findings to the FSIS inspector at the plant.
   To any extent possible, consider information provided by FSIS to minimize duplication of effort.
   The FDA Liaison Office is the Director, Office of Emergency Operations, HFA-615, (866-300-4374).
   The USDA Liaison Office is the Deputy Administrator, Field Operations, Food Safety and Inspection Service (202-720-8803).
3. FSIS and AMS and EPA re: Regulatory Activities Concerning Residues of Drugs, Pesticides, and Environmental Contaminants in Foods (225-85-8400).
4. FSIS (NE and SE Regional Offices), DE Department of Agriculture, MD Department of Agriculture, PA Department of Agriculture, VA Department of Agriculture and Consumer Services, WV Department of Agriculture Regarding Regulatory Investigations Involving Drug, Pesticide, and Industrial Chemical Residues in Animal Feeds and Meat and Poultry (225-76-4002).

5. FSIS and GA Department of Agriculture Regarding Regulatory Investigations Involving Drug, Pesticide, and Toxic Chemical Residues in Animal Feeds and in Meat Tissues (225-20-019).
6. FSIS Regarding Primary Regulatory Authority over Siluriformes Fish and Fish Products (225-20-019). https://www.fda.gov/about-fda/domestic-mous/mou-225-20-019

3.2.1.9 - Science and Education Administration/USDA (SEA)

MOU with SEA Concerning Educational Programs in the Use of Animal Drugs (225-78-1002).

3.2.2 - U.S. DEPARTMENT OF COMMERCE (DOC)

3.2.2.1 - Commerce (DOC)

MOUs with DOC and USDA Concerning Inspection of Industrial Fishery Products Intended for Animal Feed Use.

3.2.2.2 - National Oceanic and Atmospheric Administration (NOAA) - National Marine Fisheries Service (NMFS)

MOU with:

1. NOAA/NMFS Regarding Inspection Programs for Fishery Products (225-76-2001) - The National Marine Fisheries Service (NMFS) of the National Oceanic and Atmospheric Administration (NOAA), Department of Commerce, operating under the authority of the Agriculture Marketing Act and the Fish and Wildlife Act is responsible for the development and advancement of commercial grade standards for fishery products and better health and sanitation standards in the industry and for furnishing inspection, analytical, and grading services to interested parties. The major purpose is to encourage and assist industry in improving the quality and safety of its products. This MOU outlines joint responsibilities between NOAA and FDA. See IOM 3.1.3 for guidance on joint inspections when inspecting firms under the voluntary NMFS program.
   The FDA Liaison Office is the Policy Guidance Branch, Division of Programs and Enforcement Policy, Office of Seafood, Center for Food Safety and Applied Nutrition, HFS-416 (240-402-2545).
   The NMFS Liaison Office is the Seafood Inspection Program, Department of Commerce, NOAA (301-713-2355).
2. NOAA/NMFS Concerning Enforcement of Laws (225-86-2000) - Against Illegal Commerce in Molluscan Shellfish.
   FDA will support NMFS Lacey Act investigations to the extent that regulatory authority and resources allow. This may include conducting food sanitation inspections of suspect shellfish shippers, reviewing interstate shipping records and obtaining affidavits to the extent possible, collecting and analyzing shellfish samples to be used as evidence of violations, and removing adulterated shellfish from the marketplace. Refer to the appropriate Cooperative Agreements manual for further discussion of this MOU.
   The FDA Liaison Office is the Policy Guidance Branch, Division of Programs and Enforcement Policy, Office of Seafood, Center for Food Safety and Applied Nutrition, HFS-416 (240-402-2545).
   The NMFS Liaison Office is the Seafood Inspection Program, Department of Commerce, NOAA (301-713-2355).

3.2.2.3 - U.S. Patent and Trademark Office (USP&TO) (DOC)

MOUs with:

1. USP and TO/DOC Concerning Orphan Drugs (225-84-8000).
2. USP and TO/DOC to Establish a Product's Eligibility for Patent Term Restoration (225-86-8251).
3. DOD Concerning Food Protection (Food Safety and Food Defense) (225-16-020)

3.2.3 - DEPARTMENT OF DEFENSE (DOD)

FDA has a number of MOUs with DOD and its various elements.

3.2.3.1 - DOD MOUs

1. DOD Concerning Licensure of Military Blood Banks (225-74-1017).
2. DOD Concerning FDA Responsibility for Quality Assurance of DOD Procured Drugs and Biologics (225-97-4000).
3. DOD Concerning Food Protection (Food Safety and Food Defense (225-16-020).

FDA also has a number of Interagency Agreements (IAG) with DOD to include IAG with:

1. DOD Concerning Investigational Use of Drugs, Antibiotics, Biologics, and Medical Devices by DOD (224-75-3003).
2. DOD Regarding FDA Quality Assurance Responsibility for DOD Contracts for Medical Devices (224-82-4001).

3.2.3.2 – U.S. Army Corps of Engineers (DOD)

MOU with US Army/Corps of Engineers Concerning Consumer Protection During Natural Disasters.

3.2.3.3 – U.S. Army Medical Research and Development Command (DOD)

MOU with U.S. Army Medical Research and Development Command Regarding Quality Assurance Support for Medical Material Having Military Application (225-99-4000).

3.2.3.4 - Defense Personnel Support Center (DPSC)

1. MOU with DPSC Concerning Exchange of Information Regarding Food and Cosmetic Recalls and Hazardous Food Situations (225-82-4003).
2. The Defense Personnel Support Center purchases vast quantities of foods and drugs for use by the Armed Forces. The products are purchased on contract and must meet standards and contract specifications to be accepted. Any products failing to meet these specifications are rejected. These are mentioned in IOM 3.2.3.1 above.

FDA, under the Government-Wide Quality Assurance Program (GWQAP), furnishes information to the military regarding the capabilities of firms bidding or desiring to bid on government contracts. Occasionally Districts may be requested by the OO/OEIO/DCS/Enforcement Systems Branch to make inspections or collect samples in support of the GWQAP. When this is necessary, OO/OEIO/DCS/Enforcement Systems Branch will provide the District with specific procedures and instructions. DoD depots and hospitals must notify their command centers prior to release of their stocks. For this reason, prior to visiting a U.S. Government installation to collect samples of food, drugs or medical devices, Districts should contact OO/OEIO/DCS/Enforcement Systems Branch (see Directory, ORA Headquarters Directory, Office of Enforcement and Import Operations, Division of Compliance Systems).

3.2.3.5 - Department of Navy/Bureau of Medicine and Surgery

MOU with Dept. of the Navy/Bureau of Medicine and Surgery Regarding the Microwave Oven Survey (225-77-1001).

3.2.3.6 - Defense Health Agency (DHA), Public Health Division, Veterinary Services Branch (DHA VS) (DoD)

MOU with DoD Concerning Food Protection (225-16-020) establishes a mutually acceptable understanding between DoD and FDA that aims to strengthen global food protection programs and supports the medical readiness of the US Armed Forces. Both agencies have agreed to develop information-sharing networks and processes to share information on facility audits; recalls and/or advisories, import alerts, adverse food and supplement events, laboratory findings or methods and other food protection procedures. Both agencies have further agreed to share laboratory data and research related to food protection including Food Emergency Response Network (FERN) and electronic Laboratory Exchange Network. DoD and FDA are collaborating in the development of food protection capabilities that include: joint inspections; training exercises; meetings and conferences; risk communications; and assessment of risk. All activities are coordinated by the agency Liaisons as per IOM section.

3.2.3.6.1 – DoD/FDA Liaisons

FDA's MOU with DoD Concerning Food Protection (225-16-020) requires both agencies to identify and provide points of contact (POCs)/liaisons between DoD and FDA for both routine and emergency situations and exercises.
1. DoD designates the Chief, Inter-Agency Coordination (Food Protection) Officer
2. The FDA Liaison to DoD is Kathryn A. Nagy, 404-253-1225.

3.2.4 - DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS)

This Agency has a number of MOUs with the Department and other HHS units.

3.2.4.1 - HHS MOUs

MOU with USDA and HHS Regarding General War Food Inspection (225-75-8004).

3.2.4.2 - Administration for Children, Youth and Families (ACYF)

A MOU with ACYF to Assure the Feeding Programs in Head Start Centers Conform to Federal Food Safety and Sanitation Responsibilities (225-89-2000).

3.2.4.3 - Centers for Disease Control and Prevention (CDC)

MOU with:
1. CDC Concerning In-Vitro Diagnostics (225-75-5012).
2. CDC Regarding Radiation Emergencies (225-81-6000).
3. CDC Regarding Exchange of Information and Coordination of Actions (225-82-8000).

Additional information is being provided here because of the close working agreement to assure the prompt exchange of information on suspected foodborne outbreaks.

Since it is essential that any suspected outbreaks be reported promptly to CDC, communicate any information you may learn in connection with foodborne outbreaks to your supervisor as soon as possible. Botulism Antitoxin Shipments - CDC is responsible for maintaining and shipping necessary supplies of botulinum antitoxin. When CDC makes a shipment of botulinum antitoxin, CDC will immediately, regardless of the day or time, phone the Office of Emergency Operations (OEO), HFA-615, (866-300-4374). The OEO contact will immediately phone the consignee District to advise them of the shipment.

1. Outbreaks on Foreign Flag Vessels - If an outbreak involving a foreign flag vessel or a US Flag vessel with an international itinerary comes to your attention, report it to your supervisor immediately who will then report it to OEO 866-300-4374. This situation falls under the jurisdiction of the Vessel Sanitation Program of the Centers for Disease Control and Prevention (CDC) Atlanta, Ga.
2. Outbreaks Involving Interstate Conveyances - Reports of illness attributed to travel on an interstate conveyance (plane, bus, train, or vessel) are the responsibility of FDA.

When a report of illness is received, you are encouraged to share it with state and local public health officials in case they received additional illness reports. Additionally, the procedures outlined in this Subchapter are to be followed including the following 5 items:

3.2.4.3.1 - INTERVIEWS

Interviews with the ill passenger, family members and/or physician (as applicable), should be in-depth enough to hypothesize whether the carrier may be related to the illness. Factors such as time of onset of symptoms, history of eating suspect foods, and other potential exposures should be considered. The carrier should also be contacted to determine whether other reports of illness have been received. The information developed should be evaluated to determine whether further follow-up is necessary (i.e., the carrier suspect). On those carriers where a reservation system is used, the names and phone numbers of passengers should be obtained to determine if other individuals became ill. It may be necessary to contact other passengers to determine if they consumed any food or water on the trip, and if they became ill in the time period associated with the original complaint. When a report of additional related or similar illnesses is received, immediately contact the Office of Emergency Operations, ORO, HFA-615, 866-300-4374 and relay the information. Also contact the state epidemiologist of the affected state to report the details of the illness. It may be advantageous to request assistance from them in the epidemiological investigation, particularly if patient specimens are needed to determine the cause.

3.2.4.3.2 - INFORMATION EXCHANGE AND COORDINATION

Recently FDA revised the MOU between FDA and CDC regarding exchange of information and coordination of actions. This MOU provides a framework for coordination and collaborative efforts between the two agencies. It also provides the principles and procedures by which information exchanges between FDA and CDC will take place. The new memorandum supersedes the MOU between CDC and FDA dated 4/1/82. When receiving a request for information from the CDC immediately notify the Director of the Office of Emergency Operations, HFA-615, 866-300-4374.

"FDA and CDC agree that the following principles and procedures will govern the exchange of nonpublic information between the two agencies. Although there is no legal requirement the FDA and CDC exchange information in all cases, FDA and CDC agree that there should be a presumption in favor of full and free sharing of information between FDA and CDC. Both agencies recognize and acknowledge however that it is essential that any confidential information that is shared between FDA and CDC must be protected from unauthorized public disclosure. See e.g., 21 USC sec. 331(j); 18 USC sec. 1905; 21 CFR Parts 20 and 21; 42 CFR Parts 5 and 5b; and, 42 USC sec. 301(d). Safeguards are important to protect the interests of, among others, owners and submitters of trade secrets and confidential commercial information; patient identities and other personal privacy information; privileged and/or pre-decisional agency records; and information protected for national security reasons. Any unauthorized disclosure of shared confidential information by the agency receiving the information shall be the responsibility of that agency.

3.2.4.3.3 - ROUTINE REQUESTS FOR INFORMATION

Routine Requests for Information:

1. The requesting agency must demonstrate, in writing, why it is necessary for it to obtain the requested information.
2. The agency receiving the request for information shall, based upon the sufficiency of the need-to-know demonstration described in section 1 above, determine whether it is appropriate to share the requested information with the requesting agency.
3. The requesting agency agrees that:
   a. It shall limit the dissemination of shared information it receives to internal agency offices and/or individuals that have been identified in its written request and/or have a need-to-know;
   b. Agree in writing not to publicly disclose any shared information in any manner including publications and public meetings without written permission of the agency that has shared the information;
   c. If the requesting agency receives a Freedom of Information Act (FOIA) request for the shared information, it will refer the request to the information-sharing agency; and,
   d. It shall promptly notify ORA's DIDP at ORA OSPOP Testimony – Info Sharing Team ORAOSPOPTestimony-InfoSharingTeam@fda.hhs.gov when there is any attempt to obtain shared information by compulsory process, including but not limited to a FOIA request, subpoena, discovery request, or litigation complaint or motion.
4. The agency that shares information with the requesting agency shall include a transmittal letter, along with any agency records exchanged, indicating the type of information.

3.2.4.3.4 - EMERGENCY REQUESTS FOR CONFIDENTIAL INFORMATION

In cases in which the requesting agency has a need to obtain certain information as soon as possible due to emergency circumstances, such as a foodborne illness outbreak, FDA and CDC may utilize the following procedures:

1. The requesting agency shall indicate orally or in writing to the agency in possession of the relevant information that it has the need to obtain certain identifiable information as soon as possible due to the existence of emergency circumstances and describe what the emergency circumstances are.
2. The requesting agency shall verbally agree to protect from unauthorized public disclosure any and all information that is shared, according to all applicable laws and regulations.
3. The existence of an actual emergency situation shall warrant, as determined by the agency in possession of the requested records, the waiver of the need-to-know demonstration and determination described in sections 1 and 2 (Routine Requests for Information) above. However, once the requesting agency has obtained the information it seeks, it shall comply with those procedures set forth in section 3 (Routine Requests for Information) above.

3.2.4.3.5 - LIAISON OFFICERS

Liaison Officers

1. For FDA:
   Office of Commissioner
   Contact: Mark Russo, Acting Director, Office of Crisis Management
   Food and Drug Administration
   12903 New Hampshire Ave.
   White Oak, Bldg., 32, Room 1352, HFA-600
   Silver Spring, MD 20993
   866-300-4374
2. For CDC:
   Associate Director for Science
   Harold W. Jaffee, MD, MA
   Centers for Disease Control
   Public Health Service
   Department of Health and Human Services
   Atlanta, GA 30333 404-639-7240

3.2.4.4 - Centers for Medicare and Medicaid Services (CMS)

MOU with Centers for Medicare and Medicaid Services (CMS) Concerning Blood Banking and Transfusion Programs (225-80-4000).

3.2.4.5 - Health Services Administration (HSA)

MOU with HSA Concerning Quality Assurance for Drugs, Biologics, Chemicals and Reagents Procured by HSA (225-75-8002).

3.2.4.6 - National Center for Health Statistics (NCHS)

A MOU with NCHS Regarding Exchange of Information (225-83-6000).

3.2.4.7 - National Institute of Drug Abuse (NIDA)

MOUs with:

1. NIDA Regarding Methadone Mutual Responsibilities in Implementing the Jointly Published Narcotic Addict Treatment Regulations (225-81-3000).
2. NIDA Concerning Cooperative Interaction in Expediting Domestic Scheduling of Drugs of Abuse (225-85-8251).

3.2.4.8 - National Institutes of Health (NIH)

MOU with:

1. NIH Regarding Anticancer Drugs (225-75-3001).
2. NIH and USDA Regarding Importation of Biological Specimens under US/USSR Scientific Exchange Agreement (225-74-1010).
3. NIH and APHIS Regarding the Care and Welfare of Laboratory Animals (225-83-8400).

3.2.5 - DEPARTMENT OF HOMELAND SECURITY

3.2.5.1 - U.S. Customs and Border Protection

MOU with:

1. Customs Service and the FDA Regarding Identifying Roles and Authority Concerning Electronic Products (225-74-6004).
2. Customs Service to Establish a Working Relationship for Cooperative Enforcement (225-79-4003).
3. Customs Services Regarding the Needs of the Trading Public in Expediting the Collection, Processing and the Use of Import Information (225-91-4003).

3.2.5.2 - Secret Service

The Secret Service operates under the Department of Homeland Security and is charged with the responsibility of protecting the President of the United States and certain other prominent persons. They also enforce the laws and regulations relating to currency, coins, and obligations and securities of the U.S. and foreign governments.

Authority for Secret Service to request FDA assistance, and for FDA to respond, is derived from the "Presidential Protection Assistance Act of 1976", P.L. 94-524 (90 Stat. 2475-7), Sections 1-10. Section six states in part:

"Executive Departments and Executive Agencies shall assist the Secret Service in the performance of its duties by providing services, equipment, and facilities on a temporary and reimbursable basis when requested by the Director and on a permanent and reimbursable basis upon advance written request of the Director; except that the DOD and the Coast Guard shall provide such assistance on a temporary basis without reimbursement when assisting the Secret Service in its duties directly related to the protection of the President or the Vice President or other officer immediately next in order of succession to the office of the President."

Note: At the present time the Agency is not claiming reimbursement from Secret Service until a study of total costs of our support function is completed.

FDA's authority for entry and inspection is derived from Secret Service authority and its request for FDA assistance. When called upon by the Secret Service to assist with a food service function, FDA's response is that of an advisor. Authority for decisions regarding food and beverages to be consumed by protectees is retained by the Secret Service.

Note: Do Not issue a Notice of Inspection - FDA 482 unless the investigation evolves into the collection of a sample for the enforcement of the FD&C Act. You are in the firm under the Secret Service authority.

FDA may initiate action against products encountered which are suspected of being in violation of the FD&C Act or the FPLA.

3.2.5.2.1 - LIAISON

The Secret Service may request FDA to provide food safety and food defense monitoring at National Special Security Events (NSSEs), i.e., Presidential Inaugurations, National Political Conventions, and Political Summits. Since the venues for NSSEs are large-scale retail food establishments, the ACOHAFO has designated the Office of State Cooperative Programs (OSCP), Division of Retail Food Protection (DRFP) and the OHAFO Senior Emergency Response Coordinators as the FDA lead personnel to work collaboratively with the Secret Service and the state or local entity with retail food safety jurisdiction to address food safety and food defense issues before and during NSSEs. More specific information regarding procedures, and roles and responsibilities during NSSEs is provided in the Special Event Planning Guidance (SEPG). If you are contacted by the Secret Service related to a NSSE, immediately contact your supervisor who in turn will contact the OSCP Director.

3.2.5.2.2 - PURPOSE

FDA's primary purpose in support of Secret Service is to minimize the possibility of foodborne illness or injury.

3.2.5.2.3 - CRITERIA FOR REQUESTING FDA ASSISTANCE

The decision to request FDA assistance is made by Secret Service Office of Protective Operations (Headquarters). FDA has provided certain criteria to aid Secret Service in determining how they might derive maximum benefit from FDA. Regardless what criteria are used, FDA should always respond to Secret Service requests for assistance. Secret Service considers factors other than the FDA supplied criteria in making its judgment regarding requests for assistance.

3.2.5.2.4 - SCOPE OF INVESTIGATION

Refer to the Special Events Planning Guidance document.

3.2.6 - DEPARTMENT OF JUSTICE

3.2.6.1 - U.S. Attorney

You may be contacted by the U.S. Attorney's office to discuss possible or pending cases or other matters pertinent to FDA. Notify your supervisor of these contacts. You may be accompanied by your supervisor or a compliance officer. If you are contacted by the U.S. Attorney's Office regarding any criminal issues, this is to be referred immediately to the appropriate OCI Office.

During any discussion with the U.S. Attorney, inform him that you are qualified to report the facts of whatever case or item being discussed, but inform him that you are a fact witness only and not qualified as an "expert".

3.2.6.2 - Drug Enforcement Administration (DEA) (Formerly: Bureau of Narcotics)

You should follow the procedures outlined in the Information Disclosure manual if you receive a request to share information with another Federal agency.

3.2.6.3 - Federal Bureau of Investigation (FBI)

The FBI, USDA and FDA are authorized to investigate reported tampering of FDA regulated consumer products under the Federal Anti-Tampering Act (FATA), Title 18, USC, Section 1365. In most cases, FDA's authority for such investigations is also found in the FD&C Act.

USDA and the FBI share enforcement of the FATA with FDA as described below:

1. FBI Responsibility - FDA understands that the FBI's primary response in FATA matters will be to investigate particularly those cases that involve a serious threat to human life or if a death has occurred. The FBI will also investigate FATA matters involving threatened tamperings, and actual or threatened tamperings coupled with an extortion demand.

The FBI will rely on FDA to determine if tampering with FDA products has occurred.
2. USDA Responsibility - The USDA will investigate and interact with the FBI on tampering with products regulated by USDA.

For complete information regarding FBI/FDA actions under FATA, see IOM 8.1.5.9.3.

3.2.6.4 - U.S. Marshals Service

The U.S. Marshals Service (USMS) is the enforcement arm of the federal court. The USMS is primarily responsible for the service of civil process. In other words, when FDA takes an action, such as seizure the U.S. Marshal actually serves the complaint for forfeiture and "arrests" the goods. FDA employees typically accompany the U.S. Marshal to assist in identifying the goods which are to be seized. The USMS is also responsible for ensuring the safe conduct of judicial proceedings and protecting federal judges, jurors, and other members of the federal judiciary. District Offices may find it useful to contact the local U.S. Marshals when preparing a situation plan to deal with issues of personal safety while conducting inspections or other operations. See IOM 5.3.1.1. and **http://www.usmarshals.gov/**

3.2.7 - DEPARTMENT OF LABOR: OCCUPATIONAL SAFETY AND HEALTH ADMINISTRATION (OSHA)

The MOU with OSHA Concerns Standards for Electronic Product Radiation (225-74-6008).

3.2.8 - TREASURY DEPARTMENT

Many different agencies operate under the direction of this department. These include the Internal Revenue Service, and the Alcohol and Tobacco Tax and Trade Bureau. Agreements and MOUs with the Treasury Department will be discussed below.

3.2.8.1 - Alcohol and Tobacco Tax and Trade Bureau (TTB)

FDA and TTB share jurisdiction over alcoholic beverages. The MOU between FDA and TTB (formerly the Bureau of Alcohol, Tobacco, and Firearms (ATF)) delineates the enforcement responsibilities of each agency with respect to alcoholic beverages (MOU 225-88-2000). This MOU, among other things, confirms that TTB will be responsible for testing alcoholic beverages to determine the extent of an adulteration problem and that when FDA learns or is advised that an alcoholic beverage is or may be adulterated, FDA will inform TTB. FDA will also provide laboratory assistance and health hazard evaluations at TTB request. TTB generally has responsibility for alcoholic beverage labeling; however, FDA also has jurisdiction over the labeling of wine with less than 7% alcohol by volume (such as alcoholic ciders and most wine coolers), and beer described in the TTB's Ruling 2008-3 (https://www.ttb.gov/images/pdfs/rulings/2008-3.pdf) as not being a "malt beverage" (also see FDA Guidance for Industry: Labeling of Certain Beers Subject to the Labeling Jurisdiction of the Food and Drug Administration, (https://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/ucm166239.htm).

Labeling questions for these alcoholic beverages that are under FDA's jurisdiction should be directed to Office of Nutrition and Food Labeling, Center for Food Safety and Applied Nutrition, 240-402-2373.

Based on this MOU (225-88-2000), FDA should refer all complaints involving alcoholic beverages (distilled spirits, wines, and malt beverage products except for labeling issues related to wine with less than 7% alcohol by volume and beer described in the TTB's Ruling 2008-3 as not being a "malt beverage") to TTB using the procedure outlined below. When a complaint is received from a consumer, it should be entered into CMS with initial evaluation "Not an FDA Obligation" and initial disposition "Referred to Other Federal Agency". If the complaint is reporting a suspected tampering, notify OCI by emailing a link to the CMS complaint to ocisaichqs@fda.hhs.gov. In all cases, a copy of the CMS consumer complaint report should be forwarded directly to the TTB Market Compliance Office with a copy to the FDA liaison officer to facilitate appropriate follow up between the two agencies at the headquarters level.

TTB Market Compliance Office can be reached at 202-453-2251 (Email: Market.Compliance@ttb.gov; Fax: 202-453-2873). The FDA Liaison Officer (Office of Food Safety, Center for Food Safety and Applied Nutrition) can be reached at 240-402-1700 (Email: FDA-TTB-Liaison-Officer@fda.hhs.gov; Fax: 301-436-2632).

3.2.8.2 - Internal Revenue Service (IRS)

MOU with IRS Concerning Legal Actions Taken by FDA Against Alcoholic Beverage Firms for Under filling of Containers (225-71-2006).

The FDA Liaison Office is the Division of Enforcement, Office of Compliance, Center for Food Safety and Applied Nutrition, HFS-605 (240-402-2094).

The ATF Liaison Office is the Chief, Industry Compliance Division (202-927-8100).

3.2.9 - DEPARTMENT OF VETERANS AFFAIRS VETERANS ADMINISTRATION (VA)

MOU with the VA are:
1. Concerning Exchange of Medical Device Experience Data (225-75-5011).
2. Concerning Communications and Cooperation Regarding Clinical Research with Investigational New Drugs and Devices, Including Biologicals (225-82-8400).

3. To promote cooperation and coordination between the Food and Drug Administration and the Veterans Health Administration for the purpose of enhancing food safety and sanitation in food operations serving health care facilities of the Department of Veterans Affairs (225-93-2000).

IAGs with the VA are:
1. VA Concerning FDA Responsibility for Quality Assurance for Drugs, Biologicals, Chemicals and Reagents Procured by VA (224-76-8049).
2. VA Regarding FDA Quality Assurance Responsibility for VA Contracts for Medical Devices (224-82-4002).
3. To provide mammography inspections, pursuant to Public Law 102-539 and Public Law 104-262, to Veterans Health Administration facilities.

3.2.10 - CONSUMER PRODUCT SAFETY COMMISSION (CPSC)

MOUs with CPSC are:
1. CPSC Concerning CPSC Use of FDA Documents (225-74-8001).
2. CPSC Regarding Jurisdiction with Respect to Food, Food Containers, and Food Related Articles and Equipment (225-76-2003).

3.2.11 - ENVIRONMENTAL PROTECTION AGENCY (EPA)

The EPA administers many Acts one of them is the National Environmental Protection Act (NEPA). FDA must be guided by this Act when assisting in voluntary destructions, disposal of laboratory wastes, etc.

Do not condone the wanton pollution of waterways, uncontrolled burning, the creation of a public nuisance or other questionable disposal practices. Note that certain products should not be disposed of in a conventional manner (e.g., sanitary landfill, flushing down the drain, etc.). In particular, certain products that have been banned in the past (chloroform, methapyrilene, hexachlorophene, PCB, etc.), are classified by EPA as hazardous and toxic substances and may require a special method of disposal by a licensed hazardous disposal facility. Any possible hazardous or toxic substance (carcinogen, mutagen, etc.) should not be disposed of without prior consultation by the firm with the U.S. Environmental Protection Agency and/or the regulating state authority. Refer to 21 CFR 25 and the National Environmental Protection Act for guidance regarding the environmental impact of voluntary destructions.

3.2.11.1 - EPA MOUs

MOUs with:
1. EPA Regarding Matters of Mutual Responsibility Under Federal FD&C Act and Federal Insecticide, Fungicide and Rodenticide Act (225-73-8010).
2. EPA Regarding Potable Water on Interstate Conveyances (225-78-4006).
   The EPA administers a regulatory program in this area, but FDA has the responsibility of notifying the ICC headquarters when problems are found. FDA will, if deemed appropriate include conveyances in their inspection/monitoring schedule. Both agencies will coordinate enforcement efforts, thereby avoiding duplication of efforts.
3. EPA Concerning Control of Drinking Water (225-79-2001).
   FDA has responsibility for water, and substances in water, used in food and for food processing and bottled drinking water.
   FDA will take appropriate regulatory action to control bottled drinking water and water and substances in water, used in food and for food processing.
   The FDA Liaison Office is the Division of Programs and Enforcement Policy, Office of Plant and Dairy Foods and Beverages, Center for Food Safety and Applied Nutrition, HFS-305 (240-402-1488).
   The EPA Liaison Office is the Drinking Water Technologies Branch, Drinking Water Standards Division (202-260-3022).
4. EPA and USDA (FSIS and AMS) re: Regulatory Activities Concerning Residues of Drugs, Pesticides, and Environmental Contaminants in Foods (225-85-8400).

3.2.12 - AGENCY FOR TOXIC SUBSTANCES AND DISEASE REGISTRY (ATSDR)

The ATSDR (formerly CDC Superfund) staff has been designated as the lead agency for the DHHS response to chemical emergencies. The CDC ATSDR Public Health Advisors are located at the EPA Regional Offices. These advisors would not only alert your office of chemical emergencies but would be invaluable in answering questions concerning the severity of the problem and discussing protective measures. Under no circumstances, are FDA employees to enter areas designated as hazardous.

If it is necessary to contact ATSDR employees, their addresses and phone numbers are listed below:

AGENCY FOR TOXIC SUBSTANCES AND DISEASE REGISTRY (FORMERLY KNOWN AS SUPERFUND)

Louise A. House
EPA Region I
ATSDR
EPA Bldg.
60 Westview St.
Lexington, MA 02173
617-860-4314

George Pettigrew
EPA Region VI (6HE)
1445 Ross Ave.
Dallas, TX 75202
214-655-8361

Arthur Black
EPA Region II
Rm 3137C
26 Federal Plaza

Denise Jordan-Izaguirre
EPA Region VII
Waste Management Branch
726 Minnesota Ave

New York, NY 10278
212-264-7662

Kansas City KS 66101
913-551-7692

Charles J. Walters
EPA Region III
841 Chestnut Bldg.
Philadelphia, PA
19106
215-597-7291

Glenn J. Tucker
ATSDR Region VIII (8HWM-FF)
Waste Management Div.
Suite 500
999 18th St.
Denver, CO 80202
303-294-1063

Robert E. Safay
Air & Waste Mgmt Div.
Region IV
345 Courtland St.
Atlanta, GA 30365
404-347-1847

William Q. Nelson
ATSDR Region IX
75 Hawthorne St
Rm 09261
San Francisco, CA 94105
415-744-2194

Louise A. Fabinski
Emerg. & Remedial Br.
EPA Region V (M-SHS-6)
77 W. Jackson Blvd
Chicago, IL 60604
312-886-0840

George Thomas
EPA Region X (MSHW113)
1200 6th Ave.
Seattle, WA 98101
206-553-2113

Some situations where ATSDR guidance is indicated are mentioned below.

In wrecks the physical impact usually causes most damage. Toxic items in the same load, this is illegal, may rupture and add to the contamination. In train wrecks, other railcars loaded with chemicals, oils or other contaminating materials may rupture and contaminate food and drug products in otherwise undamaged cars. Removal of the wreckage may cause further physical damage or chemical contamination. Exposure to weather may also adversely affect the products.

Do not overlook the possibility that runoff of toxic chemicals from wrecked and ruptured cars may contaminate adjacent or nearby streams supplying water to downstream firms under FDA jurisdiction.

Chemical spills occurring on land or water can pose a serious threat to the environment and contaminate FDA regulated products both directly and indirectly.

Hazardous waste sites also pose a hazard to the immediate environment, as well as offsite, if runoff contaminates nearby surface waters or if leachate contaminates ground water supplies.

3.2.13 - FEDERAL TRADE COMMISSION (FTC)

The MOU with FTC Concerns Exchange of Information (225-71-8003).

3.2.14 - U.S. NUCLEAR REGULATORY COMMISSION (NRC)

The U.S. Nuclear Regulatory Commission and the U.S. Department of Health and Human Services, Food and Drug Administration signed a MOU (225-03-4001) on August 26, 1993 (FR Vol. 58, No. 172, 09/08/93, 47300-47303). The purpose of the MOU is to coordinate existing NRC and FDA regulatory programs for medical devices (including utilization facilities used for medical therapy), drugs, and biological products utilizing byproduct, source, or special nuclear material regulated under the Atomic Energy Act of 1954, as amended. These regulatory programs include activities for evaluating and authorizing the manufacture, sale, distribution, licensing, and labeled intended use of such products.

Medical devices affected by this MOU include but are not limited to: in vitro diagnostic kits (radioimmunoassay); utilization facilities licensed to perform medical therapy; and teletherapy and brachytherapy sources, systems, and accessory devices. Biologicals include, but are not limited to, licensed in vitro diagnostic kits (radioimmunoassay), and certain radiolabeled biologics for in-vivo use. Drugs include all those that contain byproduct, source, or special nuclear material.

The organizations in FDA that are responsible for regulating these products are CDRH, CDER, and CBER.

The FDA Liaison Offices are the Center for Devices and Radiological Health, Director, Office of Regulatory Programs (301-796-5895), Center for Drug Evaluation and Research, Director, Office of Compliance, HFD-300 (301-796-3100), and the Center for Biologic Evaluation and Research, Director, Office of Compliance and Biologics Quality, HFM-600 (301-827-6190).

The NRC Liaison Office is the Director, Office of Nuclear Material Safety and Safeguards (301-504-3352).

3.2.15 - U.S. POSTAL SERVICE (USPS)

FDA cooperates with postal authorities in areas of mutual concern. If contacted by postal authorities, extend courtesy and cooperation. In any doubtful situation or incidents involving excessive expenditure of time and/or resources, check with your supervisor.

3.2.15.1 - Change of Address Information

At times during an investigation or inspection it may become necessary to visit local post offices to obtain new or forwarding addresses of individuals involved. Procedure:

1. Introduce yourself and display your credentials to the local P.O. clerk or official.
2. State the information desired.
3. Present the clerk or official on duty the statement in writing on FDA letterhead using the wording from IOM Exhibit 3-3 which may be reproduced or typed on district letterhead.
4. If you are still refused information or delayed in any manner, contact the nearest U.S. Postal Inspector to handle the matter.

5. At this time there is no charge for providing this information to a Federal Agency. The regulation promulgating a fee has been stayed.

3.2.15.2 - Postal Box Information

At times during an investigation or inspection it will become necessary to obtain the name and address of the holder of a postal box (PO Box).

Procedure:
1. Introduce yourself and display credentials to the local P.O. clerk or official.
2. State the information you desire.
3. Present the clerk or official the statement in writing on FDA letterhead using the wording from IOM Exhibit 3-3 which may be reproduced or typed on district letterhead.
4. At this time there is no charge for providing this information to a Federal Agency. The regulation promulgating a fee has been stayed.
5. If you are still refused the information or are delayed in any manner, contact the nearest U.S. Postal Inspector to handle the matter.

3.2.15.3 - Authority

The authority for providing forwarding address information to government agencies is defined in 39 CFR 265.6(d)(5)(i) which states as follows:
(5) Exceptions. Except as otherwise provided in these regulations, names, or addresses of postal customers will be furnished only as follows:
(i)To a federal, state, or local government agency upon prior written certification that the information is required for the performance of its duties.

Additionally, 39 CFR 265.6(d)(7) may apply: Address verification. The address of a postal customer will be verified at the request of a federal, state, or local government agency.

3.2.16 - FIRM LOCATIONS

Many firms FDA is required to inspect are difficult to locate, including growers, farms, and other types of operations in rural areas. Directions to these firms can be obtained from many sources, including:
1. Visits to Post Offices.
2. If the envelope has a postal meter number and no return address, check with the USPS to determine the name of the firm or holder of that "PB Meter" number.
3. Visits to local health departments.
4. Visits to county extension services.
5. Visits to USDA - Agricultural Stabilization and Conservation Offices of Soil Conservation Service Offices.

Many of these offices have maps of the counties, municipalities, etc. which can be purchased or copied and used with their guidance to find the firms.

After the directions are obtained or the maps copied, copies of the maps with directions can be included in the factory jacket.

3.2.17 - FEDERAL FOOD SAFETY COALITION

In August 1999, FDA began an interagency Federal Food Safety Coalition with other federal agencies in an effort to focus on food protection of high-risk populations. The group's objective is to promote the development of effective public health protection systems for food safety within federal programs using the FDA Model Food Code, emphasizing foodborne illness interventions, to reduce the occurrence of the five leading illness risk factors. A formal MOU or partnership has not yet been developed. The agency members are as follows:
1. Dept. of Veterans Affairs, Veterans Health Admin.
2. United States Department of Agriculture, Food and Nutrition Service Child Nutrition Division
3. Dept. of Justice, Bureau of Prisons
4. Dept. of Health and Human Services:
   a. Head Start Program
   b. Administration on Aging
   c. Indian Health Services
   d. Centers for Medicare and Medicaid Services
   e. Food and Drug Administration, Center for Food Safety and Applied Nutrition
5. CDC – Vessel Sanitation Program
6. Department of Defense:
   a. US Air Force
   b. US Army
   c. US Coast Guard
   d. US Navy
7. Department of Interior, National Park Service
8. US Congress, Office of the Attending Physician

SUBCHAPTER 3.3 - STATE OPERATIONAL AUTHORITY

3.3.1 - STATE OPERATIONAL AUTHORITY

Establishment Inspections - All state and local officials have some type of jurisdiction over the food and drug establishments located within their state or local boundaries, regardless of the interstate movement or origin of the products involved. Some states divide the responsibility for food, drugs, etc., among the various agencies within the state. See IOM 3.3.3[1].

Samples - All state laws provide authority to collect samples of food, drug, and other products within the state.

Embargoes - FDA does not have embargo authority. Some states have embargo and detention authorities, these authorities are specific within each state. FDA does have

administrative detention authority for medical devices and food. Administrative detention for medical devices and food can be used when the Agency has reason to believe that the article is adulterated, misbranded, or presents a threat of serious adverse health consequences to humans or animals. See FD&C Act section 304(g) and (h), IOM 3.2.1.3, 2.2.10, and 2.7.1 for administrative detention information.

Some state laws empower their inspectors to place an immediate embargo on products that are, or are suspected of being, adulterated or misbranded or otherwise in violation of their laws. As a cooperative measure most state agencies will have their inspectors place an embargo at the request of an FDA representative. Do not routinely request such embargo. District assignments may include instructions relative to cooperative embargoes.

In all instances, exercise care in requesting embargoes. In accordance with Field Management Directive 50 (FMD 50), the appropriate state agency should be notified of pending or recommended compliance/enforcement actions within five working days. When a state institutes an embargo at FDA's request, the District must assure that cooperating officials are kept informed of the status of the resulting administrative or legal action. The District must promptly notify state officials when the resulting action is final so that the state can update records and issue required releases for the lot. This helps prevent inordinately long holding times by the state.

Embargoes should not be considered as a mere convenience to the Food and Drug Administration but as an important and effective cooperative measure to be applied only when circumstances indicate such action.

Disaster Operations - Following major disasters, FDA regional directors and District directors will arrange for close cooperation with local and state food and drug officials, Health Departments, the Public Health Service, and other agencies engaged in comparable work. When requested to do so, FDA District personnel will assist local and state officials during such emergencies. At such times FDA personnel may be temporarily commissioned by local or state authorities and provided the authority to place embargoes (See IOM 8.1.5.8.6).

3.3.1.1 - FDA Personnel with State Authority

Certain states have designated selected FDA employees as special representatives or agents of the particular state agency. In these cases, they have furnished the FDA individuals with official state credentials. The FDA representatives given this authority will receive instructions and training, by their District, in the proper exercise of the powers conferred on them and must operate within the guidelines established by their District to monitor this authority. This is particularly important whenever state embargo powers may be used.

3.3.1.2 - Joint Inspections

Joint inspections with state or local inspectors are arranged by the District supervisory personnel. Joint inspections are conducted in the same manner as inspections by FDA alone and findings are discussed with the accompanying inspector. The cooperating inspector may wish to take action against the merchandise or the firm under pertinent local or state laws.

3.3.1.3 - FDA Commissioned State Personnel

Qualified state regulatory officials may be commissioned under section 702(a)(1)(A) of the FD&C Act.to conduct examinations and investigations, which can include conducting inspections, collecting samples, copying, and verifying records and carrying out an administrative detention order (following approval by the FDA District Director) under the FD&C Act.

3.3.1.4 – State Contract Inspections

FDA contracts with state regulatory partners to provide enhanced regulatory oversight of its regulated firms. Contract programs include Human Food, Animal Food, Shell Eggs, Medical Device, and Mammography Quality Standards Act (MQSA). The state regulatory partner must have equivalent regulations or be a commissioned official (except for MQSA).

Field Management Directive 76 (FMD-76) governs the oversight of the state contract audit program for all contract programs except MQSA.

All certified MQSA Inspectors are required to receive a satisfactory audit from a certified MQSA auditor during each Federal Fiscal Year. https://www.fda.gov/federal-state-local-tribal-and-territorial-officials/contracts/mqsa-inspection-contract-program

3.3.2 - STATE MEMORANDA OF UNDERSTANDING

The FDA has entered into agreements with various state and local agencies covering a variety of issues and work sharing agreements. At the present time not all the states have entered into agreements with FDA. A listing of current MOUs for states, the District of Columbia, and the Commonwealth of Puerto Rico are on FDA's MOU page.

3.3.3 - STATE AUTHORITIES AND PHONE CONTACT NUMBERS

This section contains information regarding various state enforcement authorities. Some states operate under state laws patterned after the FD&C Act of 1906 or the current FD&C Act. However, most of the states operate under a

"Uniform FD&C Act" which was developed by the Association of Food and Drug Officials (AFDO).

States that have adopted the Uniform FD&C Act as their legal guideline have in most cases adopted the entire act. The food authority in most cases includes among other things the adoption of the food and color additive provisions, pesticide residue amendments, enrichment guidance, etc. The Uniform FD&C Act also includes a provision for automatic adoption of changes in the FD&C Act. Some state legislatures have also included this provision in their laws. Some other provisions of the Uniform Act adopted by state include the new drug provisions, medical device laws, and cosmetic requirements.

Some states have also adopted the Association of American Feed Control Officials (AAFCO) model bill as their legal guideline for feed inspections.

In most cases the contact for "Consumer Protection Issues" would be located in the Office of the State Attorney General and would usually cover consumer fraud and other consumer protection issues. The State Attorney General's staff usually has mechanisms to deal with health fraud issues not efficiently dealt with by traditional FDA approaches. Contact your District Health Fraud Monitor for guidance in cooperative efforts with the State Attorney General's staff.

A complete listing of the personnel and programs at the state and local level may be found in the FDA Internet Directory of State and Local Officials which was prepared by the Office of Partnerships (HFC-150) at https://www.fda.gov/ForFederalStateandLocalOfficials/default.htm or http://www.afdo.org/

3.3.3.1 - Alabama (AL)

Alabama has adopted the FD&C Act of 1906 and the 1970 AAFCO as their legal guideline. The control agencies are Agriculture and Health. They have not adopted the new drug provisions, the medical device law, nor the automatic adoption provisions.

3.3.3.2 - Alaska (AK)

Alaska has adopted the Uniform FD&C Act without the automatic adoption provision and have not adopted either AAFCO feed bill. The controlling agencies are Health, Social Services, and Environmental Conservation. Alaska has adopted the various provisions of the Uniform bill.

3.3.3.3 - Arizona (AZ)

Arizona operates under the Uniform FD&C Act and the 1970 AAFCO Feed Bill. The controlling agencies are Health, Pharmacy, and the State Chemist. They have not adopted the medical device law, cosmetics law, nor the automatic adoption provisions of the Uniform FD&C Act.

3.3.3.4 - Arkansas (AR)

Arkansas operates under the Uniform FD&C Act and the 1970 AAFCO Feed Bill. The agencies in control are Health and the Plant Board. They have not adopted the new drug provisions or the automatic adoption provision.

3.3.3.5 - California (CA)

California has adopted the Uniform FD&C Act and the 1970 AAFCO Feed Bill along with the automatic adoption provisions of the Uniform FD&C Act. The controlling agencies are Agriculture and Health.

3.3.3.6 - Colorado (CO)

Colorado has adopted the Uniform FD&C Act and the automatic adoption provisions of the Uniform FD&C Act. The controlling agencies are Agriculture and Health. They have not adopted either version of the AAFCO Feed Bill.

3.3.3.7 - Connecticut (CT)

Connecticut has adopted the FD&C Act, the Uniform FD&C Act and the 1958 AAFCO Feed Bill along with the automatic adoption provisions of the Uniform FD&C Act. The controlling agencies are Agriculture and Consumer Protection.

3.3.3.8 - Delaware (DE)

Delaware has adopted the Uniform FD&C Act and the 1970 AAFCO Feed Bill along with the automatic adoption provisions of the Uniform FD&C Act. The controlling agencies are Agriculture, Health, and Pharmacy. They have not adopted the food and color additive amendments, the pesticide residue amendment, enrichment amendment, new drug provisions, medical device law, and the cosmetics law.

3.3.3.9 - Florida (FL)

Florida has adopted the Uniform FD&C Act and the 1970 AAFCO Feed Bill along with the automatic adoption provisions of the Uniform FD&C Act. The controlling agencies are Agriculture and Health.

3.3.3.10 - Georgia (GA)

Georgia has adopted the Uniform FD&C Act and the 1970 AAFCO Feed Bill but not the automatic adoption provisions of the Uniform FD&C Act. The controlling agencies are Agriculture and Pharmacy. They have not adopted the food additive, color additive or pesticide residue amendments.

3.3.3.11 - Hawaii (HI)

Hawaii has adopted the Uniform FD&C Act and the 1970 AAFCO Feed Bill along with the automatic adoption provisions of the Uniform FD&C Act. The controlling agencies are Agriculture, Health and the Attorney General.

3.3.3.12 - Idaho (ID)

Idaho has adopted the Uniform FD&C Act and the 1958 AAFCO Feed Bill and has not adopted the automatic adoption provisions of the Uniform FD&C Act. The controlling agencies are Agriculture, Health, and Pharmacy. They have not adopted the food additive, color additive or pesticide residue amendments of the Act.

3.3.3.13 - Illinois (IL)

Illinois has adopted the Uniform FD&C Act and the 1958 AAFCO Feed Bill along with the automatic adoption provisions of the Uniform FD&C Act. The controlling agencies are Agriculture and Health. They have not adopted the enrichment provisions of the Act.

3.3.3.14 - Indiana (IN)

Indiana has adopted the Uniform FD&C Act and the 1970 AAFCO Feed Bill along with the automatic adoption provisions of the Uniform FD&C Act. The controlling agencies are Health and the State Chemist.

3.3.3.15 - Iowa (IA)

Iowa has adopted the 1906 FD&C Act and the 1970 AAFCO Feed Bill along with the automatic adoption provisions of the FD&C Act. The controlling agencies are Agriculture, Health and Appeals, and Pharmacy.

3.3.3.16 - Kansas (KS)

Kansas has adopted the Uniform FD&C Act and the 1958 AAFCO Feed Bill and has not adopted the automatic adoption provisions of the Uniform FD&C Act. The controlling agencies are Agriculture and Health.

3.3.3.17 - Kentucky (KY)

Kentucky has adopted the Uniform FD&C Act and the 1970 AAFCO Feed Bill along with the automatic adoption provisions of the Uniform FD&C Act. The controlling agencies are Human Resources, Pharmacy, and the University of Kentucky Registration Services.

3.3.3.18 - Louisiana (LA)

Louisiana has adopted the Uniform FD&C Act and the 1970 AAFCO Feed Bill along with the automatic adoption provisions of the Uniform FD&C Act. The controlling agencies are Agriculture and Health. They have not adopted the provisions of the medical device law.

3.3.3.19 - Maine (ME)

Maine has adopted the Uniform FD&C Act and the 1970 AAFCO Feed Bill but not the automatic adoption provisions of the Uniform FD&C Act. The controlling agencies are Agriculture and Pharmacy. They have not adopted the food and color additive amendments nor the new drug provisions or the medical device law.

3.3.3.20 - Maryland (MD)

Maryland has adopted the Uniform FD&C Act and the 1970 AAFCO Feed Bill along with the automatic adoption provisions of the Uniform FD&C Act. The controlling agencies are Agriculture and Health. They have not adopted the enrichment provisions of the Act.

3.3.3.21 - Massachusetts (MA)

Massachusetts has adopted the Uniform FD&C Act and the 1970 AAFCO Feed Bill but not the automatic adoption provisions of the Uniform FD&C Act. The controlling agencies are Agriculture and Health. They have not adopted the new drug provisions of the Act.

3.3.3.22 - Michigan (MI)

Michigan has adopted the Uniform FD&C Act and the 1970 AAFCO Feed Bill but not the automatic adoption provisions of the Uniform FD&C Act. The controlling agencies are Agriculture, Commerce, Licensing and Registration. They have not adopted the enrichment provisions or the cosmetics law.

3.3.3.23 - Minnesota (MN)

Minnesota has adopted the Uniform FD&C Act and the 1970 AAFCO Feed Bill but not the automatic adoption provisions of the Uniform FD&C Act. The controlling agencies are Agriculture and Pharmacy. They have not adopted the enrichment provisions, the new drug provisions, the medical device law, nor the cosmetic law.

3.3.3.24 - Mississippi (MS)

Mississippi has adopted the 1906 FD&C Act and the 1970 AAFCO Feed Bill but not the automatic adoption provisions of the Uniform FD&C Act. The controlling agencies are Agriculture, Commerce, and the State Chemistry Lab. They have not adopted the food additive, color additive, and pesticide residue amendments, nor the new drug provisions or cosmetic law.

3.3.3.25 - Missouri (MO)

Missouri has adopted the Uniform FD&C Act and the 1970 AAFCO Feed Bill but not the automatic adoption provisions of the Uniform FD&C Act. The controlling agencies are Agriculture and Health. They have not adopted the enrichment provisions of the Act.

3.3.3.26 - Montana (MT)

Montana has adopted the Uniform FD&C Act and the 1970 AAFCO Feed Bill along with the automatic adoption provisions of the Uniform FD&C Act. The controlling agencies are Agriculture and Health.

3.3.3.27 - Nebraska (NE)

Nebraska has adopted the Uniform FD&C Act and the 1970 AAFCO Feed Bill but not the automatic adoption provisions of the Uniform FD&C Act. The controlling agencies are Agriculture and Health. They have not adopted the new drug provisions nor the medical device and cosmetic laws.

3.3.3.28 - Nevada (NV)

Nevada has adopted the Uniform FD&C Act but not the automatic adoption provisions of the Uniform FD&C Act. They have not adopted either version of the AAFCO Feed Bill. The controlling agencies are Agriculture and Health. They have not adopted the enrichment provisions of the Act.

3.3.3.29 - New Hampshire (NH)

New Hampshire has adopted the Uniform FD&C Act and the 1970 AAFCO Feed Bill but not the automatic adoption provisions of the Uniform FD&C Act. The controlling agencies are Agriculture and Health.

3.3.3.30 - New Jersey (NJ)

New Jersey has adopted the Uniform FD&C Act and the 1970 AAFCO Feed Bill but not automatic adoption provisions of the Uniform FD&C Act. The controlling agencies are Agriculture and Health. They have not adopted the pesticide residue amendment.

3.3.3.31 - New Mexico (NM)

New Mexico has adopted the Uniform FD&C Act and the 1958 AAFCO Feed Bill but not the automatic adoption provisions of the Uniform FD&C Act. The controlling agencies are Agriculture, Environment, Health, and Pharmacy. They have not adopted the food additive or color additive amendments.

3.3.3.32 - New York (NY)

New York has adopted the Uniform FD&C Act and the 1970 AAFCO Feed Bill along with the automatic adoption provisions of the Uniform FD&C Act. The controlling agencies are Agriculture and Markets, Health, and Pharmacy. They have not adopted the cosmetics law.

3.3.3.33 - North Carolina (NC)

North Carolina has adopted the Uniform FD&C Act and both versions of the AAFCO Feed Bills along with the automatic adoption provisions of the Uniform FD&C Act. The controlling agency is Agriculture. They have not adopted the enrichment provisions of the Act.

3.3.3.34 - North Dakota (ND)

North Dakota has adopted the Uniform FD&C Act and neither version of the AAFCO Feed Bill but not the automatic adoption provisions of the Uniform FD&C Act. The controlling agencies are Consolidated Laboratories, Health, and Pharmacy.

3.3.3.35 - Ohio (OH)

Ohio has adopted the Uniform FD&C Act and the 1970 AAFCO Feed Bill but not the automatic adoption provisions of the Uniform FD&C Act. The controlling agencies are Agriculture and Pharmacy.

3.3.3.36 - Oklahoma (OK)

Oklahoma has adopted the Uniform FD&C Act but neither version of the AAFCO Feed Bills nor the automatic adoption provisions of the Uniform FD&C Act. The controlling agencies are Agriculture and Health. They have not adopted the food additive or color additive amendments, the enrichment provisions nor the new drug provisions.

3.3.3.37 - Oregon (OR)

Oregon has adopted the Uniform FD&C Act and the 1958 AAFCO Feed Bill along with the automatic adoption provisions of the Uniform FD&C Act. The controlling agencies are Agriculture and Pharmacy. They have not adopted the cosmetics law.

3.3.3.38 - Pennsylvania (PA)

Pennsylvania has adopted the 1906 FD&C Act and the 1958 AAFCO Feed Bill but not the automatic adoption provisions of the Uniform FD&C Act. The controlling agencies are Agriculture and Health. They have not adopted the food additive, color additive, and pesticide residue amendments nor the enrichment provisions.

3.3.3.39 - Rhode Island (RI)

Rhode Island has adopted the Uniform FD&C Act and the 1970 AAFCO Feed Bill along with the automatic adoption provisions of the Uniform FD&C Act. The controlling agencies are Environmental Management and Health.

3.3.3.40 - South Carolina (SC)

South Carolina has adopted the Uniform FD&C Act and the 1958 AAFCO Feed Bill but not the automatic adoption provisions of the Uniform FD&C Act. The controlling agencies are Agriculture and Health.

3.3.3.41 - South Dakota (SD)

South Dakota has adopted the Uniform FD&C Act and the 1970 AAFCO Feed Bill but not the automatic adoption provisions of the Uniform FD&C Act. The controlling agencies are Agriculture, Commerce and Regulations. They have not adopted the new drug provisions, medical device law, nor the cosmetics law.

3.3.3.42 - Tennessee (TN)

Tennessee has adopted the Uniform FD&C Act and the 1970 AAFCO Feed Bill but not the automatic adoption provisions of the Uniform FD&C Act. The controlling agency is Agriculture.

3.3.3.43 - Texas (TX)

Texas has adopted the Uniform FD&C Act and the 1970 AAFCO Feed Bill along with the automatic adoption provisions of the Uniform FD&C Act. The controlling agencies are Health and the State Chemist.

3.3.3.44 - Utah (UT)

Utah has adopted the Uniform FD&C Act and the 1970 AAFCO Feed Bill along with the automatic adoption provisions of the Uniform FD&C Act. The controlling agencies are Agriculture and Health. They have not adopted the new drug provisions.

3.3.3.45 - Vermont (VT)

Vermont has adopted the Uniform FD&C Act and the 1970 AAFCO Feed Bill along with the automatic adoption provisions of the Uniform FD&C Act. The controlling agencies are Agriculture and Health. They have not adopted the enrichment provisions.

3.3.3.46 - Virginia (VA)

Virginia has adopted the Uniform FD&C Act and the 1958 AAFCO Feed Bill but not the automatic adoption provisions of the Uniform FD&C Act. The controlling agencies are Agriculture and Pharmacy.

3.3.3.47 - Washington (WA)

Washington has adopted the Uniform FD&C Act and the 1958 AAFCO Feed Bill along with the automatic adoption provisions of the Uniform FD&C Act. The controlling agencies are Agriculture and Pharmacy.

3.3.3.48 - West Virginia (WV)

West Virginia has adopted the 1906 FD&C Act and the 1970 AAFCO Feed Bill but not the automatic adoption provisions of the Uniform FD&C Act. The controlling agencies are Agriculture, Health, and Pharmacy. They have not adopted the food additives or color additive amendments, the new drug provisions, the medical device law, and the cosmetics law.

3.3.3.49 - Wisconsin (WI)

Wisconsin has adopted the Uniform FD&C Act and the 1958 AAFCO Feed Bill along with the automatic adoption provisions of the Uniform FD&C Act. The controlling agencies are Agriculture and Pharmacy. They have not adopted the enrichment provisions, the new drug provisions, the medical device law, and the cosmetics law.

3.3.3.50 - Wyoming

Wyoming has adopted the Uniform FD&C Act and the 1970 AAFCO Feed Bill but not the automatic adoption provisions of the Uniform FD&C Act. The controlling agency is Agriculture.

SUBCHAPTER 3.4 - INTERNATIONAL ARRANGEMENTS

3.4.1 - INTERNATIONAL ARRANGEMENTS

The Agency has over the years entered into agreements with foreign governments regarding the quality of foods, drugs, and other products exported to the United States. Refer to FDA's website at https://www.fda.gov/international-programs/international-arrangements/cooperative-arrangements for additional information.

3.4.2 - MUTUAL RECOGNITION AGREEMENTS

3.4.2.1 - European Community

Changes in FDAMA have required that FDA begin the process of acceptance of mutual recognition agreements relating to the regulation of FDA regulated commodities,

facilitate commerce between the US and foreign countries and other activities to reduce the burden of regulation and to harmonize regulatory requirements. See Section 410 of FDAMA. Additional specific information is available at https://www.fda.gov/international-programs/international-arrangements/mutual-recognition-agreement-mra.

3.4.2.2 - Food Products

In July 1999, the United States and the EC signed the "AGREEMENT BETWEEN THE UNITES STATES OF AMERICA AND THE EUROPEAN COMMUNITY ON SANITARY MEASURES TO PROTECT PUBLIC AND ANIMAL HEALTH IN TRADE IN LIVE ANIMALS AND ANIMAL PRODUCTS". This agreement is very much like a mutual recognition agreement and is based on the equivalence process. It covers a very wide range of human food products, all of animal origin, such as milk and dairy products, seafood, honey, wild game, snails, frog legs and canned pet food. For purposes of this agreement, the EC is considered one "party" and not 15 Member States. Activities to begin assessing equivalence are underway.

SUBCHAPTER 3.5 - NON-GOVERNMENT AGREEMENTS

The Agency has entered agreements with various non-governmental groups to formulate various programs and guidance See FDA's Cooperative Agreements page.

3-1 FDA/USDA JURISDICTION

This table summarizes information concerning jurisdiction overlap for human food products regulated by either or both FDA and USDA. It does not cover products made for on-site consumption such as pizza parlors, delicatessens, fast food sites, etc.

This table does not apply to meat and meat products intended for use in animal food.

FDA JURISDICTION	USDA JURISDICTION		
21 USC 392(b) Meats and meat food products capable of use as human food shall be exempt from the provisions of this Act to the extent of the application or the extension thereto of the Meat Inspection Act. FDA responsible for all non-specified red meats (bison, rabbits, game animals, zoo animals and all members of the deer family including elk (wapiti) and moose)). FDA responsible for all non-specified birds including wild turkeys, wild ducks, and wild geese. For products not intended to use for human food this exemption does not apply. Any ingredient, including meat and meat food products, used in animal food is regulated by FDA.	The Federal Meat Inspection Act regulates the inspection of the following amenable species capable of use as human food: cattle, sheep, swine, goats, horses, mules, or other equines, including their carcasses and parts. It also covers any additional species of livestock that the Secretary of Agriculture considers appropriate. Mandatory Inspection of Ratites and Squab (including emu) announced by USDA/FSIS April 2001	The Poultry Products Inspection Act (PPIA) defines the term poultry as any domesticated bird. USDA has interpreted this to include domestic chickens, turkeys, ducks, geese, and guineas. The Poultry Products Inspection Act states poultry and poultry products shall be exempt from the provisions of the FD&C Act to the extent they are covered by the PPIA. Mandatory Inspection of Ratites and Squab announced by USDA/FSIS April 2001	The Egg Products Inspection Act defines egg to mean the shell egg of domesticated chicken, turkey, duck, goose, or guinea. Voluntary grading of shell eggs is done under USDA supervision. (FDA enforces labels/labeling of shell eggs.)
Products with 3% or less raw meat; less than 2% cooked meat or other portions of the carcass; or 30% or less fat, tallow, or meat extract, alone or in combination. Products containing less than 2% cooked poultry meat; less than 10% cooked poultry skins, giblets, fat, and poultry meat (limited to less than 2%) in any combination. * Closed-face sandwiches. Any meat or meat food product used in or for animal food is regulated by FDA, regardless of %	Products containing greater than 3% raw meat; 2% or more cooked meat or other portions of the carcass; or greater than 30% fat, tallow, or meat extract, alone or in combination. * Open-face sandwiches.	Products containing 2% or more cooked poultry; 10% or more cooked poultry skins, giblets, fat, and poultry meat in any combination. *	Egg products processing plants (egg breaking and pasteurizing operations) are under USDA jurisdiction.
FDA is responsible for shell eggs and egg containing products that do not meet USDA's definition of "egg product." FDA also has jurisdiction in establishments not covered by USDA, e.g., restaurants, bakeries, cake mix plants, etc. Egg processing plants (egg washing, sorting, packing) are under FDA jurisdiction.			Products that meet USDA's definition of "egg product" are under USDA jurisdiction. The definition includes dried, frozen, or liquid eggs, with or without added ingredients, but mentions many exceptions. The following products, among others, are exempted as not being egg products: imitation egg products, dietary foods, dried no-bake custard mixes, eggnog mixes, acidic dressings, noodles, milk and egg dip, cake mixes, French toast, sandwiches containing eggs or egg products, and balut and other similar ethnic delicacies. Products that do not fall under the definition, such as cooked products, are under FDA jurisdiction.
Cheese pizza, onion and mushroom pizza, meat flavored spaghetti sauce (less than 3% red meat), meat flavored spaghetti sauce with mushrooms, (2% meat), pork and	Pepperoni pizza, meat-lovers stuffed crust pizza, meat sauces (3% red meat or more), spaghetti sauce with meat balls, open-faced roast	Chicken sandwich (open face), chicken noodle soup	Homogeneous cheese and meat products, e.g., cheese balls with pepperoni, must contain more than 50 percent meat to be amenable to

beans, sliced egg sandwich (closed-face), frozen fish dinner, rabbit stew, shrimp-flavored instant noodles, venison jerky, buffalo burgers, alligator nuggets, noodle soup chicken flavor	beef sandwich, hot dogs, corn dogs, beef/vegetable pot pie.		USDA inspection. Cheese products that contain 50 percent or less meat are considered products of the dairy food industry and, thus, are exempt from USDA inspection. When cheese and meat are separate components in a package, the packaged product is amenable, provided, it contains 2 percent cooked meat.

Jurisdiction for products produced under the School Lunch Program, for military use, etc. is determined via the same algorithm although the purchases are made under strict specifications so that the burden of compliance falls on the contractor. Compliance Policy Guide 565.100, 567.200 and 567.300 provide additional examples of jurisdiction. IOM 3.2.1 and 2.7.1 provide more information on our interactions with USDA and Detention Authority.

* These percentages are based on the amount of meat or poultry product used in the product at formulation.

HISTORY OF MENU ITEMS

DATE 4/25/03

PLACE Hyatt Hotel, St. Louis, MO

MENU ITEM	SUPPLIER	DATE REC'D	PRE-PARED	ADVANCE PREPARED	LOCATION	STEPS IN PROCESS	TEMP OF	TIMES	EMPLOYEE(S) INVOLVED
Egg Rolls (Appetizer)	Independent Foods St. Louis, MO	4/20	yes		freezer	bake	5º-230ºF	1600-1730	R. Brown
Ravioli (Appetizer)	ITAL-AMER Foods St. Louis, MO	4/21	yes		freezer	deep fry	5º-300ºF	1700 - 1730	B. Black
Cheeses (Appetizer)	Fox Dairy St. Louis, MO	4/24	yes		cooler	slice	40ºF	1350 - 1450	C. White
Pate (Appetizer)	Joe's Butcher Shop E. St. Louis, IL (liver)	4/10		yes 4/10 Chef Welsh	freezer	thaw slice plate	5º-40ºF 40ºF 40ºF	? -1600 1600-1630 1630-1700	K. Green " " " "
Produce (Salad)	Lombardi's St. Louis, MO	4/24			cooler	wash plate cool	55ºF 75ºF 75º-40ºF	0730 0845-0945 0945-1730	B. Black & K. Green
Crown Potatoes	"	"			"	slice bake plate	75ºF 75º-225ºF 200ºF	0900-1030 1030-1200 1700-1730	R. Brown & A. Smith
Prime Rib	Joe's Butcher Shop E. St. Louis, IL	4/24			"	roast slice plate	36º-140ºF 135ºF 130ºF	1500-1800 1800-1830 1930-1900	Chef Welsh C. White Chef Welsh
Wine Chateau St. Juan 2001 2000 Marion Cabernet	Sonoma Valley CA "								

HISTORY OF MENU ITEMS **DATE** **PLACE**

MENU ITEM	SUPPLIER	DATE REC' D	PRE-PARED	ADVANCE PREPARED	LOCATION	STEPS IN PROCESS	TEMP OF	TIMES	EMPLOYEE(S) INVOLVED

U.S. FOOD & DRUG ADMINISTRATION

To: Postmaster

Agency Control Number:
Date:

ADDRESS INFORMATION REQUEST

Please furnish this agency with the new address, if available, for the following individual or verify whether or not the address given below is one at which mail for this individual is currently being delivered. If the following address is a post office box, please furnish the street address as recorded on the boxholder's application form.

Name:
Last Known Address:

I certify that the address information for this individual is required for the performance of this agency's official duties.

(Signature of Agency Official)

(Title)

FOR POST OFFICE USE ONLY

[ ] MAIL IS DELIVERED TO ADDRESS GIVEN
[ ] NOT KNOWN AT ADDRESS GIVEN
[ ] MOVED, LEFT NO FORWARDING ADDRESS
[ ] NO SUCH ADDRESS
[ ] OTHER (SPECIFY):

NEW ADDRESS

BOXHOLDER'S STREET ADDRESS

Agency return address

Postmark/Date Stamp

Under the authority of 39 CFR 265.6(d)(5)(i) and (d)(7)

265.6 Availability of records.

(d) Disclosure of names and addresses of customers. Upon request, the names, and addresses of specifically identified Postal Service customers will be made available only as follows:(5) Exceptions. Except as otherwise provided in these regulations, names, or addresses of Postal Service customers will be furnished only as follows: (i) To a federal, state or local government agency upon prior written certification that the information is required for the performance of its duties. The Postal Service requires government agencies to use the format appearing at the end of this section when requesting the verification of a customer's current address or a customer's new mailing address. If the request lacks any of the required information or a proper signature, the postmaster will return the request to the agency, specifying the deficiency in the space marked 'OTHER'. A copy of PS Form 1093 may be provided.

(7) Address verification. The address of a postal customer will be verified at the request of a Federal, State, or local government agency upon written certification that the information is required for the performance of the agency's duties. "Verification" means advising such an agency whether or not its address for a postal customer is one at which mail for that customer is currently being delivered. "Verification" neither means nor implies knowledge on the part of the Postal Service as to the actual residence of the customer or as to the actual receipt by the customer of mail delivered to that address. The Postal Service requires government agencies to use the format appearing at the end of this section when requesting the verification of a customer's current address or a customer's new mailing address. If the request lacks any of the required information or a proper signature, the postmaster will return the request to the agency, specifying the deficiency in the space marked "OTHER".

INSTRUCTIONS FOR COMPLETING IOM EXHIBIT 3-3

If you have already attempted to locate the individual or firm by sending mail marked on the outside of the envelope "DO NOT FORWARD. ADDRESS CORRECTION REQUESTED", without results, then proceed with this form according to the instructions below.

INSTRUCTIONS

1. Address the request to the Postmaster at the post office of the last known address.
2. Insert FEI # if known; or assignment or sample number for Agency Control number.
3. On the lines provided, give the name and last known address, including zip code, of the individual or firm. Do not include any other identifying information such as race, date of birth, social security number, etc.
4. The Postal Service provides the service of address verification to Government agencies only. For this reason, the Postal Service requires the signature and title of an agency official to certify that the address information requested is required in the performance of the agency's official duties. The agency official should be if possible, the chief of the office requesting the information. In the interests of efficiency, the signature may be preprinted or rubber-stamped.
5. Type or stamp the agency's return mailing address in the space provided at the bottom of the request. Include your full name and title or the appropriate person’s full name and title to whom the form should be returned to. Mail or deliver the request to the Postmaster at the post office of the last known address.

You are not required to submit this request in duplicate or to furnish a return envelope.

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4.1 – General

Collecting samples and conducting inspections (both of which are discussed in Chapter 5) and reviewing imported products at entry (which is discussed in Chapter 6) are the primary ways investigators contribute to ORA's mission of *protecting consumers and enhancing public health by maximizing compliance of FDA-regulated products and minimizing risks associated with those products*.

This chapter will provide further information to support you in those tasks, mainly to assist you in collecting, documenting, and submitting samples for analysis and/or review. While this chapter details the process of collecting samples for many of the situations you are likely to encounter, it is important to note that each sample collection is unique. If you should encounter situations not covered in this chapter and need additional information, consult with your supervisor and, if needed, the relevant servicing laboratory.

4.1.1 – Purpose – Why Do We Collect Samples?

Collecting samples is a critical part of FDA's regulatory activities. We collect samples of FDA-regulated products for a variety of reasons, such as:

1. to gather information about potential safety issues (i.e., surveillance).
2. to document a violation.
3. to support the government's charge that there is a violation of the law.

This chapter contains information on the following topics:

1. the types of samples investigators collect,
2. roles and responsibilities of investigators when collecting samples,
3. procedures for collecting and reporting of samples, and
4. examples of special sampling situations.

4.1.1.1 – What is a valid sample?

A valid sample is the starting point--and keystone--for most regulatory actions. Evidence, as you know, is required to support your observations and reports of violative conditions—and samples of FDA-regulated products can be used as evidence. However, to be used as evidence, the sample must support the government's charge that there is a violation of the law. It must also conform to the rules on admissibility of evidence, such as demonstrable chain of custody.

In general, a properly collected and prepared sample (in other words, a *valid* sample) contains or is accompanied by the following:

1. A portion of the lot[1] of goods for laboratory analysis and a 702(b)[2] reserve portion of the goods, if appropriate, and/or documentation demonstrating the violation represented by the lot.
2. A report of your observations of the lot.

[1] A lot generally means a specific quantity of a finished product or other material that is intended to have uniform character and quality, within specified limits, and is produced according to a single manufacturing order during the same cycle of manufacture.

[2] Section 702(b) of the FD&C Act [21 USC 372(b)] requires the FDA to furnish, upon request, a portion of an official sample for examination or analysis to any person named on the label of an article, the owner thereof, or his attorney or agent.

3. Labels and labeling, or copies of such, which "accompany" the goods.
4. Documentary evidence of federal jurisdiction over the lot, including where the violation was committed; information about individuals responsible for the violation; and similar information.
5. Signed statement (affidavit) from individuals who may be called upon as witnesses should there be a subsequent court action.

While inspections and investigations may precede sample collection, under the law, a *valid* sample must ultimately be obtained for judicial cases to proceed.

4.1.1.2 – What are your responsibilities when collecting a valid sample?

Proper sample collection is the keystone of effective enforcement action. Approach every sample you collect with diligence and thoroughness, and the mindset that you may be asked to testify in court regarding all details associated with the sample, including the actions you took while collecting it. Take regulatory notes regarding your sample collection that will provide sufficient detail to refresh your memory at a later date (see IOM 2.1 for additional information on regulatory notes). Be objective, factual, accurate, and thorough. Mistakes or deficiencies, however trivial they may seem, can damage the government's case.

Sample numbers are obtained using the FDA sample reporting systems. For samples that are not in import status, you are responsible for obtaining sample numbers in the Field Accomplishments and Compliance Tracking System (FACTS) in advance of collecting a sample and completing the Collection Report (C/R) in FACTS. For samples collected while products are in import status, sample numbers are obtained when Import C/Rs are completed in FDA Import Systems (OASIS/SERIO).

You are responsible for timely completion of the Collection Report after collecting the sample (See IOM 4.6.2 for minimum information to be entered into FACTS).

4.1.1.3 – Personal Safety while Collecting Samples

It is important to note that, while sampling, you may encounter situations that could have safety and personal protective equipment (PPE) considerations. Hazards and/or dangers associated with sampling could include, but are not limited to:



1. Dusts
2. Explosion hazards
3. Confined spaces
4. Farms and poultry houses
5. Altered atmospheres and environments
6. Biological hazards (e.g., Hantavirus, BSE, parasites, fungus)
7. Chemical hazards
8. Physical and radiation hazards
9. Ergonomic hazards

The IOM Safety Chapter (IOM Chapter S) contains basic information to help you anticipate, recognize, evaluate, and apply control strategies to eliminate or minimize hazardous conditions and unsafe practices you may encounter.

Due to the variability of potential safety situations during sampling, it is not feasible to describe what to do in each instance. The decision of what to do in each individual circumstance rests with you, your Industrial Hygienist liaison, and your program division management.

When you are unsure about the best and safest way to collect a sample, talk to your supervisor.

4.1.2 – Authority to Collect Samples

IOM section 2.2.2 outlines FDA's authority to collect samples and provides references to relevant sections of the Food Drug and Cosmetic Act (FD&C Act). Understanding the statutory authority can assist you in your daily work, including when faced with a refusal to permit a sample collection, for example. You can find detailed information about the statutory and regulatory frameworks underpinning our FDA sampling authority in chapter 2 of the IOM.

Section 801 of the FD&C Act [21 U.S.C. 381] gives the FDA the authority to collect samples of FDA-regulated products which are being imported or offered for import into the United States (see IOM 6.1 for more information on FDA's import operations and import authority).

4.1.3 – Responsible Parties

There are many types of individuals that can be responsible for assuring FDA-regulated products are neither adulterated nor misbranded. You should be familiar with the following definitions. It is important to properly identify these parties when you collect a sample so that the appropriate action can be taken if a sample is violative.

4.1.3.1 – Dealer

Dealer means the person[3] who has possession of the FDA-regulated product at the time the sample is collected. Note that the dealer may not necessarily be the owner of the goods, but the one in possession of them at time of sample collection, such as a third-party logistics company. In addition, the dealer may or may not be the party responsible for the violation (i.e., responsible party).

For example, in the case of a "301(k) sample," the responsible party will always be the dealer. Under Section 301(k) of the FD&C Act [21 U.S.C. 331(k)] it is prohibited to alter, mutilate, destroy, obliterate, or remove the whole or any part of the labeling of, or the do any other act with respect to FDA-regulated products, if such act is done while held for sale (whether or not the first sale) after shipments in interstate commerce and results in such article being adulterated or misbranded. IOM 4.1.4.2.2 provides additional information on 301(k) samples.

If the person you are collecting samples from may be subject to FDA regulatory action, given a likely or known violative condition of a lot, you should issue them a Form FDA 482 before collecting samples. See IOM 4.1.2. If in doubt about the need to issue a Form FDA 482, it's better to err on the side of caution and proceed with issuing the form. If there is no EIR, attach a copy of the FDA 482 to the collection report (C/R). See IOM 4.6.4

4.1.3.2 – Manufacturer

Manufacturer means the person that makes the FDA-regulated product. If you collect a sample from the manufacturer, then the dealer and manufacturer are the same.

Determining if the manufacturer is the party responsible for the violation will depend on several factors and, in most situations, will require further investigation. For example, if you collect a sample of animal food at a farm where a customer experienced death of their animals and that sample is confirmed to be adulterated, then an investigation to determine where, and at what stage, the adulteration occurred should be conducted. If the adulteration is determined to be caused by the animal food manufacturer, then the manufacturer committed a prohibited act as the introduction or delivery for introduction into interstate commerce of any food that is adulterated or misbranded is prohibited under Section 301(a) of the FD&C Act [21 U.S.C. 331(a)].

[3] Section 201(e) of the FD&C Act [21 U.S.C. 321(e)] defines the term *person* as an individual, partnership, corporation, or association. Throughout this chapter this definition is used.

4.1.3.3 – Shipper

Shipper means a person (e.g., the manufacturer or a freight broker) who arranges for the transportation of food or other commodity in the United States by a carrier or multiple carriers sequentially.

4.1.3.4 – Carrier

Carrier means a person (e.g., owner-operator, partnership, corporation) who physically moves a product by rail or motor vehicle in commerce within the United States. The term carrier does not include any person who is transporting product while operating as a parcel delivery service.

4.1.4 – Official Samples

Title 21, Code of Federal Regulations, Part 2.10 (21 CFR 2.10) describes the criteria required for a sample of FDA-regulated product to be considered an *official sample*. A sample is an *official sample* if records (see IOM 4.4.4) or other evidence obtained show that the shipment, or other lot of the article from which the sample was collected, was:

1. Introduced or delivered for introduction in interstate commerce, or
2. Was in or was received in interstate commerce, or
3. Was manufactured in a Territory or the District of Columbia.

Section 201(a)(2) of the FD&C Act [21 U.S.C. 321 (a)(1)] defines the term *Territory* as any Territory or possession of the United States, including the District of Columbia, and excluding the Commonwealth of Puerto Rico and the Canal Zone.

A sample of a device, tobacco product, counterfeit drug, or any object associated with drug counterfeiting, no matter where it is collected, is also an *official sample*. Section 304(a)(2) of the FD&C Act [21 U.S.C. 334(a)(2)] permits proceeding against these articles, when violative, at any time.

Import samples are official samples and require you handle them with the same care and diligence as domestic official samples (see IOM 6.4).

Official samples can be either *physical* or *documentary* (the latter referred to as DOC samples). The only difference between a physical official sample and a DOC official sample is that the physical article is not collected for a DOC sample since DOC samples consist only of records. Both physical and DOC samples are official samples if they meet the description in 21 CFR 2.10. Details about collecting these samples are provided in IOM 4.1.4.2, for physical samples, and 4.1.4.1, for DOC samples.

Every sample collection is unique. Whether you are collecting a physical sample or a DOC sample, one thing that remains consistent is that both types of official samples (i.e., physical and DOC) need to be representative of a lot for which federal jurisdiction can be established. If violative, the official sample will serve as a basis for enforcement action.

The FDA has various enforcement tools that can generally be divided into the following categories: advisory actions and other notices of violations; administrative actions; and judicial actions (see IOM Chapter 2 for more information about FDA's regulatory tools). While a *valid* sample is typically the starting point, and keystone, for most regulatory actions, there are different requirements for collection of an official sample, depending on the FDA's intended enforcement action. Advisory actions (IOM 2.4) and administrative actions (IOM 2.5), which do not involve the judicial system, do not require the collection of an official sample (physical or DOC). However, the requirements to collect official samples may vary depending on your assignment, program, and/or division. If you are recommending an advisory action, consult with your supervisor to determine if an official sample is required. DOC samples, which include the collection of records demonstrating interstate commerce, are required for judicial actions, such as seizure and injunction.

For the FDA to initiate a legal action, interstate jurisdiction must be established. Most often, this is done by documenting interstate movement of a product by copying records ("getting the records") of a shipment represented by an official sample. There are products and situations where interstate commerce is not required to act against a violative product (for example, in cases involving counterfeit drugs, medical devices, oleomargarine/colored margarine, or products manufactured in a territory of the United States). If you encounter these situations, discuss the need for collecting interstate commerce records with your supervisor, or follow established procedures within your division or program regarding the collection of interstate commerce records.

The type of interstate records (transportation records, freight bill, waybill, bills of lading. etc.) to be collected are outlined in IOM 4.4.4. Note that the evidence required to demonstrate interstate commerce, and the types of records needed to establish it, depends upon the violation and the type of judicial action proposed.

To meet the criteria of a *valid* sample, the official sample must meet all of the following conditions:

Accompanied by records that establish both the federal jurisdiction and the identity of the individual(s) having knowledge of the lot's movement and custody of its records [see IOM 4.4.4]. (Evidence of interstate movement is not required for medical device samples but, according to policy, is to be obtained when a seizure, injunction, prosecution, or civil penalty is contemplated).

Representative of the lot from which it was collected.

If a physical sample, large enough to permit proper laboratory examination and provide a 702(b) reserve portion when necessary. (See IOM 4.3.2.2 for more information on collecting 702(b) portion.)

Handled, identified, and sealed in such a manner as to maintain its integrity as evidence, with a clear record of its chain of custody.

Every official sample (physical or DOC) will be fully documented at the time of collection (that is, recorded in your regulatory notes) and a collection report prepared, unless instructed otherwise by the program or assignment.

4.1.4.1 – Documentary Samples (DOC Samples)

4.1.4.1.1 – What is a documentary official sample (DOC sample)?

A DOC sample is not a sample of records. It is a sample representing a lot of a regulated article (e.g., food, drug, biologic, or device). Other elements of an official sample described in IOM 4.1.4 are required and apply except DOC samples are not officially sealed. DOC samples consist of the article's labels (photocopies or photos), accompanying labeling (e.g., leaflets, brochures, promotional materials, including internet websites) and documentation of interstate movement (e.g., freight bills, bills of lading, affidavits; see IOM 4.4.4). Refer to Section 201 of the FD&C Act [21 U.S.C. 321] for the definition of labels (201(k)) and labeling (201(m)). Typically, your DOC sample would also include additional documents (i.e., supporting evidence), such as photos of the product, drawings, sketches or schematics, production records, diagrams, invoices, or similar items. (See IOM Exhibits 4-1 and 4-2.) These additional records typically demonstrate the violation you are documenting. For example, production records for a specific lot may show a violation of GxPs[4]. A physical sample is not required, because under GxPs FDA does not need to show the product fails to meet a specification. Failure to meet GxPs renders the product adulterated. In the cases of misbranding, the labels or labeling may be all that is required to demonstrate the violation.

Because no product is collected, a Form FDA 484, Receipt for Samples, is not issued for DOC samples.

[4] GxP is a term which includes all practices related to manufacturing FDA products, e.g., good manufacturing practices, good clinical practices, good laboratory practices, etc.

See IOM 4.7.2.5 and speak to your supervisor about any division or program specific guidance on identifying records associated with a DOC sample. Do not officially seal these records. List all records on the collection report (C/R). Use a continuation sheet (FDA 464a) if necessary. If any photos are taken as part of the DOC sample, the electronic media must be officially sealed per IOM 5.6.7.5. Attach the documents and photos along with any other records associated with the sample to the printed C/R. See IOM 4.6.4.

When the anticipated action is not judicial, records of interstate commerce and documentation of violations may be collected and added to the EIR in lieu of a DOC sample. If you are unsure if you should collect a DOC sample or document interstate commerce in your EIR, consult your supervisor.

4.1.4.1.2 - When Should You Collect a DOC Sample instead of an Actual Physical Sample of the Product?

A DOC sample is collected when an actual physical sample is not practical. For example, in instances in which the article is:

1. very large or complex,
2. fixed, as in the case of a permanently installed device,
3. too expensive/cost prohibitive to sample,
4. no longer available,
5. there is no need for laboratory examination,
6. must remain in place due to on-site emergency purposes, like a single piece of life support equipment which must remain in emergency service until a replacement is available.
7. going to be recommended for seizure based on misbranding charges. For instance, if during availability check, the lot sampled is found to have been distributed, but a new shipment, identically labeled, is on hand, then the new shipment may be sampled on a DOC basis since another physical sample and examination is not required. In this case, regulatory action may proceed based on the earlier examination, and thus, only labeling, transportation records, the appropriate dealer affidavits, and an inventory of product on hand need to be obtained.

A variation of this procedure involves collecting one or more units and removing (stripping) the original labels/labeling from the product container. It is frequently easier and quicker to collect relatively inexpensive units for field stripping than it is to photocopy or photograph all accompanying labels. In these cases, the sample is handled in the same manner as any other DOC sample, once the original labeling has been removed and the remainder of the sample destroyed. You will want to provide a prominent explanation on the collection report to alert reviewers that the original units collected were destroyed after the original labeling was removed. Note, however, that this field-stripping procedure is not appropriate in instances in which complete, intact, and labeled units are desired for exhibit purposes, even though there is no intention of analyzing the units obtained.

A DOC sample collected to document deviations of GxPs should contain records that adequately document the deviations encountered. You should explain what is being documented in the remarks section of the C/R of the documents obtained. Fully describe any record collected as part of the DOC sample, and wherever possible, indicate the page of the document that demonstrates the deviation.

Documentary (DOC) samples are not required to support advisory actions such as untitled or warning letters and regulatory meetings. However, records of interstate commerce should always be collected and incorporated into the establishment inspection report (EIR) to document FDA jurisdiction over any products suspected to be in violation. An affidavit (see IOM 4.4.5) identifying the product(s) of concern, labels/labeling, invoices, statements regarding interstate commerce, and key evidence of violations should be prepared for

signature by the appropriate party and attached to the EIR in support of advisory actions. DOC samples should always be prepared in situations in which further FDA judicial and/or administrative action is anticipated such as seizure, injunction, warrants, administrative detention, suspension of registration, mandatory recall, and prosecutions. Investigators in training may still be required to prepare documentary samples as directed by their supervisor.

4.1.4.2 – Physical Samples

Refer to IOM 4.1.4.2.1 – 4.1.4.2.11 for some examples of situations warranting collection of physical official samples and how you should proceed in collecting them.

4.1.4.2.1 – In-transit sample

In-transit samples are those collected from lots being transported in vehicles or held on loading/receiving docks of steamships, truck lines, or other common carriers. A lot is considered to be in-transit if it meets any of the following characteristics:

1. A bill of lading (BOL) or other order to ship the lot interstate has been issued; or
2. The owner/shipper or agent acknowledges, preferably by signed affidavit, that they ordered the lot to be shipped interstate; or
3. The owner or operator of the common carrier acknowledges, preferably by signed affidavit, that they have an order from the shipper to move the lot interstate.

Refer to IOM 4.2.4, 4.2.5.1, and 4.3.3 for special considerations when collecting an in-transit sample.

4.1.4.2.2 – 301(k) sample

A 301(k) sample is typically defined as a sample collected from a lot of food, drugs, devices, tobacco products, or cosmetics that has become adulterated or misbranded while being held for sale, regardless of whether or not its first sale, after shipment in interstate commerce. See Section 301(k) of the FD&C Act [21 U.S.C. 331(k)] for complete language surrounding this prohibited act. The term *301(k) sample* is shorthand to describe certain samples collected from lots that become violative after shipment in interstate commerce.

Since some act took place that resulted in the adulteration or misbranding of a previously non-violative product after shipment in interstate commerce, it is necessary in any *301(k)* documentation that you:

1. Identify the act causing or leading to the adulteration or misbranding,
2. Establish when and how this act occurred, and
3. Identify the individual(s) responsible for causing the violation.

This last feature, more than any other, distinguishes a *301(k) sample* from other physical official sample types. When you report the sample collection, the responsible party will always be the dealer. See IOM Exhibits 4-1 and 4-7.

Consider the following example of a 301(k) sample and steps taken to establish it: To document *Listeria monocytogenes* adulteration, for instance, of a ready-to-eat food caused by contamination of a raw material at the finished product manufacturer, you would need to document receipt of an unadulterated, raw material as well as the subsequent adulteration caused by the firm's handling or processing of the raw material during the manufacturing of the ready-to-eat food. As such, you would need to show that there was *L. monocytogenes* at the manufacturer that either did, or may have, contaminated the ready-to-eat finished product. To establish a violation of 301(k), you would also need to demonstrate that the raw material was not adulterated *prior* to receipt at the manufacturer. Towards this end, you would collect an official sample of the unadulterated raw material. (You would also typically collect an investigational sample consisting of environmental swabs from

the processing areas and/or equipment for analysis of *L. monocytogenes* to attempt to determine the location in which the unadulterated, raw material was contaminated.) The interstate commerce is demonstrated for the sample, not through the product manufactured at the location, but the incoming product that was not adulterated.

301(k) samples can also be used to document adulteration (including noncompliance with GxPs) or misbranding of other regulated commodities, including medical devices, drugs, and biologics. Note the following guidance associated with 301(k) samples and various commodities. For example, when collecting a 301(k) sample associated with a drug product, you should attempt to document 'adulteration' or 'misbranding' of the active ingredient by the firm's actions. There may be cases where the active ingredient was not received in interstate commerce. In these instances, you would instead document the container or another ingredient that was received in interstate commerce. In cases involving biologics, for example, a DOC sample may be collected of a container or bag used for collection of whole blood, because the product (whole blood) was collected at the donor site being inspected. Since the whole blood is collected onsite, there is no interstate commerce for it. However, the firm subsequently may have adulterated or misbranded the anti-coagulant (a drug) in the blood bag.

And when collecting a 301(k) sample for medical devices from a finished device manufacturer, you should collect and document all of the following:

1. Interstate shipment records for receipt of a component.
2. The manufacturing records showing inclusion of the component in the finished device.
3. Records showing the finished device was held for sale or distributed, regardless of whether or not in interstate commerce.
4. Labels, labeling for the finished device.

Your observations and documentation should demonstrate the firm’s actions adulterating (e.g., GMP issues) or misbranding (e.g., labeling) the finished device that was distributed in relation to the associated component.

4.1.4.2.3 – Post-Seizure (PS) sample

A lot under seizure is in the custody of the U.S. Marshals Service. If either the claimant or the government desires a sample from the seized lot, it may be collected only by court order. In most cases, the order will specify how the sample is to be collected and may provide for each party to collect samples. If the order was obtained by the claimant, permit the claimant's representative to determine how to collect the sample. If the method of collection is improper, you may make constructive suggestions, but do not but do not challenge or interfere with the method that is chosen. You should, however, report exactly how the sample was drawn. Unless the claimant objects, mark subsamples collected with the notation, “PS", your initials, and the date. PS samples are official samples. Do not pay for post-seizure samples, or any samples collected of a lot reconditioned under a Consent Decree. See IOM 4.2.8.1.

4.1.4.2.4 – Import sample

Import samples are physical samples of products that originate from another country, collected while the goods are in import status. Import status ends when U.S. Customs and Border Protection (CBP) releases the article from the import database system. (See IOM Chapter 6.)

4.1.4.2.4.1 – Special Domestic Import Sample (SDI)

SDIs are import samples collected from lines that are released from import status immediately after collection and before sample analysis is complete. This sample type is used primarily for the collection of perishable products and special sampling assignments. This sample type may also be used for other designated sampling situations as directed. (See IOM chapter 6.4.9.)

4.1.4.2.4.2 – Mail Entry sample

A mail entry sample is a sample of an imported product that enters the United States through the U.S. Mail.

4.1.4.2.5 – Domestic import sample (DI)

DI samples are official samples of foreign products that have passed through customs and are now in domestic commerce. The FDA may have previously taken a sample of the product while in import status, or the product may have been permitted entry without being sampled. If sampled while still in import status, the samples collected are import samples, and not DI samples. However, once the product leaves import status and enters domestic commerce, any sample collected from it is then considered an official DI sample.

When collecting DI samples, especially if a violation is suspected, attempt to determine the port of entry and the importer of record (the party in whose name the entry is made, see IOM 6.9.43). Report this information on the C/R, where you should include the name of the country of origin of the product and the country code, if known.

A sample is classified as DI, if any of the following situations apply:

1. The label declares the product to be from a foreign country,
2. The label bears the word, *imported*,
3. Records obtained or reviewed reveal the product originated in a foreign country,
4. It is known that the product is not grown or produced in the United States; is packed as a single item with few, or no other ingredients added; and is not manipulated in any major manner that would otherwise change the product or its composition. For example, olive oil imported in bulk and merely repacked with no added ingredients and no manipulation would be a DI sample; while pepper, which is processed, ground, and packed after entry would not. However, retail packages of ground pepper processed and packaged in a foreign country would be DI samples
5. Samples of imported raw materials, which are collected before further processing or mixed with other ingredients.
6. DI samples are significantly different from other official samples in another important respect. Unlike domestic products, for which considerable information is readily available on manufacturing and distribution channels, it is frequently difficult to identify the responsible parties for products of foreign origin once they enter domestic commerce. The most practical way to achieve this is to establish a paper trail of records going back as far as possible in the distribution chain to the actual entry.
7. Preface the sample number with the prefix “DI” in the same manner that other sample type prefixes are used (e.g., "DOC", “INV”, "PS") on:
    - The physical product (sample),
    - Related documents
    - Official Seals

4.1.4.2.6 – Additional Sample

This is a physical sample collected from a previously sampled lot of either a domestic or imported product. Note the following sample numbering approaches:

1. In instances of additional import samples, the sample collected must have the same sample number as the original sample collected.
2. In instances of additional domestic samples, the sample collected will have a different sample number, but it must be flagged as an Additional sample and the original sample number referenced in the *Related Sample* block on the C/R.

4.1.4.2.7 – Reconditioning sample

Reconditioning samples are taken from lots that have been reconditioned under a consent decree, or other agreement, to bring the lots into compliance with the law. The sample is taken to determine if the reconditioning was satisfactorily performed. These samples should be submitted as official samples.

4.1.4.2.8 – Audit/Certification sample

A sample collected to verify analytical results provided by a certificate of analysis or private laboratory analysis that purports to show a product complies with the FD&C Act and/or regulations. This sample type is typically used with import samples. See IOM 4.1.4.2.4.

The ORA Lab Manual, Volume 3, Section 7 provides specific guidance on FDA audit samples. FDA audit samples provide an opportunity for investigators to examine privately sampled, regulated commodities for conformance with an associated, submitted private lab package. Prior to collecting the FDA audit sample, you should carefully examine the associated lot for comparison to the private lab package evidence (i.e., photographs and documentation). Examples of items to note during such examination and comparison to the private lab's packet include:

1. Evidence of marked containers distributed throughout the lot, indicative of a representative sample.
2. Marked cases that are consistent with the submitted lab package.
3. Quantity removed for sampling is consistent with the lab package.

Careful attention should also be paid to any indication that the containers selected for sampling by the private sample collector have been staged for sampling. Staging is relected through markings, deliberate damage to labeling, and placement within the pallets, for example.

If you find evidence that a non-conforming private sample was collected, it is important that you immediately terminate audit activities/sampling and report the adverse findings to appropriate compliance staff for evaluation. The agency will then make decisions on a lot-by-lot, case-by-case basis regarding the entries and/or sampled products submitted for importation.

Note, too, that audit samples should be recorded under the same PAC codes as surveillance samples and can apply towards the completion of applicable work plan and/or performance goals.

4.1.4.2.9 – Induced Samples

An induced sample is an official sampled ordered or obtained in response to some type of advertisement or promotional activity. The sample is procured by mail, telephone, online order, or other means, without disclosing any association of the requester or the transaction to the FDA. See IOM 4.3.4.2 for additional information.

4.1.4.2.10 – Undercover Samples (Commonly Known As Undercover Buys)

An undercover sample (or undercover buy) is an official sample, obtained in much the same manner as an induced sample. Undercover buys may be made at the point of sale, or via a purchase completed online, by email, text, or by phone. Explanations and/or cover stories, developed ahead of time, are necessary to dispel any suspicions about the requester that may surface in face-to-face, phone, or email discussions. Undercover

buys are frequently used in investigations of health fraud or complaints of illegal activity, in which the information cannot be substantiated or refuted through more conventional means.

Undercover buys may be used to augment an existing investigation or inspection effort and may be performed to document violations in firms with a history or pattern of noncompliance. See IOM 4.3.4.2 for additional information on how to collect induced samples, a type of undercover buy. Your supervisor or the assignment will provide specific instructions and procedures to be followed when collecting an undercover sample. For example, you may induce the sample by telephone or online. You may need a "cover story" if collecting multiple containers of the product. If collecting an undercover sample as part of a special assignment, you will rely on instructions provided in the assignment. Note, too, that your division or program may also have specific procedures to follow when conducting an undercover buy.

4.1.4.2.11 – Online Samples

An online sample is an official sample purchased online, versus being collected at a physical location. Samples may be collected online as induced or undercover buys, but in both cases, the FDA should *not* be identified as the purchaser of the product. Routine samples may also be purchased online as directed by your supervisor or by assignment.

Interstate commerce is still documented for these samples. Interstate commerce evidence can be obtained by documenting the location from which the sample is shipped and the method of its delivery (e.g., UPS, USPS, or FedEx). These online samples may be collected and paid for using dedicated and unidentifiable equipment (i.e., FDA laptop, FDA cell phone, and FDA credit card). Your supervisor and/or the specific assignment will provide instructions and procedures to be followed when collecting an online sample. See IOM 4.1.4.2.9, 4.1.4.2.10, and 4.3.4.2 for additional information.

4.1.5 – Investigational Samples (INV)

Investigational (INV) samples are *not* official samples. They are collected to document observations, support regulatory actions, and/or provide other information. As such, they do need to be collected from lots in interstate commerce or under federal jurisdiction. The sample itself does not need to be from a product regulated by the FDA. Because these samples can be used as evidence in court, they must be sealed, and their integrity and chain of custody protected. Examples of INV samples include:

1. Samples flagged as factory food samples or in-line samples. These samples may consist of raw materials, in-process, and unpackaged finished products that demonstrate manufacturing conditions. See IOM 4.3.6.6.3.
2. Samples associated with exhibits. These may be filth exhibits and other articles taken for exhibit purposes during inspections to demonstrate manufacturing conditions, storage conditions, employee practices, or other conditions. Typically, filth exhibits submitted as part of an INV sample are not tied to any specific lot of product but are meant to illustrate the conditions at a firm. For example, samples flagged as INV Samples of filth exhibits frequently consist of apparent rodent excreta pellets, apparent nesting material, apparent rodent-gnawed material, and other evidence of rodent activity. Multiple sub-samples collected along the entire perimeter of a room in a manufacturing facility, food storage area, or warehouse may be used to demonstrate a rodent infestation. See IOM 4.6.2.7.7.
3. Environmental samples – See IOM 4.3.6.6.1.
4. Certain complaint samples: These are injury and illness investigation samples from certain complaints in which there is no federal jurisdiction, or the alleged violation offers no basis for subsequent regulatory action.

Contrastly, complaint samples from lots for which federal jurisdiction *is* clear should be submitted as official samples. See IOM 4.1.7

When identifying the sample/subsamples and documents related to the sample, and filling out seals, preface the sample number with "INV" in the same manner as other sample prefix types are used (e.g., "DOC", "DI").

Note: Photographs taken to document conditions observed, or subsamples collected, are included as *exhibits* to establishment inspection reports. Photographs taken of labeling and records (e.g., bill of lading (BOL), invoice, and manufacturing records) that are associated with sample collections are included as *attachments* to collection reports. See IOM 4.7.2.4, 5.6.5 and 5.6.7

4.1.6 – Survey Samples

Survey samples are part of the FDA's proactive sampling, conducted on a surveillance basis to gather data or other information on FDA-regulated products. Survey samples are not official samples. Samples collected under the Drug Quality Sampling and Testing (DQST) program are examples of survey samples. Concerning interstate records for DQST refer to CP 7356.008.

4.1.7 – Non-Regulatory Sample

Non-regulatory samples are those collected and analyzed by the FDA for other federal, state, or local agencies of products over which the FDA has no jurisdiction.

4.2 – Dealer Interactions

Maintaining a positive professional interaction with the dealer helps to facilitate the sample collection.

4.2.1 – Dealer Definition and Good Will

For sample collection purposes, the dealer is the person who has possession of a particular lot of goods. The dealer does not have to be a firm or company in the business of buying or selling goods. It may be a private individual, a physician, or a public agency—individuals or parties who obtain products to use, but not to sell. The dealer may also be a party who does not own the goods, but has possession of them, such as a public storage warehouse or transportation agency.

Establishing good rapport with the dealer is important to the success of your objective. All dealers, including hostile ones, should be approached in a friendly manner, and treated with fairness, honesty, courtesy, and consideration. A dealer may be called as a government witness in a court case, and a favorable attitude on their part is to be sought. Never use strong-arm tactics or deception, but rather be professional and demonstrate diplomacy, tact, and persuasion. Do not make unreasonable demands.

Consider the following suggestions to promote positive exchanges with dealers:

1. Introduce yourself to the dealer by name, title, and organization.
2. Present your credentials for examination, and, if appropriate, issue an FDA 482, Notice of Inspection. See 5.1.4.2.1 and 5.5.1.
3. Explain the purpose of your visit. Be prepared to answer the dealer's questions and attempt to relieve any apprehensions while at the same time being careful not to reveal any confidential information.
4. Do not disparage the product, its manufacturer, or shipper.

5. Do not reveal the suspected violation unless the dealer is responsible, or unless you ask him/her to voluntarily hold the goods. The very fact we are collecting a sample is often reason enough to arouse the dealer's suspicions about the legality of the product.

6. In the instance that an FDA 482 is not necessary for collecting a sample, but the dealer requests one anyway, go ahead and issue the requested FDA 482. Attach a copy to the C/R. See IOM 4.6.4.

4.2.2 – Dealer Objection to Sampling Procedure

If the dealer objects to your proposed sampling technique, attempt to reach a reasonable compromise on a method that will provide a satisfactory, though perhaps not ideal, sample. Assure the dealer that you will make every effort to restore the lot to its original state, that you are prepared to purchase a whole unit to avoid leaving broken cases, and that the agency will reimburse them for additional labor costs incurred as a result of sampling. See IOM 4.2.8. If a reasonable compromise cannot be reached, proceed as a refusal to permit sampling.

4.2.3 – Refusal to Permit Sampling

Challenges to FDA authority while collecting samples may be encountered by a dealer who, for various reasons, including both personal and professional ones, opposes the activities of the agency, or of governmental units in general.

Refusals to permit sample collection commonly emerge unless you can identify a section of the law which specifically authorizes it. The suggested approach for dealing with these individuals is to use patient, tactful persuasion, pointing out that the sample is a part of the investigations authorized in Section 702 of the FD&C Act [21 U.S.C. 372]. If you have not already done so, issue an FDA 482, Notice of Inspection, (except in the case of foreign inspections – see IOM 5.1.4.2.3) as soon as it becomes apparent the dealer will continue to object.

Point out and discuss the authorities provided by in the following FD&C Act sections: 702(a), 702(b) [21 U.S.C. 372(a) and (b)] and 704(a), 704(c), 704(d) [21 U.S.C. 374(a), (c), and (d)] and the precedent case mentioned in IOM 2.2.1. If refusal persists, point out the criminal prohibitions of Section 301(f) of the FD&C Act [21 U.S.C. 331(f)].

If samples are still refused, leave the premises, and contact your supervisor immediately. Refer to IOM 5.1.4.2.3 and Compliance Policy Guide manual section 130.100 for further discussions on resolving the impasse.

If an FDA 482 has been issued prior to a sample refusal situation, the copy of the FDA 482 is to accompany the EIR, or a memorandum outlining the facts of the refusal if no EIR is prepared. If you are on a foreign inspection in which an FDA 482 is not issued, reference relevant Compliance Programs and Chapter 3 of the Guide to International Inspections and Travel Manual for reporting guidance.

4.2.3.1 – Limiting or Preventing Collection of Samples of a Drug

Preventing an authorized representative of the FDA from collecting drug samples may be considered as limiting the inspection. If you have appropriately issued an FDA 482, Notice of Inspection, and the dealer impedes your ability to collect samples, point out and discuss the authority provided by Section 501(j) of the FD&C Act [21 U.S.C. 351(j)] under Section 707 of the Food and Drug Administration Safety and Innovation Act (FDASIA), that potentially deems all drugs manufactured at the facility adulterated in the case of limiting an inspection. In situations where you have begun an inspection, but no FDA 482 is issued (e.g., foreign inspections), document this fact and the limiting activities in your notes based on the authority described above.

If refusal persists, point out that adulteration under Section 501(j) of the FD&C Act [21 U.S.C. 351(j)] could lead to further prohibited acts under Section 301(a), (b), and (c) [21 U.S.C. 331(a), (b), (c)].

Also see IOM 2.2.1.4.

4.2.4 – Carrier In-Transit Sampling

Caution: First see IOM 4.3.3 for conditions that must be met before collecting in-transit samples from common carriers.

When collecting samples from in-transit lots in possession of a commercial carrier, issue the carrier or the carrier's agent an FDA 482. Attach a copy to the copy of the C/R. See IOM 4.6.4.

4.2.5 – Receipt for Samples

When you collect a sample after issuing an FDA 482, Notice of Inspection, always issue the appropriate sample receipt FDA 472, Carriers Receipt for Samples, or FDA 484, Receipt for Samples. The receipt is to be issued to the owner, operator, or agent-in-charge, upon completion of the inspection, but prior to leaving the premises.

Always issue an FDA 484 for samples of prescription drugs, including narcotics and controlled substances. See IOM 4.2.5.3, 4.2.5.4, and 5.1.4.2.3.

Note: There are several situations in which you should not issue an FDA 482 and FDA 484. For example, an FDA 482 or FDA 484 should normally not be issued for induced, undercover, or online samples. In addition, check with your division/program policy on issuing an FDA 482 and FDA 484 while collecting surveillance samples at retail establishments (e.g., grocery store, big-box retail store).

4.2.5.1 – Carriers/In-Transit Lots

See an example FDA 472, Carrier's Receipt for Sample, under IOM Exhibit 4-4. Give the original receipt to the carrier or the carrier's agent. See ORA SOP-000530, Sample Obligation and Processing concerning payment for samples for routing of FDA 472.

4.2.5.2 – Dealer Requests Receipt

When collecting physical samples of regulated products not in connection with an establishment inspection (EI) or in instances where no FDA 482 has been issued, do not routinely issue an FDA 484, Receipt for Samples, except for prescription drugs, narcotics, and/or controlled substances. See IOM 4.2.5.3 and 4.2.5.4. If any dealer specifically asks for a receipt, prepare, and issue an FDA 484, and route a copy with records associated with the C/R. See IOM 4.6.4.

4.2.5.3 – Narcotic and Controlled Rx Drugs

Regulations of the Drug Enforcement Administration (DEA) impose strict controls and comprehensive record-keeping requirements on persons handling narcotics and controlled substances. As a result, an FDA 484 must be issued for all samples of such drugs collected by the FDA.

Each dealer in narcotic and controlled drugs is assigned its own unique DEA registration number. Any time you collect a sample of a narcotic or controlled drug, be sure the dealer's DEA registration number is entered in the appropriate block of the FDA 484. Be sure to double check the number for accuracy, as an error on your part may result in possible investigation for drug shortages.

When samples of narcotic or controlled drugs are collected, the complete DEA registration number must be entered under the FIRMS DEA NUMBER block on the FDA 484, and the Receipt for Samples given to the person from whom the samples were collected.

When completing the FDA 484 for samples of narcotic or controlled drugs includes the trade and chemical name; strength of drug; sample size; container size; lot, batch, or control number; manufacturer's name and address;

division address and the sample number. See IOM 4.6.4. Use of the FDA 484 as a Receipt for Samples of these drugs has the approval of DEA. (See reverse of FDA 484).

4.2.5.4 – Prescription Drugs (Non-Controlled)

Issue an FDA 484, Receipt for Samples, when samples of prescription drugs are collected from dealers, individuals, or during inspections. Attach a copy of the FDA 484 to the C/R. See IOM 4.6.4.

4.2.5.5 – Preparation of FDA 484

Exhibit 4-5 provides instructions for completing the FDA 484, Receipt for Samples, and an example of a completed FDA 484.

4.2.5.6 – Routing of FDA 484

The signed original Receipt for Samples (FDA 484) should be given to the firm, preferably to the individual you gave the FDA 482 and FDA 483 (as applicable). See IOM 4.2.5.3 regarding receipts for narcotics and controlled drug samples.

Copies of the FDA 484 should be attached to the C/R and to the establishment inspection report (EIR) if the sample was collected during an inspection.

An FDA 484 attached to the C/R can be used to avoid repetition of the descriptions of the subsamples when numerous subsamples are collected. If you use an FDA 484 for this purpose, be sure the numbers you assign to the physical subsamples match those on the FDA 484, and that the sub-descriptions are adequately described. See IOM Exhibit 4-5. If errors are noted after issuance, handle the same way as instructed per IOM 5.5.10.9. Also, the Remarks section of the C/R should include notation of this practice if used.

4.2.6 – Dealer Identification of Lot and Records

Positive identification of sampled lots and the records covering their sales and shipment are essential to legal proceedings. The dealer's identification of a sampled lot and their identification of the records covering interstate shipment should be factual and specific. If there is any question about accurate identification of the lot or records, be sure to determine all facts and establish identification as clearly as possible. Be alert to any identifying marks, too, which may later be used on the witness stand for positive identification.

4.2.6.1 – Private Individuals

When collecting official samples from private individuals, ask the individual to initial and date the label, wrappings, promotional literature, etc. This will aid in positively identifying the product and related documents in any court proceedings that may develop months, or even years later.

4.2.6.2 – Seriously Ill Individuals

If you collect samples from an individual for contemplated regulatory action, and it is obvious the individual is seriously ill, you should attempt to locate and obtain a corroborating statement and identification from someone else. This corroborating witness should have personal knowledge of the facts and be available if the principal witness cannot testify in a legal proceeding.

4.2.7 – Sampling from Other Government Agencies

IOM subchapter 3.2 for sampling information specific to other government agencies (OGA).

4.2.8 – Payment for Samples

Payment for all samples, except those collected under authority of a court order or decree, shall be offered to the individual from whom the sample(s) were obtained regardless of the amount. See IOM 4.2.8.2.

An exception to this is import samples. The FDA does not pay for import samples at the time of collection. The importer should bill the appropriate division office. The FDA will not pay for violative import samples. See 21 CFR 1.91.

4.2.8.1 – Post Seizure (PS) and Reconditioning Samples under Court Order

You should not pay for, or offer payment for, any post seizure (PS) or other similar sample-- including those from reconditioned lots--if collected under authority of a court order or decree. If the dealer insists on payment before permitting sampling, show them the court order. If you are still refused sampling, contact your supervisor immediately for further instructions. You may be instructed to notify the U.S. Attorney.

4.2.8.2 – Determining Sample Cost

If you are collecting samples from firms or the representatives of firms who have federal supply, Veterans Administration, or other contracts with the federal government, the cost of the sample shall be determined by the scheduled price. Inquire of the firm if it is on contract for the item. If so, pay only the scheduled price.

Some dealers may wish to charge their regular selling price. However, if the cost of the sample seems excessive, try to persuade the dealer to charge a lower price that is more equitable. If asked, inform the dealer that the government considers a fair price to be the dealer's invoice cost plus a nominal charge (usually 10-15%) for freight, handling, and storage.

If you are unable, through tactful discussion, to convince the dealer to lower the sample cost, do not haggle over the price to be paid. If the cost seems exorbitant, check with your supervisor to determine if the sample size can be reduced, or for further instructions. Whenever there is a disagreement over sample cost, ask the dealer to bill the division and report the circumstances in the collection remarks field on your C/R.

If divisions encounter requests for payment for method validation samples (either direct submission by firms to labs or during collection from responsible firms), they should contact the appropriate Office of New Drugs in CDER or CVM, so that communication may take place with the application sponsor. If product is being collected from commercial distribution not in the control of the sponsor/manufacturer, then the division should expect to pay wholesale cost. Expenses for new drug application (NDA) method validation samples should be charged to a Prescription Drug User Fee Act (PDUFA) reimbursable central account number (CAN).

4.2.8.3 - Method of Payment

There are four ways to pay for samples.

- The sample costs may be billed to the division. Encouraging dealers to bill the division is the preferred method for paying for samples.
- The treasury debit card may be used at point of sale (POS)
- You may use your travel card to make a cash withdrawal to purchase samples *only* when in travel status. You may never use your travel card to purchase a sample at POS.
- Personal funds may be used to pay for the sample. While ORA policy currently allows for you to pay for samples with your own personal funds then submit for reimbursement, you should speak to your supervisor about alternatives prior to using personal funds to pay for a sample.

See IOM 4.6.2.45.

4.2.8.3.1 - Costs Billed to Division

Billing sample costs to the division is, in many instances, the most practical method of payment. This is particularly true where substantial costs are involved due to large sample size; expensive samples; the samples

collected involve third parties, such as carriers and public storage warehouses; or in instances when delivery followed by subsequent billing is the dealer's normal business practice.

Sampling from public storage warehouses and common carriers incurs costs that are normally billed because the owner of the product is unavailable. Determine the identity of the owner or the owner's agent and estimate the value of the goods sampled. Arrange with the owner or owner agent to bill the division.

ORA SOP-000530, Sample Obligation and Processing, describes the process for paying invoices to the division for samples. There are two related documents that investigators should provide to the firm when the firm will bill the division. One is Form-000870, a Vendor Process Payment Letter, and provides guidance to the vendor how to send their bill to the FDA. The other is Form-000874, a list of DFA contacts that the dealer should submit information to. These forms can be provided in hard copy at the time of sample collection or e-mailed to the firm after sample collection. If the forms are e-mailed, be sure to download the form to your computer and share the actual document (and not the links provided here). You should keep in mind that the links are dynamic and the information in them may change. Be sure that you give the dealer the current letter and contact.

4.2.8.3.2- Treasury Debit Card

The Treasury Debit Card program is voluntary. Details about joining the program can be found on the ORA Treasury Debit Card Program SharePoint Site. If you carry a treasury debit card, it may be used at point of sale (POS) to purchase samples. If the vendor will not accept the debit card, you may use an ATM to get cash to pay for the sample.

The treasury debit card should only be used to purchase samples, not to buy supplies or to pay for shipping costs.

When traveling, you may use your government issued travel card to obtain cash from an ATM and add the expense of the sample and ATM fee to your voucher. The treasury debit card may be used to purchase samples online. When purchasing samples online, the cost of shipping and handling may be included in the cost of the sample.

If you use a treasury debit card, be sure to complete all appropriate paperwork and submit it as directed on the SharePoint site.

4.2.8.3.3 - Payment with Personal Funds

As previously noted, you are expected to encourage the dealer to bill the division for the cost of the sample. Personal funds to purchase samples should be used as a last resort when other methods of payment are not available. You must use personal funds to purchase samples. It is not mandatory to use personal funds. You may obtain a treasury debit card and use it instead. If you choose to use personal funds, speak to your supervisor before doing so. You will not be able to obtain reimbursement via a local voucher. Reimbursement for samples paid for from personal funds will be made via submission of an OF-1164 form as described under the Division of Financial Operations (DFO) Budget Execution procedures.

Sample costs cannot be charged directly to your government credit card. Using your government travel credit card to obtain a cash withdrawal is not ideal. However, you can use your government travel credit card to withdraw an ATM advance to pay for your sample only when you are in travel status. You are required to obtain your supervisor's approval (via email or other written form), prior to using your government travel credit card, to make a cash withdrawal to purchase samples. The amount of the withdrawal should be limited to the cost of the sample. You should submit your itemized claim for samples along with the cash withdrawal

fee, as applicable, as part of your voucher using the electronic travel management system. Include the following information and documentation when submitting the voucher for reimbursement: sample number, receipt for the sample purchase, receipt showing the cash withdrawal fee if applicable, and approval from your supervisor to use the government travel credit card.

4.2.8.3.4 - Online Payment

Online samples, if they are undercover buys, should be paid for using a dedicated and unidentifiable FDA credit card. Other special assignment online samples should be paid for using a district or division P-card. The sampling assignment should provide guidance for an online payment. If guidance is not found in the assignment, check with your supervisor for program or division specific procedures to pay for online samples. Do not use your government travel or personal credit card to pay for online samples.

The treasury debit card may be used to purchase online samples including any shipping charges from the vendor. The treasury debit card may not be used to purchase shipping materials, coolants, or to ship samples to the lab. See the ORA Treasury Debit Card Program FAQs.

4.2.8.4 – Sampling – Labor Charges

Additional labor, such as use of forklift, or other assistance may be required to move merchandise, skids, pallets or perform other actions, to properly sample and restore a lot. Usually, assistance with such labor will be available on the premises from the firm's employees. If you determine assistance is needed but unavailable at the firm, contact your supervisor to determine next steps.

There is usually little need to discuss payment when requesting nominal use of labor or equipment. However, if there is an indication that firm management expects payment, attempt to reach a clear understanding of the charges before proceeding. If the charges to be incurred appear reasonable, and the cost is minor (about $25.00 or less), proceed with the work and add the charges to your sample cost. However, if substantial costs are involved, consult with your supervisor before making a commitment to pay.

Where the charges are substantial and have been authorized by your supervisor, arrange for the cost of labor and/or machinery to be billed to the division. Handle these charges separately from the actual cost of the sample. Determine the hourly rate and keep track of time, labor, and/or machinery used. Prepare a short memo outlining the charges and submit it to your division.

4.2.9 – Dealer Voluntary Hold

This section deals solely with a *voluntary hold* on regulated products. See IOM 2.7.1 for specific statutory authorities for detaining meat, poultry, egg products, and medical devices.

There is no specific authority for requesting a voluntary hold on a lot but, voluntary holds by a dealer shall be encouraged in instances where the lot sampled is clearly adulterated. By voluntarily holding, the dealer prevents further distribution of suspected violative goods until seizure or other appropriate action can be accomplished.

4.2.9.1 – Perishable Goods

Except in rare instances, it is generally not practical to hold highly perishable items unless the analysis can be completed within 24 hours. You should confer with your supervisor before requesting a voluntary hold on perishable items.

4.2.9.2 – Obtaining a Voluntary Hold

When the lot is clearly adulterated, or when instructed to do so by your supervisor, request that the dealer voluntarily hold the product. Explain the rationale for the request and a potential timeframe for the hold. If the dealer objects, discuss their responsibility under the law and the public health consequences that may result. If the dealer indicates a reluctance to voluntarily hold the lot, call their attention to Section 301(a) of the FD&C Act [21 U.S.C. 331(a)].

Since the action is voluntary, we cannot require the dealer to do all the things we might ask them to do. While requests for voluntary holds are generally granted, a dealer may act or suggest an alternative approach.

Always place a time limit on voluntary holds using your best estimate of how long it will approximately take to complete the analysis and reach a division decision. In estimating this time frame, you'll want to consider such factors as: location of the examining lab, difficulty of the analysis required, turnover rate, storage conditions, and the perishable nature of the merchandise. Note: Your division's compliance branch can request an extension of the voluntary hold. Also, be sure to document the voluntary hold in your regulatory notes and in the dealer's affidavit.

Also note the following special situations and/or potential responses from a dealer regarding voluntary holds:

If the dealer declines to hold the lot, but proposes returning it to the shipper, the dealer should be warned NOT to return the goods to the shipper and advised that the FDA does not condone shipping violative goods. Direct their attention to Section 301(a) of the FD&C Act [21 U.S.C. 331 (a)].

If the dealer offers to voluntarily denature or destroy the lot in lieu of voluntary hold you should provide or arrange for supervision/oversight of the denaturing per IOM 2.8.1. If the dealer proposes to recondition the lot themselves, refer them to your division compliance branch for approval of their method. See IOM Subchapter 2.6 and IOM 2.6.3.

If the dealer still refuses, discuss the situation with your supervisor. A state embargo (see IOM 3.3.1) or administrative detention (IOM 2.5.11) may be the next action.

4.3 - Collection Technique

In most cases, when collecting a sample, you must ensure that the sample collected is a good representation the dealer's lot. The goal of collecting a sample for laboratory analysis is to provide the laboratory a part of a lot that represents the overall lot. This means that the way you collect the sample, as well as all the activities involved before it arrives at the lab, should leave the product in the sample, and in the same state, as the product that remains at the dealer. So, for example, a refrigerated sample collected for microbiological analysis should remain refrigerated until it is delivered to the laboratory.

4.3.1 - Lot Restoration and Identification

4.3.1.1 - Restoring Lot(s) Sampled

After completion of your sample, restore lots to their original condition. Do not leave partially filled shipping cases, or short-weight or short-volume containers in the lot after sampling. Do not leave the lot in any condition that might encourage pilferage or make it unsalable.

When collecting from either full cases or bulk containers, replace sampled units by back-filling from a container selected for that purpose. Avoid contaminating the back-filled units. If necessary, correct the contents' declaration

on the containers that were sampled to reflect the actual contents now present. Refer to IOM 4.2.2 if the dealer objects to back-filling because of company policy, different codes involved, or for other reasons. As a last resort, accede to the dealer's wishes and sample intact units, but record the facts in your regulatory notes and place a brief explanation on the C/R.

After collecting your sample, carefully re-close all containers and shipping cases. If necessary, request assistance from the dealer's employees to help restore the lot, or arrange, through the dealer, to employ outside help. See IOM 4.2.8.4.

4.3.1.2 - Identifying Lot(s) Sampled

Identify each container from which units are taken with the date, your initials, and the sample number. **NOTE:** For import samples, identify each master container from which units are taken with the following information: FDA, division abbreviation, sample date, and the lead investigator’s initials.

Should the dealer object to your identification procedure, attempt to reach a compromise, such as, placing the identification in an obscure location. If the dealer still objects, accede to their wishes, but record the facts in your regulatory notes.

Positive identification of the containers sampled is important if it becomes necessary to resample the lot(s), or if a detention, seizure, or other action ensues. It also aids the dealer in differentiating between containers that have been opened by the FDA, as opposed to those opened by pilferage or torn open by rough handling. It may be necessary to mark more containers than sampled to assure proper identification of the lot, for example when a lot may be split for distribution after sampling. This must be done by using permanent identification, for example, through handwritten identification or by using a rubber stamp.

Note that many inks have the potential to penetrate the product and act as a contaminant, interfering with the analysis. As such, do not use markers on sample containers that allow for any penetration into the product.

Many inks will penetrate to the product and act as a contaminant, interfering with the analysis. Do not use markers on sample containers which allow penetration into the product.

Water base markers will run when damp and must be covered with tape.

Do not permanently identify articles that are borrowed and will be returned to the dealer.

See 4.7.2.3 for identification techniques.

4.3.2 - Sample Size

To determine sample size, first consult your assignment. If the assignment doesn't specify the sample size, follow the guidance in the applicable Compliance Program. The IOM SAMPLE SCHEDULE (found at the end of this chapter after the Exhibits), should be used if the Compliance Program doesn't state the sample size. If none of these sources furnish the sample size, consult with your supervisor or the relevant laboratory. Also, collect sufficient sample when necessary to allow for the 702(b) portion if appropriate. See IOM 4.3.2.2 and 4.3.2.3.

4.3.2.1 - Medical Device Samples

The following table represents the devices for which there are instructions on physical sampling in Compliance Policy Guides:

Device	CPG Reference
Clinical Thermometers	See CPG 335.800
Condoms	See CPG 345.100
Surgeons and Patient Exam Gloves	See CPG 335.700

In addition to providing instructions on sample size, these compliance policy guides provide guidance on criteria to determine adulteration and whether or not regulatory action should be recommended.

Also see the following references with regards to collecting medical device samples:

WEAC-MEMO-2012-04-13.01_Medical Device Sampling Guidance Memo and OEIO Field Examination, Label Examination, and Sampling Work Instructions.

Review your assignment and, if needed, discuss it with your supervisor prior to collecting physical samples of medical devices.

4.3.2.2 - 702(b) Requirement

Under section 702(b) of the FD&C Act (21 U.S.C. 372(b)), when the FDA collects a sample of a food, drug, or cosmetic for analysis, FDA must, "upon request, provide a part of such official sample for examination or analysis by any person named on the label of the article, or the owner thereof, or his attorney or agent."

When the sample schedule, assignment, or other instruction does not specifically provide for the 702(b) portion, collect a sufficient amount to provide this required portion and indicate duplicate availability in the FACTS C/R by checking the 702(b) box. You are not required to obtain a 702(b) portion in the following instances exempted by statute or by regulation 21 CFR 2.10(b):

1. Devices and tobacco products are not included in the statutory requirement of Section 702(b).
2. The amount available for sampling is less than twice the quantity estimated to be sufficient for analysis. If this is the case, collect all that is available.
3. The cost of twice the quantity estimated to be sufficient for analysis exceeds $150.00. If the sample is critical, and the cost exceeds $150.00, consult with your supervisor.
4. The sample cannot, by diligent use of practicable preservation techniques available to the FDA, be kept in a state in which it could readily and meaningfully be analyzed in the same manner and for the same purposes as the FDA's analysis. Examples of this include fresh produce, water samples, and environmental swabs. If you are at all unclear on this point, consult with your supervisor, or servicing laboratory, to confirm that practicable preservation techniques are indeed not available.
5. The sample is collected from a shipment being imported or offered for entry into the United States (import samples).
6. The sample is collected from a person named on the label of the article or their agent, and such person is also owner of the article. For example, it is not necessary to obtain a 702(b) portion if the sample is collected from a lot owned by and in the possession of the manufacturer whose name appears on the label.

7. The sample is collected from the owner of the article or their agent, and the article bears no label--or if it bears a label, no person is named on it.

In the remarks section of the C/R, describe the specific circumstances and justification for not collecting the 702(b) portion. The documentation is not needed if the product is a device or tobacco product, or the assignment or compliance guide already states why the 702(b) portion is not needed.

Note regarding filth samples: Regardless of the exemptions under 21 CFR 2.10(b) listed above, collect the 702(b) portion for filth samples, unless your supervisor directs otherwise.

4.3.2.3 - Collecting the 702(b) Portion

As noted already, whenever possible, collect separate subsamples in order to provide the firm a portion as required by Section 702(b). Each duplicate subsample should be collected from the same bag, box, case, or container. The total sample should be *at least twice* the quantity estimated to be sufficient for analysis, including a reserve portion for the servicing FDA laboratory. If unable to collect separate subsamples, ensure that the total amount collected for each sample subsample, or the total amount collected from an undivided sample, is at least twice the amount estimated to be sufficient for analysis. See IOM 4.6.2.58.

4.3.3 - In-Transit Samples

The exterior of any domestic package thought to contain an article subject to FDA regulation and in the possession, control, or custody of a common carrier may be examined (to include being photographed, information on the outside copied, etc.), and records of the shipment may be obtained. However, such package may not be opened by an FDA employee, or by an employee of the common carrier at the request of an FDA employee, except as provided below.

4.3.3.1- Examination without a Warrant

The Office of Chief Counsel has advised that FDA employees may--without a warrant--open, examine the contents of, and/or sample a package that is part of a domestic commercial interstate shipment in the possession, control, or custody of a common carrier only if:

- The consignor or consignee affirmatively consents to examination and/or sampling of the contents; or the agency has reliable information that the carrier regularly carries FDA-regulated articles, and the facility where the sampling is contemplated is subject to FDA inspection. Reliable information may come from agency files, the carrier itself, other customers of the carrier, etc., and
- The Agency has reliable information that a particular package sought to be examined is destined for, or received from another state, and contains an FDA-regulated article. [Such information may be found on the exterior of the package and/or shipping documents in specific terms. Information may also come from a reliable source that establishes the consignor is in the business of manufacturing and/or shipping FDA-regulated articles using a distinctive type of package (shipping container), and the package in question meets such description and shows the consignor to be such firm.]

4.3.3.2 - Examination with a Warrant

Confer with your supervisor on any question concerning the need for an inspection warrant to examine the contents and/or sample an in-transit package. Your Compliance Branch should be consulted if criteria for requesting a warrant are not clear.

If a decision has been made to recommend a warrant, the Office of Policy, Compliance and Enforcement, Division of Compliance and Enforcement (OPCE/DCE) should be contacted. Follow the procedures outlined in the Regulatory Procedures Manual 6-3.

If a common carrier reports a violative article that it discovers under its own package-opening procedures, independent of any request by an FDA employee or any standing FDA cooperative program with the carrier, the FDA may still need an inspection warrant to examine the material. Unless all the conditions for independent sampling in IOM 4.3.3.1 exist, you must consult with your supervisor, who can arrange for a headquarters consultation as outlined above.

Note: Where the identity of an interstate product is known or apparent--by virtue of it being visible in bulk or being in labeled containers or packages whose contents can be verified by shipping records, and where such product is under FDA jurisdiction at a given location--it may be sampled according to established IOM procedures.

4.3.3.3 - Resealing Conveyances

If it is necessary to break the commercial seal to enter a railcar or other conveyance, reseal the door with a numbered self-locking "U.S. Food and Drug" metal seal. Record in your regulatory notes (and on C/R if sample taken) the number of the car or conveyance, the identifying number on any car seals removed, and the number of the FDA metal seal applied.

4.3.4 - Special Sampling Situations

There will be situations that arise where the dealer may need to sample product for you due to safety and/or other concerns. After evaluation of the situation and prior to allowing dealer sampling, contact your supervisor for appropriate guidance and concurrence. If permissible, all dealer sampling must be done with your direct oversight. Note dealer sample collection in your C/R.



Do not collect human or animal biological materials (for example, urine, feces, sputum, blood, blood products, organs, tissues) or FDA-regulated products potentially contaminated with biological materials unless arrangements for special handling and special treatment have been made in advance with the ORA Safety Office. Most ORA-servicing laboratories are not prepared or certified to handle these materials. In addition to guidance for special sampling situations provided below, sampling guidance may also be found in IOM Subchapter 1.5 – Safety under IOM 1.5.3 - Sampling.

Some products like essential oils should not be collected in plastic containers or paraffin-coated caps. Use glass, cork, foil covered, or non-plastic, non-paraffin closures. If unsure of the appropriate container/lid type, contact your servicing lab for guidance.

Please contact your servicing lab to determine an appropriate sampling container and sample size for medicinal and other gases.

4.3.4.1 - Samples Collected During Investigations of Complaints, Counterfeiting, Tampering, Foodborne Disease, and/or Injury/Illness

Detailed instructions for investigating and sampling products in connection with consumer complaints, tampering, foodborne outbreaks, injury, and adverse reactions, etc., appear in Chapter 8 of the IOM.

Be cognizant of conserving scarce resources when investigating consumer complaints that do not involve injury, illness, or product counterfeiting/tampering. Unnecessary samples waste both operational and administrative resources. For example, there is little need to collect a physical sample of an insect-infested box of cereal from a complainant. Both you and the consumer can readily see it is insect infested. The laboratory would also find it insect infested. No practical purpose would be served by either collecting or examining such a sample. Photographs can be used to document the infestation.

During consumer complaint investigations/follow-up events--when blood or body fluid contamination is suspected, and when there is no apparent illness or injury--samples should not be collected without first contacting Emergency Operations. This is due to the lack of confidence in the analytical methods and the results associated with certain blood and body fluid samples. As such, the decision to collect a sample will be made on a case-by-case basis, and in consultation with the Office of Regulatory Science, Emergency Operations, and the Office of Medical Products and Tobacco Operations.

4.3.4.2 - Undercover Buy Samples

If this sample type is desired, your supervisor will provide specific instructions and procedures to be followed. This planning will likely involve the following factors or questions:

1. Whether to use your correct name or an alias. Caution: if you use an alias, do not use a similar name or a name with initials the same as yours (for example., Sidney H. Rogers should not use Samuel H. Right). In addition, do not use a division office or resident post as a return address when ordering products or literature.
2. Whether to use order blanks contained in the promotional package, advertisement, or promotional activity; or whether false ones will be used.
3. Whether money orders, your credit card numbers, bank checks, or your personal checks should be used for payment. It depends on the situation, but money orders are preferred since these do not involve personal accounts.
4. Where the requested items are to be sent. For example, will you use a rented P.O. Box, home address, General Delivery, etc.
5. How the address and/or your name is to be recorded on the order blank. A code may be used either in your name or address, so any follow-up promotional material sent to that name and address can be keyed to your original order.

Do not telephone your order in from the office or your home phone because the firm may have "Caller ID" and be able to identify your location by the phone number. For samples induced online, use a non-FDA network computer.

When it has been decided to induce a sample and you have discussed the procedures with your supervisor, prepare the order and obtain the money order, or other payment document. When all documents for ordering the item(s) are prepared--photocopy all the materials, including the addressed envelope, for your C/R--and submit the order.

When the order is received, identify the sample item; all its accompanying materials, such as pamphlets, brochures, etc. (including all wrappings containing any type of printing, identification, numbers, post-marks, addresses, etc.); and submit the item and exhibits in the same manner as any other official sample. If payment of the item was by personal check or credit card number, attach a photocopy of the canceled check or credit card

receipt, if available. You may do this later, after clearance of the check or charge slip. Samples induced online should include a record of the purchase process, including point of sale, relevant emails, and documentation of where and how the sample was received and collected.

4.3.4.3 - Collecting Surveillance Samples on Farms

Specific instructions have been developed for the collection of surveillance samples on farms or from on-farm packinghouses or processors, including pre-notification, interaction with the farm personnel, payment for samples collected on farms and sample size(s). Though these instructions only apply to surveillance samples, they may also be considered for illness investigations or for cause sampling but are not required.

On farm sample collections should be limited to instances where it is specifically mentioned in an assignment. When you are planning to collect surveillance samples on a farm, you should call the farm at least 24 hours in advance to notify the farm of FDA's intent to collect samples and share the commodity of interest.

During the pre-notification call, the investigator should also determine an estimate of what the sample(s) will cost if the farm decides to charge for the samples. The investigator will take enough cash to cover the cost of the samples collected and not ask the farm to bill FDA as may be done in other sampling situations. If the farm decides to charge for samples and you did not bring cash, use the government travel card to withdraw cash from an ATM and withdraw the exact amount needed to cover the cost of the samples. As a last resort, personal funds may be used, do not ask the farm to bill FDA.

If the investigator collecting the sample is a PHS Commissioned Officer, the investigator will explain to the farm representative that he/she will be wearing his/her uniform. During this conversation, the officer will describe the uniform he/she will be wearing (e.g., blues, khakis) and also explain why the officer wears the uniform as a Commissioned Officer in the Public Health Service.

When on farm and viewing the inventory of product to be collected, the investigator will determine if the sample size needed will exhaust the farm's supply of the product or may cause the farm to not be able to meet customer needs. If so, consideration should be given to not collecting the sample or if possible, modifying the size of the sample. If the sample collection will exhaust the entire inventory, the investigator should discuss this with responsible farm management and determine how soon inventory will be restored and if the farm management believes the sample collection will impose an economic disadvantage to the farm. If the responsible party states that it will cause an economic disadvantage, the investigator should not collect the sample at that time, but rather plan to return at another time when additional inventory will be available for sampling or consider selection of another site for collection.

Samples collected from farms should be identified as Investigational (INV) and interstate commerce is not necessary. Produce samples collected from farms do not require the collection of a 702(b) portion.

4.3.4.4 - Collecting Feed Samples for Bovine Spongiform Encephalopathy (BSE) Analysis

You need to be aware of proper safety procedures for collecting, packaging, and shipping domestic and imported feed samples. The main objective of safety recommendations is to minimize exposure to feeds and feed dust at the time of sample collection and to minimize future exposure through feed dust on clothing or equipment. Please contact ORA Safety Office for available safety trainings. See IOM Chapter S – Safety.



Safety precautions should be followed for ALL sample collections for BSE analysis, both import and domestic. Use of these procedures will also minimize exposure risk to other potential pathogens. Given the risks associated with exposure to both BSE and other pathogens, you are strongly encouraged to follow safety procedures whenever any dusty feed samples are collected. and it is encouraged to follow these procedures whenever any dusty feed samples are collected.

Minimizing dust exposure can be accomplished as follows:

- Use of recommended personal protective equipment (PPE) to be used by personnel collecting feed samples:
    1. Respiratory protection: at a minimum half-mask air-purifying respirator (face-sealing) with P100 filters (HEPA)
    2. Ocular (eye) mucous membrane protection: goggles
    3. Percutaneous (through skin openings such as cuts, abrasions- unbroken skin poses no known hazard) – waterproof gloves on hands; cover skin lesions, cuts, abrasions with waterproof dressing
    4. Clothing contamination – disposable coveralls
- Collection and bagging procedures:
    1. Minimize dust as much as possible when collecting 16 – 1 oz subs and combining them into one sample.
    2. Wipe the outside of whirl-pak bag with a water-dampened paper towel in a clean area and place this bag into another whirl-pak bag **(double bag the sample).**
- Cleanup and PPE removal:
    1. When in a dust-free area, remove the disposable coveralls by turning inside-out, rolling up and placing in a plastic bag for disposal.
    2. Wipe shoes with water dampened paper towel.
    3. Remove goggles and respirator; wipe outside of goggles and respirator with water-dampened paper towel.
    4. Place goggles and respirator in clean carrying bag.
    5. Place all wipes in the disposal bag with the disposable coveralls.
    6. *Place the bag in a trash receptacle on site if the firm permits or carry out and dispose of properly at your FDA office.*

See IOM Chapter S - Safety, Sections S.9.7, S.9.10, S.13.6 and S.13.10.4.

4.3.4.5 – Collecting Samples During Foreign Inspections

An FDA 482, Notice of Inspection (Section 704(a) of the FD&C Act [21 U.S.C. 374(a)]) is not required to be issued to a foreign facility prior to conducting an inspection or collecting a sample, unless the firm is a U.S. Military facility, however; credentials should be presented to the top management official. See IOM 5.1.4.2.1 and 5.1.3.

Please note that an FDA 484, Receipt for Samples (Section 704(c) of the FD&C Act [21 U.S.C. 374(c)]), is issued to the owner, operator, or agent in charge (OOAC), describing any samples obtained during the course of an inspection.

You should follow the specific assignment instructions for sample collection at foreign firms. Consult with your program foreign division point of contact for additional guidance for collecting and shipping foreign samples.

4.3.4.6 – Notification for FDA Samples Collected During a Foreign Establishment Inspection or During FDA Activities in a U.S. Territory Outside of the Customs Territory of the United States

When shipping a sample collected during a foreign establishment Inspection or during FDA activities in a U.S. territory outside of the Customs territory of the United States (e.g., Guam, American Samoa, etc.), follow these notification procedures:

FOOD SAMPLE: After the sample has been collected, prepared, and ready for shipment, but before it is delivered to the carrier, email the Division of Food Defense Targeting (DFDT) Watch Commanders oraoeiodfdtwatchcommanders@fda.hhs.gov and cc the Division of Import Operations (DIO) Information Duty Officer (IDO) FDAImportsInquiry@fda.hhs.gov with the following information:

1. Name of carrier (UPS, FedEx, etc.)
2. Date to be shipped
3. Tracking number(s)
4. Number of packages
5. Declared contents (Example "FDA Food Sample for analysis")
6. Product(s): Description of product(s), sample size including individual retail package size (if collected),
7. FDA Lab and address to be shipped to
8. Name and office address for the contact point (Person shipping the sample)
9. Manufacturer: Name and full address of the facility who manufactured the product(s)

The DFDT will address anything related to Prior Notice (PN). The DFDT is available to file and provide PN confirmation numbers 24 hours a day, 7 days a week. Once a PN is filed, the DFDT will provide the PN confirmation number by return e-mail so that it can be provided to the carrier at the time sample is delivered for shipment. If necessary, the shipper can email or call the DFDT at any time and ask for the Watch Commander on duty. If contacting the DFDT by phone, please call direct @ 571-468-1488 or, if able to call toll free, use 866-521- 2297. If any non-PN issues arise with the shipment and importation of the sample, email the IDO. The IDO can facilitate communication to the field divisions, through the Division Import Activity Liaisons (DIALS), to help expedite CHAPTER 4 INVESTIGATIONS OPERATIONS MANUAL 2022 4-58 the shipment.

NON-FOOD SAMPLE: After the sample has been collected, prepared, and ready for shipment, but before it is delivered to the carrier, email the DIO Information Duty Officer (IDO) FDAImportsInquiry@fda.hhs.gov with the following information:

1. Name of carrier (UPS, FedEx, etc.)
2. Date to be shipped
3. Tracking number(s) Number of packages
4. Declared contents (Example "FDA Sample for analysis")
5. Product(s): Description of product(s), sample size including individual retail package size (if collected),
6. FDA Lab and address to be shipped to
7. Name and office address for the contact point (Person shipping the sample)
8. Manufacturer: Name and full address of the facility who manufactured the product(s).

If any issues arise with the shipment and importation of the sample, email the IDO. The IDO can facilitate communication to the field divisions, through the Division Import Activity Liaisons (DIALS) to help expedite it.

4.3.5 - Aseptic Sample

Aseptic sampling is often used in the collection of in-line samples, environmental samples, product samples from bulk containers and collection of unpackaged product that is being collected for microbial analysis.

Aseptic sampling is a technique used to prevent contamination by your sampling technique. Aseptic sampling involves the use of sterile sampling tools and sterile containers. Good aseptic sampling technique is demonstrated when the sample is contacted only by the sterile sampling tools or the sterile container used for sampling. Samples collected using good aseptic technique are important as they will support testimony that the bacteriological findings accurately reflect the condition of the lot at the time of sampling and, ideally, at the time of the original shipment. Aseptic sampling is critical to not only samples that will undergo microbiological analysis, but also to samples subject to chemical tests that might be altered by microbial activity. For chemotherapeutics, make sure that the shipping conditions ensure that microbial populations remain inactive and do not have the opportunity to degrade the analyte. The most ideal approach, whenever possible, is to collect intact, unopened containers.

Products in 55-gallon drums, or similarly large containers, either aseptically filled or heat processed, should not be sampled while the shipment is en route, unless the owner accepts responsibility for the portion remaining after sampling. Try, instead, to arrange sampling of these products at the consignee's location so the opened containers can be immediately used or stored under refrigerated conditions.

For more guidance on aseptic techniques, you may consult the course, Food Microbiological Control 10: Aseptic Sampling, available to FDA employees through the OTED Intranet Site.

4.3.5.1 - General Procedures

If it is necessary to open containers, draw the sample and submit it under conditions that will prevent multiplication or undue reduction of the bacterial population. Follow the basic principles of aseptic sampling techniques. Take steps to minimize exposure of the product, sampling equipment, and the interior of sampling containers to the environment.

4.3.5.1.1 - Sterilized Equipment

Use only sterilized equipment and containers. These can be purchased sterile, obtained from a servicing laboratory, or in an emergency, at local cooperating health agencies. If pre-sterilized metal tools are unavailable, the metal tools can be sterilized immediately before use with a propane torch. If using this tool, permit it to cool in the air or inside a sterile container before using. Another acceptable method, albeit of last resort, is soaking the tools with 70% alcohol and flaming off. Ensure collection controls used are within the manufacturer's expiration date prior to use.

If it is necessary to drill, saw, or cut the item being sampled (such as large frozen fish, cheese wheels, frozen fruit, etc.), use stainless steel bits, blades, knives, etc., that can be flame sterilized with 70% alcohol wherever possible. Note that wooden-handled sampling instruments are particularly susceptible to bacterial contamination (because of wood being of porous nature), are difficult to sterilize, and thus should be avoided.

4.3.5.1.2 - CAUTIONS



Be extremely careful when using a propane torch or other flame when sterilizing tools and equipment. Evaluate environmental and other conditions pertaining to explosive vapors, dusty air, flame-restricted areas, firm policy and/or management wishes. Also, the use of supportive devices should be considered when the torch is not being handheld. In addition, be sure all flammable liquids, such as alcohol, in your filth kit are in metal safety cans and not in breakable containers.

If it is necessary to handle the items being sampled, then use sterile disposable-type gloves. Surgeon's gloves are a good choice. Use a new glove for each sub and submit an unopened pair of gloves as a control. See IOM 4.3.5.5.

4.3.5.1.3 - Opening Sterile Sampling Containers

Plan your aseptic sampling approach, including organizing your sampling tools prior to sampling. When opening sterile sampling containers, work rapidly and efficiently. Open sterile sampling containers only to admit the sample and close it immediately. Do not touch the inside of the sterile container, lip, or lid. (See IOM 4.3.4)

4.3.5.1.4 - Dusty Areas

Do not collect samples in areas where dust or atmospheric conditions may cause contamination of the sample, unless such contamination may be considered a part of the sample.

4.3.5.2 - Sampling Dried Powders

Cautions - The proper aseptic sampling of dried milk powder, dried eggs, dried yeast, and similar types of products is difficult because they are generally packed in multilayer, poly-lined paper bags. These may be stitched across the entire top, may have filler spouts, or the top of the poly-liner may be closed or sealed with some type of "twists".

The practice of cutting an "X" or "V," or slitting the bag and folding the cut part back to expose the contents for sampling, should not be used because it creates a resealing problem; the opening cannot be properly repaired.

Note the following procedures have been approved by the scientific units at headquarters, and should be used when sampling based upon the way the product has been packaged:

4.3.5.2.1 - Bag And Poly-Liner Stitched Together Across Top Seam

1. Remove as much dust as possible from the seam end by brushing it and then wiping it with a cloth dampened with alcohol. Note: This does not sterilize the bag, as porous paper cannot be sterilized.
2. Remove the seam stitching carefully (and dust cover, if any) and spread open the walls of the bag and the poly-liner enough to permit sampling--being careful that no extraneous material, such as dust, bits of twine, paper, etc., drops into the product.
1. Carefully scrape off the surface of the product with a sterile device and aseptically draw the sample from the material below.
2. Carefully reclose the bag and re-stitch by hand, or by machine if a firm, or FDA-portable, sewing machine is available.

4.3.5.2.2 - Bag Stitched Across Top And Poly-Liner Twist-Closed And Sealed With "Twist" Device - Wire, Plastic, Etc.

1. Brush, alcohol wipe, and remove stitching as described above.
2. Remove the "twist" seal and carefully open poly-liner, using caution that no extraneous material drops into the product.
3. Draw aseptic sample in same manner as in step 3 above.
4. Carefully close the poly-liner with a twisting motion and reseal with "twist" seal, arranging it so it will not puncture the poly-liner. Then re-sew bag as in step 4 above.

4.3.5.2.3 - Bags With Filling Spouts

The filling spout will be located at one side of the top stitching and will pull out to either form a top or side spout.

1. Brush and alcohol wipe the area around the spout and carefully pull-out spout to reveal the opening. It is better to have the bag on its side while pulling the spout, so any dust in the opening falls *outside* the bag.
2. Carefully spread apart the sides of the spout and aseptically draw the sample. A trier or long-handled device is usually better for this type of opening because of the limited opening.
3. Carefully close the spout with a firm twisting motion and be sure the opening is closed prior to pushing it back into the bag.

4.3.5.3 - Collecting Water Samples

When it is necessary to collect water samples for bacteriological examination, use the following procedures:

1. Use sterile bottles. If de-chlorination of the sample is necessary, you should place sodium thiosulfate, sufficient to provide a 100 mg/l concentration, in the clean bottles prior to sterilization. The sodium thiosulfate will prevent the chlorine from acting on the bacteria and assures, when the sample is analyzed, that the bacterial load is the same as when collected.
2. Carefully inspect the outside of the faucet from which the sample will be drawn. Do not collect the sample from a faucet with leaks around handle.
3. Clean and dry the outside of the faucet.
4. Let the water run from the fully open faucet for at least 30 seconds or for 2 or 3 minutes if the faucet is on a long service line.
5. Partially close the faucet to permit the collection of the sample without splashing. Carefully open sample bottle to prevent contamination, as in any other aseptic sampling operation.
6. Fill bottle carefully without splashing and be sure no water from your hands or other objects enters the bottle. Do not over fill the container. Leave a small air bubble at top.
7. Unless otherwise instructed, the minimum sample size for bacteriological examination is 100 ml.
8. Pack the sample into a clean insulated shipping container with clean ice packs to keep the sample cool while in transit. Do not use wet ice to ship the sample to the lab.
9. Deliver the sample to lab promptly. If the sample is not examined within 24 hours after collection, the results may be inaccurate.

Note: When documenting specific situations in a plant, you may need to vary this procedure to mimic the actual conditions used by the firm.

4.3.5.4 - Sample Handling

Please see the following other sample types and techniques recommended to assure their integrity:

1. For frozen samples, pre-chill sterile containers before use and keep samples frozen with dry ice. Use ordinary ice or ice packs for holding and transporting unfrozen samples that require refrigeration. See IOM 4.7.3.5 and 4.7.3.6.
2. Under normal circumstances, dried products may be shipped unrefrigerated except in cases where they would be exposed to high temperatures, that is, above 37.8oC (100oF).
3. Submit samples subject to rapid spoilage (for example, specimens of foods involved in poisoning cases, etc.) by immediate personal delivery to the analyst where feasible.
4. For light-sensitive drug samples, ensure the use of appropriate light-restricting containers.
5. For inflammable material samples (for example, alcohol-based hand sanitizers), use appropriate and approved containers, cushioning materials, and safe sample-handling instructions per the FDA Safety Office.

4.3.5.5 – Closed Controls

When collecting any samples using aseptic techniques, submission of unopened, closed controls are required. See SOP-001052 (ORA Field Bulletin #30 – Food Program Area – Instruction for Environmental Sampling) for more information on environmental samples. Field Guidance documents can be found on the FDA SharePoint site.

For each lot of sterile sampling equipment used to take the sample, submit closed controls identified as one or more subsamples (also known as control subs).

For each lot of sterile sampling equipment used to take the sample, submit closed controls identified as one or more subsamples (also known as control subs).

List control subs on your C/R. Control subs should be identified with a different nomenclature than the physical sample, in other words, a, b, c versus 1, 2, 3. Provide control sub lot number(s) and expiration date(s), if applicable.

Examples of various control subs and techniques to be employed are:

1. Sterile Containers: Where sterile containers are used to collect aseptic samples, submit one unopened container that was sterilized in the same manner as containers used for sampling.
2. Sterile Disposable Gloves: If sterile disposable gloves are used to handle the product, submit one unopened pair of gloves as a control.
3. Sterile Swabs/Sponges: When collecting environmental samples with swabs or sponges, submit an unopened swab or sponge as a control.
4. Sterile Sampling Equipment: Where pre-sterilized sampling tools are used (for example, scoops, containers, swabs, whirl-pak bags, spoons, spatulas, triers, etc.), the closed controls will consist of one unopened sampling tool from each lot used.

4.3.6 – Documenting Filth and Other Contamination

Documenting the presence of filth or other deleterious material, involves the collection of samples using strategies and techniques that represent the product or condition. These samples are selective and generally contain more subs (larger) than samples collected for economic or misbranding purposes.

When widespread evidence of filth or other adulteration is present, 402(a)(4) conditions (see Section 402(a)(4) of the FD&C Act [21 U.S.C. 342(a)(4)]) are documented through the combination of selective sampling (IOM 4.3.6.3) and field examination (IOM 4.3.6.1).

Documenting filth--such as rodent, insect, or bird contamination--requires thorough examination of numerous lots of products to determine the extent of adulteration, along with collecting investigational (INV) samples (IOM 4.1.5) inclusive of filth exhibits and photographs supporting the nature and extent of the evidence. Separate filth sub samples should be collected from various areas within the firm to illustrate the extent of questionable conditions that led to adulteration.

Numerous lots of regulated products should be examined, as you collect official samples of those products demonstrating violative conditions. Filth, such as rodent, insect, or bird contamination, observed on the exterior of food containers, on pallets containing the product, or on the floor adjacent to the products should be selectively sampled and treated as sub samples of the official sample. Documenting potential adulteration of several lots helps establish the widespread nature of the adulteration. Compliance Policy Guide (CPG) 580.100 Food Storage and Warehousing - Adulteration - Filth (Domestic and Import) can help you determine what to collect for the sample, as well as determine minimum criteria for direct reference seizure. (Consult your supervisor when you find evidence that meets the criteria set forth in CPG 580.100.)

When observations indicate that a ready to eat food may be suspectable to microbiological contamination, samples may be selectively collected. The samples collected should document manufacturing conditions conducive to adulteration. Refer to IOM sections 4.3.6.5 for instruction on selectively collecting microbiological samples.

When regulatory action appears to be warranted, document recent sales of product from the lot in question. If unsure of the significance of your observations, speak with your supervisor for guidance.

4.3.6.1 - Field Examination to Document Contamination

A field examination is a physical inspection performed on a product to determine the product's condition, its integrity, or practices used during its storage. The examination includes physically examining several containers (cases, cans, bags, units, etc.) of a product. When conducting such exams, take care to describe your observations for each container of product examined and all sub samples collected, ensuring to record the violative nature of the lot along with any exhibits supporting your observations in your regulatory notes and subsequent C/R Collection Remarks, C/R Continuation Sheet FDA Form 464a, or Analyst Worksheet FDA Form 431. Observations should be recorded as to accurately and specifically describe the following: general storage conditions, violative condition(s) of the lot, physical relationship of the violative lot to other lots in the area, how you conducted the examination, and the number of units you examined. Use quantitative observations, (for example, "insect cast skins and 12 live and dead insects were observed on the exterior product bags of a pallet containing 6/50 lb. bags of Triticale Meal. The pallet was located approx. 20 feet east of the elevator shaft, adjacent to pillar identified as #8 on the floor plan diagram.").

As in the example notation above, report, if present, the number and location of live and dead insects, rodent pellets, or other potential sources of adulteration discovered inside the containers, as well as on their exterior

surfaces. Provide diagrams and measurements of areas of urine or other bio-chemical stains on each container and the extent of penetration. Correlate findings of the examination with photographs and the physical sub samples you've collected. Providing a floor plan diagram identifying the locations where subsamples were collected helps visualize the overall violative condition(s).

The subsamples collected from obviously violative lots may be reduced to decisively selected exhibits in instances in which the field examination is carefully described and documented. The field examination and the report of findings will serve as the analysis.

4.3.6.2 - Random Sampling

When sampling to determine the characteristics of a lot, or the condition of a lot is not known without further analysis, samples should be chosen at random. Samples collected at random yield information about the average composition of the product lot. Random sampling methodology is used when you have no information or method of determining which units are violative. If a violation exists, it will be found by laboratory methodology at a specific confidence level, pending the sample size chosen.

The sample size to be collected is usually described in your assignment. If the assignment doesn't specify one, follow the guidance found in the applicable Compliance Program, or the IOM Sample Schedule Charts after the Exhibits in this chapter. If no sample size guidance is furnished, discuss an appropriate sample size and 702(b) portion with your supervisor (see IOM 4.3.2.2 and 4.3.2.3). The general rule is to collect samples from the square root of the number of cases or shipping containers in the lot (or available for sampling if lot size is unknown) but not less than 12 or more than 36 subs. Subs are collected in duplicate when including a 702(b) portion. If there are less than 12 containers, all should be sampled.

4.3.6.3 - Selective Sampling

When there is widespread evidence of filth or other adulteration present, random sampling methodology is undesirable and unnecessary. Under these conditions, examine the lot and select portions of product to sample that demonstrate the violative nature of the lot.

When selectively collecting samples, ensure you include exhibits such as diagrams and photographs that demonstrate the violative condition, along with identifying the containers of product that were sampled from that lot. Exhibit 4-22 contains selective sampling criteria and guidance for sampling for filth, chemical contamination, and mold contamination.

4.3.6.4 - Abnormal Containers

See IOM SAMPLE SCHEDULE CHART 2 - Sampling Schedule for Canned and Acidified Foods for listing can defects.

4.3.6.5 - Microbiological Samples

During inspections of firms producing products susceptible to microbial contamination (for example, peanut butter; dried milk; dairy products; frozen, ready-to-eat seafood; crème-filled goods; breaded items; prepared salads; etc.), sampling may be warranted, based on observations or as directed in the Work Plan, Compliance Program, or assignment. Follow instructions under IOM 4.3.6.6 when collecting microbiological samples to document manufacturing conditions conducive to adulteration.

4.3.6.5.1 – Collection Of Samples For Molds

Mold Samples: During inspections of manufacturers such as canneries, bottling plants, milling operations, etc., it may be necessary to collect scrapings or swabs of slime or other material to verify the presence of mold. The sample should represent the conditions observed at the time of collection and consist of sufficient material to confirm and identify mold growth on the equipment. If possible, take photographs and obtain scrapings, or bits of suspect material. Describe the area scraped or swabbed (for example, "material was scraped or swabbed from a 2" x 12" area".)

Suspected filth, collected from ceilings, walls, and equipment, for mold examination must be kept moist by placing it in a container filled with a small amount of a 3-4% formalin solution. Large amounts of slime may be placed in a wide-mouth glass jar with either a 1% formaldehyde solution, or a 3-4% formalin. Note: Formalin is normally sold as a standard stock solution of 37%. To obtain the required 3-4% formalin solution, you'll need to mix 10 ml of the 37% stock solution with 90 ml of distilled water. This will yield the appropriate strength solution necessary to "fix" the mold.

Although formaldehyde or formalin are the preservatives of choice, if they're not available, you may preserve the subs in either a 50% alcohol solution or in acetic acid (full strength vinegar).

Special health/safety note: Formaldehyde/formalin is a common sensitizing agent that can trigger an allergic reaction in normal tissue after single or repeated exposures. It is also classified as a known human carcinogen (cancer-causing substance) by the International Agency for Research on Cancer and as a probable human carcinogen by the U.S. Environmental Protection Agency (EPA). Investigators must understand the hazardous properties of formaldehyde/formalin so that control measures can be taken to minimize their exposure to it.

The above instructions apply to the collection of raw material, in-line, and finished product samples for mold. However, in-line and finished product subs such as doughs, etc., which may be harmed by formaldehyde, may be frozen. Check with your laboratory for its recommendation regarding preserving mold samples.

4.3.6.6 – Collection of Environmental and Product Samples for Food Susceptible to Contamination with Pathogenic Microorganisms

Sampling for products susceptible to microbial contamination and the environment in which they are produced may help identify the presence of pathogenic microorganisms before they can cause illness. With the recent increase in foodborne outbreaks and inspections identifying links between outbreaks and environmental contamination (including that associated with non-food contact surfaces), there will be an increased focus on routine environmental sampling during inspections. Conduct environmental surface sampling as directed by the work plan, compliance program or assignment, or based on inspectional observations. If you are unsure of the circumstances under which to perform environmental sampling, consult with your supervisor. Also see IOM 5.8.7.3 for inspectional guidance for firms producing products susceptible to contamination with pathogenic microorganisms.

Collection of environmental and product samples for microbiological testing requires a thorough understanding of critical factors associated with the production of the specific product being inspected. In other words, to prove the establishment is being operated in an insanitary manner, it is necessary to show the manufacturing operation or conditions at the facility that are likely to, or have contributed to, the bacterial load of the product. When feasible, inspections should include equipment conditions before a day's production begins as well as the clean-up at the end of the day's production. Note that for environmental Salmonella sampling, it is preferable to sample before the plant conducts a wet cleaning operation.

Environmental sampling should include sponges or swabs of food contact surfaces (particularly for Listeria monocytogenes) and non-food contact surfaces (particularly for Salmonella serotypes), based on observations, or as directed. Environmental monitoring supplies should be brought into the firm using precautions to prevent the transfer of foreign material into the processing area.

In-line sampling should be conducted based on observations or as directed. When visible microbial contamination is observed, collect finished product as directed in the compliance program or assignment.

When conducting environmental sampling or product sampling for microbiological testing, whenever applicable, an investigator/microbiologist team approach should be used. For environmental sampling, an additional employee is recommended to assist with the collection and/or recording of information.

4.3.6.6.1 - Environmental Sampling

CFSAN has developed guidance on the specific locations within a firm to collect environmental samples to increase the likelihood of detecting Listeria monocytogenes and Salmonella that may be present. See IOM Exhibit 4-20 and 4-21 and SOP-001052 (ORA Field Bulletin #30 – Food Program Area – Instructions for Environmental Sampling for guidance on environmental sampling/locations for these microorganisms. In addition, please view the training video Environmental Sampling in Food Manufacturing mentioned in SOP-001052 (ORA Field Bulletin #30 – Food Program Area – Instructions for Environmental Sampling), which provides technical and procedural information on environmental sampling.

In most cases, it is preferable during your discussions with a firm not to mention FDA's intent to collect environmental samples until, immediately, before sampling begins. Advance notice/pre-announcement of environmental swabbing may possibly provide the firm with the opportunity for unscheduled sanitation activities. Any such actions by the firm could potentially inhibit microbial recovery and compromise environmental sample(s).

During the initial phases of the inspection, the investigator should conduct a walkthrough assessment observing and mapping operations, including the location of equipment, flow of the product, foot traffic of employees, forklift/mule traffic patterns, segregation of raw material versus finished products, and consider sampling areas where food is exposed and being processed, particularly post-treatment/pasteurization.

The “Zone Concept” identifies and prioritizes processing areas from highest risk and closest to the product, to lowest risk and farthest from the product, for potential contamination, including harbor growth and “niches” for targeted pathogens, and therefore, should be implemented upon conducting environmental sampling as follows:

Zone 1: Refers to all direct food contact surfaces, such as slicers, mixers, conveyors, utensils, racks, worktables, etc. For inspections focusing on the presence of Salmonellae, such as firms producing peanut products and other dry product environments, food contact surfaces are normally not sampled unless specifically requested in the assignment or CP. In contrast, for inspections focusing on detection of Listeria monocytogenes, such as firms producing seafood or cheese products in a wet environment, sampling of food contact surfaces is essential.

Zone 2: Encompasses the areas directly adjacent to food contact surfaces (Zone 1). For investigations focusing on Salmonellae, this is the area where environmental contamination is most likely to directly affect safety of the product. In a small production room, Zone 2 encompasses all non-food contact surfaces in the processing area, such as the exterior of equipment, framework, food carts, equipment housing, gears, ventilation, and air-

handling equipment, and floors. In a much larger room for example, one that measures20,000 square feet), Zone 2 is the area in the immediate vicinity of food contact surfaces, such as around the exposed product where you could envision a pathway to product contamination either through the actions of people or machines.

Zone 3: The area immediately surrounding Zone 2. Zone 3 is an area which, if contaminated with a pathogen, could lead to contamination of Zone 2 via actions of people or the movement of machinery. Examples of Zone 3 areas include: corridors and doorways leading into food production areas or areas in a large production room that are further away from food-handling equipment than typical zone 2 areas. Walls, phones, forklifts, and "mules", even if physically located in Zone 2, should be considered part of Zone 3 due to a decreased likelihood of cross-contamination.

Zone 4: The area immediately surrounding Zone 3, generally considered a remote area. Zone 4 is an area which, if contaminated with a pathogen, could lead to contamination of Zone 3 via the actions of people or machinery. Examples of Zone 4 areas include an employee locker room (if not immediately adjacent to food production), rooms, dry goods storage warehouse, finished product warehouse, cafeterias, hallways, and loading dock area.

Every effort should be made to conduct Listeria sampling when the facility has been in production for at least four hours and before any wet cleaning is performed. In instances with smaller firms that have short production periods, swabbing should be conducted during the mid-to-tail-end of their production schedule.

In most cases, subsamples for Salmonella will be collected from the Zones 2 – 4 (see below), concentrating primarily on Zone 2. Samples should be collected from the equipment itself, particularly equipment mounting and support structures. When targeting Listeria, swabs will be collected primarily from Zones1 and 2. Perform most of the sampling for Listeria in, on, and around food contact equipment, focusing on areas where food is exposed and being processed, particularly post-treatment/pasteurization.

A large majority of the environmental samples collected should be taken from Zones 1 (when directed and depending on the organism in question) and 2, and, to a lesser degree, Zone 3 areas. Very few, if any, environmental samples should be taken from Zone 4 areas.

Swab subsample numbers for each organism are as follows:

For Salmonella environmental swabbing, collect at least 100 swabs/subs and ideally 300 or more subs.

For Listeria environmental swabbing, collect at least 50 swabs/subs and ideally 100 or more subs.

Document the possible link between the source of an environmental sample and contamination of the food product using both written descriptions and photographs. Describe the location of the sample in relation to areas where food is exposed and any mechanical or human activities you observe that might cause an organism to be spread beyond this niche environment. The division's response to a positive swab will depend on the proximity of the sample location to the processing line and the likelihood of cross-contamination between the swabbed surface and food or food contact surfaces.

On occasion, firms may opt to collect their own swabs in conjunction with your sample. If this occurs, request the firm to provide their results when available.

Medical Devices:

Environmental sampling for medical device manufacturers should follow the same strategies outlined above, as well as any other instructions provided by your supervisor.

4.3.6.6.2 - Environmental Sampling Equipment and Instructions For Large and Small Area Environmental Surface Sampling

These instructions should be followed to ensure standardization of FDA environmental sample technique across divisions:

For environmental sampling, the broth or buffer serves two purposes: 1) to neutralize sanitizer that may be on surfaces that you are sampling, and 2) to provide nutritional requirements for the organisms of interest to survive the transport to the laboratory.

Dey-Engley (D/E) neutralizing broth or buffer[5] has been shown to be effective as a neutralizing agent against the widest range of sanitizing agents that may be in use by a firm and, per ORS, is the one to be used for general purpose environmental sampling.

For large area environmental sampling, handheld sponges or sponges on a stick should be used. The sponges on a stick reduce manual contact with the sponge during the sampling procedure and are good for accessing tight spaces. Dacron tip swabs are recommended for small area environmental sampling (approximately 10cm x10 cm, or 4 x 4 inches).

Sampling Equipment:

If sources cannot be located for sponges or swabs pre-hydrated with D/E Neutralizing buffer or broth, use un-hydrated sponges and swabs along with single use tubes of D/E neutralizing broth. Do not add additional D/E buffer or broth to other types of hydrated sponges and swabs that contain either a neutralizing broth or an enrichment broth, as this may dilute the concentrations of both components to the extent that they will not be effective.

Handheld sponges or sponges on a stick pre-hydrated with D/E neutralizing broth if available, dry handheld sponges or sponge on a stick, swabs pre-hydrated with D/E neutralizing broth, dry swab in swab tube with screw on cap or single use tubes of D/E Broth are recommended.

If you need sourcing information for equipment, please contact the Division of Domestic Human and Animal Food Operations (DDHAFO) at (301) 796-0360.

Other general sampling supplies you will need for environmental sampling:

1. Sterile gloves
2. Hand sanitizers (wash and sanitize hands often during sampling)
3. Cooling medium for samples
4. Boxes or coolers
5. Labels to ID samples
6. Permanent marker

[5] The terms broth or buffer are used interchangeably for this product.

7. Flashlight
8. Sterile metal spatulas (small) or other sterile implement to scrape debris out of cracks

It is important to use sponges or sponges on a stick for the large majority of samples, since you can sample and "scrub" a larger area with a sponge compared to a swab. Swabs are only appropriate for areas that are inaccessible to sponges.

Sampling Method:

For large area environmental sampling, handheld sponges or sponges on a stick should be used. The sponges on a stick reduce manual contact with the sponge during the sampling procedure and are good for accessing tight spaces. Dacron-tip swabs are recommended for small area environmental sampling (approximately 10cm x10cm, or 4 x 4 inches) and for cracks and crevices.

Gloves:

For collection of environmental samples in Zones 2 –through 4, and for firms targeted as part of routine surveillance inspections only, it is not necessary to change gloves between each sub provided that the investigator or analyst remains in the same zone and the integrity of the gloves is not compromised during the course of collecting the sub, (that is, glove has not ripped, or brushed against a lab coat, etc.) For example, if 50 swabs are collected in Zone 2, the investigator or analyst would not need to change gloves between each of these subs until moving to another zone, or to another distinct processing room or area, unless the condition of the gloves warrants changing. Regardless, though, gloves should be sanitized between each sub by applying a 70% solution of ethyl alcohol (preferred) or 70% isopropyl alcohol. Note, too, that collection of a large number of subs in one area would necessitate several changes of gloves.

For swabs collected in Zone 1 and during "for-cause" inspections (such as those conducted in response to a current or previous outbreak, or an emergency), continue to follow the established policy and change gloves between each sub as described in the Environmental Sampling training video.

Sampling of Dry Surfaces:

Using a felt-tip black permanent marker, label the sterile bag containing the sponge with appropriate sample information.

1. Wash and sanitize your hands to the mid-forearm. Use clean disposable paper towels for drying your hands.
2. From the outside of the sponge bag, manipulate the handle toward one side. Pull off the top of the whirl-pak bag holding the Sponge-stick along the perforation. Using the tabs on both sides of the wired band, pull gently to open the bag. Do not remove the Sponge-stick.
3. Pour into the Sponge-stick bag 9-10 ml or sufficient volume of DE neutralizing broth on the side *away* from the handle to hydrate the sponge (do not get broth on the handle). Be careful not to touch the opening of the broth container to any non-sterile surface before or during this transfer.
4. Massage the sponge through the outside of the bag to facilitate absorption. From the outside of the bag, push the Sponge-stick to the upper portion of the bag. While pushing the sponge-stick up from the bottom of the bag, squeeze excess D/E broth from the sponge back into the bag. The sponge should be moist but not dripping wet.

5. Using aseptic technique, unwrap and place a sterile glove upon the hand you will use for swabbing. Do not touch any non-sterile surface (i.e., clothes, skin, counter tops, etc.) with the outside surface of the sterile glove. The other hand can be left ungloved for manipulation of non-sterile surfaces and materials if preferred.

6. Remove the Sponge-stick from the bag using your gloved hand. Using even and firm pressure, push the sponge in one direction across the desired area of the environmental surface 10 times vertically, then 10 times horizontally. If visible soil or residue is present, sample the surface by vigorously rubbing the sponge over the designated area until the soil or residue is removed. Sampling of large flat surfaces (i.e., floor, table tops, and conveyor belts) should cover areas as referenced above, and dependent on if the area is unclean, or has been cleaned and sanitized. It may be necessary to wet the sponge with additional neutralizing broth when sampling large and/or porous areas. Try to use only enough buffer to keep the sponge gliding smoothly over the surface. If there is excess buffer, squeeze it back into the whirl pack bag and continue until you have sampled the entire sampling site.

7. After sampling, return the sponge to the original Whirl-Pak bag with any excess buffer, snap off the handle in accordance with the product instructions that accompany the Sponge-stick, and submit as a subsample.

8. Remove the used sterile glove and discard.

9. Squeeze as much air out of the bag as possible. Roll the top of the bag over several times until it is folded all the way down to the sponge. Fold in the tabs to lock the fold in place. Place the sponge bag inside another empty Whirl-Pak or equivalent bag and seal as before. Both bags must be tight enough to provide both a leak proof seal and minimal airspace during shipment of the moistened sponge.

10. As soon as possible, place the double-bagged sponge inside an insulated cooler, with pre-frozen gel packs to keep the samples cold, but not frozen, and transport/ship the sample to the servicing lab for analysis so it is received by the lab within 24 hours of collection.

Sampling of Wet Surfaces:

Sample using aseptic techniques with a dry Sponge-stick following the general instructions above for removing the Sponge-stick from the bag, and for swabbing. After sampling, return the Sponge-stick to the original sterile Sponge-stick bag and using aseptic techniques, add 10 ml of D/E neutralizing broth to the bag. Proceed as instructed in #5-10, above.

Small Area Environmental surface sampling procedure (approximately 10cm x10cm, or 4 x4 inches):

Swabs are suitable for sampling only very small areas that cannot be accessed any other way. For example, the swab can be used to sample the material in a hole in the floor such as might be encountered when a piece of floor-mounted equipment has been removed from an area and the bolt hole that remains has not been repaired/filled. Swabs may also be useful for sampling floor cracks, or the inside of tubular equipment mounts.

Sampling of Dry Surfaces:

Collect samples using aseptic techniques with the swab pre-hydrated with D/E Neutralizing Solution. Using even and firm pressure, swab in one direction across the desired surface 10 times vertically, then 10 times horizontally, then 10 times diagonally. If visible soil or residue is present, sample the surface by vigorously rubbing the swab over the designated area until the soil or residue is removed. Return the swab to its vial,

place in a Whirl-Pak bag, and as soon as possible, place inside an insulated cooler with pre-frozen gel pack for transport/shipment to the laboratory.

Dust and debris scrapings may also be collected using a sterile implement from facilities producing dry products, such as nuts and powders. In these cases, a minimum of 5 to 10 grams should be collected with 100 grams being optimum. When sampling mops or brooms, swabbing with a sterile sponge pre-hydrated with D/E Neutralizing solution is an efficient method, although mop strands and broom bristles may also be clipped and submitted.

Sampling of Wet Surfaces:

Collect the sample using aseptic technique using the dry swab in the same manner as noted above. After swabbing, still using aseptic technique, add D/E neutralizing solution to the swab and transport to laboratory as noted above.

Collect debris on equipment and from floor defects, joints, and gaps. Debris can be scraped out using a sterile implement, such as a small metal spatula. A minimum of 5 to 10 grams should be collected, with 100 grams being optimum.

Closed Controls:

For environmental samples only, collect one closed control for each distinct lot of sterile equipment used and submit with the final collection of subs on the last day of sampling.

Open Controls:

Open controls are not to be submitted for environmental sample collections.

Sample Numbering:

Often, multiple days are required to collect an appropriate number of environmental swabs. If an environmental surface sample is collected on multiple days during an inspection, use a new sample number for each day, (for example., sample no. 100000 on the first day and sample no. 100001 on the second day). The subs should be numbered sequentially (for example, subs 1-100 on the first day and subs 101-175 on the second day). Link the sample numbers to the assignment for tracking purposes. Environmental swab subs should be numerical—that is, 1, 2, 3, etc., while control subs should be alphabetic—that is, a, b, c, etc.

Product codes have been created to allow for the tracking of environmental samples by commodity; Drugs and Foods. When entering data into the FACTS systems for environmental samples, the collector of the sample will select the correct “Sample Basis” and enter the correct product code based upon the commodity.

All environmental samples, including swabs, soil, water, and animal scat, are to be identified as Investigational (INV). Use the following environmental sampling product codes:

1. 52Y[][]07 for Farm Environmental Swabs/Samples
2. 52Y[][]08 for Process/Manufacturing Environmental Swabs/Samples
3. 52Y[][]** for Animal Carcass Rinse/Swabs, where **= 01 (Beef), 02 (Chicken), 03 (Lamb), 04 (Pork), 05 Turkey), 06 (Other Animal Swabs)

4. 52Y[][]09 for Postharvest Water (for Agriculture use)
5. 52Y[][]10 for Preharvest Water (for Agriculture use)
6. 52Y[][]11 for Spent Sprout Irrigation Water (use for testing)
7. For Drug Environmental Swabs/Samples use product code 66Y[][]07.

Do NOT use the product code of the covered product for environmental samples.

4.3.6.6.3 – In-Line Sampling/Factory Food Sample

In-line sampling should be conducted as directed or based on inspectional observations.

Each in-line subsample will consist of approximately 114 g (4 oz), in duplicate (702(b) portion), if that amount is available (Also see IOM 4.3.2.2 - 702(b) Requirement). All in-line samples must be collected aseptically. In addition, each inline sample should include open and closed controls. The open control should be "opened" prior to sample collection, and "closed" when sampling is concluded. The open control should be placed near the location where the sample is being collected. The inside of the open control should be exposed only to the air in the environment. Do not set open controls, such as gloves, directly onto the floor, or in contact with equipment, etc. If different lots of sampling equipment are used (for example, two different lots of gloves are used during sampling) then each lot should be represented by both an open and a closed control.

The following are areas vulnerable to microbial growth in which in which you'll commonly collect in-line samples (Note that this is not a comprehensive list since each firm will be different, and sampling will be dependent processing/packaging techniques, as well as the type of finished product produced):

"Raw" ingredients used in the manufacturing of finished foods (including those conveyed by bulk tankers) should be considered for sampling to determine the effect of subsequent processing on bacterial content. Of particular concern are raw materials that can support microbial growth, are not normally cooked or prepared in a manner that is lethal to pathogenic microorganisms (such as dairy, soy, corn, or sugar syrup-based products), and adequate controls to ensure the safety of the finished product are not in effect. Since the major portion of some finished food products are not homogeneously contaminated, it may be necessary to collect multiple subsamples of the raw material(s) to establish a reliable microbial base line.

Obtain sequential subsamples with the view of bracketing each step of the processing operation, in particular those steps suspected as routes of product contamination. A series of in-line samples should be collected during the first part of a shift, and a duplicate series during the latter part.

If products or components are heated (for example, blanched, boiled, etc.) take subsamples immediately before, and immediately after, heating, before possible insanitary equipment and processing delays contribute to bacterial increases. Particular attention should be given to determine routes of cross-contamination from the raw product to the "heated" product, especially if this heating step is critical to the destruction of pathogenic organisms.

If a product is capable of supporting microbial growth and is not being handled expeditiously, sample before and after this particular processing step.

Take time and temperature measurements of cooking, freezing and cooling procedures. Sample when appropriate to demonstrate possible microbial growth. Large masses of ingredients may cool or warm slowly enough to permit microbial growth.

Improperly cleaned equipment may contaminate the product with bacteria. This may result in either a uniform or a spotty increase in bacterial numbers. If possible, scrapings of questionable material should be in sufficient quantity to be easily weighed and quantitatively diluted, if collected for analysis.

4.3.6.6.4 - Finished Product Sampling

Collect finished product as directed in the compliance program, assignment, or by your supervisor. Collect product from production on the day of the inspection and from the previous day's run. Sampling multiple lots should be considered, depending on the type of product and process used. The subsamples should consist of ten (10) retail size containers, at least 114g (4 oz) each, in duplicate (702(b) portion.

If the finished product is also to be analyzed for Salmonella, collect samples in accordance with instructions in the IOM. See Salmonella Sampling Plan, Schedule Chart 1.

For medical devices labeled as sterile, but with suspected or apparent defective packaging, refer to CPG 300.400 for additional information and consult with your supervisor for additional instructions.

4.3.6.6.5 - Reporting Environmental Sampling Results on the FDA 483

Environmental sampling in ORA's foods program has received heightened focus as of late, as evidenced by increasing assignments in the field. To better support consistent policy in this area, criteria for reporting positive environmental sample results on the FDA 483 has been outlined by the Office of Chief Counsel (OCC) and the ACRA. Note the following guidance in support of this policy. This applies to the foods program only.

Significant positive environmental sample results, from swabs collected at food firms, are to be reported on the FDA 483 if the results are known prior to the conclusion/closeout of the inspection. However, this does not mean you should unnecessarily extend inspections to include the results. The reasoning behind the implementation of this policy is that it addresses the following important activities and objectives:

1. Informing the firm of positive results where food products are concerned.
2. Eliciting firm feedback in response to positive results.
3. Providing an opportunity to provide relevant information to both regulators and the public when released under FOIA, thereby potentially uncovering, and linking other investigational information that can aid in the determination of root contamination cause(s).
4. Fulfilling our responsibility to document positive environment sample results as significant observations that can contribute to potentially unsafe conditions posing risks to public health.

Positive environmental sampling results should be noted on the FDA 483 when the following conditions are met:

1. The sampling is related to a current or future foods program inspection/investigation.
2. The inspection has not been closed (Note: it is not requested that the period of inspection be extended for the purpose of receiving analysis results).
3. The positive sample finding(s) you uncover represent a significant observation, for instance, you are able to clearly demonstrate a route of contamination from the environment to the product by establishing positive sample result(s) in Zones 1 and/or 2 for *Listeria,* or positive sample result(s) in Zone 2 and/or 3 for *Salmonella.*

Note that findings in Zone 3 (*Listeria*) and Zone 4 (for either pathogen) should not be reported on the FDA 483 as they normally are not considered significant--except in combination with positive findings in Zones 1 or 2, as these additional findings would further strengthen regulatory action.

Note regarding medical devices:

Positive environmental sampling results for medical devices may be reported on the FDA 483 with concurrence from the Compliance Branch and CDRH.

4.3.6.7 - Samples for Viral Analysis

Sample instructions will be issued by the appropriate center, on a case-by-case basis.

4.3.7 - Economic Violations

4.3.7.1 – Net Weight and Volume Determinations

In cases where you are directed to collect samples for short weight or volume, consult with ORS regarding the number and size of subsamples and the servicing laboratory to be used, unless already outlined in an assignment. Consult with your management about whether or not a field examination is required during the sample collection.

Exhibit 4-6 is FDA form 485, Field Weight Sheet, and may be used if conducting a field examination.

Instructions for use of the form are on the second page of the exhibit.

To use the form, weigh 48 units, if that number is available, selected at random from the square root of the number of cases in the lot with a minimum of 6 and a maximum of 12. Where units are selected from the production line, do so in representative manner. Report the code weighed and if short weight, the quantity in the code. Unless otherwise instructed, do not weigh leaking containers. Identify each unit with the corresponding sub number on the Field Weight Sheet (FDA 485).

Submit the units indicated by the asterisks on the FDA 485 plus twelve additional weighed units for reserve if the average net is below that declared on the label.

4.3.7.2 Economic Labeling

See FDA's Industry Resources on the Changes to the Nutrition Facts Label for guidance. See CFSAN's Office of Dietary Supplement Programs and Office of Nutrition and Food Labeling websites as well as FDA.gov for the most up-to-date information regarding claims in labeling. (Note: access to ONFL SharePoint site must be requested.)

Also, see CPGM 7321.005 to determine enforcement priorities for food labeling violations, including those related to the Food Allergen Labeling and Consumer Protection Act (FALCPA).

4.3.8 - Organoleptic Examinations

Examination of many products may be conducted on the spot without fixed laboratory equipment. These examinations vary from simple visual observations for gross filth, such as rodent pellets in wheat, to the detection of odors of decomposition in seafood. Organoleptic examinations for regulatory purposes shall be made only by those individuals qualified by training or experience to conduct such examinations.

Review your Compliance Program Guidance Manual and IOM 4.3.6.1 and 6.3 for field examination techniques that may be applicable to specific products or a specific industry. Compliance Program Guidance Manuals also contain decomposition sample schedules.

4.3.8.1 - Whole-Bag Screening

When making filth examinations by screening shelled peanuts, dried bean, peas, and similar products that are packed in large containers (for example, in 50-125 lb. bags), use the portable, folding, whole-bag screens available in your division.

Conduct the examination in a well-lit area. Set up screen and adjust height to permit opening the bags directly onto the high side of the screen. Place another bag or container on the screen's low side to catch the screened product.

Place a sheet of clean butcher or similar paper in screen body to catch screenings and insert screen wire over paper.

Open stitches of bag being examined to permit approximately ten- to twenty-pound portions to enter onto high side of screen. Gradually work the product across the sieve to the low side and into the receiving container. Do not push large quantities rapidly across screen because insects, eggs, stones, excreta pellets, etc., will be carried along with the product and will not sift through the sieve openings.

Examine the screening from each bag and subjectively report live or dead insects, rodent excreta pellets, or other obvious filth. Submit screenings as separate subs if actionable.

4.4 – Documents Collected with Sample

An official sample is not complete without records documenting its existence in interstate commerce. Additional documents may be collected, such as processing records and laboratory procedures used by the dealer.

Follow your division or program procedures for maintaining hardcopy and/or electronic records covered in this section. See 4.6.4 – Routing.

4.4.1 – General Considerations/Procedures regarding Documents

Ensure the copies of records obtained pertain specifically to the sample collected. If copies of certain records are unavailable (for example, shipping records are no longer available at the site or have been destroyed due to age), you should add statements documenting the circumstances on the affidavit and, if possible, document where these records could still be obtained and from whom.

Do not remove the dealer's only copy of records. Whenever possible, scan, photograph, or photocopy it. Reproductions must be reviewed to ensure all relevant information is readable and to verify the copy you receive is an accurate representation of the original record.

Digital tools may also be used to enhance the contrast of documents scanned or photocopied to make them more readable. Whenever enhancement is applied to a document using any method, document the steps taken in your notes and the corresponding collection report.

In cases where the finished product being sampled is not shipped to interstate customers, but is formulated from raw materials with interstate origin, jurisdiction may be established by documenting the interstate shipment of one or more major raw materials. (This would be a 301(k) sample. See IOM 4.1.4.2.2.) An affidavit from a knowledgeable and responsible firm official may be used to link copies of records showing interstate movement of the raw material with copies of records showing subsequent use in the lot being sampled; if documentation of the use in production is not available or clear, statements on an affidavit may be collected to support the linkage.

4.4.2 – Identifying Sample Records

Identify copies of all records obtained (except copies of FDA forms) and attach to the collection report labeled with the sample number (including the prefix if appropriate), collection date, and collector's name or initials (the investigator who completes the collection report is the collector, See IOM 4.6.2.10). If more than one document (other than FDA forms) is to be attached to the collection report, include a sequential document number as part of the document label which will be used to refer to the document in the list of documents as part of the collection report in FACTS; copies of FDA forms may be assigned a sequential document number for identification in the collection report, but should not be labeled or altered from their original form. If a document (other than FDA forms) is more than one page in length, it should be numbered to allow reviewers to determine if any pages are missing. See IOM 5.6.7.5 and 5.6.11.2.

Here is an example of this labeling, where it is applied to the second page of the third document attached to a collection report:

"DOC117883

7/12/2022

ENH

Document 3, Page 2 of 12"

If the firm maintains their records electronically, see IOM 5.6.7.5 and 5.6.11.2.

4.4.3 - Evidence Required

When documenting known violative situations with a sample and its related records, you need to consider whether you have established FDA's jurisdiction, documented the interstate commerce, shown a violation, and determined responsibility for the violation (JIVR). See IOM 2.3.1.

When the violative nature of a sample is not known at the time of collection--for example, when laboratory analysis is necessary to determine the adulteration of a product regulated by the FDA--collection of available documentation to support a potentially violative situation should be considered. Consult with your supervisor for guidance.

4.4.3.1 – General Considerations for Evidence

When you are collecting evidence, including samples, to demonstrate a violation(s), it is important to understand the specific charges that may be made and the anticipated action the agency may take. Most charges would be made against the product or a person and are prohibited acts that can be found in Section 301 of the FD&C Act [21 U.S.C. 331]. Additional information and guidance on the evidence required to support certain judicial actions is available in the Regulatory Procedures Manual, Chapter 6.

Note that throughout this section, the term dealer is used with the same meaning as outlined in subsection 4.1.3.1 of this chapter; essentially, the dealer means the person who has possession of the FDA-regulated product at the time it is been collected, regardless of the firm's operations. A dealer may be a manufacturer, warehouse, or other operator.

Below are the most common prohibited acts encountered by investigators and the kinds of evidence you may collect to demonstrate such violations. Since each case is different, you must consider carefully if you have collected the appropriate evidence to show the violations that may be charged. You should also keep in mind that

more than one prohibited act may be applicable to a product, or person, and so you should be prepared to document multiple violations related to the same product, or document multiple instances of the same prohibited act that occurred related to multiple products.

You should also consider the appropriate action the division will be taking. If the division would be considering an injunction, for instance, it is important to demonstrate that the violative action is ongoing and that collecting recent evidence to demonstrate that multiple lots of product/s were violative will support such an action. For a seizure action, you will need to consider if the division will pursue a single lot seizure or a mass seizure of products. Evidence required for a mass seizure needs to show an ongoing, widespread, uncorrected condition that causes all products the dealer holds at a location to be violative. Be sure to discuss the appropriate action with your supervisor who will likely want to confer with compliance branch and the center. However, do not let delays conferring with others delay your collection of evidence. (See 4.4.3.2)

4.4.3.1.1 - Introduction into Interstate Commerce (FD&C Act 301(a) and 301(d) charges)

If the dealer is shipping adulterated or misbranded product, collect evidence showing the dealer distributed the product in interstate commerce. You should obtain evidence showing the date of shipment and the specific shipping information of the product. Your evidence must show shipment to another state or territory of the product in question.

This prohibited act also includes “delivery for introduction into interstate commerce.” If you cannot obtain evidence showing shipment in interstate commerce, then you need to show that the dealer had knowledge that the person they were distributing it to intended to introduce the article into interstate commerce. See Section 301(a) or (d) of the FD&C Act [21 U.S.C. 331(a) or (d)].

4.4.3.1.2 - Adulteration or Misbranding in Interstate Commerce (FD&C Act 301(b) charges)

Collect evidence showing that the specific product in question was in interstate commerce at the time that it was rendered violative. See Section 301(b) of the FD&C Act [21 U.S.C. 331(b)]. If you are documenting a shipper violation at a dealer, it is your responsibility to show the storage conditions at the dealer did not contribute to the violation. Obtain an affidavit describing handling of the goods after receipt, and any other information that supports the violation. An example of this could be a refrigerated or frozen product that was shipped without proper refrigeration and “spoiled” before receipt at the dealer. Keep in mind when documenting this violation at a dealer who received the product, that there is also the violation found in section 4.4.3.1.3. Either or both charges may be made, and both should likely be documented.

4.4.3.1.3 - Receipt in Interstate Commerce (FD&C Act 301(c) charges)

If the dealer knowingly receives adulterated or misbranded product, collect evidence showing receipt of violative product in interstate commerce. The documentation collected may be the same as that collected in section 4.4.3.1.2. In general, when making this charge, you should demonstrate that the dealer was aware of the violative condition of the product before the delivery or accepted the delivery knowing the product was violative. Whether it was sold or given away is immaterial. See Section 301(c) of the FD&C Act [21 U.S.C. 331 (c)].

If the dealer causes the adulteration or misbranding of an FDA-regulated product, it is a 301(k) violation. See 4.4.3.1.6 below.

4.4.3.1.4 - Manufacture Within a Territory (FD&C Act 301(g) charges)

Under this prohibited act, the product does not need to be shipped in interstate commerce. The mere act of manufacturing a violative product in a territory (as defined in Section 201(a) of the FD&C Act [21 U.S.C. 321(a)(2)) is prohibited. Collect evidence revealing that the product was manufactured within any territory. Note that the term territory does not include the Commonwealth of Puerto Rico. See Section 301(g) of the FD&C Act [21 U.S.C. 331(g)].

4.4.3.1.5 - False Guaranty (FD&C Act 301(h) charges)

A guaranty typically involves a statement that the product being sold to the dealer in in compliance with the FD&C Act or FDA regulations. In addition to evidence showing the guaranty is false (for example, the product was adulterated when received) obtain copies of the specific guaranty. Also collect any shipping records associated with the violative product. Each guaranty usually covers a specific sale (and delivery) on or about a definite date to the holder of the guaranty. Although interstate commerce is not required, you should obtain evidence demonstrating that the consignee normally engages in some kind of interstate business. See Section 301(h) of the FD&C Act [21 U.S.C. 331(h)] and 21 CFR 7.13, 201.150 and 701.9.

4.4.3.1.6 - Dealer Violation (FD&C Act 301(k) charges)

For this prohibited act, you must collect records showing the dealer received the product in interstate commerce and that the product was made violative by the dealer. One example of this is adulteration of product in a filthy warehouse where there is rodent activity and there is evidence that the product is being adulterated with filth by the rodents (for example, a rodent infestation). Another example is where a drug manufacturer receives an unadulterated active pharmaceutical ingredient and by failing to follow GMPs manufactures a violative product. In both cases, collect evidence of interstate origin of the article (in our examples, the product found adulterated by rodents or the active pharmaceutical ingredient) and proof of a specific action which adulterates or misbrands the article (for example, evidence of rodent activity or failure to follow GMPs). See Section 301(k) of the FD&C Act [21 U.S.C. 331(k)] and IOM 4.1.4.2.2.

4.4.3.2 – Evidence for Seizure, Injunction or Criminal Prosecution

For a seizure action (see IOM 2.8.3), the FDA must fulfill the following: establish jurisdiction over the product, show its interstate movement, and document a violation. However, it is not necessary to establish responsibility for the violation.

You should obtain copies of all available records that show the article was introduced into or in interstate commerce or held for sale after shipment in interstate commerce. Additional information on the requirements for seizure actions can be found in the RPM, Chapter 6-1. See also 21 U.S.C. 334 (FD&C Act 304) - Seizure.

For an injunction (see IOM 2.8.4) or criminal prosecution (see IOM 2.8.5), the proof required depends on the violations of the law. Information on the specific requirements for these actions can be found in the RPM, Chapter 6-2 and 6-5. See also 21 U.S.C. 331 (FD&C Act 301) - Prohibited Acts.

4.4.3.3 - Complaint or Injury Samples

Generally, samples collected from complainants during investigation of injuries or foodborne out-breaks are investigational in nature and significant documentation of interstate commerce is not collected. However, if the nature of the contamination or adulteration is such that regulatory action may be warranted, the interstate nature of the

sample should be well documented. Affidavits from the consumer, retailer, and wholesaler should be obtained as applicable.

At times, even though you may not be able to obtain physical portions of the involved item, a Documentary Sample can be collected by photographing the container, contents, labels, codes, etc., and by obtaining necessary affidavits and interstate records. See IOM 8.1.5 for additional instructions on tampering, counterfeit, and other complaint samples.

4.4.4 - Documenting Interstate Shipments

The minimum set of records ordinarily submitted with an official sample will consist of a copy of the invoice covering the sale of the lot, batch, or unit to the dealer; the transportation record showing interstate commerce; and an affidavit signed by the dealer that identifies both the lot, batch, or unit sampled and the applicable records. See IOM 4.4.2.

Documentation obtained at a location other than the dealer where the sample was collected should be the subject of a memorandum to accompany the collection report.

Note: In the case of imported products that have been released to domestic commerce, documentation of the sample should also include the port of entry and the importer of record, if possible, to facilitate investigation by the home division if necessary.

4.4.4.1 - Sales Records

An invoice does not establish interstate commerce and thus federal jurisdiction. It does not prove actual movement of an FDA-regulated product. However, it may provide information as to the value of the goods, the carrier, date of shipment, etc., and bear a Food and Drug type guarantee. Collect copies of the invoice to show the owner's intent to sell the product and tie other records to the sample. If the invoice covers numerous items, be clear on which lines correspond to the sampled products and identify those in the collection report. Other records which may be collected in addition to an invoice to show product sales are: copies of purchase orders, receiving records, canceled checks, correspondence, etc. If no invoice is available for a sample, one or more of these should be collected and included in the collection report.

In addition, invoices often show details about the contents of a shipment and its value, and a Bill of Lading (BOL) may not. For example, a BOL may indicate one pallet of canned food, but the invoice will declare that the purchaser paid for “50 cases of 6 containers each of #10 cans of green beans” and include the cost per container. Tying the Invoice and BOL together shows exactly what product was shipped in interstate commerce under the BOL. The BOL often refers to an invoice # and vice versa as well. The affidavit is critical to tie the two together.

Invoices covering in-transit shipments usually are not available. For these samples, document any available transportation record that establishes the lot to be in interstate commerce. Be sure to name the shipper and consignee if known. Where positive identification of a shipment cannot be made by personal observation, obtain a statement from the carrier's agent identifying the shipment sampled as having been delivered by the consignor on a certain day for delivery to the consignee. Include in this statement reference to the specific transportation record covering the shipment. The transportation record will generally be available after the shipment is delivered.

4.4.4.2 - Transportation Records for Common Carrier Shipments

Section 703 of the FD&C Act [21 U.S.C. 373] provides for mandatory access to and copying of all records showing interstate movement of commodities subject to the Act. This is provided the request is in writing, and the records are in the possession of common carriers, or persons receiving or holding such commodities.

Section 704(a) of the FD&C Act [21 U.S.C. 374(a)] provides mandatory access, upon presenting your credentials and issuing a written notice of inspection, to documents covering the interstate movement of non-prescription drugs for human use, prescription drugs, and restricted devices. The authority applies to inspection of any factory, warehouse, establishment, or consulting laboratory in which prescription drugs, nonprescription drugs for human use, or restricted devices are manufactured, processed, packed, or held.

Note: At times, you may have only the name of the carrier (trucking company), with no address or phone number. If you are unable to locate the trucking company, contact the local office of the U.S. Department of Transportation (DOT) Federal Motor Carrier Safety Administration (FMCSA). Local contact information can be found at the FMCSA field office contact information website.

4.4.4.2.1 - Refusal To Permit Access To Records In Possession Of Common Carriers

Refusal to permit access to and copying of all records showing interstate movement of articles subject to FDA jurisdiction is unlawful provided the request for such permission is issued in writing. You cannot state that the law requires the records be furnished to FDA unless you also explain that it is required only after a written request is issued. If refused, after providing a written request as outlined below, politely explain that the law requires the records to be furnished. You are more likely to get the records through courteous persuasion and tact than through stressing the force of law.

4.4.4.2.2 - Written Request For Records

If a carrier, consignee, or any other person refuses to supply I.S. records, and it is apparent they will not do so without a written request, report the facts to your supervisor. Do not routinely issue a written request for I.S. records since evidence so obtained may not be used in the criminal prosecution of the person from whom it was obtained.

If the request is being made of a carrier who has no responsibility for the violation, issue a written request only after approval by Division Management. When authorized by your supervisor to issue a written request, prepare a statement, using the following guidance, or as otherwise directed by your supervisor:

"Pursuant to Section 703 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 373) permission is hereby requested for access to and copying of all records showing quantity, shipper, and consignee, showing movement in interstate commerce and/ or the holding after interstate movement of_____."

Clearly identify the specific lots that are the subject of the request, the firm, and the individual to whom the request is given.

4.4.4.2.3 - Bill of Lading

The shipper who delivers the goods to the carrier for shipment, prepares the bill of lading (BOL), which is an order for the carrier to move the goods. When the carrier's agent signs the BOL, they acknowledge receipt for the shipment. The carrier's office in city of origin of shipment maintains a copy of the BOL. Information normally included on the BOL is the name and address of shipper, name and address of consignee, date of shipment, name of carrier, vehicle number, and a description of the goods.

4.4.4.2.4 - Freight Bill

This record is prepared by the transportation company for the purpose of collecting freight charges. It includes the same information found on the BOL, plus additional data about the carrier's handling of the shipment and costs involved. Railroads prepare freight bills at their destination offices, where copies can be made. Waterborne vessels and aircrafts may combine the BOL and freight bill into one form. Copies are filed at both origin and destination offices of these carriers. Truck lines prepare freight bills at the origin office, and both origin and destination offices should have copies. The dealer should have a freight bill if they received the goods directly in interstate commerce.

4.4.4.2.5 – Waybill

The transportation company uses the waybill in its own operations, and it accompanies the shipment during transit. Copies are not generally given to the shipper or consignee but can be obtained from the carrier. Other transportation records are generally more readily available than waybills. Air freight waybill numbers are designed so that the originating line and point of origin are encoded in the waybill number itself. Each airline has a numerical code description, indicated by the first two digits of the number. The three letters, which next follow indicate the point of origin. For example, Waybill No. 01LGA, designates American Airlines (01) as the carrier, and La Guardia Field (LGA) as the point of origin. Most airline offices have a copy of "Official Air Freight Transmittal Manual," which lists the codes. Other express shipping companies/parcel services, such as Federal Express and United Parcel Service, may establish their own codes for air freight waybills. Air freight waybills may be referred to as air bills, airway bill or air waybills, depending on the company/service.

4.4.4.3 - Mail or Parcel Service Shipments

Record the facts obtained from the dealer on the FDA 463a, Affidavit, or FDA 463, Affidavit (Parcel Post/Service). See IOM Exhibit 4-9.

Collect shipping documents, including the shipping label, shipping details, and proof of delivery of the shipment. To obtain documentation for USPS shipments, ask the dealer where the sample is being collected, and ask the dealer to use the shipment label reference number to print the shipping documents from https://www.usps.com. If the article was shipped with Express Mail®, point-by-point tracking details are available. To obtain documentation for parcel service (for example, UPS and Fed Ex shipments, ask the dealer to use the “tracking number” to print the shipping documents from the parcel service’s website. Always attempt to collect copies of the original wrappings showing cancellation of origin office and address sticker if the dealer is the recipient of the shipment, since the recipient will usually not be able to print the shipping label. Wherever possible, collect an affidavit to link the carrier’s (for example, UPS, FedEx, etc.) tracking number document to the actual shipment and delivery documentation and attach to the collection report.

If the shipment is not recent, the dealers may not have access to the records through their accounts. In this case, a visit must be made to a major parcel service/ parcel post office to obtain the documentation.

4.4.4.4 - Shipment by Privately-Owned Conveyance

Obtain on the FDA 463a, Affidavit, a dealer's statement setting forth the facts, including the date and manner of receipt. The affidavit by the dealer may not be evidence, since the dealer lacks personal knowledge of the point of origin. If possible, ascertain the name and home address of the driver of the conveyance, vehicle license number, the name and address of the driver's employer, or the owner of the conveyance and the driver's license number. Obtain an Affidavit, from the driver setting forth the facts of the shipment. See IOM Exhibit 4-10.

4.4.4.5 - Form FDA 1662, Copy of Invoice/Shipping Record

A Form FDA 1662 can be used to record invoice and/or shipping record information--see Exhibit 4-8. Invoice information can be entered in Section I, Copy of Invoice. For invoice information, record entries covering items sampled and indicate omissions by asterisks. If the invoice bears a Food and Drug guarantee, copy the guarantee on the back of the FDA 1662. Bill of Lading or Freight Bill information can be entered in Section II, Copy of Shipping Record. Enter the type of shipping record in Block 21. If only one section is used, leave the other section blank and submit the entire form.

4.4.5 – Affidavits

Statements on various affidavit forms may be obtained from individuals who have in some way dealt with the goods sampled, know material facts relating to the movement of the goods, and/or to events affecting their condition. Such facts, recorded in writing and signed by the individual who can testify in court to those facts, can be used either to establish federal jurisdiction or the responsibility for a violation. The statement may cover the following items: identify documents proving I.S. movement of goods sampled, name the individual who can testify to the identity of the goods sampled, and certify that the sample collected is from the lot of goods covered by the records. While these statements may be obtained from firm management, when possible, it may be necessary to obtain affidavits from other knowledgeable individuals if management is not personally aware of, and cannot testify to, such matters. See IOM 4.5.1 for additional requirements for Bioresearch Monitoring affidavits.

4.4.5.1 - General Considerations for all Affidavits

You should have the affiant read the statement and make necessary corrections before signing the affidavit. Mistakes, corrected and initialed by the affiant, are an indication that they have read and understood the statement. A handwritten statement on the affidavit by the affiant, declaring that they have read and understood the statement, is a valuable tool to counter the possibility the affiant might later claim ignorance of what was signed.

During investigations of alleged tampering incidents, complainants must be advised of the provisions of the Federal Anti-Tampering Act (FATA). A general discussion of the FATA, its provisions for investigation, filing of false reports, and tampering can be useful and informative to those individuals. See IOM 8.1.5.9.9

Before the individual signs the statement, ask them to affirm that the affidavit is true and accurate. A statement to that effect can also be added at the conclusion of the affidavit. See IOM Exhibit 4-11.

You should only sign the affidavit in the presence of and immediately after the affiant has signed it. As the wording on an affidavit above your signature reads, "Subscribed and sworn to before me at ***," with “subscribed,” in this context, meaning to attest by signing--your signature is attesting to the fact that the affiant has read and understood the statement and has confirmed that the statement is the truth. You MUST NOT sign an affidavit until after the affiant swears (affirms) to you the written statement that they have signed is true. You and the affiant should sign all pages of a multi-page affidavit. If you provide a copy of the affidavit to the affiant, it must be a copy and not the original, which now serves as an official FDA document.

If the affiant requests to have legal counsel review the document before they are willing to sign, and such review would not significantly delay the course of the sample collection or other activity, the affiant may make a copy of the unsigned document and provide it to their counsel. If the review will significantly delay the course of the sample collection or other activity, attempt to reach a mutually agreeable resolution with the affiant. If none can be reached, document the matter as a refusal to sign the affidavit. See section 4.4.5.3.

If the affidavit is signed, offer to provide a copy of the signed document to the affiant. Retain the original signed document for submission with the collection report. If a refusal is encountered to sign the affidavit, see instructions just below in section 4.4.5.3.

4.4.5.2 – Affidavits for Non-English or Limited English Proficiency Speakers

In cases where the affiant does not speak English, prepare the affidavit on form FDA 463a in the affiant's native language. If necessary, enlist the assistance of a translator. Having a qualified translator present is necessary to explain the statement and assist in discussion. The affiant will only sign the version in their native language—even though a translated English version will also be prepared--as that would be the one the affiant can attest to. After the affiant signs the affidavit that was written in their native language, you will then sign the native language version as the affiant has sworn this statement to you.

As noted, a second affidavit should be created to translate the statement into English, with the translator as the affiant. This affidavit includes the translator's qualifications and the English translation of the statement. The translator will swear the translation of the native language affidavit is accurate. After the translator signs the second affidavit, the FDA employee will sign it. Note that the translator and witness to the second affidavit cannot be the same individual. The translator's signature is to be placed following the written English translation and their credentials written in the narrative section of the affidavit. The second affidavit should be appended to the original.

If the affiant requests to have legal counsel review the document before they are willing to sign, and such review would not significantly delay the course of the sample collection or other activity, the affiant may make a copy of the unsigned document and provide it to their counsel. If the review will significantly delay the course of the sample collection or other activity, attempt to reach a mutually agreeable resolution with the affiant. If none can be reached, document the matter as a refusal to sign the affidavit. See section 4.4.5.3.

If the affidavit is signed, offer to provide a copy of the signed document to the affiant. Retain the original signed document for submission with the collection report.

4.4.5.3 - Refusal to Sign the Affidavit

Prepare the statement as described above even if it is apparent the affiant will refuse to sign the affidavit. Have the affiant read the affidavit. If they decline, read it to them. Request the affiant correct and initial any errors in their own handwriting. Ask the affiant if the statement is true and correct. Ask them to write at the bottom of the statement: "I have read this statement and it is true, but I am not signing it because..." in their own handwriting.

If the affiant still does not sign the affidavit, you should write a statement noting the refusal situation. Write this near the bottom and within the body of the affidavit; it is only necessary to include this statement on the last page of the document. Detail the actions taken by both parties, such as: "I recorded the above facts as the affiant revealed them. The affiant then read the statement and avowed it to be true." Or, in contrast: "The affiant refused to read and sign the statement and stated their reason for refusing to sign was 'upon advice of corporate counsel.'" (An affiant might also refuse, claiming "corporate policy," or something similar, among other reasons). Sign and date this statement in the body of the document; only sign in the signature block if the affiant signs the affidavit. Once the refusal is documented on the affidavit, it is not necessary to include any additional narrative under the "Refusals" heading of the EIR.

After the refusal has been documented, and if the affiant requests a copy of the unsigned affidavit, inform them that copies of refused affidavits are not routinely provided to firms, but may be requested under FOIA.

4.4.5.4 - Confidential Source

You should take special precautions when obtaining an affidavit from a confidential source or whistleblower. The affiant may be reluctant to sign a statement that reveals their identity. See IOM 5.4 for guidance on interviewing confidential source or whistleblower.

4.4.5.5 - Affidavit (Dealer/Warehouseman FDA 1664)

The Affidavit (Dealer/Warehouseman), FDA 1664, is used to document the dealer or warehouseman identification of the lot and related records. See IOM Exhibit 4-12.

Fill in all blanks on the form as applicable. There are sufficient blanks for listing up to three invoices, and up to three shipping records covering the lot in question. Any unused blanks should be lined out. You should also strike out the words or letters in parentheses that are not applicable.

Be certain that the dealer knows what they are signing. Before the individual signs the statement, they should be asked to affirm the affidavit is true and accurate.

4.4.5.6 - Affidavit (FDA 463a)

Unusual sampling situations may present circumstances that do not lend themselves to presentation on the FDA 1664 or 1664b. In these situations, record the facts on an FDA 463a, Affidavit.

There is no prescribed format for composing the statement, however, you should positively identify the affiant by name, title, and address at the beginning of the statement and show why they are qualified to make the statement. The facts can be arranged in an order roughly paralleling that of the FDA 1664. In general, a narrative that describes the events and circumstances chronologically is most manageable. Whatever format is used, the recorded facts must be intelligible to the reader unfamiliar with the transaction. See IOM Exhibit 4-7, 4-10, 4-11, 4-13 and 4-14.

Ascertain all the facts and record those that are material, relevant, and to which the affiant can affirm.

Narrate the facts in the words of the affiant, using the first-person singular. Do not use stilted terms such as, "that" as in the expression "that I am the president of..." If the statement is long and complex, break it down into logical paragraphs.

Have the affiant read the statement and make necessary corrections before signing the affidavit. Mistakes that have been corrected and initialed by the affiant are an indication that they have read and understood the statement. A handwritten statement by the affiant declaring that they have read and understood the statement is a tool to counter the possibility the affiant might later claim ignorance of what was signed.

Before the individual signs the statement, they should be asked to affirm the affidavit is true and accurate. A statement to that effect can also be added at the conclusion of the affidavit. Only sign in the signature block if the affiant signs the affidavit. See IOM Exhibit 4-11.

4.4.5.7 - Affidavit (Jobber FDA 1664a)

Form FDA 1664a is used to document movement of goods from a jobber to a dealer. See IOM Exhibit 4-14. Complete all blanks as applicable. There are sufficient blanks to list up to three invoices and three shipping records. Line out any unused blanks and strike out all words and letters in parentheses that are not applicable.

Be sure the jobber knows what they are signing. Before the individual signs, they should be asked to affirm that the affidavit is true and accurate. A statement to that effect can also be added at the conclusion of the affidavit. Only sign in the signature block if the affiant signs the affidavit. See IOM Exhibit 4-11.

4.4.5.8 – Affidavit (Parcel Post/Service FDA 463)

Always attempt to collect copies of the original wrappings showing cancellation of origin office and address sticker. In uncomplicated situations, the FDA 463, Affidavit (Parcel Post/Service) may be used. See IOM Exhibit 4-9. Before the individual signs the statement, he should be asked to affirm that the affidavit is true and accurate. A statement to that effect can also be added at the conclusion of the affidavit.

4.4.5.9 – Affidavit (In-Transit Sampling FDA 1664b)

See IOM 4.1.4.2.1 and 4.3.3.3 for definition and sampling procedures. When obtaining samples from in-transit lots, if it is a straightforward uncomplicated sample requiring no unusual explanations, the FDA 1664b, Affidavit (In-Transit Sampling) may be used. See IOM Exhibit 4-3. Otherwise, use the regular Affidavit, FDA 463a.

4.4.6 – Documenting Sample Manufacturing

During collection of a sample at a manufacturer or similar entity, collection of available manufacturing records may be warranted to help establish interstate commerce, document manufacturing issues, or for other reasons depending on the reason for sampling.

The records you collect should generally show the receipt of a component, part, or ingredient after shipment in interstate commerce; the use of that component, part or ingredient in the finished product that is being sampled, the acceptance and release of the finished product for shipment/delivery; and, where applicable, documentation of potentially significant deficiencies in those activities which may render the product adulterated or misbranded (301(k)). If documentation is not present in one or more of these areas, an affidavit from a knowledgeable individual may be collected in conjunction with other documentation to establish the manufacturing of the products being sampled.

When collection of manufacturing records is indicated, consider collecting the following types of records to support your sample:

1. Receiving Records - Some firms may maintain a receiving log, receiving record, or an entry in an electronic system to indicate receipt of the components, parts, or ingredients used in production of an FDA-regulated product. Obtain documentation showing the receipt of at least one component, part, or ingredient used in the production of the finished lot, batch, or unit being sampled--such as a component that has moved previously in interstate commerce.
2. Manufacturing records – Depending on the firm and the commodity, records showing the manufacture of finished products may vary, including documents referred to as batch records, device history records, etc. Obtain documentation showing the incorporation of the component, part, or ingredient above, into the finished product lot, batch, or unit being sampled.
3. Acceptance records – Depending on the firm and the commodity, records showing the responsible individual(s) who accepted and released the products for distribution may be present on a form, in an electronic system, in an email, or documented in some other manner. Obtain the documentation showing the authorization for release of the lot, batch, or unit being sampled.

4. Manufacturing deficiencies – When samples are collected, particularly as part of an inspection, one or more potential deficiencies may be observed in the manufacturing process that could result in the products being adulterated or misbranded. Where this is known at time of sampling, obtain documentation supporting these potential deficiencies.

4.4.7 - Labels And Labeling

All samples collected must include copies of the product label and any other labeling associated with the product collected, unless the sample collected is unlabeled (for example, as with inline samples and INV samples).

Refer to Section 201 of the FD&C Act [21 U.S.C. 321] for the definition of *label* (201(k)) and *labeling* (201(m)).

Labels and labeling are critical to establishing FDA's jurisdiction over a food, drug, device, tobacco product, or cosmetic. In addition, labels/labeling are important for other reasons, such as determining which regulatory provisions and/or prohibited acts may apply to the product.

No special effort is needed to obtain copies of a label when it is affixed to the individual units collected. However, you should note that goods may be accompanied by labeling that is not affixed to the product, and in these instances, will need to obtain clear and complete copies of that additional/accessory labeling. You can obtain a copy of the original labeling by requesting an exact duplicate copy of the original from the dealer, or through photographing, scanning, or photocopying the original labeling. Even though your sample assignment may not specifically request the collection of accompanying labeling, you should still determine if such labeling exists--and if it is present--collect it.

Unless directed otherwise by your compliance program (CP) or assignment, collecting one clear and complete copy of original labels and labeling is sufficient. Scan or photograph the labels and labeling digitally so that they can be readily reviewed by various individuals located in separate offices. Do not collect the actual label or labeling if *only* one copy is available as this may inadvertently correct any misbranding that may be present or introduce misbranding via the removal of legally mandated information. Instead, if this is the case, take photographs or other copies of the single, actual label as described above. Furthermore, do not collect a *print proof* or any type of prototype as your copy of the original product label or labeling.

When documenting labeling violations, refer to the relevant Compliance Program or discuss with your supervisor if more than one original copy is required. Another means to achieve this is that a sample of product may be collected and its label stripped in order to obtain original labels.

4.4.7.1 – Definition: Labels and Accompanying Labeling

A label is a display of written, printed, or graphic matter appearing upon the immediate container of an article.

Labeling includes all labels and other written, printed, or graphic matter appearing upon any article, or any of its containers or wrappers, or accompanying (not necessarily affixed to) such article. Labeling includes such materials as--circulars, booklets, placards, displays, window streamers, books, article reprints, websites, instructions/directions for use, manuals, technical bulletins, etc.--that supplement or explain a product and/or are part of an integrated distribution system for the product.

4.4.7.2 – Collection: Labels and Accompanying Labeling

When collecting physical copies of labels/labeling, request that the dealer identify collected copies of accompanying labeling with their initials and the date (Note: a manufacturer may be considered a dealer if the product being sampled is located at the manufacturer). This initialing and dating is important as it will identify

these copies of labeling if they are introduced into court at a later date. If the labels/labeling are obtained electronically, verify with the dealer that the provided files accurately represent the labels/labeling requested. In many cases, labels/labeling may change over time, so ensure that the copies provided are in fact relevant to the lot, batch, or unit sampled--particularly for documentary samples where the product and its labeling may no longer be present at the dealer.

Prepare a dealer's affidavit on the FDA 463a, being sure to include the relationship of the labeling to the goods. This affidavit should include the following information, where relevant:

1. Description of Labeling – Describe, at least briefly, each piece of labeling by name or by using an identifiable quote. If labeling contains a revision number or other identifier, include that information (for example, a leaflet entitled, "Do You Have Tired Blood", a window streamer entitled, "Amazing New Tranquilizer", or an operator's manual entitled, "ABC Treatment Unit, Model 5600, Revision 1.2). Also note the quantity of such labeling on hand, when relevant.
2. Location of Labeling - Report the location of each different piece of literature and how much or many is at that location. If the labeling and the product are in functional proximity at a point of sale, provide diagrams or photographs of their relationship.
3. Method of Distribution - Determine how the labeling is made available to consumers and/or the public. Describe how it is displayed, such as: for voluntary pick-up; mailed to prospective customers; distributed without being displayed; placed in the shipping container with each product shipment; etc. If the labeling and the product are found at a manufacturer or distributor, document the role that the labeling will play in the distribution of the product (for example, e.g., to whom will it be sent and when).
4. Source of Labeling - Describe who created/provided the labeling, such as whether the labeling was sent to the dealer by the shipper of the goods, or if the dealer prepared the labeling themself, or if it originated from another source. It is important to document this information to establish and "fix" responsibility in the event the agency pursues action against that individual/firm. It is not necessary to determine or fix responsibility in order to seize the goods. If the labeling may cause misbranding of the products being sampled, also document the shipment of the labeling, if a source other than the dealer supplied the labeling.
5. Instructions to Dealer - The manufacturer or shipper may provide sales promotion instructions to the dealer. Obtain copies of such instructions if available.

4.4.7.2 - Bulk Shipments

Do not remove the label from bulk containers such as drums, barrels, and large bags, if this will result in misbranding the article. Instead, photograph or trace the label if none other is available.

Note: Besides using tracing paper, it is also possible to trace a label on a piece of plastic, similar to a document protector, using either a ball point pen or stylus. If it is difficult to read, filling in the tracing with a marker, may help highlight the tracing.

4.4.7.3 - Unlabeled or Partially Labeled Lot

The regulations provide for controlled shipment in interstate commerce of unlabeled goods, but only if:

1. The shipper operates the establishment where the article is to be processed, labeled, or repacked.

OR

1. The shipper, when not the operator of the establishment, has obtained from the owner a detailed written agreement signed by the operator. This agreement must contain the post office addresses of both parties and describe the specifications and the processing, labeling, or repacking procedures in sufficient detail to ensure that the article will not be adulterated or misbranded within the meaning of the FD&C Act, and upon completion of the processing, labeling, or repacking.

Determine if there is a labeling agreement and obtain copies of pertinent correspondence related to the agreement.

4.4.7.3.1 - Documentation

Collect both unlabeled and relabeled units or specimens of the label to be affixed. Collect specimens of any shipping case labels and any labeling accompanied the original shipment.

Obtain evidence showing how the lot was labeled at the time of receipt how the misbranding occurred, and who was responsible. Use photographs and diagrams if necessary to portray the present condition of the lot. If any of the lot has been resold, collect documentary evidence of the resale.

4.5 - Bioresearch Monitoring (BIMO) Samples

Samples collected under the BIMO program primarily include bioequivalence samples. Collect and ship these samples per Compliance Program 7348.003, In Vivo Bioavailability/Bioequivalence Studies (Clinical), Section 8, Reserve Samples, and any specific instructions found in the assignment memo. In addition to CP 7348.003, special instructions for BIMO affidavits, collection reports, and sample shipment are included in the sections below.

4.5.1 - BIMO Affidavits

In the BIMO program, affidavits (FDA 463a) will generally be obtained to document violative conditions or unusual circumstances observed during an inspection. Additionally, an affidavit will accompany all sample collection reports, regardless of whether or not the firm provides a statement on company letterhead attesting that the test and reference product reserve samples are representative of those used in inspected BA/BE studies, and that they were stored under conditions specified in accompanying records (for example, protocol or labeling). The reason for this is because all bioequivalence samples are considered official samples, and as such must be accompanied by an affidavit.

4.5.2 - BIMO Collection Reports (C/Rs)

All subs collected for a bioequivalence sample, including investigational product, reference, and placebo, will be included on one collection report. A scanned copy of the collection report and all associated documents will be uploaded into eNSpect as an attachment to the EIR. Additional instructions specific to certain fields on BIMO C/Rs are as follows:

4.5.3 - Sample Type

The sample type for all bioequivalence samples will be “Official.” Select “Domestic-Import,” if applicable. Note that Domestic-Import samples are considered Official; this is just the way the drop-down menu is set up.

4.5.4 - Sample Description

Ensure that this field includes a description of the investigational product collected, as well as the reference and placebo if applicable.

4.5.5 - Reason for Collection

Reference the relevant compliance program (for example, CP 7348.003, "In Vivo Bioavailability- Bioequivalence Studies- Clinical"), the assignment memo, and the inspection dates if applicable. Note that there will not be a suspected violation for surveillance samples.

Then add the following statement and edit as appropriate: "Sample of bioequivalence investigational product, reference control, and placebo. Sample is representative of test product used in study supporting Protocol (insert Study #)." You will specify the analysis desired as follows: "Collected for drug assay analysis." Include the application number (for example, ANDA 12345).

4.5.6 - Associated Firms

List all firms related to the investigational product. Associated firms for the reference and placebo can be listed in the Collection Remarks field or on a continuation sheet.

4.5.7 - Product Code and Product Name

The product code and product name listed should be that of the test article.

4.5.8 - Brand Name

List the brand names for the test article, reference, and placebo, if applicable.

4.5.9 - Product Label

Quote the label and labeling from the test article, reference, and placebo (if applicable). Be sure to use Collection Remarks or a continuation if necessary and specify which labeling goes to which product.

4.5.10 - Sample Flags

There should be no sample flags for bioequivalence samples, unless the sample is a complaint sample. This is rare.

4.5.11 - Estimated Value

It may be difficult to estimate the value of a bioequivalence sample. If the firm is not able to provide you with the value of the lot remaining after sampling, use the estimated cost of the innovator if possible. If you cannot provide an estimate, leave the field blank and note in the Collection Remarks, "Estimated Value is unknown."

4.5.12 – C/R & Records Sent to FACTS Org

For domestic C/Rs, select your division from the list of values and send the hard copy C/R and all associated documents to District Office of the collecting CSO when complete. For samples collected on foreign inspections, select the appropriate center/division (for example, CDER-CP for bioequivalence samples) from the dropdown menu and send the hard copy C/R and all associated documents to the center/division office contact specified in the assignment memorandum.

4.5.13 - BA/BE Sample Shipment

See assignment memo for current name/ address of laboratory performing sample analysis.

4.6 – Reporting Sample Collections (Completing your C/R)

For each sample collected, prepare a FACTS Sample Collection Report (C/R). Remember that the C/R is the basis for most administrative and regulatory actions.

The data you enter into specific fields of the report will provide the critical information needed by compliance officers to capably prepare documents for legal proceedings and to the analyst so that the correct analysis is performed. While there may be more than one right way to describe the information you are documenting, the readers of your collection report rely on your clear and complete descriptions to understand the specific situations you have documented. See IOM Exhibits 4-1, 4-2, 4-15, and 4-16 for examples.

Also note that if changes are needed to the firm data listed in FACTS, you should update the information in the Firm Management System (FMS) or contact your division's OEI coordinator for assistance.

After collection data is entered into the FACTS system, you (the collector) must check the record for accuracy and completeness, if appropriate, send it to a supervisor for review, and then sign it electronically. Remember that the original data will be stored and permanently associated with this record, and that any future changes to the FACTS database reference tables--such as the firm files, employee names, data codes, etc.--will not alter the original data in the electronically signed sample collection record.

Ideally, the C/R should be saved before the sample is shipped to the laboratory. Occasionally, you may have to ship a sample to the laboratory before saving the C/R. In these cases, at a minimum, the C/R must be saved before the sample is received by the laboratory. There are times when you will not be able to enter all information in a C/R before you need to save it. The following fields must be completed so that you can save the C/R in FACTS:

1. Sample Class
2. Sampling Organization
3. Collector
4. Collection Date
5. Sample Basis
6. Sample Type
7. FIS Sample Number
8. Sample Description
9. Product Code
10. Product Description
11. Resp. Firm Type
12. Resp. Firm FEI Number
13. PAC
14. Sample Origin
15. C/R and Records Sent To

Before the lab will accept the sample, you must complete the following in FACTS:

1. Collector’s Identification on Package and/or Label
2. Collector’s Identification on Seal (if applicable)

3. Size of Lot

4. 704(d) (if applicable)

5. 702(b) (if applicable)

Only the collector has editing privileges for the signed, original sample collection record. As collector, you may modify the original record, but revisions should be minimized, and you must electronically sign each revision. All modifications of the original record are permanently retained as part of the original record. A permanent electronic record trail is created, capturing, and retaining every change to original and subsequent records. If retrieval of the sample collection data is needed, the original record and all changes to the original record can be retrieved. See IOM 4.5 for additional information for Bioresearch Monitoring sample collections.

4.6.1 – Sample Type

Using the list of values, choose one of the following to complete the Sample Type field in FACTS. Identify any documents associated with the sample, and the sample itself, with the corresponding prefix, if necessary, followed by the FACTS sample number.

4.6.1.1 – Additional Sample (ADD)

To identify an official physical sample collected from a previously sampled lot. However, do not report or document as an "ADD Sample" those instances when only additional records or documentation are obtained for the sample. See IOM 4.1.4.2.10.

4.6.1.2 - Audit/Certification

To identify an official physical sample collected to verify analytical results provided by a certificate of analysis or private laboratory analysis that purports to show the product complies with the FD&C Act. See IOM 4.1.4.2.8.

4.6.1.3 - Documentary (DOC)

To identify an official sample comprised of documents and photographs, collected without a physical product. See IOM 4.1.4.1 and Exhibits 4-1 and 4-2.

4.6.1.4 - Domestic Import (DI)

To identify an official sample collected from foreign products, which have passed through Customs and entered domestic commerce. Note that the country of origin must be reported on the C/R. See IOM 4.1.4.2.5.

4.6.1.5 - Food Standards (FS)

To identify a sample collected to provide information on which to base Food Standards.

Note: Samples of standardized foods are not FS Samples.

4.6.1.6 - Investigational (INV)

To identify a sample collected to document observations, and/or where interstate commerce does not exist or is not necessary (for example, environmental swabs, filth samples). See IOM 4.1.5.

4.6.1.7 - Mail Entry

This sample type is only for import operations and should not be selected in FACTS. (See IOM 4.1.4.2.4.2)

4.6.1.8 - Non-Regulatory

To identify a sample collected and analyzed by the FDA for other federal, state, or local agencies of products over which FDA has no jurisdiction.

4.6.1.9 – Official

To identify a sample that is representative of a lot of any product covered by the FD&C Act for which interstate commerce can be documented. See IOM 4.1.4.

4.6.1.10 - Post Award

To identify an official physical sample collected under the Government-Wide Quality Audit Program (GWQAP).

4.6.1.11 – Post-Seizure (PS)

To identify samples collected pursuant to a court order from a lot under seizure. See IOM 4.1.4.2.3.

4.6.1.12 - Regulatory

A sample collected or analyzed by non-FDA personnel, including samples submitted by industry. These are usually GWQAP samples.

4.6.2 – Preparation

The C/R is the starting point and the basic reference for all actions and considerations based on the sample. It contains, or bears direct reference, to every important point about the sample and the lot from which it was collected. See IOM Exhibits 4-1, 4-2, 4-15, and 4-16 for examples.

The fields described below are listed in alphabetical order for your ease of reference. (See Exhibit 4-25 for the fields listed in FACTS entry order to facilitate completing a C/R. Please note that when a PDF C/R is generated, the field names may change on the report.)

Also, any information that needs to be included regarding the sample, and that cannot be documented via FACTS, should be documented on the C/R Continuation Sheet, FDA 464a. (For example, pictorial descriptions of a field exam for a filth sample, a description of relative documents and what they demonstrate regarding the subject lot of a documentary sample, etc.)

4.6.2.1 - Accomplishment Hours

Enter the accomplishment data for every sample collected, by clicking on the "clock" icon at the FACTS task bar. In the Accomplishment hours screen, enter the PAC by selecting from the list of values and type in the number of hours spent collecting the sample. Also enter all PACs that were entered in the Collections PACs field on page 2 of the collection record. If another individual is involved in the collection, add their time by clicking on the "Add" button. See IOM exhibit 4-16 page 2.

4.6.2.2 - Analytical Assignment

Select the “beaker” icon on page 2 and enter the sample Collection PACs, Analysis PACs, PAF (Program Area Flag) and Lab Organization for your sample. Select the PAC and PAF based on the sample assignment, compliance program, or other guidance as appropriate. Select the Lab Organization based on the ORA LST Dashboard, the sample assignment, compliance program, or other guidance as appropriate. Note that the analytical PAC and PAF may be different from the collection PAC and PAF. Enter any split sample data on separate lines.

For DOC samples, leave this field blank.

Do not enter any data in this form if the sample is being delivered to a non-FACTS lab.

4.6.2.3 - Brand Name

Enter the brand name of the product. This is typically found on the labeling of the product (for example, “Blue Bunny” carrots). For medical devices, additional research may be required to determine a brand name. It is important to identify the product completely so that the compliance officer can communicate accurate information to the relevant court and U.S. Marshal in the event of a seizure.

4.6.2.4 - Carrier Name

Enter the name of the transportation company that transported the goods in interstate commerce (if known at the time of preparation of the C/R). You may need to obtain this later to fully document interstate commerce. In the case of a 301(k) sample, this is the transportation company that moved the component you are documenting across state lines. For a 301(a) sample, used to document the shipment of a violative product in interstate commerce, enter the name of the carrier utilized by the manufacturer or distributor to carry the goods across state lines. Note that a transportation company is not to be confused with a shipper which is an establishment type and the entity responsible for causing the interstate movement of the product. See IOM 4.1.3.4.

4.6.2.5 - Collection Date (Date Collected)

Enter the sample collection date using the format, mm/dd/yyyy. Note that the default date is today's date—and to be careful not to use the default date if the sample was not collected on the date the C/R is created.

Only one date can be entered if the sample collection was accomplished over several days, use the last day of the sample collection. This date should be used to identify the physical sample and any records attached to the C/R. However, you can use the Collection Remarks section to note the additional dates and any other relevant information associated with an extended, multi-day sample collection.

4.6.2.6 - Collection Method (Method of Collection)

Describe how you collected the sample and which subs are the 702(b) portion, if applicable (See IOM 4.3.2.2 and 4.3.2.3.). Relate the number and size of the sampled units and subsamples to show how each was taken; note any special sampling techniques used; and completely describe the collection method of each sub of selective samples with multiple subsamples, including your observations of the conditions. You will normally need to use a continuation sheet to describe collection of all subsamples and your description of the lot “bag-by-bag” examination. See IOM 4.7.2.1 regarding sub identification.

Example descriptions:

1. "Two cans of product randomly collected from each of 12 previously unopened cases selected at random."

2. "Subs collected using aseptic technique and placed in sterile glass jars or whirl-packs"
3. "Subs 1-10 consist of approx. 1# of product. Subsamples 1-10 collected from bulk storage Bin #1 composited in unused, brown, paper bag."
4. “Two live insects collected from seam of bag #2. Live insects were observed exiting bag, and two were collected upon exit.”

4.6.2.7 - Collection PACs

Select the appropriate Program Assignment Code (PAC) from the list of values. Select the PAC based on the sample assignment, compliance program, or other guidance as appropriate.

4.6.2.8 - Collection Reason (Reason for Collection)

Enter the reason for sample collection to include the compliance program and/or assignment directing the sample collection; the analysis desired; the suspected violation, if any; and if collected during an inspection to document violations state such and indicates the date(s) of inspection. Identify any inter-division, regional, headquarters initiated, assignment document(s) in sufficient detail so the document can be located, if necessary. See IOM Exhibits 4-1 and 4-16.

4.6.2.9 - Collection Remarks

Enter any remarks you feel are necessary and describe any special circumstances related to the sample. You may also use a "C/R Continuation Sheet", FDA 464a if you need more space.

The following information is required if applicable (this list is not meant to be all inclusive):

1. If a 704(d) [21 U.S.C. 374(d)] letter is indicated, include the name, title, email address (if available), and the telephone number of the most responsible individual at the firm to which the analysis results letter should be addressed. (IOM 4.6.2.59)
2. If a 702(b) portion is required per the compliance program, assignment, or policy--but is not collected--describe the specific circumstance and justification for not collecting the 702(b) portion. (IOM 4.6.2.58)
3. If the sample is an in-transit sample, state as such, and include the name of the individual (for example, the driver) and the firm carrying the good, their telephone number, email, as well as the location where you collected the sample.
4. If the dealer firm is a consumer, report the name, address, phone number and email of the consumer. Include a remark to indicate if the consumer has requested information about the analytical results (see IOM 8.1.3).
5. If the sample is an environmental sample of a firm, where human and/or animal food is manufactured, processed, or packed, include the name, title, email address, and the telephone number of the most responsible person at the firm to which the analysis results letter should be addressed. Note: Do not check the 704(d) box in FACTS (see 4.6.2.59). Environmental samples do not meet the criteria of 704(d) but FDA provides the sample results to firms as described in SOP-000529 and NOT-000068.
6. If the dealer is voluntarily holding the sampled product, include the name, title, email address, and the telephone number of the most responsible person at the firm to which the analysis results letter should be addressed. Note: Select the appropriate flag in FACTS as described under 4.6.2.27.3.
7. If the sample is not sealed on the same day it was collected, describe the reason for the delay and the storage conditions you’ve employed to ensure the chain of custody of the sample will be maintained.

8. If the sample is submitted to a non-FACTS affiliation entity (for example, a state) for regulatory action, provide the reason you submitted it that entity. (See IOM 4.6.2.16)
9. If the sample is flammable, identify the flash point in °F or °C.

4.6.2.10 – Collector

As collector, your name will auto populate here.

4.6.2.11 - Collector's Id On Package/Document

As the sample collector, quote your identification placed on the packages, labels, etc. (for example, "55563 12/5/05 SHR"). Samples are to be quoted with the information in the order shown in the example without additional symbols, words, or characters. See IOM 4.7.2.3. When multiple units are collected, all or at least a portion should be labeled as subsamples. Subsample numbers need to be included on the C/R. You may include the sub numbers used in this block outside of the quotes (for example, “55563 12/5/05 SHR” subs 1-30).

4.6.2.12 - Collector's Id On Seal

Directly quote the identification you used on the Official Seal applied to the sample (for example, "55563 12/5/05, Sylvia H. Rogers, Investigator" Be sure, as in the example, to include your title too. See IOM 4.7.4 and Exhibit 4-17. If you use the FDA metal seal, enter the words "Metal Seal" followed by the seal identification and number (for example, "U.S. Food and Drug 233"), entering the actual number of the seal used.

The Collection Remarks field should be used to describe any discrepancy between the date the sample was sealed and the date it was collected, as normally, the sample should be sealed on the same day as it’s collected.

4.6.2.13 - Consumer Complaint Number

If the sample relates to a consumer complaint, select the Sample Flag for Complaint sample and enter the complaint number in the Sample Flag Remarks. That way it is easy to identify what Complaint the CR is related to and more accessible on reporting.

4.6.2.14 - Country Of Origin

Select the country of origin, if known. This field is particularly important when the sample is a Domestic Import Sample.

4.6.2.15 – County

Select the county where the sample was collected (or grown, if a pesticide sample of an agricultural product, for instance). This field is particularly useful with regards to pesticide samples as it can aid later communications with state officials, in the event of a violative result. Generally, though, this field is usually not applicable for most samples.

4.6.2.16 – C/R & Records Sent to FACTS Org (Orig C/R & Records To)

Enter the District Office of the collecting CSO associated with the sample. This field requires some thought on your part, as collector, in consultation with your supervisor. For a 301(k) sample in which the dealer is responsible, this is the division where the sample was collected. Additional notes for consideration: Do not assume the address on the label is the location where follow-up to a violative sample will be initiated, and do not send the records to another division unless you know it is the division of the actual responsible firm. Field survey samples will be filed

by the collecting division. When a non-FACTS affiliation (for example, a state) is selected, provide the reason for doing so in the remarks section.

For foreign human and animal food sample collections, select FOR-HAF as the division from the dropdown menu and send the hard copy C/R and all documents to the Division of Foreign Human and Animal Food Operations.

4.6.2.17 – Controlled Prescriptions and Drug Scheduling

Controlled Prescriptions (CRx) follow a schedule set by the Drug Enforcement Agency (DEA). Details can be found at DEA Drug Scheduling. Choose the appropriate schedule from the list of values, if applicable.

4.6.2.18 - Dairy Permit Number (Permit Number)

Enter if applicable. If you are collecting samples from a dairy, obtain this number from the firm.

4.6.2.19 - Date Shipped

Enter the date of interstate shipment in the format, mm/dd/yyyy, if known. Obtain it from the documentation you collected to document interstate movement of the product. Identify the document you used to determine this date in the “Documents Obtained” section.

4.6.2.20 - Documents Obtained

Click on the "Documents Obtained” button to enter Document Type, Document Number, Document Date, and Remarks for any records collected to support a violation or show interstate movement of the product sampled. Enter an identifying number and date for invoices, freight bills, bills of lading, etc. Include the name and title of individuals signing any affidavits in the Remarks field. Be sure to describe the reason each document attached to the collection record was obtained. (For example, when referring to a bill of lading, indicate that it was collected to document the interstate movement of the product.) Also, indicate which documents were collected to document specific violations encountered during inspections. State the number of pages for each document if it contains more than one page and refer the reader to the appropriate section/page of the document that shows the deviation you are documenting. Indicate the number of photographs attached. Depending on the sample and what you are trying to document, you may use the document number to record the actual number of the document (for example, an invoice number or bill of lading number), or to order the documents attached. You should order your documents in a manner that allows easy review (as guided by your supervisor or Compliance Branch). This section may also be used to list C/R attachments, including FDA-generated forms. See IOM Exhibit 4-1.

4.6.2.21 - Episode Number

Enter an episode number if applicable. This is a number related to pesticide samples, see IOM 4.6.2.27.8.

4.6.2.22 - Estimated Value

Enter the estimated wholesale value of the lot remaining after sampling. Obtain this information from invoices or other records. (Note: this is not the value to be used for seizure bond purposes; however, it may be used by the division to evaluate whether seizure is an appropriate action.) Provide a best guess estimate value if you have no documentary reference. For DOC samples (see Exhibits 4-1 and 4-2), indicate the estimated value of the lot. If the DOC sample is collected to document a lot that has already been shipped, estimate the value, or obtain a figure from your documentation that is representative of what was shipped.

4.6.2.23 - FEI Number

The FEI number is a unique identifier used to identify firms associated with FDA-regulated products. Enter the FEI, if known, or use the “B” button to query FMS and find the FEI for the firms associated with your sample. If an FEI does not exist, you may need to add the firm to the FMS. Take care in entering search criteria to avoid creating unnecessary FEI numbers--consult your division OEI coordinator for assistance. Note that you must enter an FEI for a dealer on every C/R, unless you check the box indicating the dealer is a consumer.

4.6.2.24 - Firm Name

This will be auto filled by FACTS when you select an FEI.

4.6.2.25 - Firm Type

Using the list of values, select one of the following for each FEI entered, with respect to the product sampled:

4.6.2.25.1 – Dealer

This is always the firm from which the sample was collected. There must be a dealer entered on every C/R, unless you check the box indicating the dealer is a consumer. Note: this is not the same as the establishment type of the firm identified by the FEI. However, there are circumstances in which you may identify the same firm as the dealer and another establishment type, such as when collecting a plant in-line sample.

Note: If the dealer firm is a consumer, the name and address of the consumer should be entered in the Collection Remarks field, and the consumer's state in the State field. When the sample is an in-transit sample (see IOM 4.1.4.2.1), enter the consignee of the lot as the dealer and be sure to state in the Collection Remarks field that the sample was collected in-transit, and from whom sample originated (for example, name of driver and their carrier firm), and where sampled.

4.6.2.25.2 – Grower

Select "Grower" if the FEI identifies a producer of a raw agricultural commodity.

4.6.2.25.3 – Harvester

Use "Harvester" for an FEI identifying the harvester of the product sampled.

4.6.2.25.4 - Ingredient Supplier

"Ingredient Supplier" should be used to identify a firm that supplied a raw material or component (for example, as when documenting a 301(k) [21 U.S.C. 331(k)] situation).

4.6.2.25.5 – Manufacturer

Use "Manufacturer" with an FEI, which identifies the manufacturer of the product sampled. Note: this may be the same as the dealer when a product is sampled at a manufacturer. In this case, you can enter the FEI *twice* and identify it as both the manufacturer and the dealer.

4.6.2.25.6 – Repacker

A repacker is a firm that repacks FDA-regulated products without manipulating the product or relabeling it.

4.6.2.25.7 – Shipper

The shipper is the firm responsible for causing the interstate movement of the product. Note this is not to be confused with the Carrier, the entity physically moving the product interstate.

4.6.2.26 - FIS Sample Number

Enter the last two digits of the fiscal year. The remainder of the number will be assigned by FACTS. Note: FIS sample numbers will no longer be required when the FIS is turned off.

4.6.2.27 – Flag

Flags are used to alert readers of your C/R to what the sample is documenting and any special circumstances related to that sample. The Sample Flag will be printed at the top of your hard copy C/R. For example, when you collect a 301(k) sample, the flag will indicate that this is a 301(k) sample and alert the reader to the fact that you are documenting adulteration after shipment in interstate commerce. The following situations require an entry in the Sample Flags screen in FACTS (See IOM section 4.6.2.49 and Exhibit 4-15):

4.6.2.27.1 - 301(K) Sample

Use this flag when the sample meets the definition of a 301(k) sample (IOM 4.1.4.2). Use the Flag Remarks field to state the product or ingredient that you documented as moving in interstate commerce.

4.6.2.27.2 - Complaint Sample

Use this flag for any sample collected from a complainant during follow-up investigation. Record the complaint number in the Sample Flag Remarks.

4.6.2.27.3 - Dealer Voluntarily Holding

Use this flag when the dealer is voluntarily holding product until sample results are received. This information will be important for the compliance officer to know when preparing a seizure or other regulatory action. This information needs to be entered as soon as the C/R is created, so the laboratory can adequately prioritize sample analysis and provide a timely notification to the firm.

4.6.2.27.4 - Exhibit Sample

Use this flag when the sample is to be used exclusively for court exhibit, without analysis.

4.6.2.27.5 - Factory Food Sample

Use this flag when sample(s) of any item, used in the production of any food product, are taken during the establishment inspection. However, do not use this flag for finished product samples or for environmental samples. See IOM 4.3.6.6.3.

4.6.2.27.6 – Fumigated

Use this flag when the product has been fumigated by the FDA prior to shipping, see IOM 4.7.3.1. Enter the name of fumigant in the Flag Remarks field. However, do not use this flag for products that may have been fumigated by someone else prior to sampling.

4.6.2.27.7 - Inv. Samples Of Filth Exhibits

Use this flag when the sample consists of filth (for example, gnawings, excreta pellets, wood splinters, etc.) collected from a product or its environment. These samples are Investigational Samples and the prefix INV is added to the sample number when identifying.

Enter the product code of the filth exhibits in the Product Code field of the FACTS Sample Collection Screen. **Note the product code for exhibits consists of the Industry Code followed by "YY-99" or "Y--99" as below:**

In a food firm = 52YY-99
52 = Misc. food related items
Y = Exhibits
Y = Sub class - None
- = Dash
99 = Evidence exhibits n.e.c.

In a drug firm = 66Y--99
66 = Misc. drug related
Y = Exhibits
- = Dash
- = Dash
99 = Evidence exhibits n.e.c.

Other industries: Handled in same manner using applicable industry code(s).

4.6.2.27.8 - Pesticide Sample

After flagging a pesticide sample, the basis for sampling must be entered in the Flag Remarks field as either "Pesticide Compliance" or "Pesticide Surveillance." Additionally, the name of the county and state, or country where sample was grown, must be entered in the appropriate fields in the Collection Record.

Pesticide Episode – Such an "episode" is defined as a violative finding associated with a pesticide, or other chemical contaminant, and all samples collected in follow-up to that finding. All samples must be associated with one responsible firm (grower, pesticide applicator, etc.) and one specific time period (for instance, growing season).

Here are a few examples of pesticide episodes and points of clarification:

1. Samples of cantaloupes from Mexico reveal violative residues. Note: Any destination point samples or subsequent compliance samples from the same shipper or grower, along with the original sample, would be considered an episode.
2. Grower Jones has violative residues of chlorothalonil on collards for which there is no tolerance. Note: Field samples, I.S. samples, and packing shed (or warehouse) samples of these collards would all be part of the same episode.
3. Grower Jones also has violative residues of omethoate on kohlrabi that are discovered about two months later. Note: This is a separate episode.
4. Along with the omethoate on kohlrabi, Grower Jones has violative residues of omethoate on beets. Note: Normally this would be considered a separate episode from the previous episode; however, if information is or becomes available showing that both residues resulted from the same application of the pesticide, or that the residues are/were closely related in some other way, the beets might be considered as part of the kohlrabi episode.
5. Grower Smith has violative residues of disulfoton and permethrin on kale. Note: This would be considered one episode because only one commodity is involved.

Also note that the Episode Number will be the sample number of the first violative sample collected in a series of samples and is used to identify the other related samples within an episode. The division must ensure that the same and correct Episode Number is used within the division, and any other divisions, involved in any

follow-up to the original violative sample. This number must appear in the Episode Number field of the FACTS C/R.

Note for Imports: The *detention without physical examination* procedures provide for recommending detention based on a single violative pesticide finding. See RPM Chapter 9-6. Given these procedures, we can anticipate that the number of compliance samples collected in follow-up to a violative finding should likely diminish appreciably and, in most cases, will be limited to occasional audit samples. These follow-up samples should also be linked to the sample number (episode number) of the original violative sample that prompted the automatic detention. This episode number will be indicated in the applicable Import Alert.

4.6.2.27.9 – Produce Related Result Requested

Use this flag when samples are collected of Raw Agricultural Commodities.

4.6.2.27.10 – Public Land Sample

Used primarily by the produce program. Samples collected on public land (not owned by any firm or farm). Use this flag for public water samples.

4.6.2.27.11 – Reconditioned

Use this flag when a sample is collected in connection with a reconditioning operation in accordance with a court order.

4.6.2.27.12 - Split Sample

Use this flag when a sample is divided between two or more laboratories.

4.6.2.27.13 - Survey Sample

Use this flag for any sample collected under a compliance program or assignment that identifies the samples are collected as part of a survey. Also, use this flag for any sample collected under the Drug Surveillance Program (CPGM 7356.008); in which case you should enter the survey number in the flag remarks section. Note that SCOPE and Total Diet Study samples are not generally considered Survey Samples.

4.6.2.27.14 - Under State Embargo

Use this flag when the lot is being held under state embargo. Enter the point of contact, their contact information, and how long the embargo is in effect, in the Flag Remarks field.

4.6.2.28 - Food Canning Establishment

Enter Food Canning Establishment Number if applicable. Information on Food Canning Establishment registration can be found at: Food Canning Establishment Registration Information.

4.6.2.29 - Hours

This is automatically populated on the hardcopy C/R based on your Accomplishment Hours (See IOM 4.6.2.1).

4.6.2.30 - How Prepared

Explain how the sample was prepared prior to submission to the laboratory, including how you identified some or all of the units, and how you wrapped and sealed the sample. Also, note any special preparation methods, such as

fumigation, freezing, refrigeration, etc., and the state in which the sample was delivered to the laboratory (for example, in paper bags, original container, etc. If coolants or dry ice were used, also indicate that here. It is important to be specific about how you protected the integrity of the sample and the chain of custody (for example, “Subs identified as noted, placed in unused, brown paper bag; bag taped shut and FDA seal completed (as noted) and applied, bag identified as noted in pen/ink. FDA 525 attached to sealed bag, placed in brown, cardboard box and prepared for shipment, then delivered to division security guard desk for UPS pick-up”). If a 702(b) portion is collected, describe how that portion was handled and prepared as well. See IOM 4.3.2.2 and 4.3.2.3. If the sample was collected by multiple participants, clearly explain which steps were performed by each participant.

4.6.2.31 - Lot Size

Enter the amount of goods that were on hand before sampling as determined by your inventory of the lot. Include the number of shipping cases and the size of the components with units (for example, 75 (48/12 oz.) cases, 250/100 lb. burlap bags, 4/100,000 tab drums, 24 cases containing 48/12/3 oz. Tins). Note that some programs require specific units here to evaluate appropriate sampling size (e.g., mycotoxins lot size in lbs. or fluid ounces).

For DOC samples (see Exhibit 4-1 and 4-2) indicate the size of the lot manufactured as described in the records collected, e.g., “one x-ray machine” or “5000 syringes.” In the remarks section, describe the amount of any product remaining on hand at the time the DOC sample was collected.

If accompanying literature is involved, for either a DOC or physical sample, describe and state the amount on hand (for example, “5000 syringes and 1000 promotional brochures”).

4.6.2.32 - Manufacturing Codes

Click on the "Manufacturing Codes" button to enter and identify all codes, lot numbers, batch control codes, etc., and how they are displayed on labels, containers, and shipping containers. Enclose the code in quotes. For example, code embossed on can cover, "87657888" or code applied in ink on side of container, "0987878." Also indicate the manufacturing codes used on products for which a DOC sample was collected--for example, "serial number "ABC" stamped on metal plate." See IOM Exhibit 4-2.

Enter any expiration dates in the Exp. Date field.

4.6.2.33 - National Drug Code (NDC)

Enter if applicable

4.6.2.34 - Payment Method

Select one of the following from the from the list of values: "Billed," "Borrowed", "Cash," "Credit Card", "No Charge," or "Voucher." (The “Credit Card” option means you used your personal credit card as a last resort.)

4.6.2.35 - Product Code

Enter the 7-character product code, consulting the Product Code Builder for guidance. Note, too, that when 301(k) samples are collected, the full product code of the finished product must be entered. See IOM Exhibit 4-1. See IOM 4.6.2.27.7 for product codes for filth or evidence exhibits. Other special product code considerations include environmental samples. See environmental sample identification instructions under IOM 4.3.6.6.2.

4.6.2.36 - Product Description

Enter a complete description of the product including the common or usual name and the product packaging/container system. (For example, “Aspirin tablets packed in clear, non-flexible plastic bottle with white screw on top with yellow stick-on label and black printing. Bottles packed in white, paperboard boxes with black printing. Paperboard boxes packed in brown cardboard boxes with black printing.”) If you need additional space, continue the description in remarks. See IOM Exhibit 4-1.

4.6.2.37 - Product Label

Quote pertinent portions of the label, such as: brand name, generic name, quantity of contents, name and address of manufacturer or distributor, code, etc. In the case of drugs, quote the potency, active ingredients, and indicate whether an Rx or non-Rx. Quote sufficiently from accompanying literature to fully identify. In the case of a DOC, sufficiently describe the article to adequately identify what has been sampled.

NOTE: When the product sampled is packaged in a container, shipping case or similar container, quote the pertinent labeling from the container.

When quoting from a label, or labeling, use exact spelling, capitalization, punctuation, arrangement, etc., as found on the original label(ing). Do not insert [sic] within the quote to highlight when a word is misspelled. Use asterisks in a series of three (***) to indicate any omissions.

4.6.2.38 - Product Name

Product Name field is auto completed by FACTS when you select the product code.

4.6.2.39 - Recall Number

If the sample was collected as part of a recall investigation, in which the recall number is already known, enter the recall number.

4.6.2.40 - Receipt Issued (Receipt Type)

Select "FDA472", "FDA484", or "None" from the list of values.

4.6.2.41 - Related Samples

This field is used to identify a sample number to which other sample information can be linked. When you collect more than one sample from a single shipment, or there is more than one sample relating to a possible regulatory action, designate one sample as the "lead" sample. Enter that sample number in this field of the collection record for each related sample. Other related sample numbers should be listed in the Collection Remarks field.

4.6.2.42 - Resp. Firm Type

Choose the appropriate type from the list of values for the firm most likely to be responsible for a violation. For a 301(k) [21 U.S.C. 331(k)] sample, the responsible firm should be "Dealer." You should only enter one firm with the firm type you designate as the responsible firm type.

4.6.2.43 - Sample Basis

Select from the two choices, as described below, on the list of values.

"Compliance" means the sample was collected on a selective basis as the result of an inspection, complaint, or other evidence of a problem with the product. "Surveillance" means the sample was collected on an objective basis where there was no inspectional or other evidence of a problem with the product.

Please note that official samples can be either compliance or surveillance in nature, and that INV samples can also be either. See IOM Exhibit 4-16 for more information.

4.6.2.44 - Sample Class

Make a selection from the following list of values: "Collaborative Study," "Criminal Investigation," "Division Use Sample", "Normal Everyday Sample," "Petition Validation," "Quality Assurance," "State Partnership," or "Total Diet."

4.6.2.45 - Sample Cost

Enter the cost of the sample. If no charge, enter 0. If, as a last resort, you use your personal credit card to pay for the sample, enter the amount paid in this field and select "Credit Card" in the Payment Method field. If you are unable to determine the cost of the sample and the firm states that they will bill you later, enter the estimated cost in this field and state that it is an estimate in the Collection Remarks field.

4.6.2.46 - Sample Delivered Date

Enter the date on which the sample was delivered to the laboratory or for shipment. For DOC samples, you must leave this field blank. If you make an entry, you must enter a laboratory.

4.6.2.47 - Sample Delivered To

Enter the person to whom you delivered the physical sample. If delivered to your own sample custodian under seal, show delivery to servicing laboratory or sample custodian. If delivered in-person to an analyst, report "In person to Analyst Richard R. Doe." If you shipped the sample, enter the name of the carrier to whom the sampled was delivered. Also, enter the carrier shipment tracking number. If the sample is shipped by air, enter the air waybill number. If shipment is by parcel post, give the location of the post office (for example, "P.P., Austin, TX") For a DOC sample, this field may be left blank. If the sample is being sent to a non-FACTS laboratory, enter the laboratory here.

4.6.2.48 - Sample Description

Briefly describe what the sample consists of (for example, three unopened, 200-tablet bottles; 20 lb. case of iceberg lettuce; or DOC sample consisting of records, literature, and photographs, etc.).

4.6.2.49 - Sample Flags

Click on the "Sample Flags" button to choose an appropriate flag using the list of values. See IOM 4.6.2.27 and Exhibit 4-15.

4.6.2.50 - Sample Number

Select the pre-assigned sample number using the list of values. Be certain the Sample Number matches the one you used to identify the sample. If no value is selected the system will generate a sample number when the record is saved.

4.6.2.51 - Sample Origin

Choose "Domestic" or "Domestic/Import" from the list of values.

4.6.2.52 - Sample Sent To

Collecting divisions are instructed to submit samples utilizing the Lab Servicing Table (LST) Dashboard located on the intranet on the ORS Sample Distribution site. See IOM 4.6.4. If you are splitting the sample among multiple laboratories for various analyses, enter each laboratory separately. Generally, in that case you will have more than one PAC code. If, because of your assignment, you are aware the sample should be forwarded to a second laboratory after the first analysis is complete, include that information in the Collection Remarks field. However, you should only enter a laboratory in this field if you are sending the sample there, not if the laboratory will be expected to forward it. For a DOC sample, leave this blank. If the sample is to be sent to a non-FACTS lab, leave this field blank, enter the lab in the Sample Delivered To field, print a copy of the collection record and enclose it in the FDA 525 attached to the sample.

4.6.2.53 - Sample Type

Make a selection from the list of values. You can enter only one value. If more than one type applies, choose one and indicate the other in remarks. If the sample is a domestic import, be sure to enter "DI", so that you can enter the foreign manufacturer. See IOM 4.6.1.

4.6.2.54 – Sampling Organization

Make a selection from the list of values. This should be the division that actually collects the sample.

4.6.2.55 – State

Select the state from where the sample was collected. If the dealer firm is a consumer, select the consumer's state.

4.6.2.56 – Status

This field is pre-filled by the system as "In-Progress." Select "Ready for Review" from the list of values when you are ready to send the record to your supervisor for review, if you are required to do so. After supervisory review, if appropriate, change the status to "Complete." This will cause the electronic signature form to be activated.

4.6.2.57 - Storage Requirements

Select from the following list of values:

1. Ambient – Used to indicate product is stored under conditions in which the temperature is not controlled.
2. Frozen (self-explanatory).
3. Refrigerated (self-explanatory).
4. Flashpoint – Used to designate the flashpoint of a flammable substance (Identify the flash point in °F or °C in the ‘Remarks’ section).

Note: This field is not required for DOC samples.

4.6.2.58 - 702(b) Portion Collected

Check this box if the sample you collected contains a 702(b) portion of any food, drug, or cosmetic to be held by FDA for release to the owner or person named on the label for their own analysis. This includes samples in which 1) the sample schedule already accounts for the 702(b), 2) you collected in duplicate and separated the duplicate out and 3) you collected in duplicate and did not separate the duplicate out. If you did not separate the 702(b) portion, note this in the remarks so the laboratory can separate the 702(b) portion. If no 702(b) portion was collected, do not check this box and provide reason for non-collection in the Collection Remarks section (See IOM 4.3.2.2 and 4.3.2.3).

4.6.2.59 - 704(d) Sample

Check the 704(d) box if all answers to the following questions are “yes,”:

1. Was the sample collected a food?

2. Was the sample collected during an inspection?

3. Was the sample collected from an establishment where food is manufactured, processed, or packed?

4. Was the sample collected to ascertain whether such food consists in whole or in part of any filthy, putrid, or decomposed substance, or is otherwise unfit for food?

Note: Guidance on 704(d) is provided in FMD-147 including examples of what constitutes “unfit for food”.

Include in the Collection Remarks the name, title, email address (if available) and telephone/fax number of the most responsible person at the firm. See also IOM 4.6.2.9.

4.6.3 –Lab Servicing Table (LST) Dashboard

Collecting divisions are instructed to submit samples utilizing the Lab Servicing Table (LST) Dashboard located on the intranet on the ORS Sample Distribution site. The LST Dashboard is an interactive tool showing respective sample capacities by PAF and servicing lab. The LST Dashboard can be used to identify all servicing labs with current available capacity for a selected PAF. Special notes or instructions are also included on the LST Dashboard, which may include directions pertaining to diversions and/or suspensions.

The Lab Servicing Table (LST) will continue to be updated as a reference. The LST Dashboard is a supplement to the LST.

When completing a sample collection, the Lab Selection screen will include a "Lab Reference" button that links to the LST Dashboard. After referring to the LST Dashboard to identify a lab with available capacity, select the appropriate servicing lab via the listed laboratory values.

4.6.3.1 – Other Information

The Office of Regulatory Science intranet website maintains current documents related to the Laboratory PAF managers Contact List and the Division Compliance Contacts. Questions on sample analyses, assignments, laboratory capability, or otherwise can be directed to the Office of Regulatory Science contacts listed at that site.

Additional information on sample collections and laboratories, including assignments, SCOPE and contacts, can be found at: The link to Field Guidance and Field Programs.

Also reference 4.7.5.4 - Routing of Samples.

4.6.4 – Routing

Anyone who has user access to the FACTS system has access to the electronic records contained therein, including sample collection records. Individuals requiring sample collection data can query the system and retrieve data, based on the query parameters. In those cases where an individual needs to receive immediate notification of a sample collection, the collector may communicate the sample number via email, telephone, or another means to a user, and the user may then query the system and obtain the desired data. It is not always necessary to print paper copies of FACTS sample collection records for those who have access to FACTS.

Follow division or program procedures for submitting C/Rs. If there is no established procedure, forward C/R from FACTS and original hardcopy or electronic records through your supervisor to the division office compliance branch most likely to take regulatory action.

4.7 - Sampling: Preparation, Handling, Shipping

4.7.1 – Objective

The preparation, handling, and shipping of samples is your responsibility, and must be carried out in a manner that assures the sample's integrity and supports testimony that the sample examined was the same sample you collected from the documented shipment. Samples need to be kept under lock, or in your possession, until sealed.

As few persons as possible should handle the sample to reduce the likelihood of compromising sample integrity. In order to maintain “chain of custody,” it is important that properly packaged and identified samples be opened *only* by the sample custodian(s). See ORA Lab Manual, Volume II, Section 5.8 for information about relinquishing samples.

4.7.2 - Identifying Marks

4.7.2.1 – Subsamples

Identify a representative number of subsamples (subs) with the sample or entry number (including prefix, if appropriate), collection date, and your initials. If individual sub identity must be maintained, assign and mark each sub with a separate number. In some comprehensive inspections or investigations, it may be important to correlate the manufacturing control code with the sub number.

When a variety of articles are included under one sample or entry number, fully identify each sub and describe them on the C/R. Subsamples from an INV sample should be fully identified and, where appropriate, correlated with inspectional observations, manufacturing procedures, and/or routes of contamination. See IOM 4.2.5.6 for using the FDA 484 - Receipt for Samples as a memo to accompany C/R to describe subs collected.

When multiple subs are taken from cases, bales, boxes, etc. in the lot, numerals and letters in combination may be used for identification. For example, if two cans are taken from each case in the lot, the cans may be marked as, subs 1a, 1b, 2a, 2b, etc., to identify the subs as coming from case #1, case #2, etc. If the second can or container taken from each case is the 702(b) [21 U.S.C. 372(b)] portion, it is desirable that all duplicate portions be sealed separately from the FDA portion. This fact should be so noted on the cases and C/R.

If multiple subsamples are to be collected, it may be advantageous to place identifying information--such as sub number, sample number, your initials and collection date--on peel-off labels, tape, etc., in advance of sampling to save valuable time.

Do not place peel-off labels directly on cans for canned food samples collected for-cause as these can interfere with the analysis.

4.7.2.2 - Borrowed Samples

Although most samples are purchased, some may be borrowed, non-destructively examined, and returned to the owner. These samples must be handled carefully to avoid defacing or damaging the product.

Identify borrowed samples so the identification can be removed with no damage to the product (for example, a sample bearing a sticker label that can be peeled off).

4.7.2.3 - Identification Techniques

Mark a representative number of subsamples with the sample or entry number, collection date, and your initials. Similarly identify any outer packaging, labels, or circulars. If more than one person is involved in collecting the sample, the person preparing and signing the C/R is the one to initial the subs. After identifying them, reinsert circulars removed from packages. See IOM 4.3.1.2 for procedures on identifying lots from which sample was taken.

Transparent tape, such as Scotch Magic Transparent tape, accepts ball point ink and may be used on glossy items such as glass, plastic, tin, etc. Glass, such as bottles, vials, and ampoules, may be identified by using a very fine-pointed felt or nylon marking pen and then covering the identification with transparent tape for protection.

Fine point Sharpie (permanent ink markers) may be used on paper labels. Note, too, that permanent ink markers freeze at a lower temperature than ball point pens and other markers when you find yourself sampling in freezers, or outside when it is below freezing (32°F/0 C). Do not use permanent-type markers when identifying subs in absorbent containers as the ink may penetrate into the product and contaminate the sample (for example, flour in a bag with no outer plastic layer).

Also, do not use tape on very small containers, such as ampoules, which must be snapped off or broken to remove the contents for analysis as tape wrapped around the container may interfere with the assay.

4.7.2.4 – Photographs

Unless they are part of a DOC Sample or are used to show labels or labeling, photographs are exhibits to an EIR, report of investigation, or complaint--they are not samples. Photos taken during inspections and investigations are not described on a C/R, but are submitted as exhibits with the EIR. Photographs related to DOC samples, including those of labeling, records, or the product, are identified with the sample or entry number, collection date, and initials. If photos are printed direct from film, identification of the original photo should occur on the border or backside. See IOM 4.4.2. Attach any photos to the FACTS Collection Record.

In describing photographs, do not mark the face of the print. Narrative descriptions may be placed on the mounting paper *next to* the print or, if explanatory graphics are required, you may use a plastic overlay. See IOM 5.6.7.5 for negative identification and submission procedures, and IOM 5.6.7.5 for digital photos.

For imports photographs: See IOM 6.1.8– Photographs: Identification and Storage.

4.7.2.5 - Records - Accompanying Literature and Exhibits

Identify all copies of sample records, accompanying literature, and attached documents with the sample or entry number (including prefix, if applicable), collection date, and your initials, as described in IOM 4.4.2. If an attached

document is more than one page in length, it must be numbered or attached in a manner that will always allow future reviewers to determine if any pages are missing. For example, numbering pages as in "1 of 10," or "2 of 10," etc., will let the reviewer know that a total of 10 pages should exist in the attachment.

4.7.3 - Sample Handling

All samples must be handled, packaged, and shipped to prevent compromising the identity or integrity of the sample. Samples must be packed with shock-absorbing materials to protect against breakage of containers or damage to official seals. Frozen samples must remain frozen. Perishable products may be frozen if freezing doesn't interfere with the planned analysis (for example, analyzing milk for drug residues). If you are not sure about any handling procedures, please check with the relevant laboratory. Products requiring refrigeration (for instance, fresh crabmeat undergoing bacteriological analysis) should be shipped in ice. Some products may be collected at room temperature but will need to be refrigerated or shipped under refrigeration. For example, this includes raw agricultural products collected in the field for microbiological analysis. Use your experience and knowledge to determine the most appropriate packing and shipping method and consult with the analyzing lab about any questions you have regarding sample handling.

4.7.3.1 – Fumigation

See IOM Safety Chapter regarding fumigation and preparing samples using fumigation (IOM S.12.6.2).



As soon as possible, freeze any sample containing, or suspected to contain, live insects, as long as freezing will not change or damage the product or break the container. If freezing is inappropriate to maintaining the integrity of the sample, fumigation may be carried out using air-tight containers (such as a mason-type jar with inner ring, or a polypropylene container with air-tight lid), with sufficient fumigant to kill the insect infestation. Contact your servicing laboratory for alternative fumigants.

Moth crystals, containing paradichlorobenzene (PDB), are an alternative fumigant. However, do not use mothballs or moth flakes containing naphtha or naphthalene. Also, do not use moth crystals in or near plastics, particularly Styrofoam/polystyrenes, as crazing or melting may occur. Other alternative fumigants include liquid household ammonia or ethyl acetate--either of which can be used by applying to a cotton ball that is placed inside an appropriate container; or by cutting small portions of commercial pesticide strips that are also placed in an appropriate container.

4.7.3.1.1 - Fumigation Safety Precautions

Follow safety precautions when fumigating samples. Contact your local servicing laboratory or l Safety Data Sheet (SDS) for the appropriate protective gear and handling of fumigants. Additional guidance:

1. Carry all alcohols, fumigants, and other hazardous liquids in approved safety containers.
2. When fumigants or preservatives are used, limit your exposure to these chemicals. Minimize transfer and exposure time. Avoid getting chemicals on hands or clothing. DO NOT MIX CHEMICALS.
3. Ensure that DOT regulations and guidance and International Air Transport Association (IATA) guidelines are followed when mailing or shipping samples containing a fumigant or preservative. Exceptions applying to small quantities are listed in 49 CFR 173.4.
4. The sample identification data on your packaging, the FDA-525 and C/R, must always identify the fumigant and method of fumigation, and/or preservative used.

5. Safety Data Sheets (SDS) for each chemical fumigant or preservative used must be available at each duty site and enclosed with the shipped sample. Read and follow all instructions and precautions listed on the SDS.

4.7.3.1.2 - Procedures For Fumigation

Place a small amount of fumigant, in an airtight container. Separate the fumigant from the sample with a piece of paper, paper napkin, or unscented facial tissue. Put specimen or product into container and seal tightly. Do not reopen container unless absolutely necessary. If possible, use a glass container with a lined screw lid. A mason-type jar with inner ring is also acceptable.

4.7.3.1.3 - Exceptions To Fumigation

When submitting samples or exhibits to show *live* infestation, do not fumigate. Be sure to consult with your supervisor or your servicing laboratory PRIOR to sending or bringing a live infestation into the laboratory to permit preparation for proper handling and storage. Also, do not fumigate samples submitted for pesticide residue analysis.

4.7.3.1.4 - Preservation Liquids

Insects may be killed and preserved in 70% ethyl alcohol, or a 1:1 mixture of 70% ethyl alcohol and glycerin (may be labeled as glycerol). These chemicals can be obtained from your servicing laboratory. Do not collect rodents or animal tissues unless specifically instructed. Ensure all vials or bottles of preservation liquids are tightly sealed to avoid leakage. Identification labels may be placed in containers but must be written in India ink or 2H pencil only. Keep all preservation liquids away from excessive heat or open flame.

Identify the preservative used on FDA 525, C/R, and on sample container. Enclose a copy of the SDS with the shipped sample. Follow DOT and IATA guidelines when shipping or mailing samples with preservatives as stated under Fumigants.

4.7.3.2 – Samples for Label and Labeling Review

Samples collected for label review only should be officially sealed in clear plastic bags. This will permit cursory review and, if necessary, photographing or scanning of the container label and reduce the need to break the seal each time the label is examined.

Samples may alternatively be collected of the product and the label field-stripped from the container. The product can be destroyed either onsite where it was collected, or in the office. The stripped label could also be submitted as part of a DOC sample. (See IOM 4.1.4.1). Be sure to document in your C/R all actions related to stripping the label and destroying the product.

4.7.3.3 - Samples for Pathological Examination

Tissue samples are not routinely collected for microscopic or pathological examination. Authorization must be obtained from the appropriate Center before collecting samples of this material.

When assigned to collect tissue samples, unless directed otherwise by the program, the assignment, or your supervisor--cut the tissue into 1/4-inch pieces and preserve in 10% buffered formalin, or in other suitable preservatives as directed. Do not freeze the sample since frozen tissue is not suitable for pathological studies.

4.7.3.4 - Small Sample Items

Samples in small vials, bottles, boxes, and similar type containers may be placed inside the FDA 525 envelope after identification. When the envelope is used as the sample package, place the official seal across the glued flap and the blank face of the form.

If the sample container (vial, bottle, etc.) is officially sealed, it may be placed in the same FDA 525 together with copies of the assignment.

4.7.3.5 - Frozen Samples

You should pre-chill sterile containers before collecting frozen samples. Also, transfer liquids in glass to expandable containers before freezing. If the liquid must be frozen in glass, leave sufficient headspace to allow for expansion. If freezer facilities are not available or if the sample is to be shipped, pack with dry ice in insulated containers. Note: Dry ice may be obtained from ice cream or dry ice dealers.

Your district office or resident post should have insulated shipping containers on hand, but if there are none, economical polystyrene (Styrofoam) containers are available at most variety stores. However, most polystyrene containers are not designed for shipping so will need to be packaged carefully inside shipping cartons to protect them during shipment. Note: If your division desires the return of Styrofoam freezer chests or ice packs used in shipping samples, note this fact on the C/R and FDA 525.



Caution: Dry ice is potentially dangerous and requires caution in handling and shipping. Do *not* handle with unprotected hands; or transport in your car without adequate ventilation; or place inside tightly closed metal, plastic, or similar type containers that do not breathe. If it is necessary to use this type of container, adequately vent it to prevent pressure buildup. Do not use glass containers for packaging or for storing dry ice. (Note: Failure to adequately vent a container containing dry ice may cause a dangerous pressure buildup, resulting in serious risks to personal safety (to you or anyone else potentially handling the container) and sample integrity).

Note: If a sample is to be analyzed for ammonia contamination, it must not be shipped frozen in dry ice. Use other methods of freezing if frozen shipment is necessary.

4.7.3.5.1 - Shipping Frozen Samples

If using a U.S. Government BOL, it is important to give a full and accurate description of the sample for rate purposes. If more than one commodity is in the shipment, describe and enter each sample separately.

Dry Ice Guidance

In all packages where dry ice is used, distribute the dry ice equally on all sides of the sample package using pieces as large as possible. Be sure the container is insulated on all six sides and tape all edges securely to assist in insulating the carton. However, do not place dry ice inside officially sealed packages.

Freezing by dry ice is not effective for more than forty-eight hours. For overnight shipments, use at least one pound of dry ice per pound of sample. Increase the amount for longer hauls or unusually warm weather. (Note: When samples are in plastic-type containers, the dry ice must be wrapped in paper to prevent direct contact with the plastic as the extreme cold generated by the dry ice may cause the plastic to become brittle and rupture.

All shipments involving dry ice should be next day or sooner delivery. Tests have shown the following amounts of dry ice will be adequate when this method is used:

For samples already in frozen state: 5 to10 pounds of dry ice, depending on sample size, is normally sufficient. For samples requiring only to be refrigerated: A minimum of ten pounds of dry ice is sufficient.

Note the following practices for shipping dry ice with respect to CFR 49, the International Air Transport Association (IATA) regulations, and the UPS Dangerous Goods Agreement:

For non-medical, non-hazardous U.S. domestic air packages with 2.5 kg (5.5 pounds) or less of dry ice, mark the outer carton in the following way using in prominent one-inch block letters:

1. "Dry Ice" or "Carbon Dioxide, Solid"
2. If dry ice, then also "DRY ICE; 9; UN1845."
3. A general description of the non-hazardous contents (for example, food, meat)
4. The amount of the dry ice contained in the package at the time of packaging, or a statement that there is 2.5 kg [5.5 pounds] or less in the package.
5. Use the dedicated Dry Ice Label (available from the carrier) (For an example, see IOM Exhibit 4-19). Complete the bottom portion of the sticker and note the amount of dry ice in kilograms.

For non-medical U.S. domestic packages with greater than 2.5 kg (5.5 pounds) of dry ice:

1. **Indicate in Campus Ship that you will be shipping dry ice or attach "**Hazardous Materials" shipping papers available from the carrier (note that a $5 per package of dry ice fee applies).
2. The package must be prominently marked in one inch block letters as containing "Dry Ice" or "Carbon Dioxide, Solid", UN1845 (See: IOM Exhibit 4-19).
3. A label identifying dry ice contents is available from the carrier (for an example, see IOM Exhibit 4-19).
4. The net weight of dry ice at the time of packaging must be indicated on the shipping papers and can also be marked on the outer package prominently in one-inch block letters.
5. UPS Dangerous Goods Agreement is required here. A UPS "Dangerous Goods Agreement," available from the shipper, is required to be filled out and provided to the shipper at time of shipment.

Note: The dry ice may freeze the edges of the product, so if it is imperative that no part of the sample becomes frozen, use coolants other than dry ice. Mark the FDA 525 that dry ice was used.

See IOM 4.7.5.6 when shipping sample packages containing hazardous or toxic items by air.

4.7.3.5.2 – Control

If it is necessary to ensure the shipment does not thaw in transit, place a jar or leak-proof plastic bag of chipped ice in the shipment adjacent to the sample package--but *not* within the officially sealed package. Be sure to note this approach on the C/R and ask the sample custodian to ensure that the ice remains frozen.

4.7.3.6 - Refrigerated (Not Frozen) Samples

Maintain refrigerated (not frozen) samples in a refrigerator at 4.4°C (40°F) or below. Use either wet ice or some type of "Ice Pak," "Liquid Ice," "Sno-Gel," "Kool-It," or similar product to maintain the required temperature range.

Place Ice Paks, etc., in sealed plastic bags to protect samples from possible contamination, should the container break, the ice melt, or the refrigerant penetrate the sample. Use insulated shipping containers for shipping samples to the laboratory.

4.7.3.6.1 – Control

If it is necessary to show the sample temperature did not go above the desired or specified temperature, you can use one of several methods, such as including a pre-chilled, shaken-down, maximum reading thermometer or a commercially available indicators. Take care to place the thermometer outside of the sealed sample package and attempt to place in an area anticipated to be likely to reach the highest temperature. Describe the method used on your C/R.

4.7.4 - Official Seals

Domestic samples (excluding DOC samples) should be sealed with form FDA 415a, Official Seal, or, in some situations with the FDA Metal Seal. See IOM 4.7.4.6 for use of metal seals.

Note: With the approval of your supervisor and laboratory, it is not necessary to affix an official seal to a sample that will be in the sample collector's continuous personal custody until it is submitted personally to an analyst. This procedure should be reserved for emergencies and other high-priority situations. The sample should be submitted the same day it is collected with the subs properly identified. The C/R must state you personally delivered the sample to "Analyst _____" or other appropriate staff member.

Make every effort to prepare and submit or ship your samples on the date collected so that the C/R, sub identification, and the final official seal bear the same date, and thus enhance sample integrity. However, if you cannot finish sample preparation on the same day it was collected, you must explain in the C/R Collection Remarks field what steps you took to protect the integrity of the sample (for example, I sample was officially sealed and locked in supply cabinet, or locked in safe, etc.). If you cannot ship the same date as collected, you should at least complete identifying the subs and sealing the container on that day. In cases where subs need to be identified on the next day before shipping, use an Official Seal to seal the subs. On the next day, you can break and sign the seal. Explain in your regulatory notes and attach the broken seal to your C/R.

Never place more than one sample in the same officially sealed package. Large samples with numerous subs may be split into two or more containers with more than one official seal. When a 702(b) portion is collected, it is advisable to use at least two containers with one container containing only the 702(b) portion. Clearly identify the container holding the 702(b) portion so that the lab analyst does not unintentionally break the seal and open that container. Separate official seals should be applied to each container.

Official seals may be used up to five years beyond the expiration date indicated by the manufacturer of the seal. Field offices should periodically monitor their official seal inventory and discard or destroy any official seals that are more than 5 years beyond the expiration date indicated by the manufacturer of the seal.

4.7.4.1 – Preparation of Official Seal

Inscribe the FDA 415a, official seal, with the division office name, sample number (with the appropriate prefix), the date applied, and your signature, printed name, and title. See IOM Exhibit 4-17. The seal must bear only one signature. If more than one person is involved in collecting the sample, the person preparing and signing the collection record must sign the seal.

4.7.4.2 – Application

Seal the sample package so that it cannot be opened at any point without evidence of tampering. If the surface of the sample container is of such construction or condition that the FDA-415a, official seal, will not adhere (for instance, container is a waxed container, frosted over, or sweating, etc.), then wrap or place the sample in a container to which the official seal will hold. See IOM 4.7.4.6.

To ensure the sample package cannot be opened at any point without evidence of tampering, wrap clear packing tape around the package that the seal is adhered to and across at least two sides of the official seal. The clear packing tape, however, should not cover any *text* on the official seal.

When using the self-adhering seals, the surface on which the seal is to be placed must be clean and dry. Note that the seal must also be rubbed when affixed to generate heat and help it bond.

4.7.4.3 - Sealing Method

There are many acceptable methods of officially sealing samples. Because of the wide variety of shapes and sizes of samples, and the ingenuity you may have to apply to package and packaging situations, explicit methodology will not be detailed here. If you are unsure of a sealing method, consult your supervisor.

4.7.4.4 - Protecting the Official Seal

Protect the sealed surface by wrapping the package securely with heavy wrapping paper for mailing or shipment. If your officially sealed package is not further wrapped for shipping and the tape(s) and official seal are thus exposed, you must protect the official seal from damage during shipment by:

1. Covering the official seal with a sheet of heavy wrapping paper or heavy clear plastic (for example, like that from a document protector) of sufficient size to cover the surface of the official seal.
2. Tape the protective paper or heavy clear plastic securely around the edges so it cannot come loose and expose the official seal. Do not paste or glue the paper or plastic to the face of the official seal since this will obliterate the official seal when removed.

When you protect the official seal by heavy paper, write "FDA Seal Underneath," or similar wording across the protective paper. This alerts the receiving custodian that the official seal is underneath, and to take care when removing the protective paper. Contrastly, if you cover and protect the seal with heavy clear plastic, the sample custodian will be able to copy the necessary information off the seal without removing the protective cover.

4.7.4.5 - Broken Official Seals

Reseal the sample if you should have to break the official seal. Each seal used on the sample must be submitted with the records associated with the collection record, properly initialed and dated, to provide a continuous history.

There is only one class of seal: an "official seal." Anytime a sample is sealed with the FDA 415a, or with the FDA Metal Seal, the item is "officially sealed." An officially sealed sample must sometimes be reopened to prepare it for submission to the laboratory, or for some other legitimate reason. In that situation, the original seal must show the date it was broken. When the sample is ready to be resealed, the new seal must show the date it is applied. This procedure must be followed each time the official seal on a sample is broken. Each seal will show the history of the date it was applied and broken. (See instructions in Exhibit 4-17). Indicate in the Collection Remarks field of the

FACTS C/R the fact that the seal was broken and reapplied, and attach the broken seal to the FACTS C/R. This provides an unbroken, documented chain of custody.

4.7.4.6 - Metal Seals

Where it is impossible to use the paper official seal, the numbered self-locking "U.S. Food and Drug" metal seal may be used. This seal is effective for use on wooden crates, drums, baskets, etc., where the FDA 415a cannot be used. Record the number of the metal seal used on the C/R. See IOM 4.3.3.3 for instructions on the use of the metal seal to reseal railroad cars or conveyances. When a supply of these seals is needed by your division, contact the Division of Domestic Human and Animal Food Operations (DDHAFO) at (301) 796-0360.

4.7.4.7 - Sealing Non-Sample Items

Although the primary purpose of the official seal is for sealing samples, there are times when the official seal may be used to officially seal items other than samples. For instance, the FDA metal seal is often used to seal rail cars or vehicles, as indicated in IOM 4.3.3.3.

When directed by your supervisor, you may use an official seal to seal questionable or suspicious bioresearch records encountered during an inspection or investigation to prevent their tampering or to preserve their integrity. As explained in the applicable compliance program, this procedure must have the approval of the bioresearch monitoring staff (HFC-230) prior to implementation.

4.7.5 - Sample Shipment

ORA SOP-000178 covers all shipments made by ORA.



The FDA collects a wide variety of samples, some of which may contain unstable, toxic, or hazardous materials (this includes etiological agents, radiation products, chemicals, hard swells, etc.). Therefore, use safety precautions in handling and shipping commensurate with the hazard. ORS provides guidance on shipping hazardous goods here: Shipping of Dangerous Goods (sharepoint.com). See also IOM 4.7.5.6.

4.7.5.1 Preparing the box for shipping

Place the words "SAMPLE NO" or "ENTRY NO" (in all caps)--followed by the appropriate FACTS or OASIS sample number(s) (with appropriate prefix)--on the outside of the shipping package(s) near the address label. The package(s) should be properly identified with the FDA office that is shipping the sample and the laboratory or other office receiving the sample. This alerts the receiving mail room that the package contains a sample and must go to the sample custodian.

Note that certain Department of Transportation (DOT) regulations exist pertaining to carrier inspection of packages. As such, be prepared to instruct the carrier to contact the shipper (FDA) prior to any package inspection that may require breaking the official seal. Carriers have been known to break official FDA seals during package inspection during transit, and have compromised sample integrity in the process. If an FDA 3082 - Shippers Declaration for Dangerous Goods is executed for shipments of restricted items, place a statement in the special handling section that breaking an FDA official seal is not authorized, and to contact the shipper (FDA) if there are any questions regarding the shipment. See IOM Exhibit 4-18.

4.7.5.2 - Method of Shipment

When you cannot personally deliver a sample to the examining laboratory, ship it by the most economical means, commensurate with the need for rapid handling.

4.7.5.2.1 - USPS Shipments

Before using the contract carrier, you should determine if using United States Parcel Post (USPS) is a more cost-efficient mode of shipping the sample. USPS should be used *only* for non-emergency, non-perishable samples and when the package meets USPS limits. Details on shipping by USPS can be found at How to Prepare & Send a Package | USPS. The same webpage can be used for scheduling a pick-up too.

4.7.5.2.2 – Contract Carrier Shipments

The FDA contracts with a carrier for almost all shipments. You should use the contract carrier whenever possible. (SOP-000178 provides guidance for using the contract carrier to ship samples.)

4.7.5.2.3 – Use of other Shippers for Samples

When the contract carrier cannot deliver the sample in time for the laboratory to conduct the analysis, then discuss with your supervisor other appropriate methods for shipping the sample. For example, if the contract carrier cannot guarantee overnight delivery in the morning for a sample collected during an outbreak, then use of another carrier may be permitted.

4.7.5.3 - FDA 525 - Sample Package Identification

Form FDA 525 - Place the FDA 525, sample package identification, near the official seal. Do not affix the FDA 525 on the outside of the shipping container or under the official seal. Provide the following information on the FDA 525:

1. Division or Headquarters' laboratory to which the sample is directed, City, State, and unit symbol (e.g., SRL, HFD-400, HFS-300, etc.).
2. Date.
3. Your division and symbol.
4. Sample or Entry Number.
5. Name of dealer.
6. Product Identification.
7. Address of dealer.
8. Enter the reason for collection. (Copy from C/R.) Provide reference to any sampling assignment.
9. Provide information regarding the analysis to be made.
10. The Assignment Number and Name if sample was collected as part of an Assignment.
11. When entering information for "Package___of___Packages," the number of packages should be the number of sample packages. Also enter any pertinent remarks. Also note if your division desires the return of any freezer chests, ice packs, or maximum/minimum thermometers used.
12. Provide any relevant special storage instructions. Mark the appropriate block and enter the suggested refrigeration temperature, if necessary. Elaborate in Remarks, if necessary, too.
13. Print your name.
14. See IOM 4.7.3.4 when using the FDA 525 as a sample package.

Outer Wrapper or shipping container - Always place the words, "SAMPLE NO. _____" followed by the actual FACTS or OASIS sample number(s) (with appropriate prefix) on the outside of the package near the address label. This alerts the receiving mail room that the package contains a sample and must go to the sample custodian.

4.7.5.4 - Routing of Samples

In general, samples will be submitted to an appropriate servicing laboratory with available capacity via the Lab Servicing Table (LST) Dashboard, except as directed by the Compliance Program Guidance Manual, assignment, or your supervisor.

4.7.5.4.1 - Samples to Administration Laboratories

When shipping samples to headquarters or other special laboratories, follow the procedures for each laboratory found in Exhibit 24.

4.7.5.4.1.1 - Split Samples

In instances where the sample examination duty is split between a Headquarters Division of the National Center for Drug Analysis, and an ORA laboratory then you should follow the directions noted in Exhibit 24. Also, submit the Original C/R and records to the servicing laboratory, whether or not it is affiliated with the home division.

4.7.5.4.2 - Sample Shipment to Outside Agencies

Do not ship any samples outside the FDA unless your assignment, applicable program, or your supervisor specifically instructs you to do so.

4.7.5.5- Notifying Receiving Laboratories

When frozen, perishable, or high priority items are shipped, notify the receiving division or lab by telephone, or email, that you have shipped the sample. Be sure to provide all of the following information:

1. Sample Number.
2. Name of Product.
3. PAC/PAF and/or requested analysis.
4. Number of Parcels in Shipment.
5. Carrier's Name.
6. Carrier's Waybill or Tracking Number.
7. Carrier's Train, Truck, Bus, or Flight Number.
8. Estimated Time and Date of Arrival.
9. Relevant Remarks (for instance, "Sufficient Dry Ice provided to maintain frozen until approx. 8:00 a.m., (date)").
10. Place the name and telephone number of the person that is to receive the sample on the outer shipping container near the address, with instructions to the carrier to contact the above-named individual upon arrival of the package.

4.7.5.6 - Shipment of Hazardous or Toxic Items

The Department of Transportation (DOT) regulations require certain packaging, forms, certifications, declarations, and/or statements covering shipment of hazardous or toxic items. Except for dry ice, most of the samples of hazardous or toxic materials that the FDA ships are classified as "ORM-D, Consumer commodity." Both dry ice classified as "9", and ORM-D



classifications require a certification/declaration for shipment by air, but not for shipment by surface transportation.

For shipments containing dry ice, use the dedicated Dry Ice Label (available from the carrier - for an example see IOM Exhibit 4-19). Complete the bottom portion of the sticker and note the amount of dry ice in kilograms. In addition to the label, the package itself must be clearly marked in one-inch block letters, as in, "DRY ICE; 9; UN1845".

Contact the carrier involved to execute the necessary forms, certification/declarations, packaging, marking, etc., required for the particular shipment or for hazardous or toxic items.

For further information, contact your district Safety Officer or Industrial Hygienist.

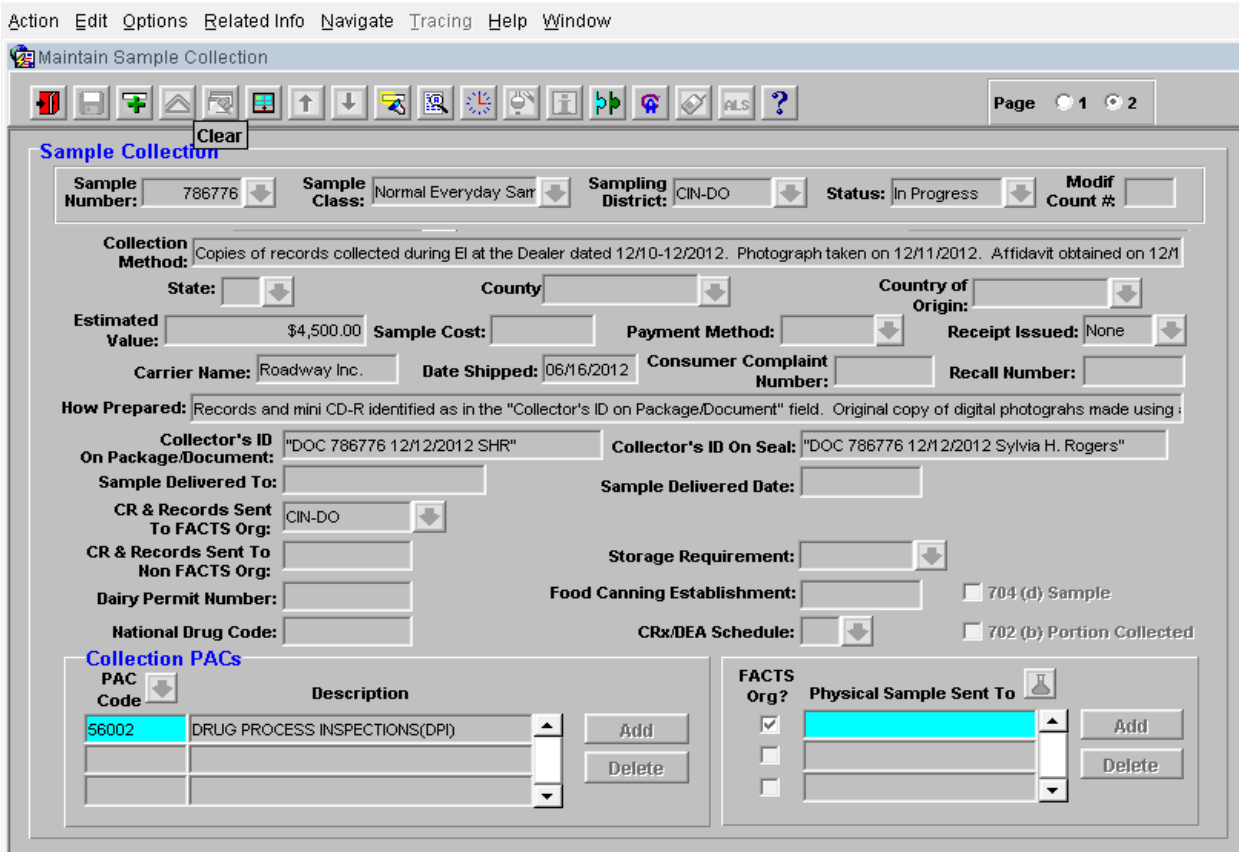
4.7.5.7 – Additional Precautions When Shipping Samples

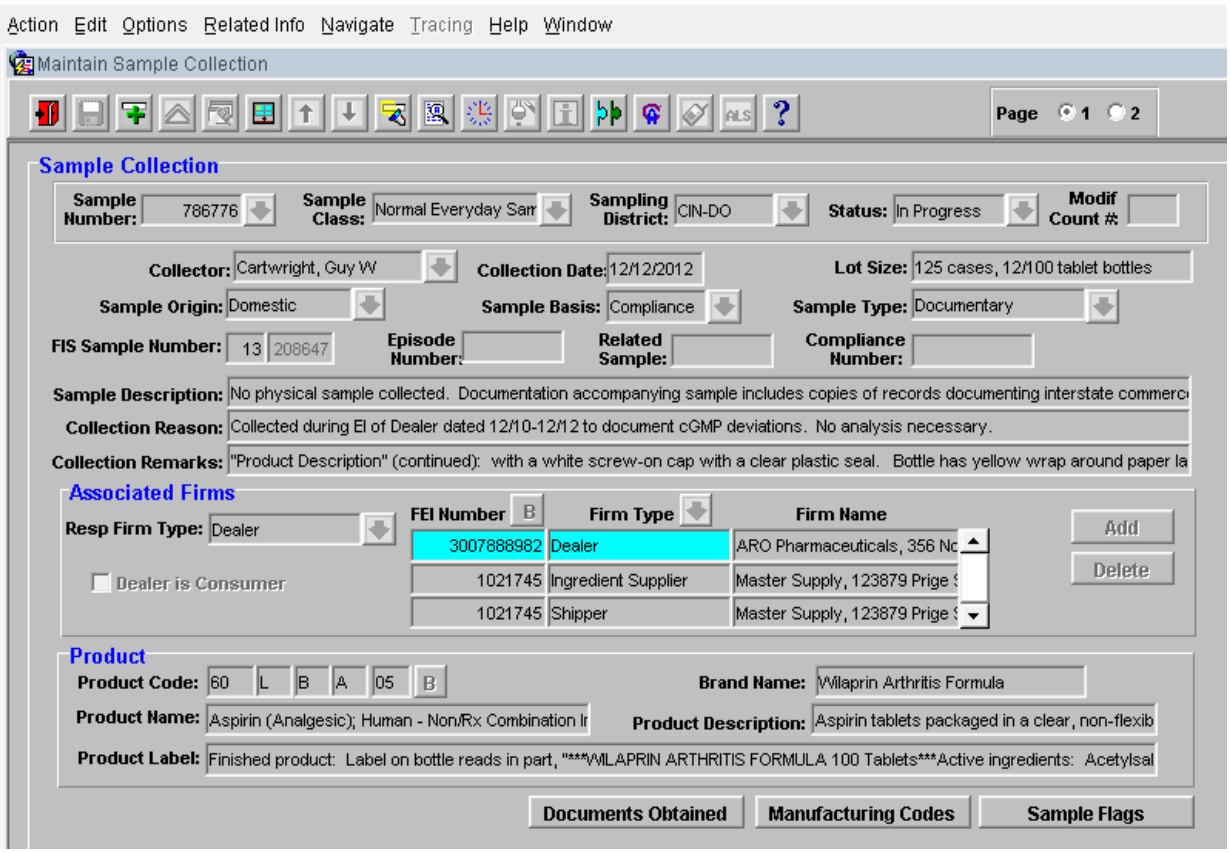
The following precautions should be observed when shipping samples:

1. Always pack liquid products in sufficient cushioning and absorbent material to absorb any breakage that might occur. Check with USPS or other carriers regarding shipment of liquids.
2. Hard swells may explode. Wrap them heavily in paper and cushioning material for shipment and submit promptly.
3. Observe special precautions when shipping products in pressurized containers to avoid exposure to excessive heat. Air shippers that ship in non-pressurized planes may also have special requirements for this type of container. Check USPS or other carrier for regulations, precautions, or restrictions before shipping products in this type of container.
4. Special precautions for both packaging and shipping radioactive substances must be observed. If necessary, consult your supervisor, the FDA radiological health representative, WEAC, or the applicable program.

   Note: The compliance program for radioactive drugs directs the manufacturer to ship samples via their normal mode of transportation to WEAC. The Nuclear Regulatory Commission (NRC) requires that firms manufacturing radioactive drugs ship only to NRC-licensed consignees. WEAC's NRC license number is 20-08361-01 with Exp. Date 11/30/2026. This license number should be used for any shipments of radioactive products to WEAC.

4-1- FACTS SAMPLE COLLECTION SCREEN





Food and Drug Administration Office of Regulatory Affairs
Collection Report
For Sample Number: 786776

This is an accurate reproduction of the original electronic record as of 01/30/2015

Flag	Flag Remarks
301(k) Sample	

Episode Number	Origin	Basis	Sample Type	FIS Smpl Num	Status
	Domestic	Compliance	Documentary	13208647	In Progress

FEI	Date Collected	Product Code	Responsible Firm	PAC	Hours
3007888982	12/12/2012	60LBA05	Dealer	56002	.5

Compliance Num	Country of Origin

Related Smpl Num	Position Class	Sampling District	NDC Number	Permit Number	Storage Rqrmnt.
	INV	CIN-DO			

Dealer is Consumer	Crx/DEA Schedule	Recall Num	Consumer Compl. Num	Brand Name
No				Wilaprin Arthritis Formula

Product Description
Aspirin tablets packaged in a clear, non-flexible plastic bottle (See "Remarks")

Product Label
See continuation.

Reason for Collection	MFG Codes	Expiration Date
Collected during EI of Dealer dated 12/10-12/12 to document cGMP deviations. No analysis necessary.	"Lot 25C83" (finished product) "Batch 5564" (active ingredient)	8/13 8/14

Firm Legal Name	Address	Type of Firm	Firm FEI	FCE
ARO Pharmaceuticals	356 Northview Dr Powell, OH 43065-9479 US	Dealer	3007888982	
Master Supply	123879 Prige Street Henderson, KY 42420 US	Ingredient Supplier	1021745	
Master Supply	123879 Prige Street Henderson, KY 42420 US	Shipper	1021745	

Size of Lot	Est. Value	Rcpt Type	Carrier Name	Date Shipped
125 cases, 12/100 tablet bottles	$ 4,500.00	None	Roadway Inc.	06/16/2012

Description of Sample
See continuation.

Method of Collection
Copies of records collected during EI at the Dealer dated 12/10-12/2012. Photograph taken on 12/11/2012. Affidavit obtained on 12/12/2012.

How Prepared
See continuation.

Collector's Identification on Package and/or Label	Collector's Identification on Seal
"DOC 786776 12/12/2012 SHR"	"DOC 786776 12/12/2012 Sylvia H. Rogers"

Sample Delivered To	Date Delivered	Orig C/R & Records To
		CIN-DO
	Lab w/Split Sample	Lab

Document Number	Document Date	Document Type	Document Remarks
1.	12/12/2012	Affidavit	Signed by Nicholas I. Herkimer, President. (1 page.)
2.	06/06/2012	Invoice	Invoice no. 2346 documenting Master Supply's sale

Date: 01/30/2015 **Page:** 1 of 3

Food and Drug Administration Office of Regulatory Affairs
Collection Report
For Sample Number: 786776

This is an accurate reproduction of the original electronic record as of 12/12/2012

			of 1 - 250 lb. drum of acetylsalicylic acid batch no. 5564 to the Dealer. (1 page.)
3.	06/16/2012	Bill of Lading	Bill of lading no. 124679 documenting interstate shipment of 1 - 250 lb. drum of acetylsalicylic acid from Master Supply, Henderson, KY to the Dealer via Roadway Inc. (2 pages.)
4.	06/16/2012	Other	"Raw Material Inventory Record" documenting the receipt of acetylsalicylic acid batch no. 5564. (1 page.)
5.	11/21/2012	Other	"ARO Pharmaceuticals Batch Record" for Wilaprin Arthritis Formula lot 25C83 documenting the manufacturing, packaging and labeling of the finished product and the related quality records. (20 pages.)

Remarks
See continuation.

Payment Amount	Payment Method	704(d) Sample	702(b) Portion	Collector's Name
		No	No	Sylvia H. Rogers

Name of Signer	Date & Time of Signature	Meaning
Sylvia H. Rogers		12/12/2012 12:40 PM ET Collector

Food and Drug Administration Office of Regulatory Affairs
Collection Report
For Sample Number: 786776

This is an accurate reproduction of the original electronic record as of 12/12/2012

Continuation:

Product Label
Finished product: Label on bottle reads in part, "***WILAPRIN ARTHRITIS FORMULA 100 Tablets***Active ingredients: Acetylsalicylic acid 500 mg.***Lot 25C83***EXP 8/2013***ARO Pharmaceuticals***Powell, OH 43065***." Paperboard carton reads in part, "WILAPRIN ARTHRITIS FORMULA 100 Tablets***Active ingredients: Acetylsalicylic acid 500 mg.***Lot 25C83***EXP 8/2013***ARO Pharmaceuticals***Powell, OH 43065***." Printing on cardboard box reads in part, "***WILAPRIN ARTHRITIS FORMULA***12/100 Tablet Bottles***Lot 25C83***EXP 8/2013***ARO Pharmaceuticals***Powell, OH 43065***." (Labeling attached as part of the "Master Pharmaceuticals Batch Record" on pages 13 - 15.)

Active ingredient: Label on drum reads in part, "***Acetylsalicylic Acid UPS***Batch No. 5564***Use by 8/14***Net Weight 250 lbs.***Master Supply Henderson, KY 42420***." (Photograph attached on page 26.)

Description of Sample
No physical sample collected. Documentation accompanying sample includes copies of records documenting interstate commerce and cGMP deviations, one photograph and an affidavit.

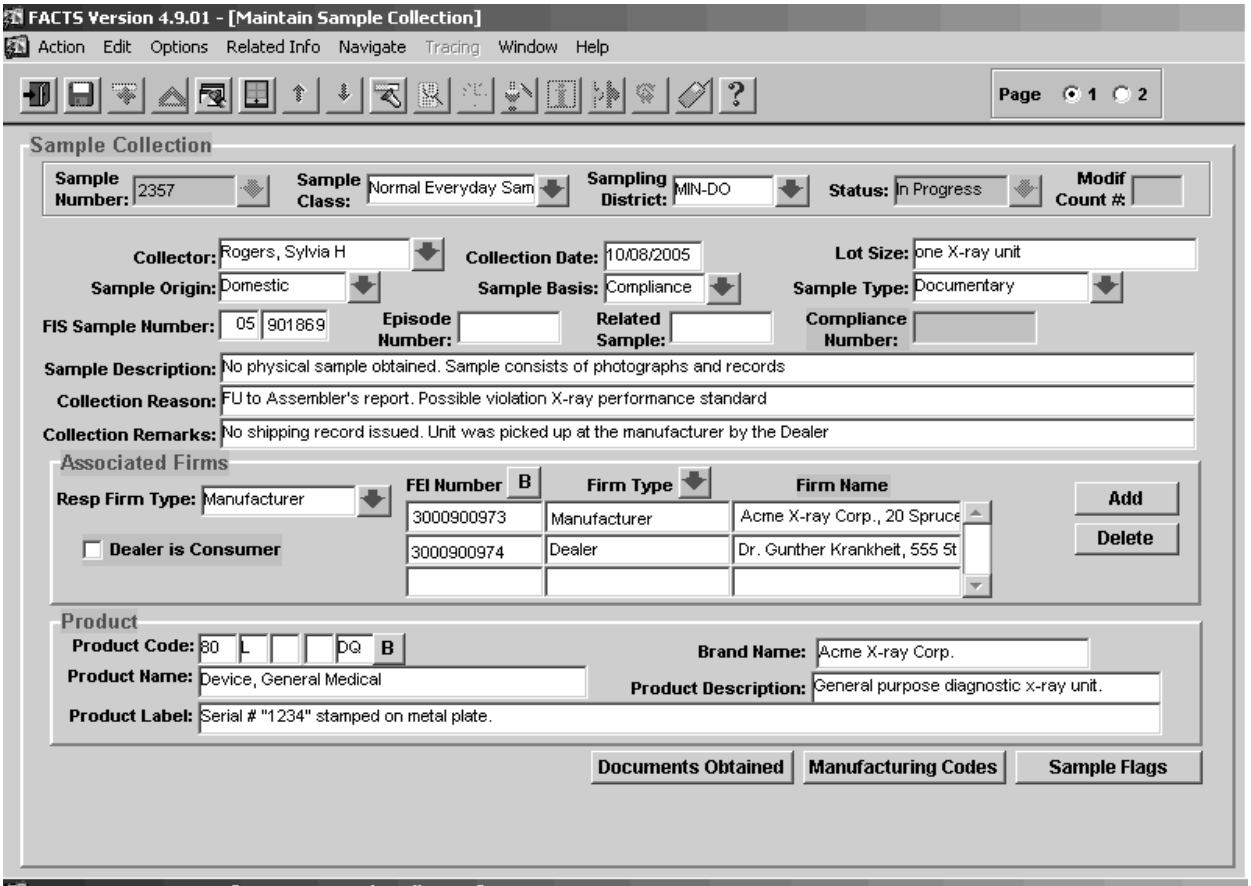
How Prepared
Records and mini CD-R identified as in the "Collector's ID on Package/Document" field. Original copy of digital photograhs made using a mini CD-R, which was officially sealed In a FDA 525 envelope as in the "Collector's ID on Seal" field.

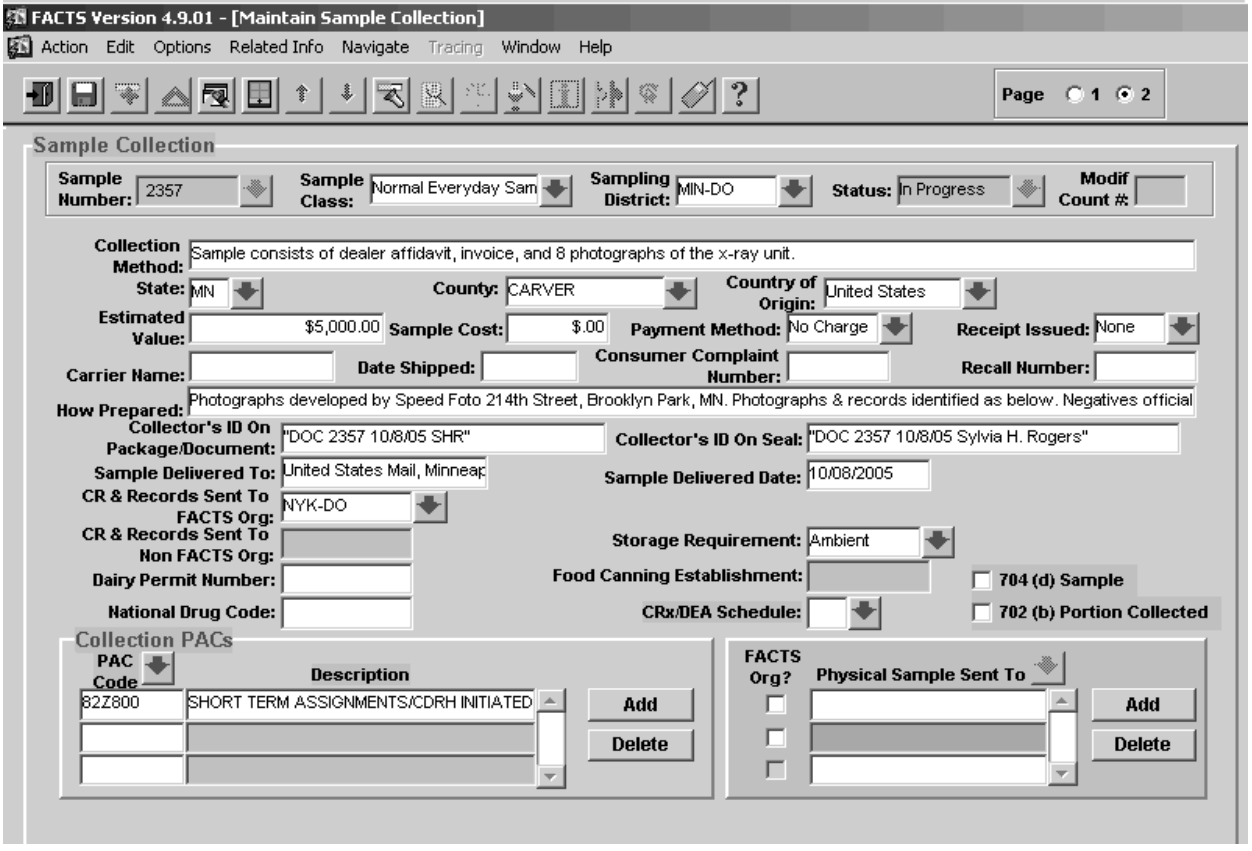
Remarks
"Product Description" (continued): with a white screw-on cap with a clear plastic seal. Bottle has yellow wrap around paper label with black printing. Bottle packaged in a white paperboard carton with black printing. Packed 12 cartons per box in a brown corrugated cardboard box with black printing.

Refer to EIR of Dealer dated 12/10-12/2012. FDA 483 dated 12/12/12 observation nos. 1 through 5 are cGMP observations related to this product.

Date: 12/12/2012 **Page:** 3 of 3

4-2 FACTS SAMPLE COLLECTION SCREEN





4-3 AFFIDAVIT (IN-TRANSIT)- FDA 1664b

AFFIDAVIT *(In-transit Sampling)*

SAMPLE NO.

STATE OF

COUNTY OF

Before me, _____ , an employee of the Department of Health and Human Services, Food and Drug Administration, designated by the Secretary, under authority of the Act of January 31, 1925, 43 Statutes at Large 803; Reorganization Plan No. IV, Secs. 12-15, effective June 30, 1940; Reorganization Plan No. 1 of 1953, Secs. 1-9, effective April 11, 1953; and P.L. 96-88, Sec. 509, 93 Statutes at Large 965 (20 U.S.C. 3508), effective May 4, 1980; to administer or take oaths, affirmations, and affidavits, personally appeared _____

_____ in the county and State aforesaid, who, being duly sworn, deposes and says: I am employed by

_____
(Carrier or firm name, city & state)

_____ as _____
(Title of position)

On _____, at _____.
(Date) *(City & state where sampled)*

The above named FDA employee collected a sample consisting of _____
(Description & number of units sampled)

_____

_____

from _____
(Enter type and number & License number of truck, bus, RR car, airplane, etc. or Firm name and shipping dock

_____ *from shipment(s) of goods consigned to or being shipped to address if from dock)*

_____
(Consignee name & address)

_____.

The aforesaid sampled shipment(s) was (were) identified to the FDA collector by _____
(Name of individual

_____, _____.
making identification) *(Title of person making identification)*

(Copy of) Shipping Record(s) _____, number _____,
(Type record - B/L, Waybill, etc.)

dated _____, issued by _____

_____, which were identified by _____
(Name & title of individual

_____, and furnished the FDA collector cover this (these) shipment(s).
identifying records)

AFFIANT'S SIGNATURE

Subscribed and sworn to before me at _____
(City and State)

this _____ day of _____, _____.

_____
(Employee's Signature)

Employee of the Department of Health and Human Services designated under Act of January 31, 1925, Reorganization Plan IV effective June 30, 1940; Reorganization Plan No. 1 of 1953, effective April 11, 1952; and P.L. 96-88, effective May 4, 1980.

FORM FDA 1664b (8/01) PREVIOUS EDITION MAY BE USED. PSC Publishing Services (301) 443-6740 EF

4-4 CARRIER'S RECEIPT FOR SAMPLE – FDA 472

DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION	DISTRICT ADDRESS AND PHONE NO. 550 West Jackson Blvd., Suite 1500, South Chicago, IL 60661 312-353-5863
TO: NAME AND TITLE OF INDIVIDUAL John B. Carr, Driver	DATE 11/06/2004
NAME AND ADDRESS OF CARRIER Transcontinental Trucking, 10 Front St. Dallas, TX 75204	SAMPLE NUMBER 27269
CONSIGNEE AND ADDRESS (Street, City, State and ZIP Code) XYZ Wholesale 111 S. Water Market Chicago, IL 60601	CONSIGNOR AND ADDRESS (Street, City, State and ZIP Code) Best Yet Packing Co. 3 First St. Young Town, TX 75002

SAMPLE(S) REMOVED FOR EXAMINATION		WAYBILL OR FREIGHT BILL NUMBER
AMOUNT OF SAMPLE	PRODUCT	
Two cases (48 count)	Lettuce - Best Yet Brand	A-23764

SAMPLE COLLECTOR'S NAME	TITLE	SIGNATURE
Sylvia H. Rogers	Investigator	Sylvia H. Rogers

FORM FDA 472 (10/01) PREVIOUS EDITION MAY BE USED UNTIL SUPPLY IS EXHAUSTED. CARRIER'S RECEIPT FOR SAMPLE

PSC Publishing Services (301) 443-6740 EF

4-5 – INSTRUCTIONS FOR COMPLETEING THE FDA 484, RECEIPT FOR SAMPLES

Block 1 - Enter the address of the home district of the firm and telephone number including area code.

Block 2 – Enter the complete name and official title of the individual to who you issue the FDA 484.

Block 3 – Enter the date the form was issued. If this differs from the sample collection date (for example in the case of environmental sampling), enter the collection date(s) in Block 9.

Block 4 – Enter the complete sample number here. Be sure to include any prefixes such as "DI" or "INV".

Block 5 – Enter the firm's legal name. This should be the firms legal name and not the DBA (doing business as), trade name, or alias.

Block 6 – If the firm is a dealer in narcotics or controlled drugs, enter their Drug Enforcement Administration (DEA) number here.

Block 7 and 8 – Enter the number, street, city, state, and zip code of the firm.

Block 9 – Enter a brief description of the article collected, including the number and size of units collected, product name, any identifying brand and code marks, and date(s) collected.

Block 10 – Check the appropriate box on the FDA 484.

Block 11 – Enter the amount paid for the sample (even if borrowed, the owner may ask rent for it) and check the appropriate box. If there is no charge, enter N/C and leave boxes blank. If, as a last resort, it is necessary for you to use your personal check or credit card and this is acceptable to the individual, enter amount and check the "Credit Card" box.

Block 12 – In instances where payment is made for the sample, whether actually purchased, borrowed or provided at no charge, and there is no dealer's affidavit, or any other document executed to show the owner's signature for receipt of payment, obtain the signature of the individual receiving payment for the sample.

If Dealer's Affidavit, regular Affidavit or other document is used, the recipient's signature will be on that document, so it is not necessary for him to also sign the FDA 484. In this case insert an applicable statement such as "Dealers Affidavit signed" in this block.

Blocks 13, 14, and 15 – Enter your name, title, and signature.

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

1. DISTRICT ADDRESS & PHONE NUMBER
158-15 Liberty Avenue
Jamaica, NY 11433
718-340-7000

2. NAME AND TITLE OF INDIVIDUAL	3. DATE	4. SAMPLE NUMBER
Richard A. Frost, General Manager	12/13/2007	25563

5. FIRM NAME	6. FIRM'S DEA NUMBER
Quality Wholesale Drug Co.	AB3632918

7. NUMBER AND STREET	8. CITY AND STATE *(Include Zip Code)*
3146 Front Street	Brooklyn, NY 11232

9. SAMPLE COLLECTED *(Describe fully. List lot, serial, model numbers and other positive identification)*

The following samples were collected by the Food and Drug Administration and receipt is hereby acknowledged pursuant to Section 704(c) of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 374(c)] and/or Section 532 (b) of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 360ll(b)] and/or 21 Code of Federal Regulations (CFR) 1307.02. Excerpts of these are quoted on the reverse of this form.
(**NOTE** : *If you bill FDA for the cost of the Sample(s) listed below, please attach a copy of this form to your bill.*)

One box of 25 - 1 cc ampules, Dilaudid HCl (hydromorphine) 2mg/cc, lot # 01032313 manufactured by Knoll Pharmaceutical Co. Orange, NJ.

Add Continuation Page

10. SAMPLES WERE	11. AMOUNT RECEIVED FOR SAMPLE	12. SIGNATURE *(Persons receiving payment for sample or person providing sample to FDA at no charge.)*
☐ PROVIDED AT NO CHARGE ☒ PURCHASED ☐ BORROWED *(To be returned)*	$15.00 ☒ CASH ☐ BILLED ☐ VOUCHER ☐ CREDIT CARD	Richard A. Frost

13. COLLECTOR'S NAME *(Print or Type)*	14. COLLECTOR'S TITLE *(Print or Type)*	15. COLLECTOR'S SIGNATURE
Sylvia H. Rogers	Investigator	Sylvia H. Rogers

FORM FDA 484 (3/06) PREVIOUS EDITION MAY BE USED

RECEIPT FOR SAMPLES

Page 1 of 1 Pages
PSC Graphics: (301) 443-1090 EF

Section 704 (c) of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 374(c)] is quoted below:

"If the officer or employee making any such inspection of a factory, warehouse, or other establishment has obtained any sample in the course of the inspection, upon completion of the inspection and prior to leaving the premises he shall give to the owner, operator, or agent in charge a receipt describing the samples obtained."

Section 532(b) of The Federal Food, Drug and Cosmetic Act [21 U.S.C. 360 ii (b)] is quoted in part below:

"Section 532(b) In carrying out the purposes of subsection (a), the Secretary is authorized to-
(1) ****
(2) ****
(3) ****
(4) procure (by negotiation or otherwise) electronic products for research and testing purposes, and sell or otherwise dispose of such products"

21 Code of Federal Regulations 1307.02 is quoted below:

"1307.02 Application of State law and other Federal law.
Nothing in this chapter shall be construed as authorizing or permitting any person to do any act which such person is not authorized or permitted to do under other Federal laws or obligations under international treaties, conventions or protocols, or under the law of the State in which he/she desires to do such an act nor shall compliance with such be construed as compliance with other Federal or State laws unless expressly provided in such other laws."

Therefore, in the event any samples of controlled drugs are collected by FDA representatives in the enforcement of the Federal Food, Drug, and Cosmetic Act, the FDA representative shall issue a receipt for such samples on FDA Form 484, RECEIPT FOR SAMPLES, to the owner, operator, or agent in charge of the premises.

Report of analysis will be furnished only where samples meet the requirements of Section 704(d) of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 374(d)] which is quoted below:

"Whenever in the course of any such inspection of a factory or other establishment where food is manufactured, processed, or packed, the officer or employee making the inspection obtains a sample of any such food, and an analysis is made of such sample for the purpose of ascertaining whether such food consists in whole or in part of any filthy, putrid, or decomposed substance, or is otherwise unfit for food, a copy of the results of such analysis shall be furnished promptly to the owner, operator, or agent in charge."

FORM FDA 484 (3/06) BACK

4-6 – FIELD WEIGHT SHEET – FDA 485

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

1. DATE: 9-16-05
2. SAMPLE NUMBER: 55532
3. PRODUCT: Spaghetti in plastic bags: "Genoa Semolina Vermicelli***Delmonico Foods, Inc. San Francisco, Calif.***Net Weight 12 ozs."
4. TYPE OF BALANCE: Gurley
5. RESPONSIBLE FIRM AND ADDRESS (Zip Code): Delmonico Foods, Inc. 4701 Canal Street San Francisco, California
6. ADDRESS WHERE WEIGHED: Medicine Bow Wholesalers 23 Railroad Ave. Cheyenne, Wyoming
7. WAREHOUSE — a. TYPE: Wholesale Grocery Warehouse; b. TEMPERATURE: 80° F; d. HUMIDITY: est. 20%
8. NO. OF — a. CASES IN LOT: 325 48/12 oz.; b. CASES SAMPLED: 12; c. SUBS WEIGHED FROM EACH CASE: 4 from each of 12 cases

9. GROSS WEIGHT *(Submit a minimum of 12 subs with at least one from each case examined. Submit the subs indicated by the asterisks adding others where necessary to identify additional subs submitted. Determine six tares. Where tares may vary widely, determine up to 12 where practical.)*

CASE NO.	SUB NO.	GROSS WEIGHT	CASE NO.	SUB NO.	GROSS WEIGHT	CASE NO.	SUB NO.	GROSS WEIGHT	CASE NO.	SUB NO.	GROSS WEIGHT
1	1	11.40	4	13	12.08	7	25	11.32	10	37	12.00
1	2	11.72	4	14	11.68	7	26	12.00	10	38	12.04
1	3*	11.60	4	15*	11.42	7	27*	11.34	10	39*	11.64
1	4	11.30	4	16	12.40	7	28	11.34	10	40	11.72
2	5	11.32	5	17	11.32	8	29	11.34	11	41	12.10
2	6	11.40	5	18	11.34	8	30	11.40	11	42	11.70
2	7*	12.00	5	19*	11.40	8	31*	11.40	11	43*	11.40
2	8	11.38	5	20	11.42	8	32	11.36	11	44	11.50
3	9	11.34	6	21	12.02	9	33	12.04	12	45	11.32
3	10	11.40	6	22	11.70	9	34	12.00	12	46	11.30
3	11*	11.42	6	23*	12.08	9	35*	11.38	12	47*	11.24
3	12	12.02	6	24	12.10	9	36	11.36	12	48	11.36
TOTAL		138.30			140.96			138.28			139.32
										GRAND TOTAL	556.86

10. PRELIMINARY TARE

TARE NO.	WEIGHT	TARE NO.	WEIGHT
1	0.22	4	0.23
2	0.22	5	0.21
3	0.21	6	0.22
TOTAL	0.65	TOTAL	0.66
		GRAND TOTAL	1.31
*NUMBER OF TARES WEIGHED			6
PRELIMINARY AVERAGE TARE			0.22

11. WEIGHING RESULTS

a. AVERAGE GROSS	11.60
b. PRELIMINARY AVERAGE TARE	.22
c. AVERAGE NET	11.38
d. DECLARED NET	12.00
e. SHORTAGE	.62
12. PRELIMINARY % SHORT	5.2%

13. REMARKS *(List observations of lot or storage conditions affecting net weights)*: Lot has been in storage since 9-1-05.

14. DISTRICT: DEN-DO
15. EMPLOYEE SIGNATURE: Sidney H. Rogers
16. EMPLOYEE TITLE: Investigator

FD FORM 485 (5/85) PREVIOUS EDITION MAY NOT BE USED FIELD WEIGHT SHEET

4-7 – AFFIDAVIT – "301(k) Sample" – FDA 463a

AFFIDAVIT	SAMPLE NO. 55533
STATE OF Kansas	COUNTY OF Sedgwick

Before me, Sidney H. Rogers, an employee of the Department of Health and Human Services, Food and Drug Administration, designated by the Secretary, under authority of the Act of January 31, 1925, 43 Statutes at Large 803; Reorganization Plan No. IV, Secs. 12-15, effective June 30, 1940; Reorganization Plan No. 1 of 1953, Secs. 1-9, effective April 11, 1953; and P.L. 96-98, Sec. 509, 93 Statutes at Large 965 (20 U.S.C. 3508), effective May 4, 1980; to administer or take oaths, affirmations, and affidavits, personally appeared Joseph H. Roe in the county and State aforesaid, who, being duly sworn, deposes and says:

I am the Vice President in charge of production of the Doe Bottling Co., Inc., 123 Main, Thistown, Kansas 67201; and as such I have knowledge of the raw material receiving and use, and carbonated beverage production at this firm.

The sample consisting of two cases, 48- 10 ounce bottles, of Kola Cola, coded ABCD, collected by Investigator Rogers on November 15, 1999 was from a lot of 2668 cases produced by this firm on October 7, 1999. The copies of our production records for October 7, 1999 consist of a Syrup Room Report dated 10-6-99, a two-page Production Report dated 10-7-99, an undated in-line Control record, and a Finished Drink Control Record dated 10-7-99. Copies of these records were provided to the investigator and cover our production of this lot.

The above described lot was made in part from a portion of a lot of bulk liquid sugar received October 3, 1999 from the Sweet Sugar Co., Boise, Idaho, in railroad tank car ATSF 98765, unloaded October 6, 1999. The copies of the Sweet Sugar Co. invoice number 468 dated Sept. 26, 1999; freight waybill number UP-3579 dated Sept. 27, 1999 issued by the Union Pacific Railroad Co.; and our receiving report number 01-23 dated October 3, 1999 were provided to the investigator and cover this shipment.

The above described lot was also made in part from a portion of a lot of Kola Cola syrup base received September 23, 1999 from the Kola Cola Co., Thattown, Texas. The copies of Kola Cola Co. invoice number KCO1928 dated Sept. 20, 1999; freight bill number X-98125 dated Sept. 21, 1999 issued by Speedy Truck Line Co.; and our receiving report number 01-01 dated Sept. 23, 1999 were provide to the investigator and cover this shipment.

The above described lot of Kola Cola was identified to the investigator by William S. Doe, Production Supervisor. I identified and provided copies of the records to the investigator.

AFFIANT'S SIGNATURE AND TITLE

Joseph H. Roe, Production Vice President

FIRM'S NAME AND ADDRESS *(Include ZIP Code)*

Doe Bottling Co., Inc. 123 Main, Thistown, Kansas, 67201

Subscribed and sworn to before me at Thistown, Kansas this 15th day of November, 1999.

Sidney H. Rogers

(Employee Signature)

Employee of the Department of Health and Human services designated under Act of January 31, 1925, Reorganization Plan IV effective June 30, 1940; Reorganization Plan No. 1 of 1953, effective April 11, 1953; and P.L. 96-88 effective May 4, 1980.

4-8 – COPY OF INVOICE/SHIPPING RECORD – FD 1662

1. LOCATION	2. NAME OF SAMPLE COLLECTOR	3. DATE COLLECTED	4. SAMPLE NUMBER
Pine Bluff, Arkansas	Sylvia H. Rogers	10-8-05	55566

SECTION I - COPY OF INVOICE

5. CONSIGNOR *(Name, Street, City, and State)*	6. CONSIGNEE *(Name, Street, City, and State)*
Captain Sam Seafood, Inc. 719 Butler Ave. New Orleans, LA	Razor Back Super Market 1207 Little Rock Dr. Pine Bluff, AR

7. GUARANTEE	8. INVOICE NUMBER	9. INVOICE DATE
-----see reverse-----	477	9-20-05

10 QUANTITY	11 UNIT SIZE	12 DESCRIPTION OF ARTICLE(S)	13 UNIT PRICE		14 TOTAL	
10 cs.	24/4.5 oz.	Horseshoe Brand Canned Medium Shrimp	2	84	56	80
5 cs.	10/5 lb.	Frozen Green Hills 21-25 Shrimp	1	10	275	00
		**********				
5cs.	24/8 oz.	Horseshoe Brand Canned Cove Oysters	5	25	52	50
		**********				
2 cs.	6/4 lb.	Frozen C&P Small Shrimp	1	50	72	00
			15. **TOTAL**		642	80

SECTION II - COPY OF SHIPPING RECORD

16. SHIPPER *(Name, Street, City, and State)*	17. CONSIGNEE *(Name, Street, City, and State)*
Captain Sam Seafood, Inc. NOLA	Razor Back Super Market 1207 Little Rock Dr. Pine bluff, AR

18. CARRIER *(Name, City, and State)*

Sea Breeze Trucking, Inc. NOLA

19. CAR OR EQUIPMENT NUMBER	20. WAYBILL DATE & NUMBER	21. TYPE OF RECORD *(Specify)*	22. RECORD NO.	23. RECORD DATE
Van 109	N/A	F/B	06641	9-20-05

24. SHIPPED FROM *(City and State)*	25. ROUTE	26. DATE SHIPPED
NOLA	N/A	9-20-05

27 DESCRIPTION OF ARTICLE(S)	28 NO. PKGS.	29 WEIGHT	30 RATE	31 CHANGES
Canned Food	20	300	172	5.16
Frozen Seafood	8	350	224	7.84

32. RECEIVED BY	33. DATE REC'D	34.				
P. Monteux s/s	9-26-05	**TOTAL**	28	650		13.00

4-9 AFFIDAVIT (PARCEL POST) – FDA 463a

AFFIDAVIT *(Parcel Post/Parcel Service)*	SAMPLE NO. 2358
STATE OF Colorado	COUNTY OF Pueblo

Before me, Sidney H. Rogers an employee of the Department of Health and Human Services, Food and Drug Administration, designated by the Secretary, under authority of the Act of January 31, 1925, 43 Statutes at Large 803; Reorganization Plan No. IV, Secs. 12-15, effective June 30, 1940; Reorganization Plan No. 1 of 1953, Secs. 1-9, effective April 11, 1953; and P.L. 96-88, Sec. 509, 93 Statutes at Large 965 (20U.S.C.3508), effective May 4, 1980; to administer or take oaths, affirmations, and affidavits, personally appeared Joseph D. Bullard in the county and state aforesaid, who, being duly sworn, deposes and says: (I) (My firm) received on or about the day of July 10th, 2005, in response to an order previously given by me, two (packages, containers, etc.) consisting in whole or in part of a product designated "4 ounces NET***Johnson's Eye Ease***Reservation Special" via: (parcel post, United States mail) (United Parcel Service) from Old Indian Herb Co. 294 N. Blackfoot St., Boise, Idaho 30854 and covered by attached copy of invoice number C-20 dated 7-2-05; after unpacking the goods the (parcel post) (parcel service) wrapper was destroyed; and on the 12th day of July, 2005, Inspector/Investigator Rogers obtained from me a sample consisting of 10-4 oz. bottles of Johnson's Eye Ease coded "J-638" on the bottle label, shipped and described as aforesaid and for which he paid me the sum of $25.00 in (cash) (voucher) (billed).

Remarks: I first learned of this product while reading the January 2005 issue of "The Retired Engineer." I use it to relieve the burning and itching in my eyes after working in the heat and dryness.

AFFIANT'S SIGNATURE AND TITLE

Joseph D. Bullard

FIRM'S NAME AND ADDRESS *(Include ZIP Code)*

Subscribed and sworn to before me at Crow, Colorado *(City & State)* this 13th day of July, 2005.

Sidney H. Rogers /

(Employee's Signature)

Employee of the Department of Health and Human Services designated under Act of January 31, 1925, Reorganization Plan IV effective June 30, 1940; Reorganization Plan No. 1 of 1953, effective April 11, 1953; and P.L. 96-88, effective May 4, 1980.

FORM FDA 463(4/83) PREVIOUS EDITIONS ARE OBSOLETE

4-10 - AFFIDAVIT – FDA 463a

AFFIDAVIT	SAMPLE NO. 55555
STATE OF Oregon	COUNTY OF Klamath

Before me, Sidney H. Rogers, an employee of the Department of Health and Human Services, Food and Drug Administration, designated by the Secretary, under authority of the Act of January 31, 1925, 43 Statutes at Large 803; Reorganization Plan No. IV, Secs. 12-15, effective June 30, 1940; Reorganization Plan No. 1 of 1953, Secs. 1-9, effective April 11, 1953; and P.L. 96-98, Sec. 509, 93 Statutes at Large 965 (20 U.S.C. 3508), effective May 4, 1980; to administer or take oaths, affirmations, and affidavits, personally appeared George W. Hughes in the county and State aforesaid, who, being duly sworn, deposes and says:

I live at 482 Abricia Ave., Klamath Falls, Oregon. On October 18, 1999, my neighbor, Dr. Samuel Thompson, asked me to pick up some medical instruments from a firm in Santa Rosa, California for him. Later that same day I drove to Santa Rosa in my 1997 Dodge Ram pick-up truck which has Oregon license plates, number FAS 682. My Oregon driver's license number is OR0123-45-6789.

The next morning, October 19, 1999, I drove to Charles Brown & Associates at 920 Grape St., Santa Rosa, California and picked up 4 containers bearing the label: "Fancy Medical Device, quantity 1." Each container contained a medical device.

I drove back to Klamath Falls, Oregon after picking up a load of wine for my wine cellar, and arrived home on or about 11:00 PM.

The next morning, October 20, 1999, I delivered the 4 containers to Dr. Samuel Thompson at his office, 2209 Timberline Ave., Klamath Falls, Oregon.

I did not charge Dr. Thompson for the pick-up and delivery because I make regular trips to pick up wine in Santa Rosa for my wine cellar.

AFFIANT'S SIGNATURE AND TITLE

George W. Hughes, Owner

FIRM'S NAME AND ADDRESS (Include ZIP Code)

Hughes Wine Cellar, 483 Abrecia Ave., Klamath Falls, 97210

Subscribed and sworn to before me at Klamath Falls, Oregon this 4th day of November, 1999.

Sidney H. Rogers
(Employee Signature)

Employee of the Department of Health and Human services designated under Act of January 31, 1925, Reorganization Plan IV effective June 30, 1940; Reorganization Plan No. 1 of 1953, effective April 11, 1953; and P.L. 96-88 effective May 4, 1980.

FORM FDA 463a (5/07) PREVIOUS EDITIONS ARE OBSOLETE PAGE 1 OF 1 PAGES

4-11 – AFFADAVIT – FDA 463a

AFFIDAVIT

SAMPLE NO. 166455

STATE OF: Florida

COUNTY OF: Orange

Before me, Paul A. Revere, an employee of the Department of Health and Human Services, Food and Drug Administration, designated by the Secretary, under authority of the Act of January 31, 1925, 43 Statutes at Large 803; Reorganization Plan No. IV, Secs. 12-15, effective June 30, 1940; Reorganization Plan No. 1 of 1953, Secs. 1-9, effective April 11, 1953; and P.L. 96-98, Sec. 509, 93 Statutes at Large 965 (20 U.S.C. 3508), effective May 4, 1980; to administer or take oaths, affirmations, and affidavits, personally appeared Nicholas I. Herkimer in the county and State aforesaid, who, being duly sworn, deposes and says:

I am the Warehouse Manager at ABC Distribution Company, 200 Harding Street, Orlando, FL 32806 and have held this position for 3 months. Previously, I held the position of Traffic Manager here for 10 years. As such, I am familiar with and can identify records associated with the receipt, storage and shipment of goods at my firm.

On or about 3/1/01, my firm received a shipment of 500 cases, 24-½ fl. oz. bottles/case of Opti-One brand 0.12% Phenylephrine HCl Ophthalmic Drops from Sawyer Corporation, 51 Summer Street, Andover, MA 01810. This shipment was delivered to my firm by Yellow Freight Company, 1553 Fairlawn Street, St. Louis, MO 63126 and is covered by Sawyer Corporation invoice number 1500 dated 3/1/01 and bill of lading number 2000 dated 3/1/01.

On 4/1/01, I identified and provided Investigator Revere copies of the documents described in this statement. On 4/1/01, Investigator Revere collected a sample consisting of 96 - ½ fl. oz. bottles of Opti-One brand 0.12% Phenylephrine HCl Ophthalmic Drops, lot number 020101, from the shipment described above. This sample was provided to the FDA at a cost of $192.00, which will be billed.

I read this statement and agree it is true.

AFFIANT'S SIGNATURE AND TITLE Nicholas I. Herkimer, Warehouse Manager

FIRM'S NAME AND ADDRESS (Include ZIP Code)

ABC Distribution Company, 200 Harding Street, Orlando, FL 32806

Subscribed and sworn to before me at Orlando, FL this 1st day of April, 2001.

Paul A. Revere

(Employee Signature)

Employee of the Department of Health and Human services designated under Act of January 31, 1925, Reorganization Plan IV effective June 30, 1940; Reorganization Plan No. 1 of 1953, effective April 11, 1953; and P.L. 96-88 effective May 4, 1980.

FORM FDA 463a (5/07) PREVIOUS EDITIONS ARE OBSOLETE PAGE 1 OF 1 PAGES

4-12 – AFFIDAVIT – (Dealer/Warehouseman) – FDA 1664

AFFIDAVIT *(Dealer/Warehouseman)*

SAMPLE NO. 55563

STATE OF: Arkansas

COUNTY OF: Jefferson

Before me, Sidney H. Rogers, an employee of the Department of Health and Human Services, Food and Drug Administration, designated by the Secretary under authority of the Act of January 31, 1925, 43 Statutes at Large 803; Reorganization Plan No. IV, Secs. 12-15, effective June 30, 1940; Reorganization Plan No. 1 of 1953, Secs. 1-9, effective April 11, 1953; and P.L. 96-88, Sec. 509, 93 Statutes at Large 965 (20 U.S.C. 3508), effective May 4, 1980, to administer or take oaths, affirmations, and affidavits, personally appeared Henry O'Rourke, in the county and State aforesaid, who, being duly sworn, deposes and says: The sample consisting of Two Cases (24/8 oz. Each) Horseshoe Brand Canned Cove Oysters collected by the above FDA employee on 3-10-99 was from shipment(s) received by us from Captain Sam Seafood, Inc. New Orleans, LA on 3-7-99 and so identified to the collector:

That the copy of invoice(s):

	NUMBER	DATE	NUMBER	DATE	NUMBER	DATE
1)	06641	3/6/99	2) 06643	3/7/99	3)	

and (copy of) shipping record(s):

TYPE: *(B/L, F/B)*	NUMBER	DATE	ISSUING FIRM OR CARRIER
1) F/B	4778	3/6/99	Acme Freight Lines, Inc. NOLA
2) F/B	A-9321	3/7/99	Thru-Fast Lines, Little Rock, AR
3)			

which were identified and furnished the collector, cover this (these) shipment(s):

That said shipment(s) was (were) entered for the account of N/A

under Lot no. _____.

The collector paid me the sum of $ 21.32 (in cash) ~~(by voucher)(to be billed)~~ for the sample.

REMARKS

AFFIANT'S SIGNATURE & TITLE

Henry O. O'Rourke, Warehouse Manager Plant #12

FIRM *(Name and address, include ZIP Code)*

Southeastern Seafood Distributors, Inc.
#4 Canal Street Dock Red River Basin Area, Little Rock, AR 72901

Subscribed and sworn to before me at Little Rock, AR
(City and State)

this 10th day of March, 1999

Sidney H. Rogers .
(Employee's Signature)

Employee of the Department of Health and Human Services designated under Act of January 31, 1925, Reorganization Plan IV effective June 30, 1940; Reorganization Plan No. 1 of 1953, effective April 11, 1953;and P.L. 96-88, effective May 4, 1980.

FORM FDA 1664(4/83) PREVIOUS EDITIONS ARE OBSOLETE

4-13 – AFFIDAVIT – FDA 463a

AFFIDAVIT	SAMPLE NO. 55545
STATE OF Tennessee	COUNTY OF Shelby

Before me, Sidney H. Rogers, an employee of the Department of Health and Human Services, Food and Drug Administration, designated by the Secretary, under authority of the Act of January 31, 1925, 43 Statutes at Large 803; Reorganization Plan No. IV, Secs. 12-15, effective June 30, 1940; Reorganization Plan No. 1 of 1953, Secs. 1-9, effective April 11, 1953; and P.L. 96-98, Sec. 509, 93 Statutes at Large 965 (20 U.S.C. 3508), effective May 4, 1980; to administer or take oaths, affirmations, and affidavits, personally appeared George R. Applegate in the county and State aforesaid, who, being duly sworn, deposes and says:

I am manager of John's Curb Market, 342 East Johnson St., Memphis, Tennessee. As such, I have knowledge of purchasing and receipt of products at the market.

On September 2, 1999, FDA Investigator Sidney H. Rogers collected from my firm a sample consisting of six - 4 pound cans of Red River Brand Pure Sorghum. This sorghum was collected from a lot of six cases, each containing 4 - 4 pound buckets (cans) purchased by me from Ted Buymore who regularly sells sorghum in this area. Ted delivered this lot of six cases to my market on August 28, 1999 in a red panel GM truck with Alabama license plates. I do not know the license number.

AFFIANT'S SIGNATURE AND TITLE

George R. Applegate, Manager

FIRM'S NAME AND ADDRESS *(Include ZIP Code)*

John's Curb Market, 342 East Johnson St., Memphis, TN 38110

Subscribed and sworn to before me at Memphis, Tennessee this 2nd day of September 1999.

Sidney H. Rogers
(Employee Signature)

Employee of the Department of Health and Human services designated under Act of January 31, 1925, Reorganization Plan IV effective June 30, 1940; Reorganization Plan No. 1 of 1953, effective April 11, 1953; and P.L. 96-88 effective May 4, 1980.

FORM FDA 463a (5/07) PREVIOUS EDITIONS ARE OBSOLETE PAGE 1 OF 1 PAGES

4-14 – AFFIDAVIT – (Jobber) – FDA 1664a

AFFIDAVIT *(Jobber)*

SAMPLE NO. 55563

STATE OF Arkansas

COUNTY OF Jefferson

Before me, Sylvia H. Rogers, an employee of the Department of Health and Human Services, Food and Drug Administration, designated by the Secretary under authority of the Act of January 31, 1925, 43 Statutes at Large 803; Reorganization Plan No. IV, Secs. 12-15, effective June 30, 1940; Reorganization Plan No. 1 of 1953, Secs. 1-9, effective April 11, 1953; and P.L. 96-88, Sec. 509, 93 Statutes at Large 965 (20 U.S.C. 3508), effective May 4, 1980, to administer or take oaths, affirmations, and affidavits, personally appeared Patrick T. Palmer, in the county and State aforesaid, who, being duly sworn, deposes and says: The lot of The lot of 325 cases, (24/ 4 ½ oz. cans) of Jolly Miller Canned Mushrooms.

which we invoiced and sold to Patriot Markets, Inc. Frankford, Pennsylvania, on 4-12-99.

was a portion/all of a parcel shipped to us by Northern Light Foods, Inc. Duluth, Minnesota.

and is covered by submitted (copy of) invoice(s):

	NUMBER	DATE	NUMBER	DATE	NUMBER	DATE
1)	3914	4/4/99	2)		3)	

and (copy of) shipping record(s):

TYPE: *(B/L, F/B)*	NUMBER	DATE	ISSUING FIRM OR CARRIER
1) B/L	20018	4/5/99	Northern Freight Carriers
2)			
3)			

REMARKS

AFFIANT'S SIGNATURE & TITLE

Patrick T. Palmer, Warehouse Manager Plant #12

FIRM *(Name and address, include ZIP Code)*

Liberty Wholesale Grocers
3210 11th Ave. Frankford, PA 19105

Subscribed and sworn to before me at Frankford, PA
(City and State)

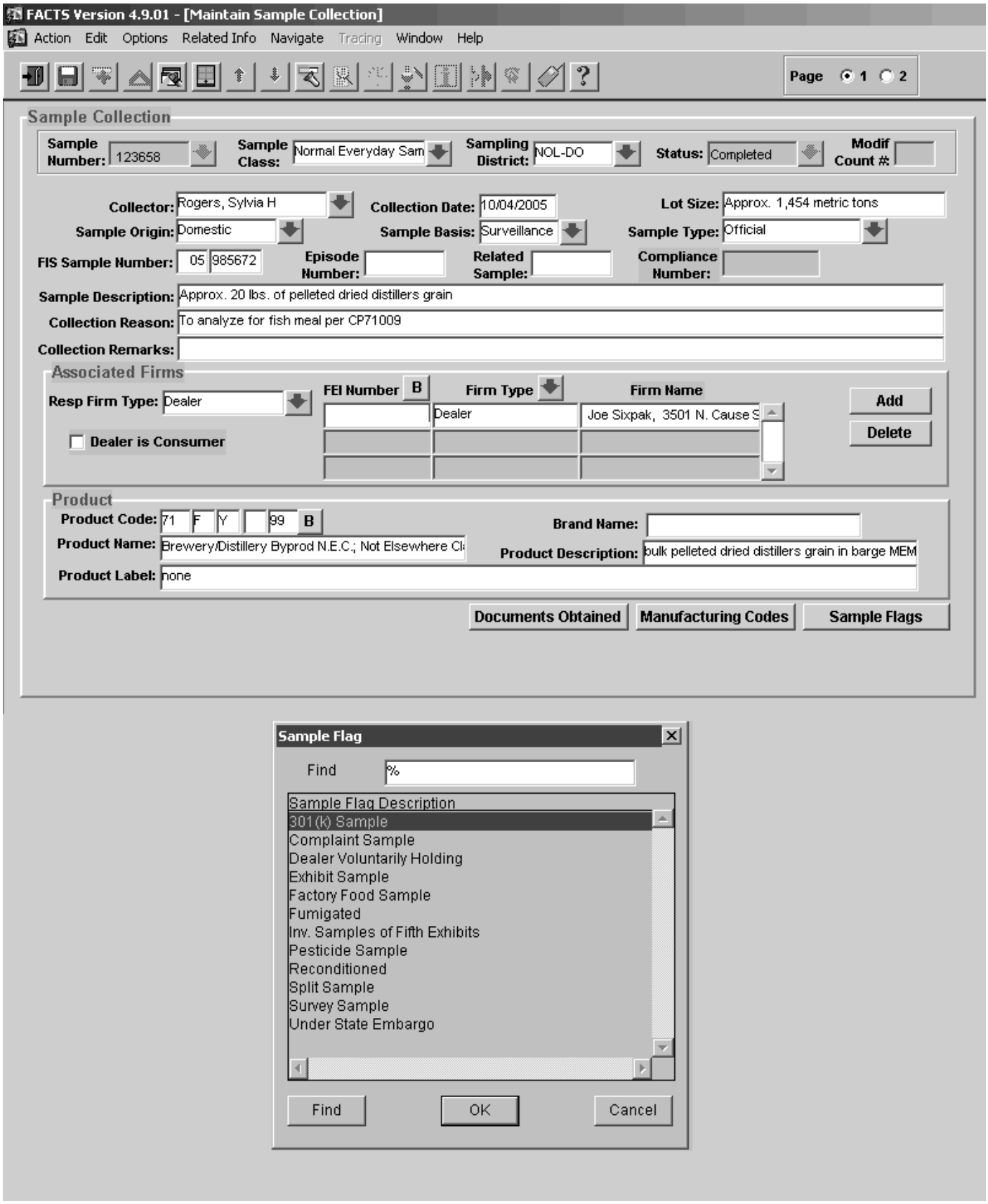
this 28th day of April, 1999

Sylvia H. Rogers
(Employee's Signature)

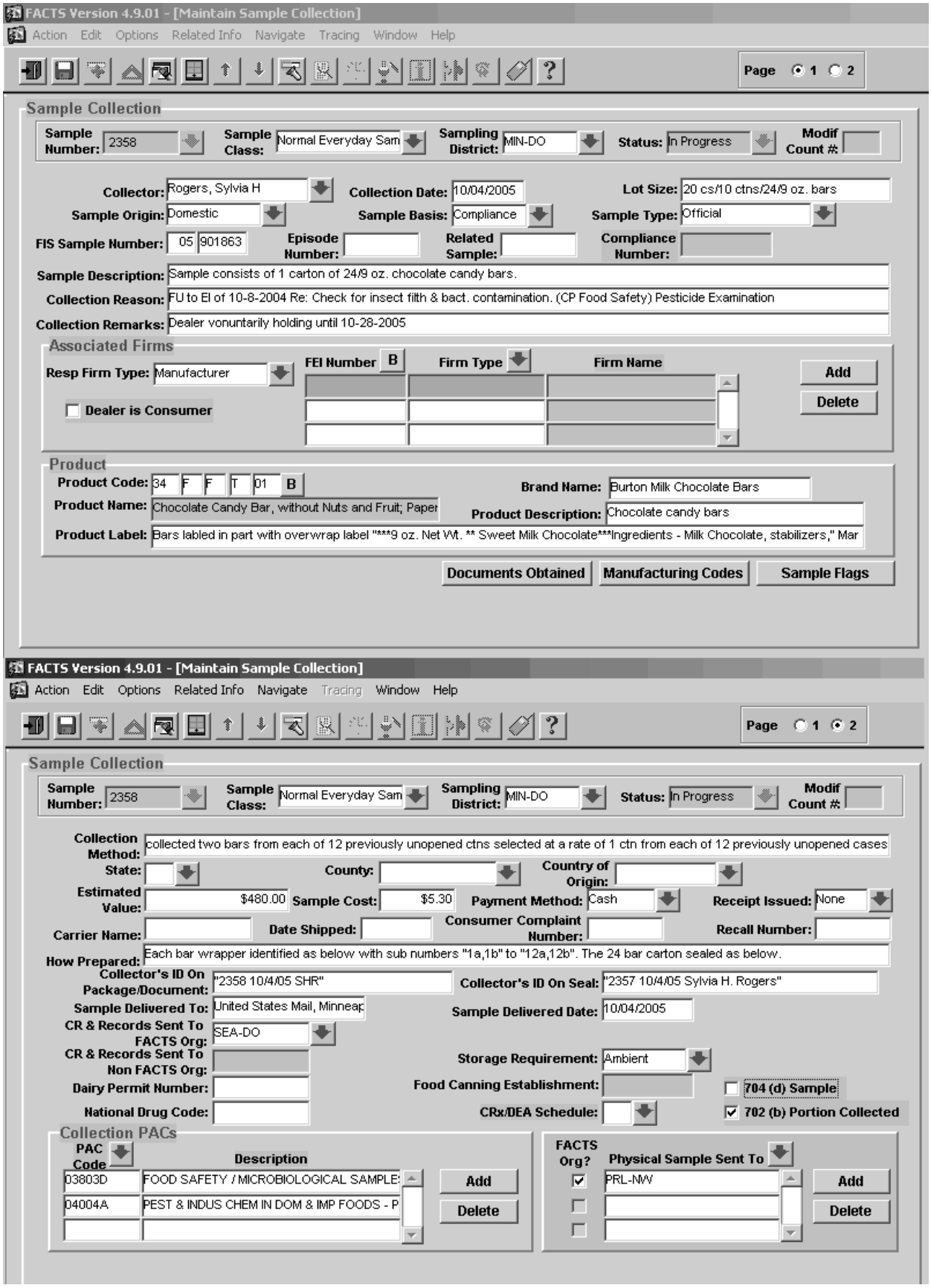
Employee of the Department of Health and Human Services designated under Act of January 31, 1925, Reorganization Plan IV effective June 30, 1940; Reorganization Plan No. 1 of 1953, effective April 11, 1953;and P.L. 96-88, effective May 4, 1980.

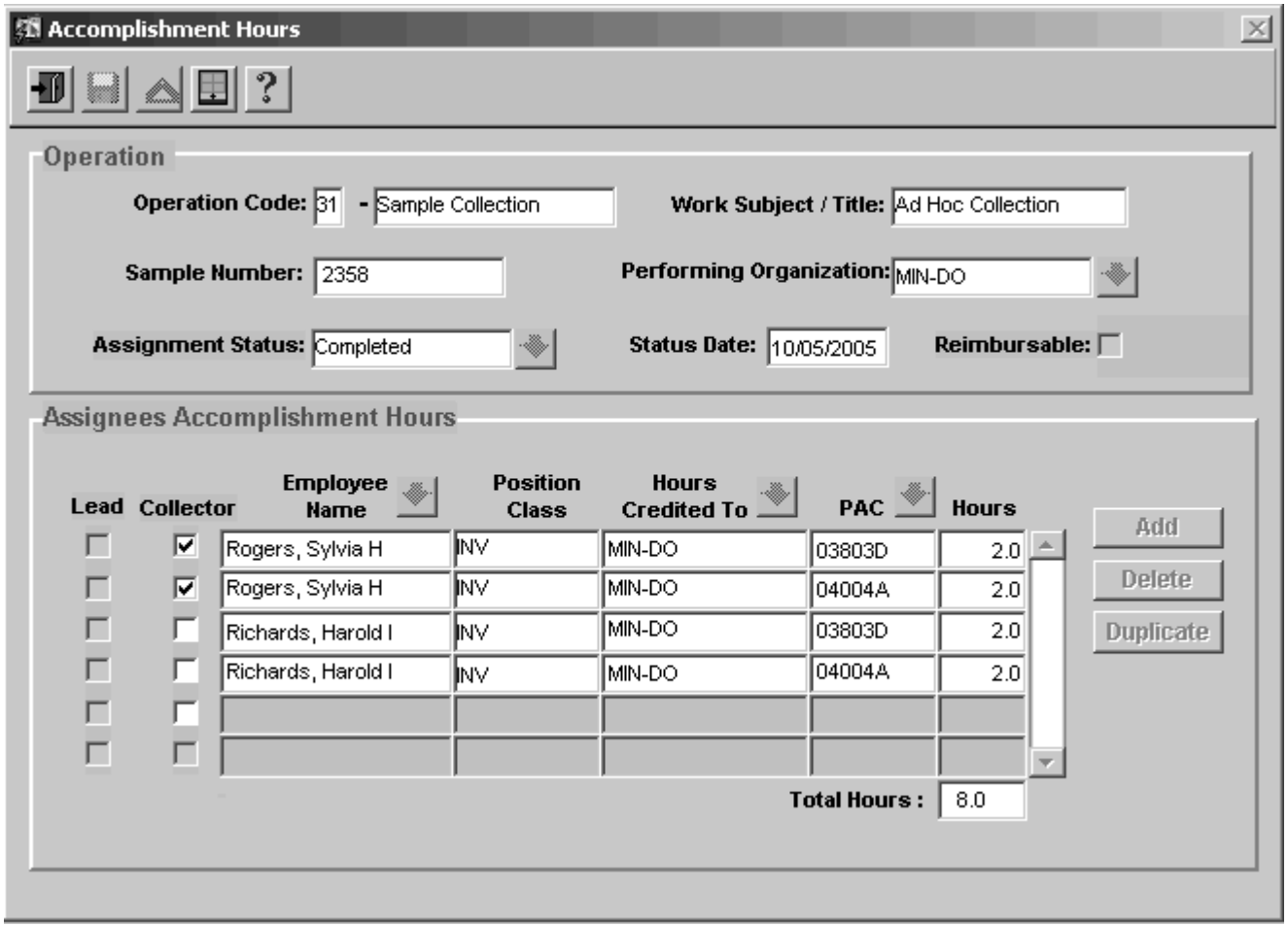
FORM FDA 1664a (7/01) PREVIOUS EDITIONS ARE OBSOLETE

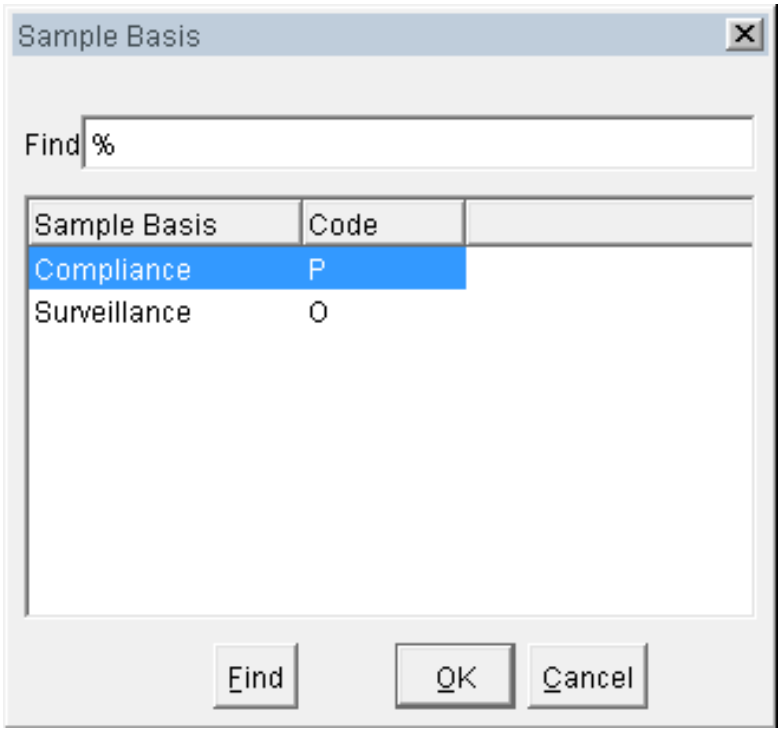
4-15 FACTS SAMPLE COLLECTION SCREEN



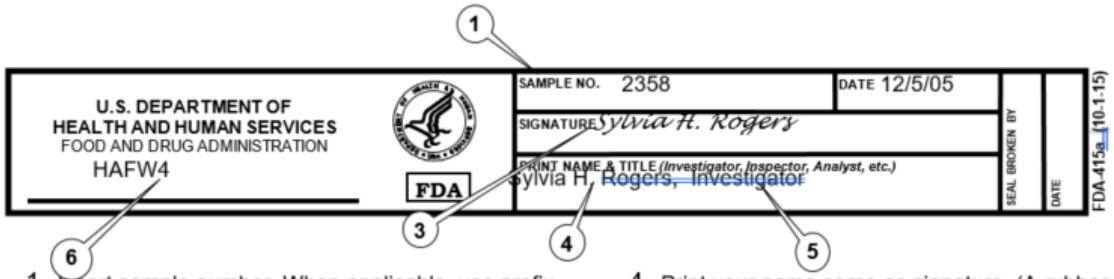
4-16 FACTS SAMPLE COLLECTION SCREEN




Accomplishment Hours
Operation
Operation Code: 31 - Sample Collection
Work Subject / Title: Ad Hoc Collection
Sample Number: 2358
Performing Organization: MIN-DO
Assignment Status: Completed
Status Date: 10/05/2005
Reimbursable:
Assignees Accomplishment Hours
Lead
Collector
Employee Name
Position Class
Hours Credited To
PAC
Hours
Rogers, Sylvia H INV MIN-DO 03803D 2.0
Rogers, Sylvia H INV MIN-DO 04004A 2.0
Richards, Harold I INV MIN-DO 03803D 2.0
Richards, Harold I INV MIN-DO 04004A 2.0
Total Hours : 8.0
Add
Delete
Duplicate


Sample Basis
Find %
Sample Basis
Code
Compliance P
Surveillance O
Find
OK
Cancel

4-17 OFFICAL SEAL – FDA 415a



1 Insert sample number. When applicable, use prefix, e.g. "INV", "FS", "DOC", "PS", etc. (See IOM 4.4.10.2)

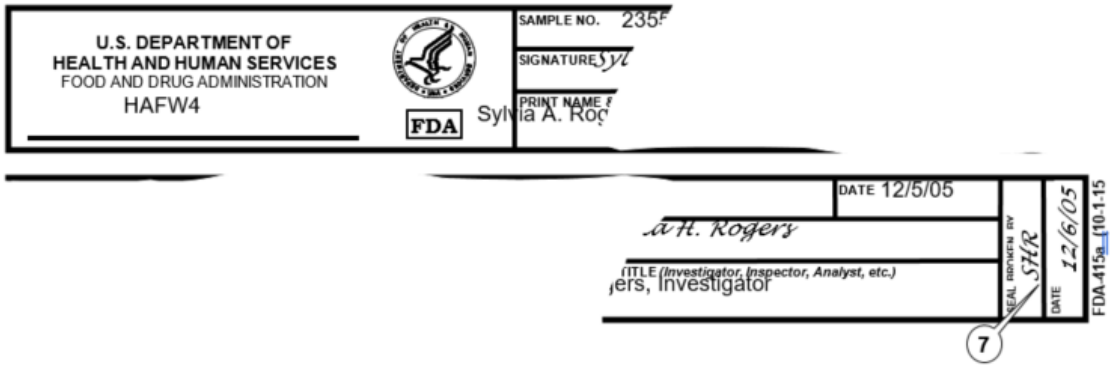
2 Insert date sealed. Use figures, month, day, year. (See # 7 below when seal is broken for any purpose.)

3 Sign your signature.

4 Print your name same as signature. (A rubber name stamp may be used if desired but use it carefully and do not smear.)

5 Print your title.

6 Print your divisional affiliation acronym (ie. HAFW4, DPQOII).



5. When seal is broken for any purpose, initial here and enter the date broken. Submit broken seal with sample records.

4-18 DECLARATION FOR DANGEROUS GOODS

Shipper

U. S. FOOD & DRUG ADMINISTRATION
6601 N.W. 25th St. Room 236
Miami, FL 33122

Air Waybill No.
Delta 7012-6140

Page 1 of 1 Pages

Collection Report Number
2555

Consignee

Food and Drug Administration
60 Eighth Street
Atlanta, GA 30309

U.S. GOVERNMENT SHIPMENT

Two completed and signed copies of this Declaration must be handed to the operator

WARNING

Failure to comply in all respects with the applicable Dangerous Goods Regulations may be in breach of the applicable law, subject to legal penalties. This Declaration must not, in any circumstances, be completed and/or signed by a consolidator, a forwarder or an IATA cargo agent.

TRANSPORTATION DETAILS

This shipment is within the limitations prescribed for *(delete non-applicable)*

PASSENGER AND CARGO AIRCRAFT | ~~CARGO AIRCRAFT ONLY~~

Airport of Departure
Miami, FL

Airport of Destination
Atlanta, GA

Shipment type *(Delete non-applicable)*

NON-RADIOACTIVE | ~~RADIOACTIVE~~

NATURE AND QUANTITY OF DANGEROUS GOODS

Dangerous Goods Identification				Quantity and Type of packing	Packing Inst.	Authorization
PROPER SHIPPING NAME OF ARTICLE as listed in the Restricted Articles Tariff Federal Aviation Regulations or IATA Restricted Articles Regulations.	Class Or Division	UN Or ID No.	Subsidiary Risk			
DRY ICE (CARBON DIOXIDE SOLID)	ORM A OR 9	UN 1845	N/A	5 Fiberboard containers net weight 20 lbs. dry ice each container	173.615 or 615	

Note: Include these notations on all Dry Ice shipments.

Additional handling Information

DO NOT OPEN THIS PACKAGE, IF PROBLEMS ARISE, CONTACT SHIPPER AT (305)555-3344

I hereby declare that the contents of this consignment are fully and accurately described above by proper shipping name and are classified, packed, marked and labeled, and are in all respects in the proper condition for transport by air according to the applicable International and National Government Regulations

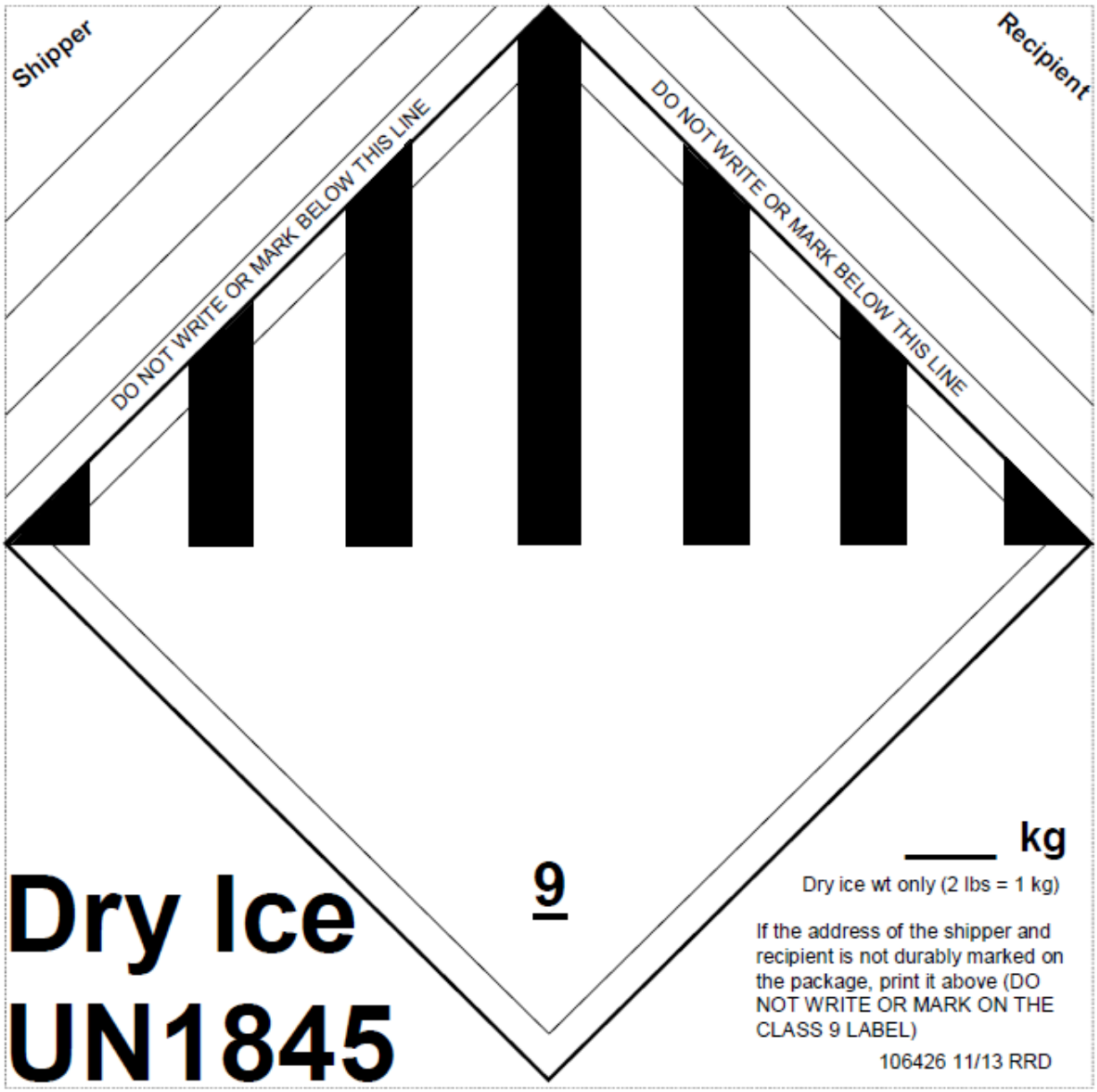
Name/Title of Person Signing
Sidney H. Rogers
Investigator

Place and Date
Miami, FL (9-8-99)

Signature *(See warning above)*
Sidney H. Rogers

FORM FDA 3082 (3/83) PREVIOUS EDITION IS OBSOLETE

4-19 DRY ICE LABEL



4-20 Environmental Sampling for Detection of Listeria monocytogenes, CFSAN Guidance

BACKGROUND

Listeria monocytogenes has been associated with such foods as raw milk, supposedly pasteurized fluid milk, cheeses (particularly soft-ripened varieties), ice cream, raw vegetables, fermented raw-meat sausages, raw and cooked poultry, raw meats (all types), and raw and smoked fish. Its ability to grow at temperatures as low as 0°C permits multiplication in refrigerated foods.[4] Listeriosis is a foodborne illness of major public health concern because of the severity of the disease (meningitis, septicemia, and pregnancy complications such as miscarriage or stillbirth), a high case-fatality rate, and a long incubation period. *Listeria monocytogenes* differs from most other food-borne pathogens because it is widely distributed, resistant to diverse environmental conditions, including low pH and high NaCl concentrations, and is microaerobic. The multitude of ways it can easily enter food processing plants and its ability to grow and survive for long periods of time (in the environment, in/on foods, and in food processing plants) under adverse conditions have made it a major concern for many manufacturing industries in recent decades.[2]

SAMPLE COLLECTION

DO Collect Samples From:	**DON'T Collect Samples From**:
Moist/wet areas with standing water	Dry, clean areas
Direct food contact surfaces	Employees – work shoes, hands etc.
Floors and related areas – Under floor mounted equipment, scales (floor and table mounted)	Hand wash or eyewash stations
Sanitizing foot mats – if disinfectant is not maintained this can be a good harboring source and point of transfer to other areas of the facility	Packaging materials – jars, lids, etc.
Cleaning Equipment – automated floor cleaning equipment, brooms, mops, waste containers especially underside, etc.	Raw agricultural products – raw peanuts etc. or any food contact surface used exclusively for raw foods.
Air conveying equipment – pressurized air lines, air hoses, condensate from pressurized air lines, HVAC evaporators and evaporator condensate pans	Outside the plant – roof, parking lot, walkways, etc.
Product conveyors – cables, belts, joints, where product residue accumulates, exposed bearings and rollers, sponge or felt rollers used to remove moisture from product	Zone 4
Motor and Electrical Housings – that are not cleaned and/ or sanitized.	
Cracked equipment – boots (shock absorbing equipment), metal joints, etc.	
Under sinks / safety stations – Under hand wash or eyewash stations if appearance of leaks, cracks, etc.	
Equipment – areas that are difficult to reach and clean, non-food contact surfaces, nooks, and crannies.	
Doorways - floor area leading directly into production areas	
Drains – Not during production	
Ice Makers – inside, scoops, underside of top of ice chamber	
Ceilings and Walls – in production areas coolers and freezers	
Door gaskets to coolers and freezers; damp insulation around pipes	

References:

1. FDA. Investigations Operations Manual 2008. 4.3.7.7 – Environmental Sampling
2. Doyle, Michael et al. Food Microbiology Fundamentals and Frontiers 2nd Ed. Pgs. 383-403.
3. Cliver, Dean and Riemann, Hanns. Foodborne Diseases 2nd Ed. Pgs. 55 – 67
4. Bad Bug Book. *Listeria monocytogenes*, Page 100
5. Control of *Listeria monocytogenes* in Refrigerated or Frozen Ready to Eat Foods Draft Guidance.

4-21 Environmental Sampling for Detection of Salmonellae, CFSAN Guidance

BACKGROUND

Salmonellosis has been known to be a food-borne disease since the late 1800s. It still remains a major food safety concern throughout the world, is the major cause of bacterial foodborne illness in the U.S and is a pathogen of significant interest to FDA. The major reservoirs for Salmonellae are raw meats, poultry, and eggs; the organism is also isolated from aquaculture products and fruits, vegetable, and nut meats. Salmonellosis outbreaks have been associated with a variety of foods, including raw seafood, fresh produce, egg products, cake mixes, unpasteurized milk, peanut butter, chocolate, and salad dressings. Salmonellae are known to survive and grow in the natural environment, including water sources. It is ubiquitous and has been recovered from some insects and nearly all vertebrates and invertebrates. This makes the recovery and identification of Salmonellae critical as an environmental contaminant.

SAMPLE COLLECTION

DO Collect Samples From:	DON'T Collect Samples From:
Floors and related areas – Under floor mounted equipment, scales (floor and table mounted)	Employees – work shoes, hands etc.
Sanitizing foot mats – if dry	Hand wash or eyewash stations
Cleaning Equipment – central vacuum systems, automated floor cleaning equipment (e.g., Tenent type walk-behind or riding sweepers, brooms, mops, etc.) Pay particular attention to the collection of floor sweepings or the dry contents of vacuum cleaner bags or tanks.	Packaging materials – jars, lids, etc.
Air conveying equipment – air filters; air ducts and intake and exhaust vents; food residue on equipment and floors if old and dry	Direct food contact surfaces –cleaned often, would be unlikely to have residual organism growth.
Product conveyors – cables, belts, joints, where product residue accumulates, if the residue is old and dry	Raw ingredients– raw peanuts refined sugar, etc.
Unsealed control and drive chambers; electrical/ mechanical service boxes that are not cleaned and/ or sanitized. Look for dry dust and residue in these boxes.	Outside the plant – roof, parking lot, etc.
Cracked equipment – boots (shock absorbing equipment), metal joints, etc.	Areas with running water and very wet areas
Under sinks / safety stations – Under hand wash or eyewash stations if appearance of leaks, cracks etc.	Zone 4

Equipment – areas that are difficult to reach and clean, non-food contact surfaces, nooks, and crannies if dry.
Doorways - floor area in doorways leading into or out of the production facility or onto the roof
Pallets – Floor under wooden or plastic pallets and pallets themselves
Floor drains - use a sponge to scrub dry residue from floor drain grids and walls

References:

1.FDA. Investigations Operations Manual 2008. 4.3.7.7 – Environmental Sampling

2. Doyle, Michael et al. Food Microbiology Fundamentals and Frontiers 2nd Ed. Pgs. 141-178.

Cliver, Dean and Riemann, Hanns. Foodborne Diseases 2nd Ed. Pgs. 55 – 67

1- SALMONELLA SAMPLING PLAN

PURPOSE:

To determine the presence of *Salmonella* in processed foods and soils/water used for the growth of foods intended for human consumption.

APPLICABILITY:

This sampling plan is applicable to the inspection of either a continuing series of production lots or to isolated lots consisting of an identifiable collection of process units (cans, bags, packages, or similar units). Additionally, the soil plan is for use during on-farm investigations requiring the sampling of soil for the presence of *Salmonella*. This plan is for use by FDA for regulatory purposes.

FOOD CATEGORIES:

Foods are listed in three categories based on the number of *Salmonella* hazards and whether a food is to be consumed by infants, the aged, or infirm.

The three defined *Salmonella* Hazards of foods are:

1. The food or an ingredient of the food is a significant potential source of *Salmonella*;
2. The manufacturing process does not include a controlled step that destroys *Salmonella*; and
3. The food has significant potential for microbiological growth if "abused" in distribution or by consumers.

Classification of Foods:

Foods have been classified into three food Categories for regulatory sampling purposes. The foods are listed in the Categories by Product Code sequence.

NOTE: For imported seafood products, see CPGM 7303.844

NOTE: For products not listed, check with your supervisor. The Division will request categorization from the Office of Field Programs/Center for Food Safety and Applied Nutrition (HFS-600), or, when time is of essence, the Division will make the categorization and obtain later concurrence from CFSAN.

Category I

This includes all foods that would normally be in Category II except that they are intended for consumption by the aged, the infirm, and infants.

Category II

This includes the foods that would not normally be subjected to a process lethal to *Salmonella* between the time of sampling and consumption. Examples are as follows:

PRODUCT CODE	FOOD ITEM

03	Bread, rolls, buns, sugared breads, crackers, custard, and cream filled sweet goods
05	Breakfast cereals, ready to eat
07	Pretzels, chips, and specialty items
09	Butter and butter products; pasteurized milk and raw fluid milk and fluid milk products for consumption; pasteurized and unpasteurized concentrated liquid milk products for consumption; dried milk and dried milk products for consumption
12	Cheese and Cheese products
13	Ice cream from pasteurized milk and related products that have been pasteurized; raw ice cream mix and related unpasteurized products for consumption.
14	Pasteurized and unpasteurized imitation dairy products for consumption
15	Pasteurized eggs, egg products from pasteurized eggs; unpasteurized eggs and egg products from unpasteurized eggs for consumption without further cooking
16	Cured fish, vertebrates; other fish products; fresh and frozen raw oysters and raw clams, shellfish, and crustacean products; smoked fish, shellfish, and crustaceans for consumption
17	Unflavored gelatin
20-22	Fresh, frozen, and canned fruits and juices, concentrates and nectars; dried fruit for consumption; jams, jellies, preserves and butters
23	Nuts and nut products for consumption
26	Oils consumed directly without further processing and oleomargarine
27	Dressings and condiments (including mayonnaise) salad dressing and vinegar
28	Spices including salt; flavors and extracts
29	Soft drinks and water
30	Beverage bases
31	Coffee and tea
33	Chewing gum and candy
34	Chocolate and cocoa products
35	Pudding mixes not cooked prior to consumption, gelatin products
36	Syrups, sugars, and honey
38	Soups
39	Prepared salads

Category III

This includes the following foods that would normally be subjected to a process lethal to *Salmonella* between the time of sampling and consumption. Examples are as follows:

PRODUCT CODE	FOOD ITEM

02	Whole grain, processed grain, and starch products for human use
04	Macaroni and noodle products
16	Fresh and frozen fish; vertebrates (except that eaten raw); fresh and frozen shellfish and crustaceans (except raw oysters and raw clams for consumption); other aquatic animals (including frog legs)
24	Fresh vegetables, frozen vegetables, dried vegetables, cured and processed vegetable products normally cooked before consumption
26	Vegetable oils, oil stock and vegetable shortening
35	Dry dessert and pudding mixes that are cooked prior to consumption
37	Frozen dinners, multiple food dinners
45-46	Food chemicals (direct additives)

SAMPLE COLLECTION

Each sub will consist of a minimum of 100 g (approx. 3.53 oz). The usual subsample is a consumer size container of a product. Subsamples should be obtained at random to ensure that the total sample is representative of the lot. When a lot consists of identifiable subsamples (e.g., different codes), sub samples should be obtained from subsamples in the proportion that the subsamples are to the whole lot.

More than one subsample may be collected from large institutional or bulk containers when the number of sub samples required exceeds the number of containers in the lot. A subsample will consist of more than one container when the lot consists of containers smaller than 100 g (e.g., 4 - 25 g containers is a subsample).

When a sample is collected by transferring it to sample containers, a sample control must be submitted which consists of an empty sample container that is exposed to the same conditions under which the sample is collected. See IOM 4.3.6.2 and 4.3.6.5 on controls. Use aseptic technique when sampling from bulk containers.

SAMPLE SIZE

The following sample sizes also apply to the finished product portion of in-line samples when analyzed for Salmonella. Each subsample will consist of at least 100 gm (approx. 3.5 oz).

The 702(b) [21 U.S.C. 372(b)] portion is included in these subsamples; however, all subs must be collected for proper analysis. Do not reduce the number of subsamples when collecting import samples.

FOOD CATEGORY	**NUMBER OF SAMPLE UNITS (SUBS)**
I	60
II	30
III	15

SAMPLE SUBMISSION

Submit all samples collected to your division's microbiological servicing laboratory unless directed otherwise by your supervisor or assignment. See IOM 4.5.5.2.

FARM INVESTIGATIONS – SOIL AND WATER SAMPLES

Soil Samples

When conducting an investigation at a farm that was implicated as the source of produce contaminated with Salmonella, and the crop is exposed to soil or water splash from the soil, such as leafy greens, cantaloupes, or cucumbers, soil samples may yield important information as to how the produce was contaminated, especially if a soil amendment such as animal manure or compost was used, or if the crops on that field were rotated and animals grazed on the land previously.

Unless specific instructions were provided by the office issuing the assignment, generally 5 sub samples are collected per field, one from the growing area on each corner, and one near the center. Additional samples may be collected based on observations, such as animal incursion, areas where water may drain, portions of the field susceptible to road dust or runoff, etc. Each field should be issued a separate sample number for ease of identification and review of data. A 1000 ml whirlpack should be filled with soil from a depth of 1 to 3 inches using a sterile scoop and double bagged. Take a photograph of each area where samples are collected and indicate the location and subsample number on a diagram of the field.

Soil samples should be submitted to the lab at 4°C (39°F) or below.

Water Samples

If specialized equipment such as a peristaltic pump are not available, collect water in a sterile, 1000 ml Nalgene sample bottle from wells and surface water. When collecting a surface water sample, a sterile pipette with a re-usable suction bulb is recommended. Using the end of the pipette, stir the surface of the sediment until the water becomes cloudy and then collect this water. *Salmonella* may form a biofilm or colonize sediments and be recovered well past the outbreak period.

Water samples should be submitted to the lab at 4 °C (39 °F) or below.

Environmental samples will be submitted as Investigational Samples (INV).

2- SAMPLING SCHEDULE FOR LOW-ACID CANNED AND ACIDIFIED FOODS

Low Acid Canned Foods

Field Examination

1. At the beginning of the inspection, conduct visual exams of warehouse stock/product offered for import for evidence of abnormal cans including swollen and leaking cans, wet cases, swarms of fruit flies around isolated pallets, etc.
2. If the visual exam or inspectional evidence indicates possible problems, such as under processed lots, lots with questionable seam integrity, or abnormal cans, exam the affected lots. Preferably field examine lots that have been warehoused at least 14 days.
3. A lot to be examined will be one production code.
4. Follow the chart below for the field examination**.** If abnormal containers are found, always collect an official sample of the lot, if possible. For lots with abnormal cans collect an investigational sample ONLY when there is not enough product available to collect an official sample. In all cases, include on the collection report: the lot size, the number of containers examined, and the number of abnormal containers found by type (e.g., hard swells).
5. The chart provides instructions on the number of cans/cases to examine depending on the size of the lot. **When the maximum number of containers / cases have been examined for the specified lot size, collect a sample if one or more abnormal containers are found.** The exam can be discontinued early based on the number of abnormal containers found. For example, if examining a lot consisting of 3409 or more cans, if 11 abnormal cans are found after examining 1000 cans, discontinue the exam and collect a sample.
   a. Flippers. Only one end is slack or slightly bulged and the end remains flat if pressed in. Cans which bulge when sharply and squarely struck end-down on a flat surface are flippers, provided that the bulged end remains flat when pressed. Flippers result from a lack of vacuum.
   b. Springers. One end of a can bulges. Manual pressure on the bulged end forces the opposite end out or the same end will spring out with release of pressure. If both ends bulge, but only one will remain flat when pressed, the can is a springer. Springers result from moderate positive pressure in the can. Buckling or extensive denting of the side wall may produce a springer.
   c. Swells. Both ends of the can are bulged. Neither end will remain flat without pressure. Soft swells yield to manual pressure, but no impression can
   be made manually on hard swells. Swells result from positive pressure in the can usually because of spoilage of the contents. Some swells, especially in acid products, may result from chemical reaction between the contents and the container.

NOTE: Other abnormalities or defects, such as visibly leaking cans, severe dents around seams, gross seam defects, severely rusted containers should be reported on C/R, (with numbers of cans defective cans observed) but not counted as "abnormal containers" for the purposes of the sequential field examination. Do not collect leakers, but report the number observed. It may be necessary to collect samples of other defects (e.g., seam defects) to support observations and document the severity of the defects. In some cases, photographs may be a suitable substitute for collection of physical samples.

If a sample is collected, identify on the C/R, by sub-sample number, the condition of each container in the sample (e.g., sub-sample 1 - flipper; sub-sample 2 - hard swell; - sub-sample x - normal). Report the results of the warehouse stock examination in the EIR and in FACTS. See IOM 5.5.7.3

Special Sample Handling: If you are shipping swollen cans, double bag, and ground ship the sample. If the cans are moderately swollen or worse, you should ship the sample with ice packs.

When the 'Reason for Collection' on the Collection Report includes can seam analysis, the CSO shall collect the can seam specifications for the cans in the sample. This is specific to the can manufacturer and can size collected in the sample. The can seam specifications will be submitted in the FD-525 along with the Collection Report for the servicing laboratory.

		PACKED 48/CASE		PACKED 24/CASE		PACKED 12/CASE		PACKED 6/CASE		*Number Abnormal Containers to Discontinue Examination Early
Lot Size Contain	Number to Examine	Lot Size (Cases)	Cases to Examine	Lot Size (Cases)	Cases to Examine	Lot Size (Cases)	Cases to Examine	Lot Size (Cases)	Cases to Examine	
192 or less	All	1 - 4	all	1 - 8	All	1 - 16	All	1 - 32	all	3
193 - 288	192	4 - 6	4	8 - 12	8	16 - 24	16	32 - 48	32	5
289 - 384	all for≤ 298 298 if greater	6 - 8	6	12 - 16	12	24 - 32	25	48 - 64	all ≤ 50 50 if greater	6
385 - 576	363	8 - 12	8	16 -24	15	32 - 48	30	64 - 96	61	7
577 - 912	433	12 - 19	9	24 - 38	18	48 - 76	36	96 - 152	72	8
913 - 1488	480	19 - 31	10	38 - 62	20	76 - 124	40	152 - 248	80	9
1489 - 3408	529	31 - 71	11	62 - 142	22	124 - 284	44	248 - 568	88	10
3409 or more	576	71 or more	12	142 or more	24	284 or more	48	568 or more	96	11

1. Sample Size for Samples Collected as a Result of a Field Exam:
   a. Official Sample

      The sample will consist of all abnormal containers and the number of normal cans specified under "2. Official Samples" below (e.g., if 8 abnormal containers are observed during the examination of a lot containing 696/ 2 lb. cans the sample will consist of the 8 abnormal cans and 48 normal cans, collected 2 cans from each of 24 cases). Open additional cases, if necessary to meet this requirement. This will provide enough product for complete analysis, including: can seam, incubation, aerobic and anaerobic growth, pH and water. Note that the sample size given for normal cans includes the 702(b) portion.

   b. Investigational Sample and Import Sample.

      Samples for laboratory examination will consist of all abnormal and 12 normal containers.

2. Other Sampling

Official Samples

   a. Filth, Micro, etc. (Includes 702(b) [21U.S.C.372 (b)] portion)

Collect each subsample to duplicate from a separate case, if possible. Mark subs 1a, 1b, 2a, 2b, etc. Collect as follows:

NET WEIGHT	SIZE OF LOT	MIN TOTAL CANS	CANS/CASE
795 gr (28 oz) and smaller	Up to 50 cases	48	2 from 24
	More than 50 cases	96	2 from 48
Over 795 gr (28 oz)	Up to 600 cases	48	2 from 24
	More than 600 cases	72	2 from 36

   b. Standards Assay (Includes 702(b) portion)

      NOTE: Sample sizes listed below are based upon the requirements of the Standards (21 CFR 145.3). When sampling products which are likely to be non-uniform throughout the lot because of variations from standards of quality, identity, fill-of-container, grade, etc., collect each subsample in triplicate from a separate case. Mark subs 1a, 1b, 1c, 2a, 2b, 2c, etc. Collect as follows:

NET WEIGHT	NUMBER OF CANS OR PACKAGES	MIN TOTAL CANS	CANS/CASE
1 kg (2.2 lbs.) or less	4800 or less	48	3 from 16
	4801 to 24,000	72	3 from 24
	24,001 to 48,000	96	3 from 32
	48,001 to 84,000	144	3 from 48
	84,001 to 144,000	264	3 from 88
	144,001 to 240,000	384	3 from 128
	Over 240,000	600	3 from 200
Greater than 1 kg (2.2lbs), but less than 4.5 kg (10 lbs.)	2400 or less	48	3 from 16
	2401 to 15000	72	3 from 24
	15001 to 24000	96	3 from 32
	24001 to 42000	144	3 from 48
	42001 to 72000	252	3 from 88
	72001 to 120,000	384	3 from 128
	Over 120,000	600	3 from 200
Greater than 4.5 kg (10 lbs.)	600 or less	48	3 from 16
	601 to 2000	72	3 from 24
	2001 to 7200	96	3 from 32
	7201 to 15000	144	3 from 48
	15001 to 24000	252	3 from 88
	24001 to 42000	384	3 from 128
	Over 42000	600	3 from 200

Acidified Foods

A lot is defined as one production code.

Field Examination

Conduct a reconciliation examination and check for damaged or destructive container closures. For example, during a visual examination the following may be observed: 1) glass containers with obvious closure defects such as excessive

torque on the lid and/or insufficient security, 2) plastic and semi-rigid containers with obvious defects such as leakers and poorly sealed lids, or 3) metal containers with damage or obvious container defects to the double seam.

Conduct a field examination if abnormal containers are observed during the reconciliation examination. Follow the applicable instructions provided above (see Low-Acid Canned Food "Field Examination" section, including chart) when performing a field examination.

Sample Collection

For acidified products, the equilibrium pH determines whether the product will support organisms of public health significance. Spoilage in such products is usually due to inadequate heat treatment to kill spoilage organisms. Spoilage may be significant because high numbers of microorganisms may affect the adequacy of the thermal process. Molds and some bacteria can grow in an acid environment and actually utilize acid as one of their nutrients; and thus, raise the pH to a level above 4.6 where *Clostridium botulinum* or other toxin-producing microorganisms can grow.

Microbial spoilage can be detected by observing swollen lids on jars or swollen can ends. The liquid may be turbid, and a whitish deposit may be visible on the product or in the bottom of the jar. See the Guide to Inspection of Acidified Food Manufacturers for additional information: http://www.fda.gov/ora/inspect_ref/igs/iglist.htmlCollect samples for pH testing. Samples must be collected randomly from the entire lot. **Sample size does not include 702(b) portion**.

1. # 10 cans – Use the following sample size for containers larger than 795 gr (28 oz): Randomly select 1 normal container from each of 12 randomly selected cases (if available) in the lot. Sample size is 12 containers.
2. # 2 half (1/2) cans – Use the following sample size for containers equal to 795 gr (28 oz) or smaller: Randomly select 2 normal containers from each of 12 randomly selected cases (if available) in the lot. Sample size is 24 containers.

If abnormal containers are encountered, collect all abnormal containers (up to a maximum of 24) in addition to the normal containers collected for pH testing (referenced above). Indicate on the C/R the total number of containers examined, and the number of each type of abnormality and defect observed. Also indicate the estimated percentage of abnormal containers in the lot.

3- PESTICIDE SAMPLES

(Includes 702(b) portion)

DO NOT FUMIGATE PESTICIDE SAMPLES

INTRODUCTION

The objectives of FDA's pesticide monitoring program are to gather information on levels and incidences of pesticide residues in the nation's food supply and to initiate enforcement actions against shipments of foods and feeds found to contain illegal pesticide residues. To meet both objectives, it is necessary to collect samples of foods and feeds for pesticide residue analysis. This section describes procedures for the collection of raw agricultural and processed commodity samples. These procedures apply to both domestic and import arenas. Additionally, a separate set of procedures for collecting samples in conjunction with special investigations, such as samples collected to determine levels of pesticide residues in soil, water, and growing crops, is included.

For pesticide samples, the laboratory will maintain a portion of the composited sample as the 702(b) [21 U.S.C.372(b)] portion.

Pesticide sample sizes no longer differentiate between Surveillance and Compliance Samples. All pesticide samples will be collected as directed below. Remember to include the state and county or country of origin in the Flag. See IOM 4.6.2.27.

For appraisal purposes, you must Flag each Domestic as to the basis for sampling in accordance with the definitions below.

Pesticide Compliance Sample. Collected on a selective basis as a result of inspectional or other evidence of suspected misuse of a pesticide on a food or feed commodity or as a follow-up to a "Pesticide Surveillance Sample" that was found to contain actionable levels of pesticide residues. Flag "Pesticide Compliance".

Pesticide Surveillance Sample. Collected on an objective basis where there is no evidence or suspicion of pesticide misuse on a food or feed commodity. Flag "Pesticide Surveillance".

Divisions have the option to collect 1 intact shipping case of fresh produce from packing sheds or large produce warehouses. The one case must meet the minimum sample size specified below. This "one case" option may be used on any import sample or on domestic Pesticide Surveillance Samples, if the collector can be assured that the "one case" collected is representative of the lot or field. If the collector is not assured of this, collect the samples according to the instructions below. This "one case" sampling does not apply to large items such as melons.

NOTE: If "one case" option is used for surveillance samples of domestic produce, describe in the Remarks Section of the CR, the basis for determining that the sample is representative of the lot or field.

Plant products: description of primary samples and minimum size of laboratory samples (total weight of all subs or units collected).

Commodity classification	Examples	Nature of primary samples to be taken	Minimum sample size and number of units of each laboratory sample
1. PRIMARY FOOD COMMODITIES OF PLANT ORIGIN			
All fresh fruits, All fresh vegetables, Frozen bulk produce (not retail) except dry pulses			
Small sized products units generally < 25 g	Berries, peas, olives	whole units, or packages, or units taken with sampling device	1 kg (2.2 lbs.)
Medium sized products units generally 25 - 250 g	Apples, oranges, corn on the cob, potatoes	whole units, or units taken with sampling device	1 kg (2.2 lbs.) (at least 10 units)
Large sized products units generally > 250 g	Cabbages, lettuce, cucumbers, grapes (bunches, except for sulfites), sweet potatoes	whole units, units taken with sampling device	2 kg (4.4 lbs.) (at least 5 units)
Pulses, Cereal grains	soybeans, peas, lentils, rice, wheat (except from rail carloads)		1 kg (2.2 lbs.) 1 kg (2.2 lbs.)
Tree nuts	(except coconuts)		1 kg (2.2 lbs.)
	coconuts		5 units
Oilseeds	peanuts		0.5 kg (1.1 lb.)
Seeds for beverages and sweets	See CP 7304.004		0.5 kg (1.1 lb.)
Herbs (*For dried herbs see section 3 of this Table*)	fresh parsley others, fresh	whole units or units taken with sampling device	0.5 kg (1.1 lb.) 0.2 kg (0.5 lb.)
Spices	See CP 7304.004	whole units or units taken with sampling device	0.1 kg (0.25 lb.)
2. PRIMARY ANIMAL FEED COMMODITIES			
Primary feed commodities of plant origin			
Legume animal feeds, and other forages and fodders		whole units, or units taken with sampling device	1 kg (2.2 lbs.) (from at least 10 units)
Straw, hay and other dried products		whole units, or units taken with sampling device	1 kg (2.2 lbs.) (from at least 10 units)
Note. See IOM Sample Schedule Chart 4, Wheat Carload Sampling for guidance in the collection of samples by trier from railcars and trucks.			
3. PROCESSED FOODS OF PLANT ORIGIN **Secondary food commodities of plant origin**, dried fruits, vegetables, herbs, milled cereal products **Derived products of plant origin**, teas, vegetable oils, juices, by-products for animal feed and miscellaneous products **Manufactured foods (single ingredient) of plant origin**, **Manufactured foods (multi-ingredient) of plant origin**, including products with ingredients of animal origin where the ingredient(s) of plant origin predominate(s), and breads			
Products of high unit value		packages or units taken with a sampling device	0.1 kg* (0.25 lb.)
Solid products of low bulk density	Hops, Tea	packaged units, or units taken with a sampling device	0.2 kg (0.5 lbs.)
Other solid products	bread, flour, apple pomace, dried fruit	packages or other whole units, or units taken with a sampling device	0.5 kg (1.1 lbs.)
Liquid products	vegetable oils, juices	packaged units, or units taken with a sampling device	0.5 L or 0.5 kg
** A smaller laboratory sample may be taken from a product of exceptionally high value but the reason for doing so should be noted in the collection report.*			
4. EGGS AND DAIRY PRODUCTS			
Poultry eggs			
Eggs, except quail and similar		whole eggs	12 whole chicken eggs, 6 whole goose or duck eggs
Eggs, quail and similar		whole eggs	24 whole eggs
Milks		whole unit(s), or unit(s) taken with a sampling device	0.5 L

Commodity classification	Examples	Nature of primary samples to be taken	Minimum sample size and number of units of each laboratory sample
5. PROCESSED FOODS OF ANIMAL ORIGIN **Secondary food commodities of animal origin**, skimmed milks, evaporated milks, and milk powders **Derived edible products of animal origin**, milk fats, butters, butter oils, creams, cream powders, caseins, etc. **Manufactured food (single ingredient) of animal origin**, **Manufactured food (multi-ingredient) of animal origin**, (including products with ingredients of plant origin where the ingredient(s) of animal origin predominates(s))			
Liquid milk, milk powders, evaporated milk and cream, cream, dairy ice cream, yogurt		packaged unit(s), or unit(s) taken with a sampling device	0.5 L (liquid) or 0.5 kg(solid)
Notes. (i) Evaporated milks and evaporated cream in bulk must be mixed thoroughly before sampling aseptically. *(ii) Milk powder in bulk should be sampled aseptically, passing a dry borer tube through the powder at an even rate.* *(iii) Creams in bulk should be mixed thoroughly with a plunger before sampling but foaming, whipping, and churning must be avoided.*			
Butter and butter oils (butter, whey butter, low fat spreads containing butter fat, anhydrous butter oil, anhydrous milk fat)		whole or parts of packaged unit(s), **or** unit(s) taken with a sampling device	0.2 kg or 0.2 L
Cheeses, including processed cheeses	units 0.3 kg or greater	whole unit(s) or units taken aseptically with a sampling device	0.5 kg
	units < 0.3 kg	whole unit(s)	0.3 kg
Note. Cheeses with a circular base should be sampled by making two cuts radiating from the center. Cheeses with a rectangular base should be sampled by making two cuts parallel to the sides.			
Liquid, frozen, or dried egg products		unit(s) taken aseptically with a sampling device	0.5 kg

9. GRAPES FOR SULFITES

Collect approximately 900 - 1800 g (2 - 4 lbs.) of grapes [10/100 - 200 g (1/4 to 1/2 lb.) subs]. Each subsample will consist of individual grapes, not bunches, and will be collected from different lugs (cases) on as many different pallets in the lot as possible. No grapes that are damaged during the sampling procedure should be included in the sample. However, grapes with damage prior to sampling may be included in the sample.

If sulfiting pads are present, grapes sampled should be selected from areas closest to and directly under the pad.

Monitoring activities should be focused upon lots of grapes with the highest potential for violative sulfite residues.

Direct efforts to lots of grapes sulfited through fumigation or to lots with multiple fumigations especially towards the end of the harvesting season and also to lots with significant numbers of damaged grapes (split, crushed, or unusually wet, if such damage is apparent).

Sample lots of grapes sulfited through the use of sulfiting pads, with or without additional fumigation. If at all possible, sample lots subjected to the following conditions, which could cause high sulfite residues:

- Lots subjected to un-refrigerated storage of 2 or more hours during warm weather.
- Unusual shipping conditions (ships at sea during heavy storms).
- Lots with significant numbers of damaged grapes.
- Lots containing evidence of sulfite pad damage sufficient to cause spilling of sulfiting agent onto grapes.

Special Sample Handling

Place sample in tightly closed airtight glass mason jar(s) or sealed plastic bag(s). Although no effort should be made to commingle subsamples, more than one subsample may be placed in the same container for shipping convenience.

Appropriate cooling procedures are:

Place samples in shipping container or cooler with sufficient ice or other refrigerant to keep sample refrigerated until arrival at the laboratory. Sample should be placed immediately in a refrigerator at or below 7 degrees C. If sample is not to be analyzed within a few hours, the sample should be placed in a freezer, which is maintained at or below -20 degrees C.

Or, if the sample is frozen, place the sample in a container with sufficient dry ice to keep the sample frozen until arrival at the lab. The sample should then be placed in freezer upon arrival at the laboratory.

1. **FISH AND SHELLFISH PRODUCTS**

NOTE: THIS SAMPLE SIZE FURNISHES SUFFICIENT FISH FOR HEAVY METAL ANALYSIS.

Packaged Fish, fresh, frozen, smoked, cured, or shellfish (except oysters)

Collect 12 subs - minimum sub size is 453 g (1 lb.)

Bulk Fish - .453 - 1.35 kg (1 - 3 lb.)/fish

Collect 12 subs, each sub to consist of 453 g (1 lb.) of edible fish

Bulk Shellfish (except oysters)
Collect 12 - 453 g (1 lb.) subs

Canned Fish and Shellfish Products (except oysters)
Collect 12 subs - 5 cans per sub

Other Fish and Shellfish Products

Oysters - Collect 12 1-pint subs

Fish Flour and Meal

Follow the guidance in section 5 above.

SWORDFISH FOR HEAVY METALS

These sample sizes must be used whenever sampling swordfish, either for audit, surveillance, or compliance purposes.

Whole Fish (dressed, head removed)

Characterize lot in terms of fish sizes, i.e., small, medium, and large. The following dressed weight ranges are used for classification:

Small Fish - Weighs less than 36.4 kg (80 lbs.)

Medium Fish - Weighs 36.4 - 54.5 kg (80 - 120 lbs.)

Large Fish - Weighs more than 54.5 kg (120 lbs.)

For lots consisting of 12 or more fish, the representative sample to be collected will be determined by the following formula:

$ns = (n)(Ns)/N$

ns = the number of fish in a given weight range from which subsamples must be taken

n = total number of subsamples to be collected from the lot. (In using this formula n will always equal 12)

Ns = the number of fish in a given weight range in the lot

N = the total number of fish in the lot

Example: If a lot consists of 25 fish and is characterized as: 5 small fish [less than 36.4 kg (80 lbs.)], 15 medium fish [36.4 - 54.5 kg (80 - 120 lbs.)], and 5 large fish [greater than 54.5 kg (129 lbs.)], the sample should be collected as follows:

small fish $\frac{(12)(5)}{25} = 2.4 = 2$

medium fish $\frac{(12)(15)}{25} = 7.2 = 7$

large fish $\frac{(12)(5)}{25} = 2.4 = 2$

TOTAL SAMPLE: 11 sub samples

Usually, the total sample will consist of 12 subsamples. However, due to rounding numbers of subsamples determined by the formula may be 11 or 13 in some instances. The total sample should consist of the specific number of sub samples determined by the formula in all cases.

Each sub sample should consist of approximately a 0.5 kg (1 lb.) steak cut from just below the nape of the fish. Care should be taken to avoid mutilation of fish. The sub must consist of edible flesh. If a private laboratory is conducting the analysis, individual fish from which the sub sample is taken should be identified with a tag or other suitable method. This will permit FDA to take audit samples from the same fish sampled by the private laboratories.

For lots consisting of 12 or less fish, collect 1 sub from each fish.

Swordfish Loins (slabs or sides cut from dressed whole fish which has been boned or trimmed).

Use the same formula stipulated for whole fish, with the exception that the following weight ranges should be used to characterize the lot:

Small fish loins = weighs 9.1 - 18.2 kg (20 - 40 lbs.)
Medium fish loins) = weighs 18.2 - 36.4 kg (40 - 80 lbs.)
Large fish loins = weighs over 36.4 kg (80 lbs.)

Swordfish Steaks

Collect 12 sub samples, i.e., 12 steaks, at random from different containers in the lot (as many as possible)

Canned Swordfish

Collect 12/453 g (1 lb.) sub samples at random

11. RETAIL CONTAINERS CANNED, FROZEN AND DRIED FOODS

Collect retail containers equal to the number of primary units specified above.

12. SPECIAL INVESTIGATIONS

Growing Crops

Superimpose an imaginary grid on the field dividing it into approximately 100 areas. Randomly select 10 areas to form a representative sample of the field. Collect one pound subs from each area. Combine to form a composite. If a sample is being collected to document drift, etc. DO NOT composite subs. In addition, diagram the field in the Remarks Section of the C/R and indicate sub number where each sub was collected.

For leafy vegetables, such as lettuce, cabbage, etc.: INV Samples collected in the growing field should be representative of local commercial harvesting practices If the local practice is to strip outer leaves at the time of harvest, this practice should be followed when collecting field samples. In head lettuce, for example, the lettuce may be packed directly into shipping cartons in the field, in which case 6 or 8 outer leaves are left on the head to be removed at the retail outlet. In other instances, each head is stripped of 2 or 3 outer leaves and individually wrapped in plastic, placed in shipping cartons, and the consumer receives the produce in this condition. Describe sampling method on C/R and describe how packing shed handles produce prior to shipping (e.g., washing, waxing, stripping, etc.).

Soil Samples

Collect soil samples from fields according to the following

3x3 grid diagram:

	a	b	c
1	o	o	o
2	o	o	o
3	o	o	o

Sample at the 9 locations indicated by the "o". If the field being sampled is very large, you may have to sample it using a 4x4, 5x5, or even larger grid pattern.

Subs are to be placed in clean quart glass jars, which have been washed in water, rinsed in methanol, and air dried. If methanol is not available, use washed, air dried jars and submit an empty jar as a control. Note on CR that jars were or were not rinsed with methanol.

Growing Crops

Superimpose an imaginary grid on the field dividing it into approximately 100 areas. Randomly select 10 areas to form a representative sample of the field. Collect one pound subs from each area. Combine to form a composite. If a sample is being collected to document drift, etc. DO NOT composite subs. In addition, diagram the field in the Remarks Section of the C/R and indicate sub number where each sub was collected.

GENERAL

Official Samples shall be collected whenever feasible unless they are not required to accomplish the objective of the assignment. Investigational Samples shall be collected only when Official Samples are not readily available.

Consult with your supervisor in cases of doubt as to sample cost, size, or collection technique.

When collecting samples in glass jars, line the lids with aluminum foil which has been certified by the laboratory as contaminant free or use Teflon lined lids.

If shipment of shell eggs is required and breakage may result during transit, subs may b e broken, shells discarded, and liquid magma collected in clean glass jars. Each sub jar should be properly identified.

Obtain two "6 in" deep plugs (1-2 in. in diameter from each sampling location. Place two plugs from each location in cleaned glass jars, place clean aluminum foil over top of jar and seal with screw cap.

Soil samples should be submitted to the lab at 4° C (39° F) or below.

Water Samples - Collect 3 quarts of water from the same sampling source (e.g., faucet, stream, lake, etc.) and place in cleaned, washed and methanol rinsed jars as described under "Soil Samples".

Submit water samples to lab at 4° C (39 ° F) or below.

Samples collected at Packing Sheds should be representative of the produce as shipped in commerce. DO NOT strip outer leaves from subs collected at packing sheds from bulk lots, shipping cartons ready for shipment, in-transit lots or at final destination. If the packing shed practice is to strip outer leaves prior to shipment, follow this practice when collecting the samples. Describe the sampling method on the C/R.

DO NOT USE magic markers, etc. to identify sub bags, because the ink may affect assay results. Use stick on labels to identify sub bags.

Collect samples in the container in which the dealer is packaging the product. If the dealer is packaging the product in plastic bags, collect sample in these bags. If the firm is not packing the product, collect the samples in paper bags, cardboard cartons, etc. Do not use plastic bags as this may interfere with the analysis, unless the bags are certified as contaminant free by your division laboratory.

Samples must be delivered as promptly as possible to the laboratory if regulatory action is to be taken against actionable lots.

Hold samples in cold storage until ready to be shipped or delivered to the laboratory. If the sample is of a hard fruit or vegetable (such as apples, pears, butternut

squash), and is shipped overnight delivery, it can be shipped to the laboratory unrefrigerated, but the FDA 525 should direct refrigeration upon receipt.

Use aseptic technique, where applicable, when collecting samples of finished products from bulk containers.

4- WHEAT CARLOAD SAMPLING

I. SAMPLING NORMALCARS

CAUTION: WHEN USING A GRAIN PROBE, BE CAREFUL NOT TO CLOSE THE TRIER COMPARTMENT DOORS ON YOUR FINGERS.

Collect samples only of specific assignment.

A. Equipment

1. Double tube compartmented trier, 60 in. long
2. Sampling cloth at least 60 in. long
3. 1000 ml plastic graduate
4. Paper bags or other suitable containers capable of holding more than one quart of sample and do not use canvas bags.
5. FDA Metal Car Seals for resealing railroad cars
6. Aluminum ladder
7. Block and tackle to open railcar door

B. Drawing Sample

Principal sources of grain samples are railcars, barges, and trucks. Draw 5 probes (in duplicate) for each sample taken as described below. However, if the sample is to be Field Examined, an initial sample of 5 probes drawn as indicated below will be sufficient.

Probe samples from railcars and trucks as follows:

Probe #1 - From Center of car

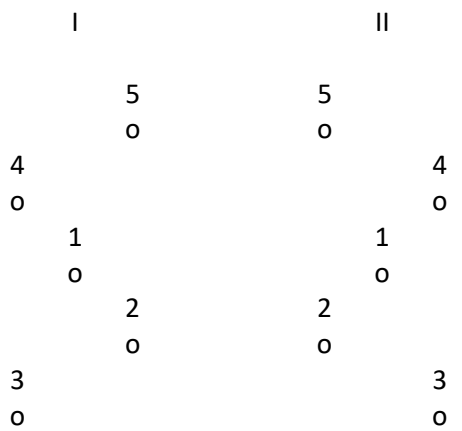
Probe #2 - From 3-5 feet back from door post toward end of the car and approximately 2 feet from the side of the car.

Probe #3 - From 3-5 feet from the same end of the car, but approximately 2 feet from the opposite side of car as Probe #2.

Probe #4 - Same as Probe #2, but opposite end of car.

Probe #5 - Same as Probe #3, but opposite end of car.

Sketches I and II below are alternatives showing the approximate sampling locations.



Insert trier in the grain at an angle of about 10° from the vertical, with the slot up and closed. Open slots. Give trier 2 or 3 short up and down motions, so that the openings will fill. Close slots (SEE CAUTION AT BEGINNING OF SCHEDULE), withdraw trier and carefully empty over sampling cloth. The cloth should be long enough to catch product from each compartment separately when you open the trier compartment doors; e.g., about 6 feet long.

C. Field Examination

Examine each pocket of the probe separately, looking for evidence of pink wheat, rodent pellets, insect damage and uneven loading or plugging. Note any insect infestation and record types of insects and whether live or dead. Count and report for each probe the number of rodent pellets, or rodent pellet fragments. Follow procedure in I.C.2 below. Count as pellets any that are sufficiently large to be readily identified by size, shape, surface coating, and/or presence of rodent hairs. Report the number of rodent pellets per sub. Measure the volume of each sub (probe) in quarts and calculate the average number of pellets per quart per I.C.2.a below. Place pellets from each sub in separate vials and submit with each wheat sub. Place each of the wheat subs in clean, paper bags.

Do not use canvas bags or take glass jars into railcars.

Substantially larger loads will require additional probing or larger samples taken from falling grain during loading or unloading operations.

Submit all suspect samples to laboratory for confirmatory analysis.

1. **Non-Violative Samples**. When field examination shows sample as non-violative, return grain to the car, unless collected for pesticide analysis. Report results in the Remarks Section of the C/R.
2. **Violative Samples**
   a. **Rodent Pellet Contamination**. The guideline for determining whether wheat is violative due to rodent contamination is: "9 mg or more rodent excreta pellets and/or fragments of rodent excreta pellets per kg of wheat."

NOTE: Since it is impractical to weigh rodent pellets and wheat in the field, the following estimations can be used. Mouse pellets average approximately 8.7 mg each and a kilogram of wheat about 2.35 pints. This translates roughly as 1 pellet per quart of wheat or 1/2 pellet per pint.

Where your field examination reveals one or more rodent pellets (or you can estimate that sufficient fragments of rodent pellets exist to equal one pellet) in a quart of wheat, take duplicate probes to furnish the claimants portion. Take the duplicate probes from the same locations as the original probes. Place the duplicates in separate containers and identify these to correspond with the original probes.

b. **Pink Wheat**. Where evidence of pink wheat or other fungicide treated wheat is found, collect 15 probe samples. Take 5 probes from each end of the car and 5 probes from the center of the car. Submit the three 5-probe portions separately, using new clean containers.

c. **Insect Damaged Kernels**. The violative status of these samples should be established by laboratory analysis. When any evidence of insect damage is revealed by cursory examination, collect duplicate samples and submit for laboratory analysis.

3. **Resealing Cars** See IOM 4.3.4.
4. **Procedures for Actionable Cars.** If field examination reveals an average of one or more rodent pellets per quart or gross evidence of insect-damaged kernels, evidence of plugging, or "pink wheat" contamination, determine any movement of the car or other disposition of the grain and notify your supervisor immediately.
5. **Preparation of Sample for Laboratory Analysis**. If a sample can be delivered to the laboratory promptly and confirmatory analysis handled expeditiously, freezing of the FDA subsamples is not necessary. The claimant's (702(b)) portion of the sample, however, must be frozen. It is preferable to freeze the subsamples in paper bags. If a freezer is not available, the subsamples (in paper bags) can be placed in a cooler box with dry ice. Do not use glass jars with dry ice. Officially seal all subsamples. If dry ice is used, you must label the shipping container as described in IOM 4.5.5.8.6. See Exhibit 4-19. Indicate frozen storage on the FDA 525.

D. Special Reporting

Submit an Analyst Worksheet (FDA-431) for each sample analyzed and found in compliance. See IOM 4.3.7.1. If field examination shows the sample is possibly actionable, report analytical results in Remarks Section of the C/R.

II. SAMPLING PLUGGED CAR

If uneven loading, layering, or "plugging" is suspected, contact your supervisor as to whether to sample or not. A 'plugged" car is a railcar, truck, or barge load of grain where the contamination is suspected of being in only one portion or layer of grain. Plugging is usually the deliberate mixing of violative grain below the surface or in isolated pockets of grain.

A. Equipment

Equipment needed is the same as in 1.A. above except:

1. Double tube grain probe must have individual compartments permanently separated.
2. Small containers of sufficient size to hold the contents of each compartment of each grain probe.

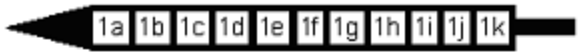
B. Procedure

1. In the Remarks Section of the C/R, draw a diagram showing actual "plugging" pattern suspected.
2. Each sample consists of thirty probes of grain with each probe compartment maintained as a separate sub. Each sample thus consists of 300-330 subs depending on whether a 10 or 11 compartment probe is used and if grain depth is sufficient to insert the probe to fully cover all compartments of the probe.
3. Probe each load and number the probes as follows:

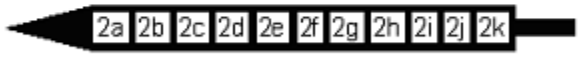
   1 4 7 10 13 16 19 22 25 28
   2 5 8 11 14 17 20 23 26 29
   3 6 9 12 15 18 21 24 27 30

4. Identify the subs by probe number plus compartment letter starting with small "a" as the compartment nearest the tip of the probe.

Example:



Probe #1



Probe #2

5. Submit sample to your division's servicing laboratory. See IOM 4.5.5.2.

5- IMPORTED WHITEFISH SAMPLING SCHEDULE

GENERAL

This Sample Schedule objective is to maintain import lot integrity from time of importation thru FDA inspection or examination and final action.

Shipments will be special manifested from non-lab ports to DO cities and other cities designated by the DD as FDA inspection points. These shipments will arrive in Customs bonded trucks under seal applied by Customs at the port of entry. Customs Entry documents and commercial invoice will accompany each shipment. The commercial invoice contains a description of the lots in the shipment and will serve as a guide in the selection of the lots to be sampled.

1. Special Manifested Shipments:
   a. Determine if seals are intact and record seal number.
   b. FDA metal seals may be broken and lots checked against invoice.
   c. Customs seals may be broken only if authorized by Customs.
   d. Lots which are not to be examined will be released by completing the "MAY PROCEED" block of the FDA-701.
   e. Sample lots to be examined by using either the Single or Sequential Sampling Plan depending on whether examination is made at the DO Lab or at the dock. The Sequential Plan can only be used where additional fish are immediately available for cutting.
2. Definition of a Lot & Selection for Examination.
   a. A lot is defined as "Each group of fish of a distinct size, listed in the invoice as from a distinct lake, will be considered as a separate lot. Where an invoice does not list lakes of origin of boxes of fish in a shipment, fish of the same size and kind will be considered to comprise a single lot. When the size of the fish or lakes of origin in a shipment are not specified, the shipment will be treated as a single lot."
   b. Limit sampling to lots containing 5 or more boxes unless deliberate splitting up of lots is suspected.
   c. Basis for Sampling. Select lots for sampling on either a "selective" or "objective" (random) basis. The criteria in selective sampling may be prior knowledge or suspicion that fish listed as from a given lake are likely to have excess cysts; that the shipper has been known to manipulate shipments; etc. Regardless of the reason for selective sampling, record the basis for sampling each lot in your examination report. Simply list the basis as "selective" or "objective" next to the results of each lot sampled.
   d. Normally, select boxes in a lot for sampling at random. However, where there's evidence of layering, selectively sample the suspect boxes.
3. Sampling Schedule.
   a. Imported samples of whitefish & related fish for parasites. The sampling schedules estimate lot quality more precisely, thereby reducing the likelihood of passing a lot which should be detained, or vice versa, due to an inadequate sample.
      SCHEDULE A below is a single sample plan for use in collecting samples for examination in the division lab or other location where it is impossible or undesirable to return and obtain additional fish.
      SCHEDULE B below contains sequential sampling plans for use when the exam is made at a customs office or a carrier's dock where you have immediate access to the lot and can obtain additional fish, if necessary.
      The sequential plan for lots of 20 to 100 boxes is presented in tabular form. The sequential sample plan for lots of 100 or more boxes is presented in a sampling chart. For small lots of 5-20 boxes, a sequential sample plan is not feasible. All import sampling plans are based on lot size and the sizes of the fish in the lot. When lots are very good or very poor quality, in terms of cyst infestation, double sample plans require a smaller sample size on the average than single sampling plans, to reach a decision.
   b. Domestic Samples for Parasites.
      i. For Laboratory Examination. Lots of 11 or more boxes; Collect at least 25 fish from a representative number of boxes. For small lots, under 11 boxes; Collect 12 fish from a representative number of boxes.
      ii. For Examination in Other Than Laboratory. Cut a preliminary sample in accordance with the appropriate double sampling plan, Schedule B. Cut the additional sample where indicated or bring the additional sample to the laboratory for examination.

SCHEDULE A - SINGLE SAMPLE PLAN

Number of Boxes in Lots	NUMBER OF KG'S (POUNDS) IN A SAMPLE 1/		
	Jumbo or Large 2/	Medium 2/	Small 2/
5 - 19 boxes	12.7 kg (28lbs)	10.5 kg (23lbs)	7.3 kg (16lbs)
20 - 100 boxes	24 kg (73lbs)	20.5 kg (45lbs)	15 kg (33lbs)
100 or over	32 kg (70lbs)	25.5 kg (56lbs)	17.8 kg (39lbs)

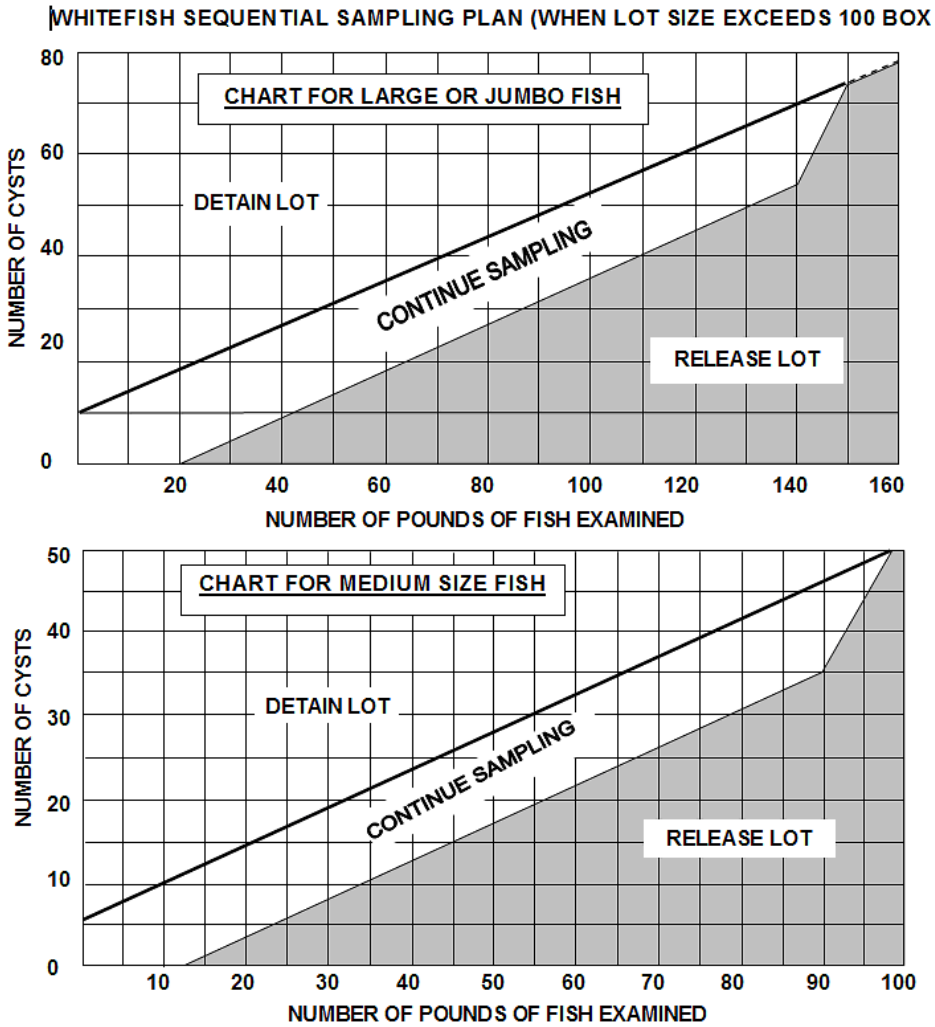
1/ When an invoice does not designate the size of the fish in the shipment and inspection reveals more than one size in the lot, use sampling plan for medium fish.

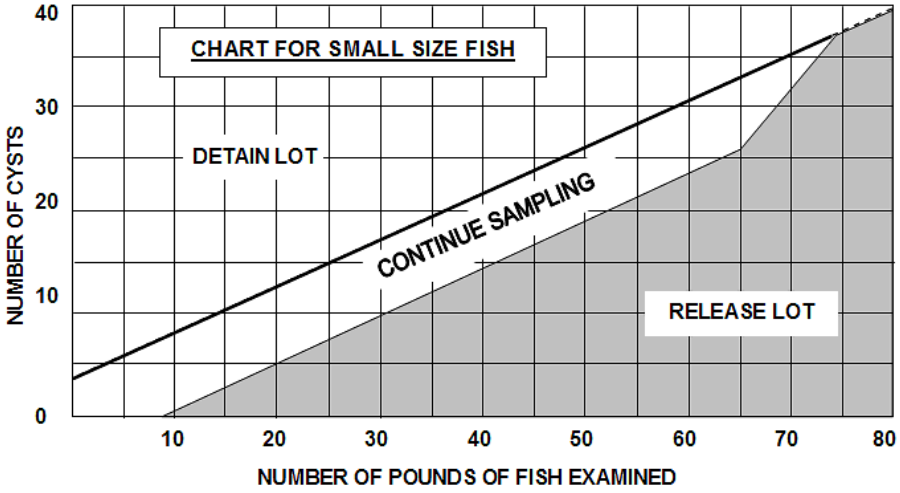
2/ RANGE OF WEIGHT OF FISH IN EACH SIZE CLASS:
SMALL Under 675 g (1 1/2lbs)
MEDIUM 675 g (1 1/2lbs) & under 1.4 kg (3lbs)
LARGE 1.4 kg (3lbs) & under 1.8 kg (4lbs)
JUMBO Over 1.8 kg (4lbs)

SCHEDULE B - SEQUENTIAL SAMPLE PLAN
1. Limited to lots of 20 - 100 boxes. 454 kg (1000lbs) to 2272 kg (5000lbs)

Size of Fish 1/	Size of preliminary Sample	Cysts/45.5 Kg (100lbs) in Preliminary Sample			Size of ADD'L SMPL	Cysts/45.5 Kg (100lbs) in sample	
		PASS	DETAIN	TAKE ADD'L SMPL		PASS	DETAIN
Large & Jumbo	16 kg (35lbs)	30 or less	70 or more	31-69	28.6kg (63lbs)	49 or less	50 or more
Medium	12.3 kg (27lbs)	26 or less	67 or more	27-66	19.5 kg (43lbs)	49 or less	50 or more
Small	8.2 kg (18lbs)	38 or less	61 or more	39-61	11.8kg (26lbs)	49 or less	50 or more

1/ When an invoice does not designate the size of the fish in the shipment and inspection reveals more than one size in the lot, use sampling plan for medium fish.
2/ For lots of 100 boxes or over, use the Sequential Sampling Chart for the particular size fish in the lot.




CHART FOR SMALL SIZE FISH
DETAIN LOT
CONTINUE SAMPLING
RELEASE LOT
NUMBER OF CYSTS
0
10
20
30
40
10
20
30
40
50
60
70
80
NUMBER OF POUNDS OF FISH EXAMINED

6- MYCOTOXIN SAMPLE SIZES

MYCOTOXIN SAMPLE SIZES				
Please consult 21U.S.C. 372(b) regarding duplicate portion for 702(b)				
HUMAN FOOD PRODUCTS				
Product	**PACKAGE TYPE/ LOT SIZE: lbs.** [1]	**NUMBER OF INCREMENTS (SAMPLE UNITS) TO COLLECT** [2]	**MINIMUM SAMPLE UNIT SIZE: g (lb.)**	**MINIMUM TOTAL SAMPLE SIZE: kg (lbs.)**
Fluid: e.g., milk and apple juice	≤ 22,000	6	500 mL (16 fluid oz.)	3 L (96 fluid oz.)
	> 22,000 ≤ 150,000[3]	20	250 mL (8 fluid oz.)	5 L (160 fluid oz.)
Processed snack food: e.g., corn chips, candy bars with/without nuts **Milk Products:** *(refer to CP 7307.001) e.g., cheese, yogurt	Consumer[3] or Bulk	10	454 (1.00)	4.5 (10)
Ground Products and Finished Food				
Grain products e.g., meal, flour grits, pasta, and breakfast cereals **Edible seeds, oil seeds and nut products** e.g., smooth butter, flour, paste **Spices**; **dried ground** e.g., ginger, pepper	≤ 2,200	10	454 (1.00)	4.5 (10)
	> 2,200 ≤ 4,400	12	454 (1.00)	5.5 (12)
	> 4,400 ≤ 22,000	15	454 (1.00)	6.8 (15)
	> 22,000 ≤ 150,000 [4]	20	454 (1.00)	9.1 (20)
Whole and non-Ground Products				
Whole Grains e.g., shelled corn, wheat, sorghum, barley, rice **Edible and oil seeds:** e.g., melon, pumpkin, sesame, soybean, sunflower **Spices; dried whole**: e.g., ginger, nutmeg **Beans:** e.g., coffee beans, pinto beans	≤ 220	10	454 (1.00)	4.5 (10)
	> 220 ≤ 2,200	15	303 (0.67)	4.5 (10)
	> 2,200 ≤ 4,400	20	227 (0.50)	4.5 (10)
	> 4,400 ≤ 22,000	30	227 (0.50)	6.8 (15)
	> 22,000 ≤ 150,000[4]	50	182 (0.40)	9.1 (20)
Peanuts and tree nuts (shelled or in-shell), except in-shell Brazil nuts e.g., peanuts, almonds, pecan, pistachios **Crunchy nut butter** **Dried fruits** e.g., figs, raisins	≤ 220	10	454 (1.00)	4.5 (10)
	> 220 ≤ 2,200	20	454 (1.00)	9.1 (20)
	> 2,200 ≤ 4,400	30	454 (1.00)	13.6 (30)
	> 4,400 ≤ 22,000	60	378 (0.83)	22.7 (50)
	> 22,000 ≤ 150,000[3]	100	227 (0.50)	22.7 (50)
	Number of bags	**NUMBER OF SAMPLE UNITS TO COLLECT**[2]	**MINIMUM SAMPLE UNIT SIZE: g (lb.)**	**MINIMUM TOTAL SAMPLE SIZE: kg (lbs.)**
Brazil nuts in-shell	< 200	20	454 (1.00)	9.1 (20)
	> 200 ≤ 800	40	454 (1.00)	18.2 (40)
	> 800 ≤ 2,000 [5]	60	454 (1.00)	27.3 (60)
ANIMAL FOOD PRODUCTS[6]				
Product	**PACKAGETYPE/ LOT SIZE: lbs.**[1]	**NUMBER OF SAMPLE UNITS TO COLLECT**	**MINIMUM SAMPLE UNIT SIZE: g (lb.)**	**MINIMUM TOTAL SAMPLE SIZE: kg (lbs.)**
Whole Grains: e.g., shelled corn, wheat, sorghum, barley, rice **Oilseeds:** e.g., soybean, cottonseed **Grain products:** e.g., cracked corn, corn screenings, wheat middling	≤ 4,400	20	227 (0.50)	4.5 (10)
	> 4,400 ≤ 22,000	30	227 (0.50)	6.8 (15)
	> 22,000 ≤ 150,000[3]	50	182 (0.40)	9.1 (20)
Oilseed and nut meals e.g., peanut meal, cottonseed meal, soybean meal **Milled corn products** e.g., corn gluten meal, cornmeal, hominy	Consumer[3] or Bulk	40	227 (0.50)	9.1 (20)
Complete mixed animal food e.g., poultry feed, cattle feed, swine feed, pet food	Consumer or Bulk	20	227 (0.50)	4.5 (10)

[1] If you have any questions, please consult the appropriate FDA Center for further assistance.
[2] Sample unit integrity must be maintained.
[3] For sampling of consumer packages, please consult the IOM or the appropriate FDA Center for further assistance.
[4] If a lot is more than 150,000 lbs., please consult the appropriate FDA Center for further assistance.
[5] If a lot is more than 2,000 bags, please consult the appropriate FDA Center for further assistance.

[6] When foods are not designated as animal food, the food should be sampled according to the schedule for human food.

7- SAMPLING SCHEDULE FOR CANNED FRUIT - FILL OF CONTAINER - AUTHENTIC PACK

Collect samples only on a specific assignment or during inspections when it appears that the firm is not filling the containers to capacity.

1. **INVESTIGATIONAL SAMPLES:** Authentic Pack Preparation. Procedure for preparing authentic factory packs.
   a. Remove 72 cans, 3 at a time, from packing line after fruit has been added and before syruping.
   b. Mark 24 cans with the sub numbers A-1, A-2, A-3, etc.; 24 cans with sub numbers B-1, B-2, B-3; and 24 cans with sub numbers C-1, C-2, C-3, etc. See IOM 4.5.2.3.
   c. Drain water from the "B" subs by inverting each can for 10 seconds, holding the fruit so it doesn't fall out.
   d. Obtain gross weight of each can and record data for each series of sub on 3 separate FDA-485 - Field Weight Sheets.
   e. Add additional fruit of the same kind and style to the "C" subs until the cans are filled to capacity. Do not tamp the contents or crush the fruit.
   f. Record the number of fruit pieces added where the size of the fruit makes the procedure reasonable. Do not make time consuming counts of small pieces of fruit or berries.
   g. Obtain the gross weight of the "C" subs after additional fruit is added and record on "C" series Field Weight Sheet.
   h. Return all 72 cans to the filling line for syruping, exhausting, sealing, etc. in normal cannery operation.
   i. Remove cans after cooking and cooling.
   j. Identify cans with a single INV Sample number.
   k. Attach FDA-485 - Field Weight Sheets to C/R.

2. **OFFICIAL SAMPLES**
   See Sample Schedule Chart 2 for sample size.

3. **SPECIAL REPORTING AND PRECAUTIONS**
   a. Report coding of cans and shipping cases.
   b. Obtain label specimen(s) for the slack filled products.
   c. Report shipments made before the inspection or since previous inspection in the same canning season.
   d. Do not prepare Authentic Factory Samples when the cannery is packing for USDA fill-of-container certification unless:
      i. USDA inspection is not continuous.
      ii. USDA Certification is for quality only.
      iii. USDA recommendations for weights are not being followed.

4. **SAMPLE SUBMISSION**
   Submit samples to your division's designated workplan servicing laboratory.

8- SAMPLING SCHEDULE FOR IMPORTS - COFFEE, DATES AND DATE MATERIAL

1. Coffee - Import Field Examination - Note: Examine a minimum of six bags of coffee beans regardless of lot size. If a significant number of defective beans or significant contamination is found during the examination of these six bags, continue the examination using the following schedule, which applies for both Import Field Examination and samples for laboratory analysis:

LOT SIZE	NO. BAGS TO BE SAMPLED
100 or less	6 bags
101 - 200	10 bags
201 - 1000	15 bags
over 1000	20 bags

   a. Sample each bag with a trier, collecting 1/2 pt. of beans from the top and 1/2 pt. from the bottom of the bag. The total quantity of beans taken from each bag must be the same, since both wharf and laboratory examinations are to be performed on a composite sample of all beans collected. Shake each sub on a #8 sieve nested in a pan. Dump the sifted beans from each sub into a bag of sufficient size to hold and permit mixing all of the subs collected from the lot. Composite the subs. Do not maintain individually.
   b. Macroscopic Filth Examine the siftings for macroscopic filth (live and dead whole insects, excreta pellets, extraneous material, and sweepings), reporting findings for each sub separately. See IOM 4.3.7.4. Transfer macroscopic filth, including all sifted material to a second bag and submit to the laboratory for confirmation. If live insect infestation is encountered, freeze the filth portion containing the insects and the composite coffee bean sample. The lot will be detained if a live insect infestation is encountered, however, proceed with the defect bean examination since the reconditioning process will depend on the results.
   c. Defect Bean Examination Thoroughly mix the composite sample of coffee beans and remove three-hundred beans at random. Examine each individual bean visually (or at a 5X magnification) for insect tunneling and mold damage. Count as moldy only those beans with 1/4 or more of the surface being moldy. Note: Each division office has examples of the various types of reject beans.

      Accept the lot if twenty or less rejects are found and discard the sample. Report your wharf examination into FACTS or OASIS, depending on your assignment; no Sample Collection Report is necessary.

   d. If twenty-one or more rejects are detected, return beans examined to the composite and submit to the laboratory. You may discontinue the examination when twenty-one rejects are detected. When a sample is submitted to the laboratory, all import field examination time is reported as a field exam in FACTS and the sample collection time is reported as an import sample collection. All necessary documents for an import sample collection must be completed.

2. Dates & Date Material - Filth

In the laboratory, dates, like in-shell nuts are sampled in accordance with a sequential sampling program, i.e., all subsamples are composited, and 100 dates are sampled at a time, repetitively, until such time they either exceed or fall under certain reject numbers. It is not uncommon to have to examine 3 to 6 (100 date) repetitions. It is therefore important for each subsample to contain at least 300-400 dates or a 3-pound chunk of date material. Bag subs separately and identify. Sample according to the following schedule:

NUMBER OF SUBSAMPLES REQUIRED

NO. CONTAINERS IN LOT*	WHOLE DATES	DATE MATERIAL
100 or less	3	4
101 - 600	8	6
601 - 1200	14	8
1201 - 2000	26	10
2001 - 2800	36	12
2801 - 6000	44	14
6001 - 9600	56	16
9601 - 15000	68	18
Over 15000	82	22

* Schedule is based upon unit containers weighing between twenty and one-hundred pounds. For containers exceeding one-hundred pounds each, consider as two or more containers. For example, a one-hundred and fifty-pound container is considered as two containers; a three-hundred pound container as three containers, etc.

   a. Identify each subsample separately.
   b. Each lot will be a separate sample. Reconditioning, if possible, will be based on lot numbers.
   c. Jujube sampling – collect according to the above schedule for dates and date material. Do not identify jujube samples as dates, *Phoenix dactyllifera*. Jujubes, *Zizphus jujube*, are usually labeled as Chinese Red Dates, Dried Red Dates, or Honey Dates and are not misbranded when labeled as such due to long standing use of these names.
   d. If live insects are noted, include these as part of the sample collected and report on the C.R. which subs contained the insects and how many insects, adult, or larvae, were noted. If live infestation is noted, place all subs from the lot sampled in large plastic *whirl-pak* bags and freeze or place in a cooler on dry ice.

9- SAMPLING SCHEDULE FOR COLOR CONTAINING PRODUCTS & COLOR ADDITIVES

The following schedule provides general guidance for collecting samples of foods and cosmetics to determine whether non-permitted colors are present, rather than to determine the actual level of a particular color. This schedule was developed with the assumption that color distribution in the lot will be homogeneous. In the case of heterogeneous products, your supervisor should contact Center for Food Safety and Applied Nutrition, Office of Field Programs, Division of Enforcement (HFS-605) to determine sample size.

INDUSTRY CODE		SAMPLE SIZE (DO NOT COMMINGLE CODES) (Min. 225 g (8 oz)/pkg Unless otherwise specified)
GRAIN AND BAKING		
02	Whole grains, Milled Grain Products and Starch	2 retail packages
03	Bakery Products, Doughs, Bakery Mixes, and Icings	2 retail packages
04	Macaroni and Noodle Products	2 retail packages
05	Cereal Preparations Breakfast Foods	2 retail packages
07	Snack Food Items (Flour, Meal, or Vegetable Base)	2 retail packages
DAIRY		
09	Milk, Butter, and Dried Milk Pdts	Liquid Pdts: 2 pts where possible Solid: 2 packages
12	Cheese and Cheese Products	2 retail packages
13	Ice Cream and Related Products	6 items per sample (If item is single serving; i.e., cup, popsicle, bar, etc.) 2 pt. containers where possible, or 1 quart or 1/2 gal
14	Filled Milk and Imitation Milk Products	2 pints
EGGS		
15	Egg and Egg Pdts	2 dozen whole eggs (e.g. colored hard-boiled Easter eggs) 2 retail pkg of egg pdts
FISH		
16	Fishery/Seafood Pdts	2 retail packages. Any collection of smoked salmon should be selective, based on inspectional evidence
MEAT & SIMULATED MEAT PRODUCTS		
17	Meat, Meat Products and Poultry	2 retail packages
18	Vegetable Protein Pdts	2 retail packages
FRUIT, NUT AND VEGETABLE PRODUCTS		
20-22	Fruit & Fruit Pdts	2 retail packages canned or glazed. 12 fresh fruit (e.g., oranges, etc.).
23	Nuts & Edible Seeds	2 retail packages
24-25	Vegetable & Vegetable Products	2 retail packages
26	Vegetable Oils & Olive Oil	Liquids - 2 pints Solids - 2 retail packages
DRESSINGS AND SPICES		
27	Dressings & Condiments	2 retail packages
28	Spices, Flavors, & Salts	Extracts - 2 pints Solids - 2 retail packages
BEVERAGES		
29	Soft Drinks & Waters	6 Retail Units (Cans, Bottles, Packets)
30	Beverage Bases, Concentrates, and Nectars	Liquids - 1 pint Solids (Powder mix, packets) - 6 Consumer Pkg Solids - 2/225 g (8 oz) or larger containers
31	Coffee and Tea	2 retail packages
32	Alcoholic Beverages	2 pints or 1 quart
CONFECTIONS AND DESSERTS		

33	Candy w/o chocolate, Candy Specialties, and Chewing Gum	2 retail packages
34	Chocolate & Cocoa Pdts	2 retail packages
35	Gelatin, Rennet, Pudding Mixes, & Pie Fillings	6 pkgs - smallest consumer size
36	Food Sweeteners (Nutritive)	2 pints

MULTIPLE FOODS, SOUPS, SALADS, BABY FOOD AND DIETARY

37	Multiple Food Dinners Gravies, Sauces and Specialties	Single Serving Dinners, etc. - 4 pkgs Two Consumer Pkgs when 1 pkg serves more than 2
38	Soups	Same as 37 Above
39	Prepared Salad Products	Same as 37 Above
40	Baby (Infant and Junior) Food Pdts	Sufficient retail pkgs to total at least 454 g (1 lb.) of food
41	Dietary Conventional Foods and Meal Replacements	Same as 37 Above

COLORS AND COSMETICS

50	Color Additives for Foods Drugs, and Cosmetics	1. Straight Color 28 g (1 oz) powder. 2. Color Mixtures 110 g (4 oz) Liquid, paste or powder. If mixture contains over 50% pure dye, 55 g (2 oz) is sufficient
53	Cosmetics	Four retail packages of the same lot code for each shade (color) in the product line, if the product is strongly colored. (e.g., Lipsticks, hair coloring products, eye mascara, eye liners, make up pencils of all types) Sufficient number of retail packages to equal 1 lb. or 1 pt. of sample if the product is lightly colored. (e.g., creams, lotions, shampoos, bath products, shaving preparations, and perfumes.) Note: Always collect a minimum of two retail units of each product.

MISCELLANEOUS

	Bulk Items (Any bulk food or cosmetic)	Dry - 454 g (1 lb) Liquid - Min 36 fl oz

10- DRUG SAMPLING SCHEDULES

(Does not include Antibiotic Preparations)

STERILITY TESTING VITAMINS, DEVICES, & DRUGS

Type of Product	Sample Size[1]	
	INV Sample[2]	Official [702(b) & Check][3]
DRUGS	36	86
DEVICES	46	106

LEGEND:

[1]Double sample size requirements when individual containers are 2 ml (2 g) or smaller.

[2]INV sample includes units (30 for Drugs & 40 for devices) for examination and 6 units for bacteriostasis.

[3]Official Sample includes units (30 for drugs & 40 for devices) for examination, units (30-40) for check, 20 units for 702(b) [21 U.S.C. 372(b)] and 6 for bacteriostasis.

Note: If a lot is aseptically filled into 200 finished units or less, sample no less than 10% of lot.

DISSOLUTION TEST - USP & NF

Unless directed otherwise by your assignment or supervisor, submit samples to your normal servicing laboratory.

SAMPLE SIZE

Collect a 200 tablet portion for drug potency analysis by the collecting division lab, plus a separate 100 tab portion to be split for dissolution testing.

MICROBIOLOGICAL EXAMINATION OF DRUGS (Other than for Sterility)

PRODUCT	MINIMUM SAMPLE SIZE (Includes 702(b) portion)	
	Sub Size	Nos. of Subsamples
Dosage Form Drugs (See #1 below), Bulk Drugs, or Raw Materials for Manufacturing	90 g or 90 ml	10

SAMPLING INSTRUCTIONS

1. Contact the laboratory (which has microbiological testing capabilities) serving your division for sample size requirements before sampling dosage form drugs containing less than 3 grains, 200 mg, or 25% of the suspect ingredient.
2. Use aseptic technique when collecting samples from raw materials or bulk containers. Implements and sample containers used must be sterile. Submit controls. See IOM 4.3.6 through 4.3.6.5.
3. Submit samples to the laboratory with microbiological testing capabilities which serves your division unless directed otherwise.

11- VETERINARY PRODUCTS, FEEDS, & BY- PRODUCTS FOR ANIMAL FEEDS

1. GENERAL

This sampling schedule may be used as a guide in the collection of surveillance or compliance samples resulting from division assignments or as a follow-up to violative inspections and/or investigations. Before collecting follow-up samples to violative inspections or investigations, contact your supervisor since it may be necessary for your division to consult with the Atlanta Center for Nutrient Analysis (HFR-SE680) when unscheduled compliance sampling is contemplated.

2. SAMPLE PRODUCT, SIZE, & SPECIAL INSTRUCTIONS

Vitamin-mineral testing, sampling instructions and information. Sample size includes 702(b) portion.

Unless excessive cost is a factor, collect at least 3 intact containers from each lot or control number. When sampling from bulk lots, collect appropriate subs from a minimum of 3 different bulk containers in the lot.

DOSAGE FORM VITAMIN-MINERAL PREPARATIONS (Single/Multiple Ingredients)

PRODUCT	NO. SUBSAMPLES	MINIMUM TOTAL SAMPLE SIZE	REMARKS
Injectables	3 vials/amps	30 ml	Split samples for sterility testing (60 vials/amps)
Tabs/Caps	3 retail units	300 Tabs/Caps	Split sample for micro tests (10/50 tab/cap subs)
Liquids	3 retail units	4 fl. oz.	Split sample for micro tests (10/2 fl. oz. subs)
Powders	3 retail units	112 g (4 oz)	Same as above

FEEDS & BY-PRODUCTS FOR ANIMAL FEEDS (Vitamin-Mineral Claims)

Vitamin A & D Concentrates, Supplements & (A&D feeding	3 retail units (1/2 gal or less)	3 lbs. (1.4 kg) 3 pints	Limit samples to those products containing at least 800 units/g Vit A and/or 80 Feeds units/g Vit D
Vitamin B2 (Riboflavin) Concentrates, Supplements, & feeds	Same	Same	Limit samples to those products containing at least 20 mg/lb.
Vitamin B12 (Cyanocobalamin) Concentrates, Supplements & feeds	Same	Same	Limit samples to those products containing at least 1 mg/lb
Multiple Vitamins Concentrates, Supplements, & feeds.	Same	Same	Limit samples to those products meeting vitamin levels listed above.

3. SAMPLE SUBMISSION

Submit all samples for Vitamin Potency analysis to the Atlanta Center for Nutrient Analysis (HFR-SE680). Submit samples for filth analysis, microbiological examination, sterility, etc. to your division servicing laboratory.

12- MEDICATED ANIMAL FEEDS SAMPLING

Medicated Premixes

1. Investigational Samples (INV Samples)

   To demonstrate suspected drug carryover or other chemical contamination during manufacturing, collect 1-900 g (2 lbs.) of static residual material in the equipment, and the finished product premixes.

2. Official Physical Samples 702(b) [21U.S.C.372(b)] Portion Included

   For expensive premixes or components, collect a total of 3/170 gm (6 oz) subs; One sub from each of 3 containers. In the case of premixes packaged in plastic; e.g., mini-packs, follow instructions under bagged premixes.

   a. Bagged Premixes

      Collect 10 - 454 g (1 lb.) subs from each lot. Sample all bags in lots under 10 bags, for a total of 10 subs from the lot.

      Collect 454 g (1 lb.) subs from at least 10 different bags selected at random in lots of more than 10 bags.

   b. Bulk Premixes

      Collect at least 10 - 454 g (l lb.) subs, from different locations in the lot providing a minimum total sample of 4.5 Kg (10 lbs.).

3. Documentary Samples (DOC Sample) - Refer to IOM 4.1.4.2 for guidance on the collection of DOC Samples.

Medicated Feeds

1. Investigational Samples (INV Sample)

   Collect 1 - 900 g (2 lb.) of static residual material in the equipment and correlate with finished feed samples to show that residues are being carried over into the finished product.

2. Official Samples (Includes 702(b) portion)
   a. Bagged Complete Feed

      Collect a total sample of not less than 2.3 kg (5 lbs.) from each lot. Collect 454 g (1 lb.) subs sampling all available bags from lots of 10 bags or less. If lot size is greater than 10 bags, collect 454 g (1 lb.) from each of 10 bags selected at random.

   b. Bulk Complete Feed

      Collect at least 10 - 454 g (1 lb.) subs from different points in the bulk lot to obtain a minimum total sample of 4.5 kg (10 lbs.).

   c. Concentrates/Supplements
      If the concentrate or supplement is relatively inexpensive, follow the sampling procedures for complete feeds. Limit sampling of more expensive drug materials, concentrates, or supplements to no more than 3 containers taking a 170 g (6 oz) or 6 fl. oz. sub from each of the 3 containers.
3. Documentary Samples (DOC Sample)
   a. Feed Subject to MFA Approval - Collect DOC Samples of products processed without required MFA approval. Where the plant does not ship in IS commerce, but ingredients are received from IS sources, document the IS nature of drug ingredients and the "Held For Sale" status of the finished feed. Labeling of drug ingredients must be submitted.
   b. Misbranded Products - Collect a DOC Sample for misbranding or labeling deficiencies. The failure to provide warning and/or withdrawal statements which could present danger to animals or man, or gross evidence of false and misleading therapeutic claims, are factors for consideration.

Sampling Precautions (See IOM Sample Schedule Chart 4)

1. Insert the trier the full length of the bag when sampling bagged premixes, or complete feeds.
2. Clean trier between sampling the different lots of premixes or complete feeds.
3. Place subs in a clean, airtight container, preferably clean glass jars.
4. Do not fumigate samples intended for potency analysis, drug carryover or cross-contamination.

Sample Submission

Submit samples to your division's servicing laboratory or as directed by your assignment or supervisor. See IOM 4.5.5.2.

13- SAMPLE SIZES WITH APPLICATION TO FOOD PRODUCTS FOR ALLERGENS

Note: Follow 4.3.2.2 concerning collection of the 702(b) portion of the sample. Guidance below does not include 702(b) portion.

All subs should be at least 100 grams of product (approximately 3.5 ounces), except in case of consumer complaint samples (see 1a).

1) **"For Cause"** samples should consist of 2 subs. "For cause" sampling should be limited to instances where there is a reasonable probability that a product may contain an allergen and the labeling of the suspect product does not indicate the presence of the allergen; for example, from a consumer complaint, a downstream consignee laboratory analysis. Only collect "For Cause" samples after consulting with your District Emergency Response Coordinator and CFSAN/OC (see IOM 8.2.3.4.3).
    a. For consumer complaint samples, collect the remainder of the consumed product in its original container and a control sub of at least 100 grams of the same product, preferably from the same lot. The consumed portion should always be all remaining product and does not need to be at least 100 grams. Do not collect samples of foods prepared by the consumer or foods in refuse containers.
2) Collect 10 subs when heterogeneous contamination is suspected. Samples may be collected randomly from multiple production lots or from random production times in one production lot.
3) During inspections or investigations of manufacturing facilities:
    a. Collect 2 subs each for samples *where cross-contamination* or undeclared allergen is suspected to be inherent in the sample may include: source ingredients, in-line samples, product scrapings from equipment, finished product (at manufacturer) and/or finished product released into commerce.
    b. Only collect equipment swabs at the direction from CFSAN.

14- SAMPLE SIZES FOR FILTH ANALYSIS

Table 1. Sample Size for Filth Analysis: Dried Fruit, Dried Peas, Dried Beans

This table provides specific instructions outlining sample sizes for dried peas, beans, and fruit products to be analyzed for filth. Guidance in CP 7303.050, Foodborne Biological Hazards, indicates that in the absence of specific instructions outlining the expected sample size for a given product, ten (10) subsamples, each with 2 lb., should be collected at random.

Note that these two CPGs provide direct reference seizure criteria, but do not provide sampling guidance (quantity to collect for lab analysis):

- CPG Sec 585.225, Black-Eyed Peas (Cow Peas, Field Peas) Dried - Adulteration with Lygus Bug Damage
- CPG Sec. 585.575 Peas and Beans Dried - Adulteration Involving Storage, Insect Damage, Rocks

For food storage and warehousing, the following may be of interest: CPG Sec. 580.100 Food Storage and Warehousing-Adulteration-Filth (Domestic and Import).

SAMPLE SIZES FOR FILTH ANALYSIS			
Please collect a duplicate portion for 702(b) [21U.S.C. 372(b)] when directed or required per IOM 4.3.2.2 and 4.3.2.3			
HUMAN FOOD PRODUCTS - Dried Fruit, Dried Peas, Dried Beans			
Product	**NUMBER OF SUBSAMPLES to COLLECT**	**MINIMUM SUBSAMPLE SIZE**	NOTES
Dried Peas and Beans	12	1 lb.	
Dates and Date Material	See Notes column	--	See specific sampling guidance in CPG Sec. 550.300. Note: There is important sampling information in MOU 225-72-2001, which is related to imported dates and which outlines responsibilities for USDA/Agricultural Marketing Service (AMS) and the FDA.
Jujubes **(also called Chinese date or red date)**	See Notes column	--	See specific sampling guidance in IOM, Chapter 4: Sample Schedule Chart 8 - Sampling Schedule for Imports - Coffee, Dates and Date Material
Prunes	10	2 lb.	See also CPG 550.700
Raisins	10	2 lb.	Imported raisins: Sample collection of import raisins should only occur when deemed appropriate by the Memorandum of Understanding (MOU) between the AMS and FDA. See MOU 225-73-2007. Only when indicated for collection, collect 10 subsamples of 2 lb. each. See also CPG Sec. 550.750.
Dried Fruit Products	6	100 units of fruit[1]	Collect six (6) subsamples, each with a minimum of 100 units of fruit.[6] Note: It's recommended to verify by count that each subsample contains at least 100 units. When that is not practical, the below weight approximations may be helpful. • Small fruits (e.g., cherries, blueberries): 2 lb. usually contains 100 units • Medium fruits (e.g., persimmons, apricots, figs): 4 lb. usually contains 100 units • Large fruits (e.g., all tamarind pods): 6 lb. usually contains 100 units

[6] There should be 100 whole fruits. When fruit has been cut into 'pieces', do not count each piece as one whole fruit.

Produce: Sample Collection and Shipment of Produce for Filth Analysis - Container and Temperature Considerations

These instructions apply to sample collections of produce to be analyzed for filth. This information is intended to supplement the information provided in the CP 7303.050, Foodborne Biological Hazards. When collecting samples of produce for filth analysis, please consider the type of container and temperature requirements on the product labeling, if there is labeling. If there is no label, or if the label does not specify a storage temperature:

- Dried produce – Collect in doubled paper bag (not plastic bags, unless in retail bags); ship at ambient temperature.
- Fresh produce – Ship at refrigerated temperature (for example, cooler with some type of "Ice Pak", "Liquid Ice", "Sno-Gel", "Kool-It", or similar materials to maintain the required temperature range). Ship overnight, if possible. Do not use bagged (or “wet”) ice.
    - For bulk product, collect each subsample in a doubled paper bag, placed inside a plastic bag or mesh bag.
    - Another option is to use the original container, if economically feasible. If the original container is used, or if the product is in bulk, consider adding packing material to the container so that the product will stay in place and not move around during shipment.

4-22 Sample Criteria for Selective Sampling for Filth

The Agency has defined minimum direct reference seizure criteria to assist in assessing filth of individual lots. Criteria for rodent, insect, and bird filth are defined Compliance Policy Guide (CPG) 580.100, Food Storage and Warehousing - Adulteration - Filth (Domestic and Import) for human foods, and reiterated in IOM sections 4.3.7.2 - 4.3.7.4. When collecting selective samples of products to show adulteration by filth, be guided by this criteria.

How FDA products are manufactured, stored, or shipped can lead to these products being adulterated directly. These products can also be deemed to be adulterated indirectly if they were manufactured, stored, or shipped under insanitary conditions. The evidence of these adverse conditions is obtained through sampling and documenting through an inspection (Chapter 5). The criteria for documenting food adulteration in this section should serve as guidance for documenting adulteration with other FDA regulated products. It is ultimately the investigator's responsibility to develop the evidence of adulteration and defining the scope of the adulteration (lot specific, product specific, location specific). Photographs taken during sampling (Chapter 5) can be very useful in court proceedings and litigation. Considerations of how product is packaged or contained should be factored when determining how to sample for adulteration. For example, it is harder to show environmental adulteration of products contained in a metal container or closed system verses a cardboard container where there may be no linings to protect the product.

When evidence of rodent, insect, bird, or other animal activity is encountered during an inspection it is your responsibility to assess the evidence you observe and determine and document whether the activity is:

- Current or old
- Isolated or widespread

If it is isolated to one lot (possible FD&C 402(a)(3) charges - contain in whole or in part filth or is otherwise unfit for food or 501(a)(1) if a drug or device product).

Widespread adulteration requires evidence and documentation to illustrate all of the firm's susceptible products are potentially adulterated because they are being prepared, packed, or held under conditions whereby they may be contaminated. These would be possible FD&C 402(a)(4) charges for food or 502(a)(2)(A) charges if a drug or device.

Your assessment and documentation of the evidence observed (diagrams, photos, and sample collections) will determine what actions may be required by either the establishment, the Agency, the Court, or all three to correct the problem. The evidence and documentation you collect and develop will be used to show, by a preponderance of evidence, that conditions at the firm have resulted, or could result in adulteration.

Your sample collection should be sufficient to document the extent of the violative conditions and not be limited to this minimum. Even where these minimum prerequisites are not met, you should collect samples as exhibits and evidence, particularly where adulteration under section 402(a)(4) of the FD&C Act [21 U.S.C. 342 (a)(4)] or 501(a)(2)(A) of the FD&C Act [21 U.S.C. 351(a)(2)(A)] may be a factor. Your evidence may be used in a subsequent action against the firm, if corrections are not made.

Consult with your supervisor as soon as possible when you find evidence which meets the criteria set forth in CPG 580.100. If you are collecting several samples, the lab should be notified in advance that samples are on their way and should be analyzed expeditiously to facilitate regulatory action. Your supervisor may also want to notify your compliance branch so evaluation of evidence for a possible mass seizure can commence.

General Guidance for Selective Sampling

When Selective Sampling consists of an actual sample of a product, however small, as distinguished from bag cuttings, rodent pellets, insects, etc., a 702(b) portion must be obtained. In such cases, collect duplicate subs of

the product to provide the 702(b) portion. This 702(b) portion is usually not an exact duplicate of the product collected for the Selective Sample, but should be collected from the same bag, box, or other container of product sampled. Whether collected from a container or bulk, the 702(b) portion should be taken as close as possible to that portion selectively sampled for analysis. Specify for each sub and duplicate collected, the origin, manner in which taken, and the examination to be made on your C/R. See IOM 4.3.3.3

Note: A 702(b) portion is not required for import samples or medical devices. However, if a dispute arises, or a potential for regulatory action exists, a 702(b) portion may be collected. Contact your supervisor for additional guidance, if necessary.

Submit each portion of bagging or container portion, rodent pellets, material from beneath sampled area, control etc., in separate vial or subsample container.

It's important when collecting a selective sample for adulteration violations that you:

- Use a coherent numbering/identification system for subsamples to avoid unnecessary confusion for the lab.
- Provide a detailed listing of individual sub descriptions on the C/R.
- If possible, provide a copy of any maps, photos, or other additional documentation to the laboratory.
- Be sure to obtain product labeling. Since samples of lots which are sampled selectively are official samples, complete labeling must be collected. See IOM 4.4.9.

Note: Whenever a portion of food is collected as part of a selective sample FD &C Act Section 704(d) applies and the C/R should be marked as such.

Documenting Rodent Contamination

The minimum direct reference seizure criteria to assist in assessing rodent adulteration of individual lots, as defined in Compliance Policy Guide (CPG) 580.100, are summarized as follows:

The storage facility is rodent infested and:

- Three or more of the bags in the lot are rodent gnawed;

Or

- At least five of the bags in the lot bear either rodent urine stains at least 1/4" in diameter, or two or more rodent pellets;

Or

- The food in at least one container in the lot contains rodent gnawed material, or rodent excreta or urine.

Whether or not the warehouse is rodent infested; IF:

- At least three bags bear rodent urine stains of at least 1/4" in diameter which penetrates to the product even though the product cannot be demonstrated to have been contaminated;

Or

- At least two bags are rodent-gnawed and at least five bags bear either rodent urine stains at least 1/4" in diameter, with or without penetration to the product, or two or more rodent pellets;

Or

- The food in at least one bag in the lot contains rodent-gnawed material or rodent excreta or rodent urine, and at least five bags bear either rodent stains at least 1/4" in diameter or two or more rodent pellets.

Additional regulatory guidance concerning rodent adulteration of pet foods can be found in CPG, 690.600 Rodent Contaminated Pet Foods.

Examination and Documentation of Rodent Contamination

Examine the exterior of the containers looking for rodent hairs, urine stains, excreta pellets, gnaw marks, holes, nesting material and live rodents. Make a diagram of the entire lot and note your findings as you examine the individual containers. You will need to include these descriptions on your C/R.

Describe excreta pellets as carefully as possible. Note whether they appear dusty or shiny; soft or hard.

Examine suspected urine stains with ultraviolet (UV) light in as near total darkness as possible. A minimum of 15 minutes is normally required for the eyes to become properly adjusted to accurately differentiate between rodent stain fluorescence and normal fluorescence of rice and certain other commodities.

Wet, fresh, or continually wetted runs may fluoresce poorly, but the odor of urine will usually be present and should be described on the C/R. Fresh dry urine stains will fluoresce blue-white, while older stains may be more yellowish/white. Rodent hairs will look like blue/white streaks. Look for the typical droplet pattern because rodents commonly urinate while in motion. Report the presence of droplet patterns on your C/R.

Urine-stained areas may be photographed under ultraviolet light conditions. Check with your supervisor about the technical aspects of this procedure. Do not mark container surfaces to outline the stained areas when taking either ultraviolet or normal photographs. This may contaminate the product by migration through the containers.

A number of things can interfere with the visual identification of urine stains. Many types of bagging and threading materials will fluoresce under UV light, however, the characteristic rodent stain fluorescence can be identified by its yellowish color and characteristic pattern. In addition, a number of products exhibit a natural fluorescence. The following products may be difficult to evaluate because of either natural fluorescence or "quenching" of UV rays, even if contaminated. ("Quenching" refers to a covering up or a decrease in the ability of a product to fluoresce.)

FOODS	NON-FOOD ITEMS
High Gluten Flour (Natural)	Burlap Bags (Quenching)
Nut Meats (Natural)	Bleached Sacks (Natural-White Glow)
Bean Flours (Natural)	Lubricants (Oils & Greases)
Brans (Natural)	(Natural-Blue/White to yellow/brown glow)
Pop & Field Corn (Natural)	Pitches & Tars (Natural-Yellow)
Wheat (Natural)	Detergents & Bleaches (Natural-White)
Starch (Natural)	Sulfide Waste Matter (Natural-Blue/White)
Spices (Natural or Quenching)	

Note clearly on your C/R if the product or package contains or is directly associated with any of the following:

1. Dried milk products (contain urea).

2. Whole grain wheat (contains urea and allantoin).
3. Animal feeds (urea is usually intentionally added).

Collecting Exhibits or Subsamples fo Rodent Contamination

When sampling lots for rodent contamination, follow the safety precautions in Safety Chapter of the IOM. Wear gloves and handle the exhibits with tweezers or forceps. Handle exhibits carefully to prevent loss of microscopic evidence. Where you separate, count, or identify the various elements of an exhibit, (e.g.: sieve and find X number of rodent pellets), maintain the counted portions separate from the other subs. Note on the C/R those subs that were counted, separated, etc.

Collect a representative number of rodent pellets for laboratory confirmation. Place the pellets in a vial or other rigid container to prevent crushing. One of the identifying characteristics the lab looks for is the presence of rodent hairs in the pellets. The more pellets examined increases the possibility of a good identification. However, do not collect all the evidence you see as this would recondition the lot.

Collect portions of urine stains or gnawed holes from containers using small scissors or a sharp knife. Leave a portion of the stain or gnawed hole intact but take a cutting large enough to provide good identification. Usually ½ inch around the stain is sufficient to allow manipulation during the lab exam. **Note:** The bag cutting should not be so large as to remove the entire contaminated portion, since this would recondition the product. For multilayer bags, be sure you cut through all layers of the bag and identify the layers with pencil. (Do not use ink as it often contains urea.) If possible, take stained cuttings from areas which have not been exposed for extended periods of time to light, in particular, ultraviolet light sources or to intense heat. If you have no alternative or cannot determine the stained areas' history, note the conditions on the C/R. Place cuttings and gnawed holes between 2 pieces of white paper, and then fold, roll, or leave flat and place into a glass container or other suitable container. This will hold the evidence in place and prevent possible loss of hairs or parasites due to static charges. Do not separate a multilayer cutting. Avoid the use of polyethylene containers as rodent hairs may adhere to containers made from this material. Put the cuttings in a large enough container to avoid excessive folding of the cutting.

Collect a minimal amount of product from under the stained area or hole, preferably just clumped product as a separate subsample. This prevents dilution of the contaminated product with uncontaminated product. Whenever you collect product, regardless of amount, collect a separate subsample to provide a 702(b) portion. See IOM 4.3.7.4.1. and identify per IOM 4.5.2.1.

Collect nesting material with minimal handling. A half cup is enough for analysis. Do not collect any rodents.

Product Control: In addition, you need to collect product controls, in duplicate to provide for the 702(b) portion. These subsamples should be collected from beneath unstained portions of the container. Collect control samples from 3 different containers.

Packaging Control: Collect a portion of unstained container, which does not fluoresce, as a separate subsample for a control. As a general guide, collect the controls from the opposite side of the bag or make the cutting large enough to separate the control area and the stain. Separate the controls from the stains and submit in separate containers. Collect at least 3 container controls for each sample. If the lot consists of different containers or bags of different manufacturers, collect controls to represent each type or manufacturer of the containers.

Submit each portion of bagging or container, pellets, material from beneath sampled area, control, etc., in separate vial or subsample container. Place the subsamples in a dark container, such as a cardboard box to protect them from light and protect the exhibits from being crushed.

Summary of Sample for Rodent Evidence

The complete official sample will consist of:

1. Subsamples of rodent excreta pellets.
2. Subsample of nesting material.
3. Subsamples of stained bagging, or portions of the containers, and any adhering pellets.
4. Subsamples of unstained bagging, or portions of the containers, which do not fluoresce, for controls (minimum three required).
5. Subsamples of small portions of the product from directly beneath the stained areas. Do not dilute the contaminated product beneath the stain with the non-contaminated product.
6. Subsamples of small portions of product to serve as 702(b) portions.
7. Subsamples of uncontaminated product from beneath the unstained bagging, or other container. These serve as controls and should be collected in duplicate to provide 702(b) portions. Collect control samples from 3 different containers.
8. Subsamples of cuttings from gnawed holes.
9. Subsamples of small amounts of product collected from beneath the gnawed holes.
10. Subsamples of small portions of product to serve as 702(b) portions.
11. Product labeling.
12. Interstate documentation.

If conditions warrant, consider collecting an INV sample per IOM 4.1.6. to document widespread rodent activity.

Documenting Insect Contamination

The criteria from CPG 580.100 below, involving dead insects only, will not be used for action against any food intended to undergo further processing that effectively removes all the dead insects, e.g., processing of cocoa beans.

The product contains:

- One live insect in each of two or more immediate containers; or one dead insect in each of three or more immediate containers; or, three live or dead insects in one immediate container; plus
- Similar live or dead insect infestation present on, or in the immediate proximity of, the lot to show a 402(a)(4) [21 U.S.C. 342 (a)(4)] violation.

Or:

- The product contains one or more live insects in each of three or more immediate containers.

Or:

- The product contains two or more dead whole insects in at least five of the immediate containers. Note: a situation such as this may follow fumigation of the lot and vacuuming of the exteriors of the bags.

Or:

- The product is in cloth or burlap bags and two or more live or dead insects are present on at least five of the containers.

Note: Some live insects must be present. Product need not be shown to have become contaminated.

Examination and Documentation of Insect Contamination

Examine the exterior of the containers (especially along seams or creases) looking for insects, larvae, webbing, nesting material, entrance or exit holes, and cast skins. Make a diagram of the entire lot and note your findings as you examine the individual containers. Describe insects or larvae carefully, noting if they are dead or alive. You will need to include these descriptions on your C/R.

Collecting Exhibits or Subsamples of Insect Contamination

Collect a representative number of insects for laboratory confirmation. Consider the use of a moistened artist brush to collect subsamples. Place the specimens in a vial or other rigid container to prevent crushing. Collect all forms of insects you see, however do not collect all the evidence from the lot or you might recondition the product. If you collect live insects, be sure to note that on your C/R. However, you should not send live insects to the lab. Freeze the subsamples prior to shipment to ensure they are not alive when you ship them. Note the fact that the subsamples were frozen on the C/R.

Cut portions of bags or containers containing suspected insect entrance or exit holes from containers using small scissors. Usually ½ inch around the holes is sufficient to allow manipulation during the lab exam. Note: The bag cutting should not be so large as to remove the entire contaminated portion, since this would recondition the product. For multilayer bags, be sure you cut through all layers of the bag and identify the layers with pencil. (Do not use ink as it often contains urea.) Place cuttings between 2 pieces of white paper, and then fold, roll, or leave flat and place into a glass container or other suitable container. This will hold the evidence in place and prevent possible loss microscopic evidence due to static charges. Do not separate a multilayer cutting. Avoid the use of polyethylene containers as insect fragments may adhere to containers made from this material. Put the cuttings in a large enough container to avoid excessive folding of the cutting.

Collect product from beneath holes which penetrate the packaging as a separate subsample. Whenever you collect product, regardless of amount, collect a separate subsample to provide a 702(b) portion. Note on the subsample itself and on your C/R which subsamples are the 702(b) portions.

Summary of Sample for Insect Evidence

The complete official sample will consist of:

8. Subsamples of insects, larvae, webbing, etc.
9. Subsamples of portions of the containers with entrance or exit holes.
10. Subsamples of small portions of the product from directly beneath holes.
11. Subsamples of small portions of product serve as 702(b) portions See IOM 4.3.7.4.1.
12. Product labeling.
13. Interstate documentation.

If conditions warrant, consider collecting an INV sample per IOM 4.1.6. to document widespread insect activity.

Documenting Bird/Avian Contamination

Per the criteria from CPG 580.100, if the product is in permeable containers (paper, cloth, burlap, etc.), and

- The product contains bird excreta in one or more containers, and you feel the insanitary storage conditions will clearly support a 402(a)(4) [21 U.S.C. 342 (a)(4)] violation

Or

- Bird excreta is present on the exteriors of at least five of the containers, and the product contains bird excreta in one.

Or

- At least 30% of the number of bags examined, but at least five bags, are contaminated with bird excreta; and at least three of the bags bear excreta stains which penetrate to the product, even though the product may not be contaminated.

Note: In all instances of bird excreta contamination the excreta must be confirmed by positive test for uric acid.

Examination and Documentation of Bird Contamination

Examine the exterior of the containers looking for bird excreta. Make a diagram of the entire lot and note your findings as you examine the individual containers. You will need to include these descriptions on your C/R.

Collecting Exhibits and Subsamples

Remove portions of bird excreta stains from containers using small scissors. Leave a portion of the stain intact but take a cutting large enough to provide good identification. Usually ½ inch around the stain is sufficient to allow manipulation during the lab exam. **Note:** The bag cutting should not be so large as to remove the entire contaminated portion, since this would recondition the product. For multilayer bags, be sure you cut through all layers of the bag and identify the layers with pencil. (Do not use ink as it often contains urea.) If possible, take stained cuttings from areas which have not been exposed for extended periods of time to light, in particular, ultraviolet light sources or to intense heat. If you have no alternative or cannot determine the stained areas' history, note the conditions on the C/R. Place cuttings between 2 pieces of white paper, and then fold, roll, or leave flat and place into a glass container or other suitable container. This will hold the evidence in place and prevent possible loss of microscopic evidence due to static charges. Do not separate a multilayer cutting. Avoid the use of polyethylene containers as bird excreta may adhere to containers made from this material. Put the cuttings in a large enough container to avoid excessive folding of the cutting.

Collect a minimal amount of product from under the stained area, preferably just the clumped product as a separate subsample. This prevents dilution of the contaminated product with uncontaminated product. Collect a separate subsample to provide a 702(b) portion (See IOM 4.3.7.4.1).

Product Control: In addition, you need to collect product controls, in duplicate, to provide for the 702(b) portion. These subsamples should be collected from beneath unstained portions of the container. Collect control samples from 3 different containers.

Identify the 702(b) subsamples, as such on subsample identification (See IOM 4.5.2.1.) Note on the subsample itself and on your C/R which subsamples are the 702(b) portions.

Packaging Control: Collect a portion of unstained container as a separate subsample for a control. As a general guide, collect the controls from the opposite side of the bag or make the cutting large enough to separate the control area and the stain. Separate the controls from the stains and submit in separate containers. Collect at least 3 container controls for each sample. If the lot consists of different containers or bags of different manufacturers, collect controls to represent each type or manufacturer of the containers.

Summary of Sample for Bird Evidence

The complete official sample will consist of:

1. Subsamples of stained bagging, or portions of the containers.
2. Subsamples of unstained bagging, or portions of the containers for controls (minimum three required).
3. Subsamples of small portions of the product from directly beneath the stained areas. Do not dilute the contaminated product beneath the stain with the non-contaminated product.
4. Subsamples of small portions of product to serve as 702(b) portions.
5. Subsamples of uncontaminated product from beneath the unstained bagging, or other container. These serve as controls and should be collected in duplicate to provide 702(b) portions. Collect control samples from 3 different containers.
   Submit each portion of bagging or container portion, pellets, material from beneath sampled area, control, etc., in separate vial or subsample container.
6. Product labeling.
7. Interstate documentation.

Documenting Chemical Contamination

Collect samples from lots suspected of dry chemical contamination in much the same manner as described for rodent urine. After collecting a sample of the contents from immediately beneath the suspected area, collect residues from the surface of the bag or container. In the case of infiltration of loosely woven bags, shake or tumble the bag over a large sheet of clean paper to collect the siftings as a sample.

Documenting Mold Contamination

The USDA/FGIS has approved a number of commercial screening tests for detecting aflatoxin contaminated corn. However, these tests usually require a chemical extraction process and are therefore not amenable to FDA field examination procedures.

The black light test (also referred to as the Bright Greenish-Yellow Fluorescence (BGYF) test) is a presumptive test used to screen and identify corn lots that should be tested further for aflatoxins. The test is based on BGYF observed under long wave (366 nm) ultraviolet (UV) light produced by the molds *Aspergillus parasiticus* and *A. flavus* on "living" corn (i.e., corn that has been stored less than 3 months). The growth of these fungi may result in aflatoxin production. Aflatoxins per se do not produce BGYF under long wave UV light. It is thought the BGYF is produced by the reaction of kojic acid formed by the fungi and a peroxidase enzyme from living corn. Corn that has been in storage for a lengthy period of time (3 months or more) may give false positive BGYF. Therefore, determine how long the corn being sampled has been in storage. If it has been in storage over three months, do not use the following field screening procedure.

Essential steps for this black light procedure are:

- A 10 lb. sample representative of the corn lot must be obtained by probing, or by continuously sampling a grain stream.
- Examine using a 366 nm UV light (portable black-lights meet this criteria).
- Wear goggles or use a viewer that screens out UV light. Shine the light on the corn sample which has been spread in a single layer on a flat surface in a darkened room.
- Use a 2 lb. portion, and carefully observe the entire corn surface one kernel at a time. Examine the entire sample using this procedure.
- Count all BGYF glowers (kernels or particles that "glow" bright greenish-yellow). Compare the BGYF color with a fluorescent standard, if one is available. Normal corn, if it fluoresces, will fluoresce a bluish white.

If four (4) or more BGYF particles are detected in the 10 lb. screening sample, collect a sample for laboratory analysis.

4-23 – AFFIDAVIT – FDA 463a

AFFIDAVIT

SAMPLE NO.
DOC1069683

STATE OF
Texas

COUNTY OF
Harris

Before me, Sidney H. Rogers, an employee of the Department of Health and Human Services, Food and Drug Administration, designated by the Secretary, under authority of the Act of January 31, 1925, 43 Statutes at Large 803; Reorganization Plan No. IV, Secs. 12-15, effective June 30, 1940; Reorganization Plan No. 1 of 1953, Secs. 1-9, effective April 11, 1953; and P.L. 96-88, Sec. 509, 93 Statutes at Large 965 (20 U.S.C. 3508) effective May 4, 1980; to administer or take oaths, affirmations, and affidavits, personally appeared Mary K. Johnson in the county and state aforesaid, who, being duly sworn, deposes and says:

I am Mary K. Johnson, Quality Systems Manager, for Texas MedTech, Inc., located at 720 MedTech Drive, Houston, TX 77001. I have held this position for approximately five years but have also previously been involved with manufacturing processes as a production operator at Texas MedTech for approximately four years. Texas MedTech is a manufacturer of automated external defibrillators (AEDs). As the Quality Systems Manager, I have oversight of quality functions including receiving inspection, complaint handling, medical device reporting, nonconformances, management reviews, and corrective and preventive actions. I am knowledgeable and familiar with all documents and records that are maintained pertaining to the design and development, manufacturing, labeling, distribution, and return policies of Texas MedTech products.

During an inspection at our facility conducted between the dates of 12/03/2019 and 12/11/2019, I provided copies of documents and records to FDA Investigator Sidney H. Rogers. These included device history records, design history file records, labels, labeling, sales records, and shipping records which pertain to the receipt of incoming components, manufacturing, acceptance testing, labeling, sale, and interstate shipment of the Texas MedTech Lifesaver AED (part number 10005-001 Rev. C). The AEDs are identified with a five digit lot number and six digit serial number as well as a part number, revision iteration, and unique device identifier for the purposes of identification and traceability.

On 10/20/2016, my firm received a supplied shipment of 100 battery packs, part number 10007-006 Rev. B and lot number 20161014, from Battery Solutions, LLC, located at 526 Portside Road, Portland, ME 04102, via FedEx. The sale of the 100 battery packs is covered by Texas MedTech Purchase Order #16207, dated 10/11/2016, and Battery Solutions Invoice #36910, dated 10/18/2016. FedEx tracking number 5812643725491 provides evidence of the shipment of battery packs on 10/18/2016 from Portland, ME to our facility in Houston, TX. These battery packs were labeled in part "***Battery Solutions, LLC***Portland, ME***AED Pro Battery Pack***DC 12V 4.2Ah***Lot Number 20161014". Upon receipt of this shipment, my firm performed an incoming inspection of the battery packs (including the review of the certificate of conformance from Battery Solutions) and placed an acceptance label containing the aforementioned information on the inspection form. The incoming inspection form for vendor lot number 20161014 shows that it was assigned internal Texas MedTech lot number 1610 (part number 20005-001 Rev. B). Battery pack serial number 2016327 was included as

AFFIANT'S SIGNATURE AND TITLE

FIRM'S NAME AND ADDRESS *(Include ZIP Code)*
Texas MedTech, Inc.
720 MedTech Drive, Houston, TX 77001

Subscribed and sworn to before me at _____, *(City and State)*

this _____ **day of** _____, **20**____.

_____ *(Employee's Signature)*

Employee of the Department of Health and Human Services designated under Act of January 31, 1925, Reorganization Plan IV effective June 30, 1940; Reorganization Plan No. 1 of 1953, effective April 11, 1953; and P.L. 96-88, effective May 4, 1980.

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AFFIDAVIT	SAMPLE NO. DOC1069683
STATE OF Texas	COUNTY OF Harris

Before me, Sidney H. Rogers, an employee of the Department of Health and Human Services, Food and Drug Administration, designated by the Secretary, under authority of the Act of January 31, 1925, 43 Statutes at Large 803; Reorganization Plan No. IV, Secs. 12-15, effective June 30, 1940; Reorganization Plan No. 1 of 1953, Secs. 1-9, effective April 11, 1953; and P.L. 96-88, Sec. 509, 93 Statutes at Large 965 (20 U.S.C. 3508) effective May 4, 1980; to administer or take oaths, affirmations, and affidavits, personally appeared Mary K. Johnson in the county and state aforesaid, who, being duly sworn, deposes and says:

part of MedTech lot number 1610.

This lot of serialized battery packs, identified internally as lot number 1610, was used in the manufacture of an AED (part number 10005-001 Rev. C, lot number 05126, and serial number 160524) which included battery pack serial number 2016327 with a final release of 12/09/2016. The manufacturing operations of this AED are documented on a traveler as part of the device history record and identified that final acceptance activities were completed.

A copy of the label for the finished AED and the battery pack were included in the device history record. The AED was labeled in part "Texas MedTech, Inc.***Houston, TX 77001***Lifesaver Automated External Defibrillator***P/N 10005-001 Rev. C***Lot Number 05126***Serial Number: 160524***Mfg Date: 12/09/2016***" while the battery pack was labeled in part "Texas MedTech, Inc. ***Houston, TX 77001***AED Pro Battery Pack***DC 12V 4.2Ah***P/N 20005-001 Rev. B***Lot Number 1610***S/N 2016327". Associated labeling, including the Instructions for Use, were provided to Investigator Rogers. These labels and labeling represent what is currently in stock at my firm. I also provided a copy of the case carton label that is applied to the shipping container at the time of shipment to the consignee. There are currently 187 finished Lifesaver AEDs in inventory with various lot numbers, all of which include the original battery pack, as documented in Texas MedTech Inventory List, dated 12/11/2019. Investigator Rogers took photographs of our inventory on 12/11/2019 as well. A distribution list was provided to Investigator Rogers which documents allocation of finished Lifesaver AEDs to consignees as of 12/09/2019.

The finished AED, serial number 160524, was allocated to Texas MedTech Sales Order #170215, dated 02/15/2017, documenting the intended sale to Prairie View High School, located at 712 West Prairie Drive, Appleton, WI 54911. The AED was sent to Prairie View High School from our facility in Houston, TX as indicated by Texas MedTech Packing Slip #1732, dated 02/17/2017, with a sales order reference of 170215. The shipment of the finished AED from our facility in Houston, TX to Appleton, WI is documented by FedEx tracking number 5823982513841 with a ship date of 02/17/2017 and delivery date of 02/19/2017.

AFFIANT'S SIGNATURE AND TITLE

FIRM'S NAME AND ADDRESS *(Include ZIP Code)*
Texas MedTech, Inc.
720 MedTech Drive, Houston, TX 77001

Subscribed and sworn to before me at _____,
(City and State)
this _____ **day of** _____, **20**____.

_____
(Employee's Signature)

Employee of the Department of Health and Human Services designated under Act of January 31, 1925, Reorganization Plan IV effective June 30, 1940; Reorganization Plan No. 1 of 1953, effective April 11, 1953; and P.L. 96-88, effective May 4, 1980.

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AFFIDAVIT

SAMPLE NO.
DOC1069683

STATE OF
Texas

COUNTY OF
Harris

Before me, Sidney H. Rogers, an employee of the Department of Health and Human Services, Food and Drug Administration, designated by the Secretary, under authority of the Act of January 31, 1925, 43 Statutes at Large 803; Reorganization Plan No. IV, Secs. 12-15, effective June 30, 1940; Reorganization Plan No. 1 of 1953, Secs. 1-9, effective April 11, 1953; and P.L. 96-88, Sec. 509, 93 Statutes at Large 965 (20 U.S.C. 3508) effective May 4, 1980; to administer or take oaths, affirmations, and affidavits, personally appeared Mary K. Johnson in the county and state aforesaid, who, being duly sworn, deposes and says:

My firm initiated CAPA-188 on 08/02/2017 as a result of increasing customer complaints reporting premature battery pack failures when using an AED to deliver potentially life-saving shock therapy to patients. We have received seven complaints in which a death occurred where the premature battery pack failure of the AED was confirmed to have contributed to the death based on complaint investigations. Medical device reports have not been filed for these deaths.

We made design changes to the battery pack through CAPA-188 and associated design change requests in December 2017. These changes were subject to PMA supplement S015 of P130124 which was approved on 06/25/2018. However, the updated battery pack has yet to be distributed to the field and, as of this inspection, we continue to receive complaints for premature battery failures. We have not recalled any AEDs despite this known malfunction.

Complaint #00411 was received on 08/14/2018 with a report that the AED with serial number 160524 malfunctioned due to battery depletion which may have contributed to the patient's death. A replacement battery pack (serial number 2016348) was sent to the customer via FedEx (tracking number 5823982517863) on 08/16/2018 as shown on Packing Slip #1874. This replacement battery pack is the same design as the original battery pack that has known premature battery depletion failures that resulted in CAPA-188 and associated design changes.

Approximately 500 battery packs with the incorporated design changes to address the premature battery depletion failures have been manufactured by our new supplier, Performance Battery Technologies, Inc., located at 234 Washington Street, Chicago, IL 60614, and are currently being held in inventory at our facility in Houston, TX. However, final acceptance activities have not been performed on the updated battery packs to allow for distribution to the field to mitigate the reported battery pack failures.

Ms. Johnson refused to read, listen to, or sign this Affidavit, per Texas MedTech policy defined in procedure number 120-0001-01, Rev B "FDA Site Inspections."

Sidney H. Rogers
12/11/2019

AFFIANT'S SIGNATURE AND TITLE

FIRM'S NAME AND ADDRESS *(Include ZIP Code)*
Texas MedTech, Inc.
720 MedTech Drive, Houston, TX 77001

Subscribed and sworn to before me at _____,
(City and State)
this _____ **day of** _____, **20**____.

_____
(Employee's Signature)

Employee of the Department of Health and Human Services designated under Act of January 31, 1925, Reorganization Plan IV effective June 30, 1940; Reorganization Plan No. 1 of 1953, effective April 11, 1953; and P.L. 96-88, effective May 4, 1980.

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4-24 – HQ LABS

Laboratory/Center	Commodity/Sample Types	Special Directions	Address
Center for Drug Evaluation and Research (CDER)	Drugs	• Do not forward original C/R and records. • Enclose a copy of the assignment memorandum in the FDA 525 envelope. • Affix the FDA 525 to the officially sealed sample package. • Submit the Original C/R and records to the home division, or forward to the home division if other than the collecting division.	Office of Testing and Research, Office of Pharmaceutical Quality, Food and Drug Administration, 645 S. Newstead Ave., St. Louis, MO, 63110, USA
Center for Food Safety and Applied Nutrition (CFSAN) • Office of Regulatory Science ○ Division of Bioanalytical Chemistry (HFS-715)	Food • Elemental Analysis • Natural Toxins • Nutrients Dietary Supplements • Ingredients • Elemental Analysis • Natural Toxins Cosmetics • Ingredients • Elemental Analysis • Natural Toxins	Conducts laboratory investigations in the broad areas of elemental analysis, natural toxins, nutrients in food, ingredients in dietary supplements, and ingredients of cosmetics.	Food and Drug Administration 5100 Paint Branch Parkway College Park, Maryland 20740
CFSAN • Office of Regulatory Science ○ Division of Analytical Chemistry (HFS-705)	• Food Additives • Allergens, • Pesticides • Dietary Supplements • Seafood Toxins • Food Defense Threat Agents • Industrial Chemical	Conducts laboratory investigations in the broad areas of food additives, allergens, pesticides, dietary supplements, seafood toxins, food defense threat agents, and industrial chemicals that may contaminate CFSAN regulated products	Food and Drug Administration 5100 Paint Branch Parkway College Park, Maryland 20740

CFSAN • Office of Regulatory Science ○ Division of Microbiology (HFS-710)	Pathogens and Toxins in: • Food • Cosmetics Also: Pathogens and Toxins from the processing environment of food and cosmetic facilities.	Develops, optimizes, and validates methods for recovery, detection, identification, and quantitation of pathogens and toxins from foods and cosmetics, and the processing environment. Maintains FDA's food-related gateway to the PulseNet System. Develops and applies subtyping methods to further enhance data generated for Pulsenet, strain identification, and molecular epidemiological investigations.	Food and Drug Administration 5100 Paint Branch Parkway College Park, Maryland 20740
CFSAN • Office of Applied Research and Safety Assessment ○ Division of Molecular Biology (HFS-025)	Food, • For Chemical or specialized equipment or skills needed for analysis Food Packaging Materials Microbiological – Food Pathogens by rapid methods	Analyzes foods when the chemical methodology is under development or unusual equipment or skills are required, such as radioactivity analysis and migration of food additives from food packaging materials. Microbiologically examines samples for potential food pathogens by rapid molecular biological testing using DNA probes, PCR, and DNA fingerprint analysis.	Food and Drug Administration 5100 Paint Branch Parkway College Park, Maryland 20740
CFSAN • Office of Cosmetics and Colors ○ Division of Color Certification and Technology (HFS-105)	Color Additive Samples for Food, Cosmetics	Conducts analyses of color additive samples submitted to FDA for certification, assigns certification lot numbers to compliant lots, and denies certification to non-compliant lots. Develops, optimizes, and validates methods for the determination of components and impurities in certifiable color additives. Develops, optimizes, and validates methods for the determination of color additives in foods and cosmetics. Conducts analyses of foods and cosmetics for color additive content when special skills and expertise are not available in the field.	Food and Drug Administration 5100 Paint Branch Parkway College Park, Maryland 20740

CFSAN • Office of Food Safety ○ Division of Seafood Science and Technology, Gulf Coast Seafood Laboratory (HFS-400)	Fish means fresh or saltwater finfish, crustaceans, other forms of aquatic animal life including, but not limited to, alligator, frog, aquatic turtle, jellyfish, sea cucumber, and sea urchin and the roe of such animals other than birds or mammals, and all mollusks, where such animal life is intended for human consumption. • microbiological and chemical • bacterial and viral pathogen, • natural marine toxins, • aquaculture drugs • products of decomposition	Conducts microbiological and chemical investigation of seafood, including bacterial and viral pathogen, natural marine toxins, aquaculture drugs, products of decomposition, and other contaminants when special skills or equipment required for analysis are not available in the field.	FDA Gulf Coast Seafood Laboratory Iberville Drive Dauphin Island, AL 36528
Center For Drug Evaluation and Research • Division Of Pharmaceutical Analysis (DPA)	Surveillance drug samples • All heparin and insulin samples.	Examines surveillance drug samples collected and shipped under current program directives. Analyzes all heparin and insulin samples.	CDER-OPS-OTR Division of Pharmaceutical Analysis (DPA) 645 S. Newstead, Ave. St. Louis, MO 63110
Center For Biologics Evaluation and Research (CBER)	Biological products	Examines and reviews biological products not covered by a Compliance Program. Prior to shipping a sample, the division should notify either the Sample Custodian, 301-594-6517, or the Regulations and Policy Branch, 301-827-6210, who in turn will notify the Sample Custodian.	Sample Custodian Center for Biologics Evaluation and Research Food and Drug Administration 10903 New Hampshire Avenue WO75-G707 Silver Spring, MD 20993-0002

Center For Devices and Radiological Health (CDRH)	• Bioburden analysis • Bioindicator analysis • Device and GWQAP device samples for physical and engineering analysis • in-vitro diagnostic device • Antibiotic susceptibility testing (including discs) requiring performance testing	WEAC is the primary laboratory for devices and radiation-emitting products. The CDRH Office of Science and Engineering Laboratories accepts medical devices and radiation-emitting products for testing, but only after assignment or approval from CDRH, Office Health Technology	WEAC 109 Holton Street (HFR-NE400) Winchester, MA 01890-1197 Patrick Regan, Director, Analytical Telephone: 781-756-9707 FAX: 781-756-9757
CDRH	Condom and Glove Samples	Send Southwest and Pacific Region condom and glove samples to the Pacific Regional Laboratory (PRS) Send all other condom and glove samples to WEAC.	Pacific Regional Laboratory (PRS) /Pacific Southwest Laboratory 19701 Fairchild Irvine, CA 92612 WEAC 109 Holton Street (HFR-NE400) Winchester, MA 01890-1197 Patrick Regan, Director, Analytical Telephone: 781-756-9707 FAX: 781-756-9757
CDRH	Radiological health samples	Send radiological health samples to: CDRH/OSEL Sample Custodian HFZ-105 WO62, 10903 New Hampshire Ave, Room 4126 Silver Spring, MD 20993 Telephone: 301-796-2558 FAX: 301-796-9795 **Note:** Contact Office of Science and Engineering Laboratories, 301-796-2558 prior to collection and shipment of any radiological product sample.	CDRH/OSEL Sample Custodian HFZ-105 WO62, 10903 New Hampshire Ave, Room 4126 Silver Spring, MD 20993 Telephone: 301-796-2558 FAX: 301-796-9795

Center for Veterinary Medicine (CVM)	Samples of veterinary products, including documentary samples, and labels/ labeling and advertising materials	Samples of veterinary products, not specifically covered by one or more of the CVM Compliance Programs. There are no laboratory facilities at MPN II. If you have questions about sampling or sample destinations, contact HFV-230 and/or the applicable program contact.	Center for Veterinary Medicine Division of Compliance (HFV-230) 7500 Standish Place (MPN II) Rockville, MD 20855
Center for Tobacco Products (CTP)	Tobacco products • Both compliance and surveillance samples	Do not collect samples of tobacco products unless directed by an assignment, approved by the Center for Tobacco Products, Office of Compliance and Enforcement, or by Division Management	Southeast Regional Laboratory (SRL), Atlanta Center for Tobacco Analysis.

4-25 C/R DATA ELEMENTS IN ORDER OF ENTRY INTO FACTS

This exhibit, which was derived from OBIMO work instructions, attempts to clarify entry of data into FACTS for a sample collection report. This exhibit, which presents C/R data elements in order of entry into FACTS from left to right and top to bottom, can assist the collector if used while completing the C/R. This exhibit includes information from IOM chapter 4 (Sampling) and clarifying remarks added in italicized font where needed. See IOM 4.6.2 for an alphabetized list of data elements.

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Sample Number: Select a pre-assigned sample number, using the list of values button, or the system will enter a sample number when the record is saved.

> *Select the number you identified your sample with. This number comes from the group of sample numbers you previously generated in FACTS.*

Sample Class: Make a selection from the following list of values: "Collaborative Study"; "Criminal Investigation"; "District Use Sample"; "Normal Everyday Sample"; "Petition Validation"; "Quality Assurance"; "State Partnership"; "Total Diet."

> *Normal Everyday Sample is the typical choice here. If you have something other than a Normal Everyday Sample, your assignment will indicate that and you should select the appropriate choice.*

Sampling Organization: Make a selection from the list of values. This is the division which actually collects the sample.

> *Typically, this is your home division e.g., BIMOW*.

Collection Date: Enter the date using the format - mm/dd/yyyy. **Note: the default date is today's date. Be careful not to use the default date if the sample was not collected on the date the CR is created. Only one date can be entered; if the sample collection was accomplished over several days, use one date. Be consistent. This date should be used to identify the physical sample and any records attached to the C/R.**

> *Be sure to verify the date appearing in this field as above. Assure the date is the actual date collected.* ***Slow down!*** *This is a critical field.*

Lot Size: Enter the amount of goods on hand before sampling as determined by your inventory of the lot. Include the number of shipping cases and the size of the components, e.g., 75 (48/12 oz.) cases, 250/100 lb. burlap bags, 4/100,000 tab drums, 24 cases containing 48/12/3 oz. tins. If accompanying literature is involved, describe and state the amount on hand. For DOC samples (see Exhibit 4-1 and 4-2), also indicate the lot size, e.g., "one x-ray machine" or "50000 syringes and 1000 promotional brochures."

> *State the size of the lot going from the largest unit to smallest, i.e., from shipping case to immediate container.*

Sample Origin: Choose "Domestic" or "Domestic/Import" from the list of values.

If the product was imported into the United States and has been released for distribution in Interstate Commerce, it is a Domestic/Import. Domestic samples come from products produced in the United States. For bioequivalence samples collected during foreign inspections at foreign Dealers, select Domestic/Import. Although these samples are not being collected from a lot of product which has passed through US Customs and entered domestic commerce, there is currently no Operation Code for a foreign sample.

Sample Basis: Choose the appropriate value from the list. Values have been changed to differentiate between environmental samples and other samples. Compliance = collected on a selective basis, complaint, evidence that there may be a problem, "for cause"; Surveillance = objective basis. For environmental samples, select Environ–Compl for compliance samples or Environ–Survl for surveillance samples. The Other–Compl and Other-Survl basis values are used for all other samples. Official and INV samples can both be either Surveillance or Compliance.

Select from the two choices on the list of values. "Compliance" means the sample was collected on a selective basis as the result of an inspection, complaint, or other evidence of a problem with the product. "Surveillance" means the sample was collected on an objective basis where there is no inspectional or other evidence of a problem with the product. Please note official samples can be either compliance or surveillance, and INV samples can also be either. See IOM Exhibit 4-16 for more information.

Note: When you have observed a violation and this sample is collected as evidence, it is a Compliance Sample. When you have not observed a violation, but are simply collecting a sample at random, such as a bioequivalence sample for drug assay, that is a Surveillance Sample.

Sample Type: Make a selection from the list of values. You can enter only one value. If more than one type applies, choose one and indicate the other in remarks. If the sample is a domestic import, be sure to enter "DI", so that you can enter the foreign manufacturer.

The sample type for all bioequivalence samples will be "Official". Select "Domestic-Import" if applicable. Note: Domestic-Import samples are also Official, however, this is the way the drop-down menu is set up. See IOM 4.5.3.

Consult IOM 4.6.1 and your supervisor to choose the correct Sample Type. This field is actually a part of your sample number. For example, if you collect a Domestic Import Sample, you add the prefix "DI" to your number so that you identify the sample as "DI 123321." Another example is investigational samples, which are collected to document observations such as rodent infestation and/or where interstate commerce does not exist or is not necessary. Filth Exhibits are always investigational samples and would be identified as "INV 123321."

FIS Sample Number: Enter the last two digits of the fiscal year. The remainder of the number will be assigned by FACTS. Note: FIS sample numbers will no longer be required when the FIS is turned off.

For FY 2009 enter 09. FIS is the Field Information System. That system predates FACTS and is still in use for some laboratory operations.

Episode Number: Enter an episode number if applicable.

> ***Pesticide Episode*** *- An "episode" is defined as a violative pesticide (or other chemical contaminant) finding and all samples collected in follow-up to that finding. All samples must be associated with one responsible firm (grower, pesticide applicator, etc.) and one specific time period (e.g., growing season). The Episode Number will be the sample number of the first violative sample collected in a series of samples and is used to identify the other related samples within an episode. The divison must assure that the Episode Number is used within the division and any other divisions which follow-up to the original violative sample. This number must appear in the* ***Episode Number*** *field of the FACTS CR. See IOM 4.6.2.27.8 for examples.*

Related Sample: This field is used to identify a sample number to which other sample information can be linked. When you collect more than one sample from a single shipment or there is more than one sample relating to a possible regulatory action, designate one sample as the "lead" sample. Enter that sample number in this field of the collection record for each related sample. Other related sample numbers should be listed in the Collection Remarks field.

> *The lead sample number is typically the first sample collected. For example, in a violative sanitation inspection you will most likely collect multiple samples. These samples could include samples of product defiled by rodents (including gnawed cardboard cases, urine stained bag cuttings, product located directly beneath urine stains, product randomly sampled throughout the lot, photographs, diagrams of lot, etc.) and filth exhibits (which can include rodent droppings, insect casings, nesting materials, etc.). Designate your first sample as the lead and list this number in the Related Samples field for all other samples collected during the inspection. Note that for the lead sample, this field will be blank. For all other samples where there are not related samples, e.g., a single sample collected, this field will be blank.*

Sample Description: Briefly describe what the sample consists of, i.e., three unopened, 200 tablet bottles; 20 lb. case of iceberg lettuce; or documentary sample consisting of records, literature, and photographs, etc.

Ensure that the field includes a description of the investigational product collected as well as the reference and placebo if applicable.

> *A statement such as, "Sample consists of retention sample for protocol GDC-695-001 consisting of one block containing three total 100g tubes: GDC 695 Gel (kit 1217), Diclofenac Sodium Gel (kit 1219), and Vehicle Gel (kit 1218)." Labeling, documents (including those other than I/S records) or photos, are also described here. For DOC samples you will state that the sample consists of photos, records and observed GMP deficiencies. Include anything here collected to document the violation.*

Collection Reason: Enter the complete reason for collection giving the suspected violation, compliance program guidance manual, and analysis desired. Identify any interdistrict, regional, headquarters initiated, assignment document(s) in sufficient detail so the document can be located, if necessary. If the sample was collected during an inspection to document violations found, state that and indicate the date of inspection. See IOM Exhibits 4-1 and 4-16.

Reference the compliance program (e.g., CP 7348.003, "In vivo Bioavailability- Bioequivalence Studies- Clinical", the assignment memo, and the inspection dates (if applicable). There will not be a suspected violation for surveillance samples. Add the following statement and edit as appropriate, "Sample of bioequivalence

investigational product, reference control and placebo. Sample is representative of test product used in study supporting Protocol (insert Study #)." You will specify the analysis desired as follows: "Collected for drug assay analysis." Include the application number, e.g., ANDA 12345.

Note there are four pieces of information to report for the Collection Reason. 1) Whether sample was collected during and inspection of the Dealer. 2) The Compliance Program and assignment is applicable. 3) The suspected violation. 4) What analysis is desired. For example, the Collection Reason could be completed as, "Sample of bioequivalence investigational product, reference control and placebo collected during EI of Dealer 10/01/2022. Sample is representative of test product used in study supporting Protocol VBD-1212 under ANDA 12345. Collected pursuant to FACTS Assignment #188118 and in accordance with CP 7348.004. Collected for drug assay analysis."

Collection Remarks: Enter any remarks you feel are necessary. Describe any special circumstances. If a 704(d) [21 U.S.C. 374(d)] letter is indicated, include the name, title, E-mail address (if available) and the telephone/fax number of the most responsible person at the firm to which the letter should be addressed. If a 702(b) sample is not collected, describe the specific circumstance and justification for not collecting the 702(b) portion unless it is a device or tobacco product, or the assignment or guide already states why a 702(b) portion is not needed. If the sample is an in-transit sample, state the sample was collected in-transit, from whom sampled (e.g. driver and carrier firm), and where sampled. If the dealer firm is a consumer, the name and address of the consumer should be entered in the Collection Remarks field, and the consumer's state in the State field. You may use a "CR Continuation Sheet", FDA 464a if you need more space.

Note: Confirmation of firm Email address and inclusion in collection remarks is integral in order to provide results in an efficient and timely manner. According to Field Management Directive (FMD) 147, if the firm has agreed to hold products pending FDA results or if the analytical results are laboratory classification 3, the Laboratory Director or their designee shall email the results of analysis to the collecting division's established email account for receipt of analytical results.

Include any additional information required to fully explain the collection. This field is also used to describe chain of custody when necessary e.g., describing what conditions the sample was held under until submitted to the laboratory. The CR Continuation Sheet is used when you have a lot of information to share, such as describing GMP deficiencies, observations, or sub-samples. In the case of a food firm where you have collected multiple subs to document filth conditions or environmental swab samples, you'll want to describe each sub, where it was collected, what it consists of, etc. This will be extremely important information when Compliance is reviewing the sample results and your report for any regulatory follow-up.

Associated Firms Section

Resp. Firm Type: Choose the appropriate type from the list of values for the firm most likely to be responsible for a violation. For a 301(k) [21 U.S.C. 331(k)] sample the responsible firm should be "Dealer". You should only enter one firm with the firm type you designate as the responsible firm type.

This designation requires some thought on the collector's part. Think about the violation you are documenting. Who caused the product to become adulterated? The example of a 301(k) sample listed above says to select the Dealer as the Responsible firm. This is because of the definition of a 301(k) violation. 301(k) prohibits the adulteration of a product <u>after</u> shipment in interstate commerce. Therefore, the Dealer caused the adulteration sometime after receipt in interstate commerce. When you

are documenting a 301(a) violation, shipment of an adulterated product in interstate commerce, your responsible firm will be the firm shipping the adulterated product or causing the shipment of the adulterated product. It can be the Manufacturer, or it can be the Dealer. A little thought on what you are documenting will make this designation clear.

Dealer is Consumer? Note: If the dealer firm is a consumer, the name and address of the consumer should be entered in the Collection Remarks field, and the consumer's state in the State field. When the sample is an in-transit sample (see IOM 4.1.4.2.1), enter the consignee of the lot as the dealer and state in collection remarks the sample was collected in-transit, from whom sampled (e.g., driver and carrier firm), and where sampled.

Commonly used for Consumer Complaint samples when you collect a sample from the complainant. Be sure to consult with your supervisor prior to collecting samples from a complainant.

FEI Number: The FEI number is a 10-digit unique identifier, which is used to identify firms associated with FDA regulated products. Use the Build button to query the database and find an FEI for firms associated with your sample. If one does not exist, FACTS will assign one to the firm. Take care in entering search criteria to avoid creating unnecessary FEI numbers. **You must enter an FEI for a dealer on every CR, unless you check the box indicating the dealer is a consumer.**

When selecting the FEI, be very careful to select the correct firm. Some tips: compare the street addresses of firms retrieved by the search, look for firms that are Workload Obligation = Y and Operational Status = OPR, if your firm is not returned by your first search don't give up, try different criteria. More often than not, we will be collecting samples from firms that we have been to before. However, if it's a new firm you will need to add that firm and notify the OEI Coordinator or your supervisor. We want to assure we do not add duplicate firms into the FACTS OEI, thus maintaining the accuracy of the OEI.

Product Section

Product Code: Enter the 7-digit product code. Use the Product Code Builder for guidance. When 301(k) samples are collected, the full product code of the finished product must be entered. See IOM exhibit 4-1. See IOM 4.6.2.27.7 for product codes for filth or evidence exhibits. Special product code considerations include environmental samples. See environmental sample identification instructions under IOM 4.3.6.6.2.

A tip for building a product code within FACTS or Product Code Builder: Enter the name of the product in the Product Name field and click on ExeQry (Execute Query). This will return a list of products containing that text for you to select from and continue to build the code.

Brand Name: Enter the Brand Name of the product. This is found on the labeling of the product. It is important to identify the product completely so the compliance officer can communicate accurate information to the court and the U.S. Marshal in the event of a seizure.

Typically found on the labeling of the product such as, "Blue Bunny" carrots. Sometimes in the case of DOC samples for medical devices you may need to dig a little to find out if there is a brand name.

Product Description: Enter a complete description of the product including the common or usual name and the product packaging/container system. For example, aspirin tablets packed in clear, non-flexible plastic bottle with white screw on top with yellow stick-on label and black printing. Bottles packed in white, paperboard boxes with black printing. Paperboard boxes packed in brown cardboard boxes with black printing. If you need additional space, continue the description in remarks. See IOM exhibit 4-1.

Completely describe the product and how it is packaged and packed in shipping containers as appropriate. Note that you go from the product to the outer most layer of packaging.

Product Label: Quote pertinent portions of the label such as brand name, generic name, quantity of contents, name and address of manufacturer or distributor, code, etc. In the case of drugs, quote the potency, active ingredients and indicate whether Rx or non-Rx. Quote sufficiently from accompanying literature to identify. In the case of a Documentary Sample, sufficiently describe the article to identify what is sampled.

NOTE: When the product sampled is packaged in a carton, shipping case or similar container, quote the pertinent labeling from the container.

When quoting from a label, or labeling, use exact spelling, capitalization, punctuation, arrangement, etc., as found on the original label(ing). Use asterisks to indicate any omissions.

*The label quote shall be an exact quote of the label. Use the same upper and lower case letters, misspellings would be quoted as appearing on the label. Start with the principal display panel and work your way top to bottom then left to right around the label. For ingredient listings, include any suspect ingredient and major ingredients. Use *** to show omissions of text and graphics. As an example, the sampled product bears an adhesive label which reads in part, "Walgreens *** Deluxe Mixed Nuts No Peanuts Net Wt. 10 OZ (283g) *** INGREDIENTS: Cashews, Almonds, Brazil Nuts, Filberts, Pecans, *** Distributed by: Walgreen Co. Deerfield, IL 60015-4616 ***". Do not use asterisks to indicate a new line of label or panel of the label. Only use asterisks to indicate you have left something out.*

Documents Obtained: Click on the "Documents Obtained" button to enter Document Type, Document Number, Document Date and Remarks for any records collected to support a violation or show interstate movement of the product sampled. Enter an identifying number and date for invoices, freight bills, bills of lading, etc. Include the name and title of person signing any affidavits in the Remarks field. Be sure to describe the reason each document attached to the collection record was obtained. For example, when referring to a bill of lading, indicate that it was collected to document the interstate movement of the product. Also indicate which documents were collected to document specific violations encountered during inspections. State the number of pages for each document if it contains more than one page and refer the reader to the appropriate section/page of the document which shows the deviation you are documenting. Indicate the number of photographs attached. Depending on the sample and what you are trying to document, you may use the document number to record the actual number of the document (i.e., invoice number or bill of lading number) or to order the documents attached. You should order your documents in a manner that allows easy review (be guided by your supervisor or Compliance Branch). This section may also be used to list C/R attachments including FDA generated forms. See IOM exhibit 4-1.

Remember that documents attached to the C/R are to be identified with the sample number, date of collection and collector's initials.

Manufacturing Codes: Click on the "Manufacturing Codes" button to enter and identify all codes, lot numbers, batch control codes, etc., and how they are displayed on labels, cartons, and shipping containers. Enclose the code in quotes, e.g., "code". For example, code embossed on can cover, "87657888" or code applied in ink on side of carton, "0987878". Also indicate the manufacturing codes used on products for which a DOC sample was collected, for example, "serial number "ABC" stamped on metal ID plate." See IOM Exhibit 4-2.

Enter any expiration dates in the Exp Date field.

Be sure to define what the code is e.g., lot number, batch number, serial number, production date, etc. If a two line code is employed by the manufacturer (such as with many canned products), it may be expressed like "12345AGB / GAV45833," where the slash indicates a separate line code.

Sample Flags: Click on the "Sample Flags" button to choose an appropriate flag using the list of values. See 4.6.2.27 and exhibit 4-15.

IOM 4.6.2.27 contains a listing and description of Sample Flags. These are used to alert the reader of your C/R what the sample is documenting if further clarification is necessary. The Sample Flag will be printed at the top of your hard copy C/R. For example, when you collect a 301(k) sample, the flag will indicate this is a 301(k) sample and alert the reader to the fact that you are documenting adulteration after shipment in interstate commerce. Use the Flag Remarks field to state the product or ingredient which has moved in interstate commerce and you have documented.

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Collection Method: Describe how you collected the sample and which subs are the 702(b) portion. Relate the number and size of the sampled units and subsamples to show how each was taken, e.g., "Two cans of product randomly collected from each of 12 previously unopened cases selected at random." Note any special sampling techniques used, e.g.: "Subs collected using aseptic technique and placed in sterile glass jars or whirl-packs" or "Subs 1-10 consist of approx. 1# of product. Subsamples 1-10 collected from bulk storage Bin #1 composited in unused, brown, paper bag." Completely describe the collection method of each sub of selective samples with multiple subsamples, including your observations of the conditions, e.g.: "Two live insects collected from seam of bag #2. Live insects were observed exiting bag and two were collected upon exit." You will normally need to use a continuation sheet to describe collection of all subsamples and your description of the lot "bag-by-bag" examination. See IOM 4.7.2.1 regarding sub identification.

Describe exactly how you collected the sample. Describe selective sampling technique if used. For example, "Two Live insects collected from seam of bag #2 and two live insects collected from seam of bag #12 (see diagram of lot sampled). Insects were seen entering and exiting bags. Insects were collected upon exit." In a rodent or insect infested warehouse, you will most likely need to use the C/R Continuation to fully describe the subs you collect and their relationship to the depth of the adulteration of product and infestation of the warehouse.

State: Select the State where the sample was collected. This field is optional for many samples. Always use it for pesticide samples.

Optional field, use for Pesticide Samples. Use the LOV (List of Values) button to select the state.

County: Select the County where the sample was collected (or grown if appropriate, i.e., a pesticide sample of an agricultural product.) This field is not needed for many samples. Use for pesticide samples to aid in later communication with State officials in the event of a violative result.

This field should be used to identify where the agricultural commodity was grown. In order to identify the county where the product was grown, you will either need to be collecting the sample from the grower or have documentation demonstrating shipment from the grower to the dealer. If the product is in a container bearing a label, do not simply assume any identified location is the actual location where the product was grown. It is common practice to reuse shipping crates in the produce industry.

Country of Origin: Select the Country of Origin, if known. This is a field of particular need when the sample is a Domestic Import Sample.

Products sampled that had been imported into the United States and released to commerce by US Customs and Border Protection are Domestic Import samples. Obtain documentation of their entry (invoices, bills of lading, Customs Form 3461, etc.) where necessary to support a case involving the Importer of Record. Remember that these samples will be identified with a prefix to the sample number of DI.

Estimated Value: Enter the estimated wholesale value of the lot remaining after sampling. Obtain this information from invoice or other records. (This is not the value to be used for seizure bond purposes; however, it may be used by the division to evaluate whether seizure is an appropriate action.) Estimate value if you have no documentary reference. For DOC samples (see IOM Exhibits 4-1 and 4-2), indicate the estimated value of the lot. If the DOC sample is collected to document a lot that has already been shipped, estimate the value, or obtain a figure from your documentation, which represents what was shipped. Many times, a DOC sample is collected merely to establish interstate commerce, in those situations, the value of the goods that traveled, or will travel, in interstate commerce is what is needed.

Estimated Value: It may be difficult to estimate the value of a bioequivalence sample. If the firm is not able to provide you with the value of the lot remaining after sampling, use the estimated cost of the innovator if possible. If you cannot estimate, leave blank and note in the Collection Remarks, “Estimated Value is unknown.”

For pesticide samples, try to obtain the size of the field from which the produce was harvested. Have the dealer/grower provide you with the estimated yield per acre and determine the estimated value based on the wholesale value of the expected yield minus your sample. Note: For DOC 301(k) samples where no product is remaining the value will be $0. For bioequivalence samples, review the documentation of the shipment to the site to determine if values are included.

Sample Cost: Enter the cost of the sample. If no charge, enter 0. If, as a last resort, you use your personal credit card to pay for the sample, enter the amount paid in this field and select "Credit. Card" in the Payment Method field. If you are unable to determine the cost of the sample and the firm states they will bill you later, enter the estimated cost in this field and state that it is an estimate in the Collection Remarks field.

Note that the "Credit Card" option is for your personal credit card, not the Government credit card. You are to obtain a cash advance from an ATM or bank and use cash to pay for samples. If the firm will bill the agency for samples, obtain the invoice to submit with your C/R if at all possible.

Payment Method: Select one of the following from the from the list of values: "Billed"; "Borrowed"; "Cash"; "Credit Card"; "No Charge"; "Voucher". The "Credit Card" option means you used your personal credit card as a last resort.

Use the LOV button to access the drop down menu. Again, note that credit card is for your personal credit card, not the Government-issued credit card.

Receipt Issued: Select "FDA472", "FDA484", or "None" from the list of values.

Use the LOV button to select which type of receipt you issued. You will only use an FDA 472 if you collect a sample from a carrier, such as an in-transit sample from a truck.

Carrier name: Enter name of the transportation company who transported the goods in interstate commerce if known at the time of preparation of the CR. You may need to obtain this later to fully document interstate commerce. In the case of a 301(k) sample, this is the transportation company who moved the component you are documenting across state lines. For a 301(a) sample documenting the shipment of a violative product in interstate commerce, enter the name of the carrier utilized by the manufacturer or distributor to carry the goods across state lines.

Note that this is a transportation company, not to be confused with a Shipper. A Shipper is an Establishment Type and is the entity responsible for causing the interstate movement of the product.

Date Shipped: Enter date in the format, mm/dd/yyyy. This is the date of interstate shipment. Obtain it from the documentation you collected to document interstate movement of the product. Identify the document you used to determine this date in the "Documents Obtained" section.

Enter the date that the product was shipped in interstate commerce. This date should be obtained from a shipping record such as a bill of lading, waybill, freight bill, etc.

Consumer Complaint Number: If the sample relates to a consumer complaint, select the Sample Flag for Complaint Sample and enter the complaint number in the Sample Flag Remarks. This way it is easy to identify what Complaint the CR is related to and more accessible in reporting.

Recall Number: If the sample was collected as part of a recall investigation where the recall number is already known, enter the recall number.

If you conduct an inspection/investigation and collect a sample as follow-up to a recall, enter that recall number here. Although any routine sample collection may lead to a recall, at the time of sampling you would not know the recall number.

How Prepared: Explain how the sample was prepared prior to submission to the laboratory; how you identified some or all the units; and how you wrapped and sealed the sample. Note any special preparation methods such as fumigation, frozen, kept under refrigeration, etc., and the form in which the sample was delivered to the laboratory, e.g., in paper bags, original carton, etc. If coolants or dry ice were used, indicate so here. It is important to be specific as to how you protected the integrity of the sample and the chain of custody, e.g., "Subs identified as noted (describe how 702(b) portion was prepared/handled – see IOM 4.7.2.1), placed in unused, brown, paper bag; bag taped shut and FDA seal completed (as noted) and applied, bag ID'd as noted in pen/ink. FDA 525 attached to sealed bag, placed in brown, cardboard box and prepared for shipment, then delivered to district security guard desk for UPS pickup".

Include here the identification of sub samples (referencing the block 'Collector's ID on Package) and exactly how you packed the sample. Did you wrap in bubble wrap? Did you tape lids down? Did you use Styrofoam peanuts or cooling materials? Include everything you did to the sample from the point you collected it and prepared it for sample submission/shipment. Also, be sure to include that the sample was officially sealed and reference the block 'Collector's ID on Seal.' If the sample was not prepared, sealed, and shipped the same day as collected, use 'Collection Remarks' to describe your efforts to maintain the integrity of the sample and chain of custody.

Collector's ID on Package/Document: As the Sample Collector, quote your identification placed on the packages, labels, etc., e.g., "55563 12/5/05 SAR". See IOM 4.6.2.11. When multiple units are collected, all or at least a portion should be labeled as subsamples. Subsample numbers need to be included on the C/R and in the EIR. You may include the sub numbers used in this block outside of the quotes, e.g., "55563 12/5/05 SAR" subs 1-30.

Quote exactly as you identified the sample. What does the "at least a portion" reference mean? When collecting samples with a large number of identical subs, such as 30 packages of shrimp that are packaged exactly the same from the same lot, it may be permissible to identify the first six subsamples with the full sample identification and the remaining subs to be identified with the sub number only. Check with your supervisor for the division policy. Note that every subsample collected will bear the sub number as this correlates to the shipping container you collected it from. As you are collecting your samples, you identify the carton, case, shipping container with FDA, sample number, sub number, date, and your initials. This allows identification that the container was opened and sampled by FDA as well as which carton which sub was collected from. Sometimes it is necessary to return and collect an additional sample from the same lot and sometimes from the same carton as a particular sub was collected from.

Collector's ID on Seal: Quote your identification used on the Official Seal applied to the sample, e.g., "55563 12/5/05 Sylvia A. Rogers". See IOM 4.6.2.11 and Exhibit 4-17. If you use the FDA metal seal, enter the words "Metal Seal" followed by the seal identification and number, e.g., "U.S. Food & Drug 233", entering the actual number of the seal used. Samples need to be kept under lock or in your possession, until sealed. The Collection Remarks field needs to describe any discrepancy between the date sealed and the date collected. Normally, the sample should be sealed on the same day as collected.

If you are unable to seal the sample on the same day of collection, describe what steps you took to maintain the sample integrity and chain of custody. For example, "Sample held under lock and key in sample preparation room until sealed on 12/5/05."

Sample Delivered To: Enter to whom you delivered the physical sample. If delivered to your own sample custodian under seal, show delivery to servicing laboratory or sample custodian. If delivered to an analyst, report e.g., "In person to Analyst Richard R. Doe." If you shipped the sample, enter the name of the carrier to whom the sampled was delivered. Enter the Government Bill of Lading Number, if used. If the sample is shipped by air, enter the air waybill number. If shipment is by parcel post, give the location of the post office, e.g., "P.P., Austin, TX." For a DOC sample, leave this field blank. If the sample is being sent to a non-FACTS laboratory, enter the laboratory here.

If delivered to the office secure lobby for pick up by carrier state so such as, "Delivered to BLT-DO secure lobby for FedEx pick up AWB #_____."

Sample Delivered Date: Enter the date on which the sample was delivered to the laboratory or for shipment. For DOC samples, you must leave this field blank. If you make an entry, you must enter a laboratory.

CR & Records Sent to FACTS Org: Enter the District Office of the collecting CSO. For foreign human and animal food sample collections, select FOR-HAF as the division from the dropdown menu and send the hard copy C/R and all documents to the Division of Foreign Human and Animal Food Operations.

Storage Requirements: Select from the following list of values: Ambient; Frozen; Refrigerated.

Storage requirements are those that the sample was stored at when collected or required based on situation. State how the sample should be stored once received by the sample custodian. Remember to complete the FDA 525 with the same information and to include any special preparations in the 'How Prepared' block.

Dairy Permit Number: Enter if applicable. If you are collecting samples from a dairy, obtain this number from the firm.

704(d) Sample:

Check the 704(d) box if all answers to the following questions are "yes,":

1. Was the sample collected a food?

2. Was the sample collected during an inspection?

3. Was the sample collected from an establishment where food is manufactured, processed, or packed?

4. Was the sample collected to ascertain whether such food consists in whole or in part of any filthy, putrid, or decomposed substance, or is otherwise unfit for food?

Note: Guidance on 704(d) is provided in FMD-147 including examples of what constitutes "unfit for food".

Include in the Collection Remarks the name, title, email address (if available) and telephone/fax number of the most responsible person at the firm. See also IOM 4.6.2.9.

National Drug Code: Enter if applicable

For samples of drug products.

CRx/DEA Schedule: Choose the appropriate schedule from the list of values, if applicable.

For samples of controlled substances.

702(b) Portion Collected: Check this box if the sample you collected contains a 702(b) Portion of any food, drug or cosmetic to be held by FDA for release to the owner or person named on the label for their own analysis. This includes samples where 1) the sample schedule already accounts for the 702(b), 2) you collected in duplicate and separated the duplicate out and 3) you collected in duplicate and did not separate the duplicate out. If you did not separate the 702(b) portion, note this in the remarks so the laboratory can separate the 702(b) portion. If no 702(b) portion was collected, do not check this box, and provide reason for non-collection in the Collection Remarks section (4.6.2.9).

When the sample size includes the 702(b) portion, you will check this box although you did not collect a separate portion to be reserved, it is intended that the laboratory will portion out the reserve and maintain, if possible.

Collection PACs Section

PAC Code: Enter the Program Assignment Code (PAC), which is most correct, from the list of values. If the PAC on your assignment is not listed, discuss with your supervisor or FACTS Lead User.

Enter all PACs you collected subs for analysis. When collecting samples, you should try to be as creative as possible. If collecting grain for pesticide analysis and that grain can go either to human food or animal food production, select PACs for both human pesticides and animal feed contaminants. Also, try to think of sampling for multiple PACs when possible. Grains is a good example here also. If collecting grains for pesticides, consider collecting a portion for Mycotoxin analysis as well. You will need to verify the labs conducting the analyses to ensure you ship your samples correctly.

FACTS Org Section

Sample Sent To: Collecting divisions are instructed to submit samples utilizing the Lab Servicing Table (LST) Dashboard located on the intranet on the ORS Sample Distribution site. See IOM 4.6.3. If you are splitting the sample among multiple laboratories for various analyses, enter each laboratory separately. Generally, in that case you will have more than one PAC code. If, because of your assignment, you are aware the sample should be forwarded to a second laboratory after the first analysis is complete, include that information in the Collection Remarks field. However, you should only enter a laboratory in this field if you are sending the sample there, not if the laboratory will be expected to forward it. For a DOC sample, leave this blank. If the sample is to be sent to a non-FACTS lab, leave this field blank, enter the lab in the Sample Delivered To field, print a copy of the collection record and enclose it in the FDA 525 attached to the sample.

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5.1 – General Inspection Information

This chapter will provide you with inspection guidance. It consists of both a general section and sections related to specific product categories. You should become familiar with the material in both the general section and your product specific area.

5.1.1 – Definition / Purpose of Inspections

An inspection, as described in Section 704(a)(1) of the Food Drug & Cosmetic (FD&C) Act [21 U.S.C. 374], involves duly designated officers or employees of the FDA physically entering (at reasonable times and in a reasonable manner), establishments subject to regulation under the Act to determine compliance with applicable FDA requirements (IOM 2.2.3). There are three general categories of inspections:

- **Surveillance (also called routine) inspections**, which are conducted to generally determine or monitor a firm's compliance with regulatory requirements.
- **Pre-approval, pre-market, or pre-license inspections**, which are conducted, when necessary, as part of the review of an application to market a new product.
- **For-cause inspections**, which are prompted when there is reason to believe a facility has serious manufacturing problems, or to investigate a specific problem/product complaint that has come to FDA's attention.

5.1.2 – Inspectional Approach

Your inspectional approach may vary depending on the reason or basis for the inspection. You should determine, during your preparation, what type of approach will work best and prove most effective for the assignment. This may mean focusing your examination on a specific location within the facility or on a particular phase of manufacturing associated with a potential concern. (For example, if you are following up on a complaint alleging records are not being contemporaneously recorded during production activities, you may want to observe the manufacturing conditions immediately after displaying FDA credentials and issuing the FDA 482, Notice of Inspection, before holding your introductory meeting or walkthrough of the plant.)

5.1.3 - Authority to Enter and Inspect (Domestic, Foreign)

(See IOM 2.2 for detailed information about your statutory authority to enter and inspect firms.)

Keep in mind that it is your obligation to fulfill the requirements described below under 5.1.4. A failure to do so may prevent use of evidence and information obtained during the inspection.

Note, too, that you may occasionally be accompanied on your inspection by other officials. These may be state or local officials who have their own inspectional authority, or other officials who do not have authority to enter the firm. You should obtain permission from the firm's most responsible individual if officials without inspectional authority wish to accompany you during your inspection. You should document in your establishment inspection report (EIR) instances in which any non-FDA officials accompany you during your inspection, and whether they entered under their own authority, or through the permission of an individual at the firm. Be sure to identify, by name and title, the responsible individual giving permission. (See IOM 5.5.1 and 5.3.4.6.2 for more).

5.1.4 - Responsibilities of Investigators

Section 704 of the FD&C Act sets requirements on how you should conduct inspections.

Accordingly, it is your responsibility to conduct all inspections at reasonable times, within reasonable limits, and in a reasonable manner. Proceed with professionalism, using ethical behavior, diplomacy, tact, and consideration. You are expected to dress neatly, professionally and in a manner that is appropriate for your assigned duties. When possible, you should conduct your inspection on consecutive business days. If there will be breaks in the inspection, you should advise firm management promptly and tell them when the inspection will resume (see IOM 5.5.1.1). During the inspection, you should update the firm management periodically to discuss your findings and any objectional conditions per IOM 5.5.12.1.

It is also your responsibility to understand the authority the FDA has under the Act and any associated regulations, as certain authorities pertain to specific products. (IOM Chapter 2.2.3 describes FDA's authority to inspect different product commodities, while IOM Chapter 2.2.4 describes the limitations of those authorities.)

Above all, remember that during any inspection in which you find or collect evidence of conditions indicating a reasonable probability that the associated products will cause imminent and serious adverse health consequences or death, you should notify your supervisor immediately.

5.1.4.1 – FDA Credentials

Display your FDA credentials to the most responsible individual onsite at the time you arrive to initiate the inspection at the firm[1] or the facility you are inspecting. The most responsible individual may also be the top management official for the firm. The top management official refers to the most responsible individual for the overall company, corporation, business, etc. However, the top management official may or may not be present during an inspection. (See IOM 5.5.1.) In a team inspection, remember that all FDA participants must display their individual credentials. Team leaders should ensure all participants have valid credentials before entering the firm.

NOTE: Although management may examine your credentials and record their number, as well as your name, do not permit your credentials to be photocopied. Federal Law (18 U.S.C. 701) prohibits photographing, counterfeiting, or misusing official credentials. Additionally, do not permit a firm to take your fingerprints. If the firm insists on taking your fingerprints, contact your supervisor.

5.1.4.2 – Forms

This section summarizes several forms you may use, as required, during most inspections. It is important to issue the correct form to the correct person. The Act specifically directs you to issue forms to "the owner, operator, or agent-in-charge."

5.1.4.2.1 - Written Notice

After showing your credentials, issue the original, properly executed, and signed FDA 482, Notice of Inspection, to the most responsible individual at the firm. Keep a copy for submission with your report. A Notice of Inspection is not required to be issued during foreign inspections (refer to 5.5.8); however, credentials should still be presented to the most responsible individual at the firm.

In a team inspection, all FDA participants must sign the FDA 482. If an FDA employee or employees join a team inspection *after* the issuance of the FDA 482, a new FDA 482 must be issued and signed, but only by the new participant(s).

If any errors are noted while issuing the FDA 482, you should make any necessary additions, deletions, or corrections, but be sure to notate them in this way: strike-throughs for deletions, brackets [ ] for additions, and initials and dates next to all changes.

[1] The terms firm and establishment are often used interchangeably. In the context of this chapter the terms mean the specific location being inspected. In some circumstances, a "firm" may be an individual (for example, a clinical investigator).

5.1.4.2.2 – Written Observations

Upon completing the inspection but before leaving the premises, provide the most responsible individual at the time of closeout (this would be the top management official if they are present) with your inspectional findings on an FDA 483, Inspectional Observations; an FDA 483a, Foreign Supplier Verification Program (FSVP) Observations (for FSVP inspections); or an FDA 4056, Produce Farm Inspection Observations (for produce safety inspections). (For more details, see Section 704(b) of the FD&C Act [21 U.S.C. 374(b)] and IOM 5.5.10 and 5.5.11.6. For details on the FDA 4056 see Exhibit 5-20)

5.1.4.2.3 – Receipts

When you collect any physical sample during an inspection, you must issue an FDA 484, Receipt for Samples, to the most responsible individual (or top management official if present). As with written observations, the original receipt is to be issued to the most responsible individual, upon completion of the inspection and prior to leaving the premises, with a copy to be kept for submission with your report. (See Section 704(c) of the FD&C Act [21 U.S.C. 374(c)], IOM 5.5.13.5, and 4.2.5 for more information on issuing the FDA 484.)

5.1.4.2.4 - Written Demands or Requests for Information

This section does not address requests for records under Section 704(a)(4) of the FD&C Act [21 U.S.C 374(a)(1)] which provides FDA authority to obtain records "in advance of or in lieu of an inspection". Please talk to your supervisor if you intend to obtain records under 704(a)(4).

There are several methods of requesting records. These may include a request for information based upon the following: Low Acid Canned Food (LACF) or Acidified Food (AF) regulations, FDA 482d, Request for FSVP Records, 703 written requests, and requests for records under the Bioterrorism Act (for more, see IOM 2.2.3.1 and 5.8.1.1).

Per CPG Sec. 160.300, any evidence associated with Requests for Records under Section 703 of the FD&C Act [21 U.S.C. 373], in other words obtained in response to a specific written request under Section 703, cannot be used in a criminal prosecution of the person from whom the evidence was obtained. With supervisory approval, in certain circumstances, you may decide to issue a 703 written request when the significance of the evidence is crucial to protecting the public health. (See IOM 4.4.4.2 for more information, including procedures for requesting records under Section 703 authority.)

5.1.4.3 – Business Premises

IOM 5.1.3. describes FDA's authority to inspect firms operating at a business location. A few unique business premise situations are described below.

5.1.4.3.1 – Premises Used for Living Quarters

All inspections where the premises are also used for living quarters must be conducted with a warrant for inspection, unless the inspection qualifies as one of the following:

- **Owner Agreeable** – The owner or operator is fully agreeable and offers no resistance or objection whatsoever. In this case, clearly document in the EIR that you are inspecting a residence and that the owner was agreeable.
- **Physically Separated** – The actual business operations to be inspected are physically separated from the living quarters by doors or other building construction, such that there is a distinct division of the premises into two physical areas: one for living quarters and the other for business operations. Do not enter the living quarters.

In both cases, proceed as any other inspection with the appropriate presentation of credentials and issuance of a Notice of Inspection.



Special note: For personal safety precautions, it is recommended that at least two credentialed FDA employees are present when conducting inspections in a residence.

5.1.4.3.2 – Facilities where Electronic Products are Used or Held

Section 537(a) of the FD&C Act [21 U.S.C. 360nn] provides the FDA with the authority to inspect the facilities of such manufacturers in certain circumstances. However, this authority is limited. The agency must find "good cause" that methods, tests, or programs related to radiation safety (such as noncompliance with a standard) may be inadequate or unreliable. (IOM 2.2.3.4 describes the authority for these inspections in detail.

IOM S.15.2 describes important radiation hazard safety considerations.

5.1.4.3.3 – Multiple Occupancy Inspections

You are required per Section 704(a)(1) of the FD&C Act [21 U.S.C 374(a)(1)] to issue a Notice of Inspection, FDA 482, to each firm inspected.

5.1.4.3.4 – Multi-Site Establishments

When firms have operations located in different sites or buildings, you should use your best judgment to determine when multiple FDA 482 forms need to be issued. For sites located a fair distance apart, it is preferable to issue an FDA 482 to the most responsible individual at each site. A helpful rule of thumb: If the sites or buildings are within walking distance, your original Notice of Inspection should be considered sufficient to cover both sites. During your initial interview with management, after you issue the FDA 482, make sure you clearly indicate to firm management the facility and sites you intend to inspect. Remember that while the Act requires the issuance of a Notice of Inspection, it does not prohibit issuing multiple notices, if management so requests. As with all our work, your good judgment and knowledge of the official establishment inventory (OEI) and the FD&C Act, are necessary in deciding what to do.

5.1.4.4 – Products Imported Under the Provisions of Section 801(d)(3) of the FD&C Act (Import for Export)

Products otherwise not permitted entry into the United States may be imported under the authority commonly called “Import for Export.”

The FDA Export Reform and Enhancement Act of 1996 (PL 104-134 and 104-180) amended the FD&C Act by adding Section 801(d)(3) of the FD&C Act [21 U.S.C. 381(d)(3)] ("Import Export") which permits the importation of unapproved drug and medical device components, food additives, color additives, and dietary supplements intended for further incorporation or processing into products destined for export from the United States. Section 801(d)(3) was subsequently amended by Section 322 of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (Bioterrorism Act), Public Law 107-188, which specified certain requirements an importer must satisfy in order to import a product under this Section. (See IOM 6.1.4.6 for more.)

5.1.4.4.1 – Requirements for Bioterrorism Act

These requirements must all be met by the importer/owner:

- A statement confirming the intent to further process such article, or incorporate such article into a product to be exported,
- The identification of all entities in the chain of possession of the imported article,
- A certificate of analysis "as necessary to identify the article" (unless the article is a device), and
- The execution of a good and sufficient bond providing for liquidated damages in the event of default, in accordance with U.S. Customs.

In addition, the initial owner or consignee must keep records showing the use of the imported articles and must be able to provide upon request a report showing the disposition or export of the imported articles. An article imported under this section, and not incorporated or further processed, must be destroyed, or exported by the owner or consignee. Failure to keep records or to make them available to the FDA, making false statements in such records, failure to export or destroy imported articles not further incorporated into finished products, and introduction of the imported article or final product into domestic commerce are all Prohibited Acts under Section 301(w) of the Act.

Filers making entry under the Import for Export provisions must identify entry/line submissions with the intended use code Import for Export and Affirmation of Compliance "IFE" (Import for Export), and supply FDA with written documentation stating the product is entered under the Import for Export provisions. A Certificate of Analysis (as necessary) and identification of all involved entities must be submitted in writing to the import program division. The import program division will ensure all written documentation has been uploaded to the entry/line. The Office of Import Operations (OIO) will make IFE entry information and documentation available to the home program division of the initial owner or consignee through the "*Import for Export - IFE*" section in OSAR Firm 360 and ORADSS report "*IMP046 Import for Export Entry Lines and Documents*"

5.1.5 – Confidential and Trade Secret Information

You have certain responsibilities under the FD&C Act, Section 301(j); Sections 359(d) and 306© of the Public Health Service Act; and Section 1905 of the Federal Confidential Statute (18 U.S.C. 1905) regarding protection of confidential material obtained during your official duties. See IOM 1.4.

The FDA has the authority to inspect most types of records including, trade secret and other confidential records. The authority does not extend to certain records such as financial data, sales data (other than shipment data), pricing data, personnel data (other than data as to qualification of technical and professional personnel performing functions subject to this chapter), and research data (other than data required to be maintained under regulations or the Act).

Manufacturers may mark information within submitted records as "confidential" or "trade secret." You may advise manufacturers they may mark as confidential those records they deem proprietary to aid the FDA in determining which information may be disclosed under Freedom of Information Act (FOIA). The firm choosing to mark or not mark a document does not change whether the information may be subject to release under the Act. (See 21 CFR 20.61(d).)

Some firms often contend that their entire process and formulas ae "trade secrets." However, the term "trade secret" should only be used to cover the manufacturing process and/or quantitative-qualitative formulation that is truly unique to the firm (see 21 CFR 20.61(a)). Confidential information, in particular, includes commercial or financial information customarily kept private, or at least closely held, by the submitter. (See 21 CFR 20.61(b).)

Therefore, and per 21 CFR 20.27, a firm's act of simply "marking records submitted to the FDA as confidential, or with any other similar term, raises no obligation by the FDA to regard such records as confidential, to return them to the person who has submitted them, to withhold them from disclosure to the public, or to advise the person submitting them when a request for their public disclosure is received or when they are in fact disclosed." The same applies to other designations that appear to be frivolous, as outlined at 21 CFR 20.61(f)(5).

Any designations whether in part or in whole by the submitter must clearly meet the definitions of "trade secret" or "confidential commercial" information. Furthermore, justification of why this information should be withheld may be requested as needed by agency information disclosure staff.

Additionally, "data and information submitted or divulged to the FDA which fall within the definitions of trade secret or confidential commercial or financial information are not available for public disclosure" (21 CFR 20.61(c)) and will be

held in confidence by the FDA unless release is required or authorized by regulation, statute, or court order. (See also 21 CFR 20.28.)

Sharing of information (regardless of the manner) must comply with the Freedom of Information Act (FOIA); other applicable laws, such as the Privacy Act and the Trade Secret Act; and FDA procedures and regulations. For more on other potentially relevant laws, see 21 CFR Part 20 Subpart–D - Exemptions, other CFR disclosure references, and RPM Chapter 3, Commissioning and Information Sharing.

Use care so that any information collected is protected from release during the inspection. This includes proactively guarding against accidental release. For example, do not leave records exposed on the seat of your GOV and do not review records on public transit where someone may view them without your knowledge (for example, peering over your shoulder). Unauthorized disclosure of confidential, commercial, or financial information, trade secrets, or personal privacy information could be a civil or criminal violation and may carry legal or other consequences for the disclosing official. (See IOM 1A.3.)

If non-public information is inadvertently, or accidentally, disclosed, follow ORA's Addressing Inadvertent Disclosures SOP. Immediately report the loss or theft of any device or equipment capable of storing data to the FDA Cybersecurity and Information Operations Coordination Center at CIOCC@fda.hhs.gov. Any information disclosure questions should be directed to the Division of Information Disclosure Policy (DIDP) at ORAinfoshare@fda.hhs.gov.

(See also IOM 5.5.9.3 concerning information sharing with persons invited by the firm to participate in the inspection.)

5.1.6 – Common Reasons for Inspections

Your assignment should provide you with information conveying the inspection basis or type of inspection to be conducted. If there is no inspection basis provided, ask your supervisor for the purpose of the inspection.

Some reasons for inspections include:

- Surveillance inspection (also called routine or workplan inspections)
- Recall follow-up
- Consumer complaint follow-up
- Follow-up to a whistleblower complaint
- Follow-up to a compliance action, such as a warning letter or seizure

The purpose of the inspection will often provide you with an area to focus on during the inspection. For example, during a recall follow-up inspection, you will likely focus on the firm's recall activities and procedures. But, regardless of the purpose of the inspection, if you observe issues in other areas that may result in product adulteration or misbranding, you should follow-up on those items diligently, too, as time permits.

5.2 – Pre-Inspection Activities

Information contained in the subsections under 5.2 is general in nature and may apply to multiple programs. For commodity specific content, refer to subchapters for the individual programs.

Good preparation helps ensure that your inspection proceeds smoothly and that all issues are covered. However, there may be times when you will not be able to conduct a thorough review of all materials or inspection information prior to an inspection, including, for example, in the event of an urgent public health emergency when you may need to travel unexpectedly to an inspection site without time for preparatory research or review. In these cases, you should plan to review the materials described in this section as soon as the situation is resolved, or you are able.

Before the start of any inspection, you should conduct several activities. Begin by reviewing the establishment's history, to include any previous EIRs, complaints, registrations, and listings, recalls, personal safety alerts, etc. The

purpose of this review is to determine the location of the establishment, obtain an overview of its operations and products and understand its compliance history.

Conducting a consumer complaint review will help you identify any complaints that require follow-up during your inspection, including any with the status “Surveillance information for next EI” that will need to be addressed and closed. (See IOM 5.2.3)

You should also review the establishment file to determine if there are any prior safety issues noted, (for example, any, documented investigator safety incidents or suggestions for specific personal protective equipment needed prior to the start of the inspection (See 5.3). Plan to review the eNSpect assignment to determine if the Personal Safety Alert (PSA) Indicator is set to “yes” for this specific firm. If so, the reason or reasons for the PSA should be listed in the Endorsement section for the previous inspection and should be accompanied by a memo to the establishment file. Note, too, that for some firms, the PSA may be in the hardcopy establishment file, and not captured in Online Search and Retrieval (OSAR). (For more, see IOM S.3.2, Personal Safety Alerts). If you discover that there has, in fact, been a past personal safety incident, you should discuss the details with your supervisor and develop a Personal Safety Plan prior to the start of the inspection. (See IOM S.3, Personal Safety.)

You should become familiar with the reporting requirements for the specific assignment, as well as the requirements of IOM 5.7 (Reporting).

If the inspection is a directed assignment from an FDA center, ORA headquarters, or another program division, read the assignment and attached materials to ensure you understand the assignment.

If the inspection is being conducted in part or solely as a follow-up to a recall or consumer complaint, refer to Chapter 7 (Recalls) or Chapter 8 (Investigations) of the IOM for additional guidance.

You should also plan to review the applicable compliance programs prior to the start of your inspection. In addition, the centers have issued numerous guidance documents for industry, which you should also become familiar with. These documents are normally posted to the appropriate center's internet website. You should also determine if there are any "import for export" follow-up assignments and be prepared to cover them as needed during your inspection. (See IOM 6.1.4.6 for more guidance.)

5.2.1 – Scope of Inspection

An establishment inspection is a careful, critical, and official examination of a facility to determine its compliance with the laws and regulations administered by the FDA. Inspections may be used to collect evidence to document violations and to support regulatory action, when appropriate; or they may be directed to obtain specific information on new technologies, commercial practices, or data for establishing food standards or other regulations.

With regards to facilitating on-the-job training or gathering multiple points of view or perspectives of firms being inspected, whenever practical, personnel with assignment authority should consider designating different investigator/s, or different lead investigators, at different times. This is recommended particularly when there have been multiple sequential NAI inspections or when the firm's management has been uncooperative.

The approach and scope (for example, full scope, limited scope; Level I, II or III; and full or abbreviated) you will use to conduct an inspection is defined by the compliance program, assignment, and/or your supervisor. Inspections may require that you conduct a general review of the firm’s operations and records for compliance, or, alternatively, that you direct your focus to certain operations or products. The degree and depth of attention given to various operations in a firm depends upon the information needed, or upon the violations suspected, or likely, to be encountered. The amount of time and attention required for a specific case will depend, at the least, on the following:

- Current compliance program
- Nature of the assignment

- General knowledge of the industry and its problems
- Firm history
- Conditions found as the inspection progresses.

As always, be sure to contact your supervisor should you encounter, or observe, any objectionable conditions that may be of public health significance, or that implicate establishments in other division(s). (See IOM Chapter S for more information on safety, the use of protective gear, dealing with potential hazards and other safety issues, and trash disposal.)

5.2.2 – Domestic Follow-up of Import for Export Entries

In preparation for a domestic inspection of the initial owner or consignee, the domestic division should:

1. Review entry/line data and entry using the "*Import for Export - IFE*" section in OSAR Firm 360 and ORADSS report "*IMP046 Import for Export Entry Lines and Documents"* to determine if the firm has records of IFE entry/lines. The entry/line data can be found in the *"Shipment Lines"* worksheets. Links to the entry/line documents can be found in the *"Links"* worksheets which will contain the entry/line number, consignee/importer information and the document links. Additionally, the link to the report can also be found on the Office of Import Operations (OIO) Import for Export intranet site.
2. If IFE entry/lines are noted in the report, follow-up of IFE entry/lines should be done during the initial owner or consignee domestic inspection. IFE entry/lines for the firm should be investigated during the inspection as outlined in section 5.5.7.5.

5.2.3 - Consumer Complaint Review

This section covers general information related to consumer and other complaints. Additional details can be found in program-specific sections, IOM 8.1.5.7, and other sections in Chapter 8 that cover complaint investigations.

Prior to conducting any inspection, you should review CMS, ORA Complaint Dashboard, Firm 360, and the firm history to become familiar with all FDA complaint/injury records. Note that you may need to request from the consumer complaint coordinator additional information about particular complaints not found, or seemingly missing, in FDA systems. Be especially alert to any complaints marked "Surveillance Information for Next EI," as these will need to be addressed during your inspection. When using OSAR and Firm 360 to review complaints, note that the "more detail" link needs to be opened to determine if the complaint was previously followed up on, or if it still requires follow-up.

5.2.3 – Technical Assistance

If you determine that specialized technical assistance is necessary in conducting inspections of new technologies, products, or manufacturing procedures, it may be available through Regulatory Technical Assistance Network (rTAN), Produce Safety Network, programmatic or national experts, other ORA components, or center scientists and engineers. Check Compliance Programs for a list of contacts for technical experts as well.

If additional technical assistance is needed, contact your supervisor.

5.2.4 – Review of Compliance Actions and Recalls

During your pre-inspectional activities, you should note any compliance actions, recalls, and/or import alerts for products related to the firm you are inspecting. These may be found in the inspection assignment, OSAR and/or Firm 360. The Compliance Management System (CMS) can also provide detailed information. Focus on any potential problems that might have led to these actions and how they relate to the firm's operations. This review can help guide your inspection activities as you will want to determine if any referenced issues are still relevant for products you will cover.

(Each program has more details in its own section of this chapter of the IOM, starting with 5.8 – Foods, 5.9 – Cosmetics, etc.)

If your inspection finds issues with current products that may result in a recall, market withdrawal, or import alert, please notify your supervisor, and reference IOM chapters 6 and 7.

5.2.5 - Coordination with Centers/Compliance Branch/Laboratories/SLTT

Coordination with internal and external partners (for example, center(s); Division Compliance Branch; state liaisons; and state, local, tribal, and territorial agencies) may be a necessary component of your pre-inspectional activities. You should refer to the inspection assignment and any relevant Compliance Program(s) to determine the appropriate contacts in your division compliance branch and/or the center(s) for your inspection. The assignment may also request a pre-inspectional meeting with the compliance officer and/or the center(s) (as in the case of a recall follow-up, in which you may need to discuss the assignment with the division recall coordinator).

Additionally, there will be inspections/investigations where coordination with the state liaisons will be important to ensure collaboration with our state and local partners. Be aware of assignment-specific directions that may require the pre-notification of state partners (like, for example, the State Board of Pharmacy for compound pharmacy inspections). (Refer to IOM Chapter 3.1 for more information on cooperative efforts regarding federal, state, local, tribal, and territorial agencies, and international cooperation. See IOM Chapter S regarding coordination with local police for personal safety preparations as necessary.)

5.2.6 – Pre-Announcement

Pre-announcements are mandatory for all medical device surveillance inspections—and some Bioresearch Monitoring (BIMO) inspections—in accordance with the criteria and instructions below. Routine produce farm inspections should be pre-announced, unless otherwise directed. (See Exhibit 5-20 for additional information about produce farm inspections). In some other program areas, pre-announcements may be made at the discretion of the program division. In general, though, it may be inappropriate to pre-announce inspections of food establishments, blood banks, source plasma establishments, and some BIMO inspections, but this is subject to program division discretion. If you are going to visit facilities where livestock (including poultry) or wild animals are housed or processed, review Exhibit 5-19 (Biosecurity). It is appropriate to discuss biosecurity procedures when you are inspecting these facilities.

ORA's primary purpose for pre-announcing is to ensure that the appropriate records and personnel will be available so that we may execute an effective inspection. It is *not* to make an appointment for the inspection. When contacting the firm, do not refer to it as an “appointment to inspect.” When planning for a pre-announcement, it is important you communicate to the establishment the purpose of the inspection and a general idea of the records you may want to review. If you find, even after making your pre-inspection request known to the firm, that neither the appropriate personnel nor records are available to you during the inspection, note this in your EIR.

In general, the Agency usually announces foreign inspections in advance, partly due to logistics such as arranging travel and access to facilities, securing visas, and partly because of the high costs of conducting foreign inspections.

Unless you are directed to pre-announce an inspection in the compliance program or assignment, discuss pre-announcing with your supervisor and assure that you have management concurrence before contacting the firm. Explain the reason for the pre-announcement in the narrative report. (Subchapters 5.8 through 5.15 of the IOM contain additional, program specific pre-inspectional activities you should follow.)

5.2.6.1 – Criteria for Consideration

The pre-announcement of domestic inspections should generally be no less than five calendar days in advance of the inspection. Should a postponement be necessary, the decision to reschedule rests with the investigator/team, but the new inspection date should not be later than five calendar days from the original date. For changes to foreign inspections work with you trip coordinator. Inspections may be conducted sooner than five calendar days, if requested by or acceptable to the establishment, and if this date is acceptable to the investigator/team.

As noted above, for pre-announcement to be effective, establishments are expected to meet the commitment to have appropriate records and personnel available during the inspection.

Pre-announced inspections must not limit an investigator's authority to conduct the inspection.

5.2.6.2 - eNSpect Reporting

In the eNSpect “Pre-Announced / Unannounced to Firm” field select “Unannounced” when no notification was provided to the firm in advance of arrival at the firm for inspection. Select “Pre-announced” when the firm was notified of the inspection prior to the CSO arrival at the firm for the inspection. (See IOM 5.7 - Reporting)

5.2.7 – Travel Coordination and Planning

Travel is an integral part of inspections. As such, it needs to be planned and well-coordinated to go smoothly. (See IOM Chapter 1.2 ORA Travel for information regarding travel authorizations using ConcurGOV (CGE).)

See IOM Chapter 1.4 - Division of Travel Operations for travel aides to assist you in domestic travel (specifically IOM 1.4.1) and foreign travel (specifically IOM 1.4.2). Additional sections in this chapter address Per Diem Rates, Actual Expense Reimbursement, Lodging, Miscellaneous Expenses, and Transportation Allowances/Expenses.

IOM Chapter S.17 - Employee and Traveler Health and Safety provides information on any occupationally related medical services you may need. For instance, immunizations needed prior to foreign travel, may be necessary. You will contact FDA Occupational Health Services (OHS) for such requests. (For more, refer to Chapter S.17.4.2 for details on Foreign Travel and S.17.5 for Employee and Traveler Safety.)

5.2.7.1 – Domestic

When preparing for a domestic inspection, consider the following questions and consult with your supervisor to help address them as needed:

- Do I need a travel authorization (TA)?
  - Is there enough time for the TA to be completed through the normal process?
- Is a government vehicle available?
  - Do I need to make a request for a specific government vehicle, such as a larger vehicle to transport a larger team for the inspection?
  - Will I have access to the government vehicle on the weekend, or before/after routine office hours, if needed?
- Do I need any special equipment?
  - Will that equipment fit in any government vehicle, or do I need to request a specific type or size of vehicle as noted above?
- Do I need to visit a resident post or laboratory while in travel status?
  - Do I have that associated contact information readily available?
- If I am pre-announcing the inspection, do I complete the TA in CGE before, or after, pre-announcement?
  - If I complete the TA after pre-announcement, will the TA be approved before I start to travel?
- If I am not pre-announcing the inspection, have I confirmed the likely operational status of firm before traveling, by reviewing a firm or establishment’s current registration, updated website presence, posted operational hours, etc.?

(For more on domestic travel, see IOM Chapter 1.4.1 Domestic Travel.)

5.2.7.2 – Foreign

Foreign travel can be stressful, but careful planning and consideration can make travel abroad easier. IOM Chapter 1.4.2 provides you with links to the Foreign Travel SharePoint site, a timeline of the coordination process, and foreign travel contacts.

Before you start your foreign travel, also consider the following:

- Do I need special equipment?
  - How will I most appropriately travel with it? In my unsecured suitcase? Or in my carry-on bag?
- Does my supervisor...
  - Have my trip itinerary in case I need to be reached?
  - Have my government cell phone number in case I need to be reached?
- If I am on a team inspection...
  - Have I or we coordinated where we will meet?
  - Has everyone exchanged government cell phone numbers and is familiar with how to dial out once inside the destination country?
- Other general considerations:
  - Have I included my emergency contact information in myr "Traveler's Profile," to be used by the agency in case of any emergency?
  - Have I received my Electronic Country Clearance, or eCC, via email? (Travelers are not supposed to start travel without this document.)
  - Have I secured and saved the local U.S. Embassy number, plus any other emergency numbers for the destination country, in case of emergency?
  - Have I registered my trip details at The Smart Traveler Enrollment Program (STEP)?
    - The Smart Traveler Enrollment Program (STEP) is a free service to allow U.S. citizens and nationals traveling and living abroad to enroll their trip with the nearest U.S. Embassy or consulate.
    - Receive important information from the embassy about safety conditions in your destination country, helping you make informed decisions about your travel plans.
    - Help the U.S. Embassy contact you in an emergency, whether natural disaster, civil unrest, or family emergency.
    - Help family and friends get in touch with you in an emergency.
  - Have I made copies of important documents (including my credentials, passport, driver's license, credit cards, vaccination cards, etc.) so that I'm able to securely keep copies with me while in travel status and at home?
  - Have I reviewed my destination country's corresponding Department of State International Travel page for the very latest health and safety information?
  - Have I packed in my carry-on bag, all necessary work items, like my regulatory notebook and credentials?

5.2.8 – Team Inspections

The use of teams to conduct inspections may be beneficial. Note that a team may consist of multiple investigators, as well as laboratory personnel, other FDA employees, and your supervisor, who may participate as part of the ORA Quality Assurance program. Individuals well versed in a particular analytical or inspectional technique or technology are often asked, or selected, to support a team, given their potentially valuable assistance and advice. Combination product inspections also often entail the use of teams so that adequate and appropriate program expertise is brought to bear on these more complex inspections. (See IOM 5.12.1)

When inspection teams are involved in an inspection, the inspecting division will designate one investigator as the team leader. If the assignment is multi-commodity, the assignment will identify the lead program, which will, in turn, identify who the lead investigator will be. The team leader serves a critical role as this person oversees the inspection and bears overall responsibility for the inspection and the EIR. See 5.2.8.1 – Team Member Responsibilities.

Each team member is responsible for preparing those portions of the report pertaining to their activities. Team members shall identify their portion of the narrative report, so they can later identify that portion as the part they performed and reported. Since reports should be written in the first-person point of view, one suggested approach for ensuring clarity surrounding each portion (or investigator contribution) is to head each portion with the statement: "The following operation(s) was/were observed and reported by Investigator _____", who can then continue their respective report in the first person.

As for signatures, all team members must sign the EIR, while only those team members present at issuance are to sign the FDA 483 or FDA 4056. Also, the issuance of the FDA 483 should not be delayed, in the absence of a team member's signature. (See IOM 5.5.10.5 for instructions for signing an FDA 4056 and a multi-page FDA 483.)

5.2.8.1 – Team Leader Responsibilities

The team leader is responsible for the following:

- Directing the overall inspection to accomplish the objectives of the assignment including all of the following most effectively:
  - Planning the inspection, including determining an orderly, efficient, and effective approach and sequence to be used, and discussing this inspection plan with the team.
  - Scheduling and coordinating team members' pre-inspection preparations.
  - Determining, to the extent possible, the firm will be open and operating.
  - Calling to pre-announce an inspection, if required.
  - Planning for needs of visiting scientists, if applicable.
  - When not familiar with all the processes or technology involved in the inspection, providing for primary coverage of those areas by other team members.
  - Modifying the inspection plan as necessary during the EI, to permit the following of leads, documenting evidence, etc.
  - Setting team policy on how communications with the firm are to be handled.
  - Discussing personal conduct in dealing with headquarters personnel as necessary.
  - Ensuring all team members understand their roles, early on, including who will take notes and who will report, etc.
  - Providing for an open and connected communications structure among team members, especially if members are working separately.
  - Reviewing inspection progress at least daily and discussing remaining objectives with team members, including setting concrete objectives for the following day.
  - Continually assessing the overall progress of the inspection to evaluate how the inspectional approach is working and to keep the division supervisor advised of the inspection's progress.
  - Providing individual guidance and direction to team members as necessary.
  - Advising each team member of reporting responsibilities and dates when drafts are to be provided.
  - Following up promptly on any delays or failures of team members to report as required.
  - Assisting the supervisor with further follow up, as needed.
- Making sure any person who joins the team after the inspection has started presents credentials and issues an FDA 482, Notice of Inspection to the firm prior to taking part in the EI (see Section 5.3.1 Notice of Inspection (Form FDA 482) for more details).
- Issuing new notebooks for taking regulatory notes during the establishment inspection (EI) to any non-ORA personnel on the team. Team leader is also responsible for instructions on notebook use, if necessary, and when the report is finished, for obtaining the non-ORA personnel individual's signature on the original EIR and their completed and properly identified regulatory notes. The team leader should then submit them to the leader’s supervisor for filing. (See IOM 2.1.3).
- Drafting endorsement text in eNSpect.

- Preparing the Summary of Findings in eNSpect.
- Ensuring all headings of an administrative nature are complete in the establishment inspection report (EIR).
- Compiling and submitting the complete EIR.
- Resolving any disputes or differences of opinion among the team members, including items which may be listed on the FDA 483, FDA 483a, or FDA 4056.

5.3 – Safety during Inspections

5.3.1 – Safety (What You Should Do to Prepare for Potential Dangers/Risks)

Refer to IOM Chapter S for general safety information.

5.3.1.1 – Personal Safety

Physical and verbal resistance to FDA inspections and threats to, or assaults on, FDA employees engaged in their work are extremely rare. However, there will be times when you are confronted by unfriendly or hostile persons. ORA offers various conflict resolution training courses to assist and prepare you for how to diffuse a situation (See IOM S.3.3). Talk to you supervisor if you need assistance finding a course.

In most instances, conducting your activities with tact, honesty, diplomacy, and persuasiveness will be enough to defuse the situation. And while at times, you may have to adopt a firm posture, you should not resort to threats, intimidation, or strong-arm tactics. (Refer to IOM 5.3.13 for Hostile and Uncooperative Interviewees.)

5.3.1.1.1 – Safety Preparation

You should be familiar with the content in IOM Chapter S - Safety, as it relates to your assignments.

Additionally, the following are suggested items the program division may consider when preparing for your next assignment to assess if there are potential personal safety issues. This list is not meant to be all inclusive.

- Does the assignment involve working with other federal agencies, such as U.S. Marshals Service, Federal Bureau of Investigations, and U.S. Customs and Border Protection, in executing search warrants, seizures, etc.?
- Does the assignment involve working with or contacting FDA's Office of Criminal Investigations (OCI)?
- Does the assignment involve a firm where there is a suspicion and/or knowledge of questionable or illegal activities?
- Does the assignment involve a suspected tampering?
- Are you visiting an individual's residence?
- What have interactions with the firm's representatives been like previously and historically? What does the firm's establishment file indicate about personal safety over past inspections? Have any FDA state counterparts or other SLTT agencies indicated a concern for personal safety?
- What is the location of the firm or the operation? Is it in an area which may be unsafe?
- Is the firm known to the agency? Has the agency any additional information which would assist in your evaluation?

If these questions or others result in a concern for your personal safety, then a Personal Safety Plan should be developed and approved by program division management before conducting the assignment. (See IOM 5.3.1.1 – Personal Safety Plan for more.)

Your program division management is most familiar with the specific firm in question, the regulated industry, as well as other local federal, state, and local officials who may be able to provide you additional information and assistance. In addition, to leaning on the expertise of your program division management, consider also inquiring about or taking relevant training courses on conflict resolution. Note too that program divisions

should notify OMPTO or OHAFO to inform headquarters of any personal safety plan that is developed, so that personal safety issues may be tracked. The headquarter component will also maintain a library of Personal Safety Plans which may also be of use to your division. The headquarter component may be contacted at the following personal safety e-mail address: orahqcsosafety@fda.hhs.gov.

5.3.1.1.2 – Dealing with Physical Resistance/Threats/ Assaults



If you receive physical resistance or threats, or if you sense the possibility of an assault, you should promptly disengage from the confrontation, get to safety, contact 911 if necessary (for immediate police or medical assistance), and call your supervisor. Your safety is more important to the United States than the inspection, or the sample collection. (Refer to IOM Chapter S.2 and S.3). As soon as you are safely able to, you should make careful and exact notes about the encounter (for instance, who said what to whom, who did what, and whether someone tried, or succeeded, in threatening, assaulting, or taking information, equipment, or samples from you). Be careful and factual in any descriptions you give or write about such events, just as you do when recording other evidence that may result in a court case. The FDA will work with law enforcement government officials (for example, the Federal Protective Service (FPS), FDA's OCI, local police, and/ or United States Marshals to assist an inspection team if there is a reasonable fear or risk of ongoing danger to the investigator).

If you have been assaulted or threatened and you are unable to reach your supervisor or other division management, you should contact the local police in the area where the assault or threat occurred. After your safety and well-being is secured, proceed with the following:

- Use care in any descriptions you give or write about such events, just as you do when recording evidence that may result in a court case.
- Be sure that any inspected facility, where weapons have been observed, or where threats or assaults have occurred, is identified on that facility's "Endorsement" page of the inspection report for that facility.
- Be sure your supervisor is fully apprised of all incident details so that any subsequent investigators or agents to that facility will be alert to the safety concerns and risks.
- Your supervisor is responsible for checking the "Personal Safety Alert" box in eNSpect and for initiating the notification process to alert other federal or state agencies that also inspect the facility of the possible danger.

(For more information see IOM S.3.1, Personal Safety Alert. For specific safety guidance related to inspections and interviews, see IOM 5.3.1.3 Hostile and Uncooperative Interviewees.)

Any perceived threat to your personal safety is of the utmost importance. Plan to exit the situation immediately and report it to your supervisor. Potential and perceived threats may include, but are not limited to, certain geographic locations (high-crime or war-impacted, for instance), concerns about entering a personal residence to conduct official business, or animals that are not caged or contained.

5.3.1.2 – Personal Safety Plan

A Personal Safety Plan is a tool developed to assist in managing and preparing for a potentially dangerous situation. Program divisions should develop a Personal Safety Plan when the conditions surrounding a specific inspection, investigation, or sample collection indicate a plan is needed. The plan allows all those involved to carefully evaluate the specific inspection, and factors surrounding it, and to prepare for a safe and successful conclusion. Utilizing personal safety concepts prior to a potentially dangerous situation is common practice and part of the training programs of many other federal agencies.

The Personal Safety Plan should be developed by the investigator, supervisor, other investigators familiar with the facility, a compliance officer, if needed, and any other individuals (program, division, or headquarters (HQ) experts,

etc.) who may be able to assist in the depth, scope, and specifics of the firm in question. Meetings held between these individuals, to ensure a well-developed and clearly understood plan, are suggested. The decision of who should help develop and/or approve the plan is made at the program division level.

The plan should document what specific roles and responsibilities are needed to conduct the inspection/investigation and/or sample collection in a risk-minimizing manner. The plan should also answer the questions: who, what, when, where, and why, concerning the potential danger(s).

Here are the seven principles of a Personal Safety Plan:

1. **Summary of potential hazards:** This section of the plan includes all the potential hazards, in detailed description, that prompted the need for a personal safety plan. Be sure to answer the questions: who, what, where, when, and why? Also describe any specific hazards that require personal protective equipment, or conditions/situations at the facility that may cause allergic reactions for some investigators or analysts. Also, summarize and include here any relevant information from past inspection reports, discussions with previous FDA, state, or local investigators, as well as information about any environmental or plant/facility-specific conditions or factors that could negatively impact or limit even a well-intended safety plan.
2. **Sources of information:** This section of the plan includes a listing of all the sources from which you gathered potential hazards, and information/data. For instance, if you gleaned information about hazards from a colleague or a state inspector, you would want to document their names, in this section, along with their respective statements. If your information came from another source; for instance, if it's database or document, make sure to include the name or title/description too. This section is important, as it documents factual evidence (sources), in the same way you notate all other evidence you gather.
3. **Response alternatives:** This section will be the *most important* part of your plan because it details what you propose to do, alternatively, to mitigate the hazards. Here, you will provide a list of practical responses to the existing risks or dangers, and options or solutions to consider. This section allows your supervisor to evaluate possible ways to handle the situation. Your explanation should also outline all the skills and tools you possess to assist you in handling the situation carefully, including trainings, experiences, and other procedures you have at your disposal. Roles and responsibilities of all involved in the plan should also be identified in this section, including those who will be based on-site and off-site.
4. **Communication:** Here you will provide all information about how communication will occur between participants on-site, between those on-site and off-site, and in collaboration with any emergency, law enforcement, or medical responders. You will also want to establish as part of your plan a predetermined frequency of check-ins with your supervisor, so that they may stay regularly apprised of your safety. Also, consider here the use of any special types of communication, for instance, code words for emergencies.
5. **Transportation:** Provide information here on how you and/or others will travel to the facility in question.
   a. Will there be a coordination point?
   b. Do you intend to use government-marked, or unmarked, cars?
   c. Who will ride in each car?
   d. What route will be taken going to and leaving the facility?

   Consider where you will park the car when you arrive at the facility. Consider what modes of communication will be used to communicate if multiple vehicles are used.
6. **Equipment:** Here, name all equipment needed to initiate this plan. Is personal protective equipment needed? Is any special sampling equipment, or other equipment, needed? Also, include any other needed equipment, such as communication tools, FDA forms, etc. You should also be sure that anything listed here is in fully functioning mode.
7. **Emergency exit strategy:** Describe in this section what your exit strategy will be in the event of an emergency. Consider emergency strategies for safety issues, as well as those needed in the event of medical emergency.

a. How will the emergency be communicated to on-site and off-site colleagues?
b. How will you exit the facility and return to your vehicle?
c. Will there be a scheduled meeting point to account for everyone who is involved?

(Your goal here is to have a very clear plan for ensuring that no one is left behind.) It should also include the action step to contact your supervisor when you return to safety.

You should follow SOP-001378 ORA Field Safety (Personal Safety) Alerts Procedure to document processes used to develop safety alerts, safety memos and safety plans when potential safety hazards associated with specific regulated firms have been identified. ORA Personal Safety Memorandum (PSM) Template (FORM-002313), and ORA Personal Safety Plan (PSP) Template (FORM-002314) are all maintained in QMiS. Additionally, reference Investigations & Inspections Safety, located on the ORA Office of Safety SharePoint site, which provides links to these documents as well as other relevant information and resources regarding personal safety.

Special note for foreign inspections: When a Personal Safety Plan is warranted, a headquarters point-of-contact (POC) will assist the inspection team. The inspection team's management may also wish to participate so that there is clear understanding of what actions will be taken for the foreign inspection.

5.3.1.3 – Interacting with Hostile and Uncooperative Interviewees

Investigations and inspections are typically conducted in a reasonable manner. Nonetheless, there will be times when you are confronted by unfriendly or even hostile persons.

Your activities must always be conducted with calm, tact, honesty, diplomacy, and, as needed, persuasiveness. Do not resort to threats, intimidation, or strong-arm tactics.

Many times, a hostile or uncooperative attitude on the part of individuals being interviewed results from fear, timidity, or previous negative encounters with law enforcement personnel. In most cases, a calm, patient, understanding, and persuasive attitude on your part will overcome the person's reluctance or hostility. Oftentimes, the mere fact that you patiently listen while individuals share their views can encourage them to be more receptive to your requests.

While we cannot predict the behavior of the individuals we meet, especially in the absence of warnings issued from previous operations, we can consult various sources and consider other indicators to alert us to potential risks. These include:

1. Establishment inspection reports, endorsements, or memorandums that may show situations where investigators encountered belligerent or hostile individuals. These reports may be FDA reports and/or state contract reports, if available.
2. Discussions and conversations with FDA, federal, state, and local inspectors and investigators that may reveal instances where uncooperative individuals and problem situations were encountered.
3. The nature of the assignment, program, or information requested, which may indicate some degree of caution is needed.
4. A firm's geography, including a city or town's reputation among local law enforcement, which may alert you that some employees of the firm may be less than cooperative during the investigation.

As always, if you find yourself in a situation which, in your judgment, indicates violence or harm is imminent, stop the inspection and make an exit as soon as possible. Once safe, contact your supervisor and document the information in your regulatory notes.

5.3.1.3.1 - Safety Precautions

The FDA recognizes that there are situations where it is advisable to take precautions for your personal safety. When this occurs, or suspect this is the case, consult your supervisor. Some procedures that may be used to alert you to danger and risks, as well as minimize them include:

1. Conducting the inspection with a team of two or more persons.
2. Requesting additional information from state and/or local agencies who also regulate and inspect the facilities in question. In many instances, your state counterparts may have more information than you currently have regarding a facility. Conducting outreach to them is especially helpful in instances where firms have not yet been inspected by the FDA but have been by state counterparts.
3. Using an unmarked government car in lieu of a marked government car that will draw more explicit attention to you and your activities, and possibly provoke feelings of fear, distrust, or ire among local residents or firm personnel.
4. Assigning and using a non-personal FDA cell phone, or alternate communication device, for the inspection team. While some investigators carry personal cell phones, the FDA strongly advises that your personal cell phone *not* be utilized to contact the firm or any of its management. Such uses in the past have resulted in inappropriate contacts from the firm to the individual FDA investigator.
5. Requesting assistance from local law enforcement agencies prior to, or during, investigations. This assistance may include requesting information about the facility you are to inspect, assistance with communication devices, and/or police protection itself, if the police jurisdiction allows for such an action.
6. Using at least two investigators in potentially or likely hazardous investigations, such as those involving methadone or Schedule II Class Drugs. Additionally, personnel from the U.S. Drug Enforcement Administration, and/or state or local law enforcement agencies may also be requested to accompany you and your teammate(s).

5.3.1.3.2 – Procedures When Threatened or Assaulted



In instances when you are physically assaulted or threatened, you should get to safety immediately then notify your supervisor as soon as you are able to. If emergency response is required, always call 911 first before contacting your supervisor. Your supervisor can also summon local police, the U.S. Marshals Service, or contact OCI headquarters for assistance (301-294-4030). OCI often has contacts with local police and federal agencies based upon previous liaisons. Also, the program division should notify headquarters at orahqcsosafety@fda.hhs.gov so that senior management may be made aware.

If you are physically attacked, you have the same recourse as any other U.S. citizen, in addition to the benefit of federal laws that protect government employees while in performance of their official duties. Your report of the incident, plus any medical attention sought and received may be used as documentation for the agency in support of any legal action taken against the firm or the individual.

5.3.1.3.3 - Notification of FBI And U.S. Attorney

It is a federal crime for anyone to kill, assault, resist, oppose, impede, intimidate, or interfere with a federal official in the performance of their official duties. (See sources of legal protection below.)

In case of an assault or threat against you, notify your supervisor immediately, so facts regarding the incident can be submitted to the FBI and the U.S. Attorney's office for immediate action.

Federal protections found in Title 18 of the U.S. Code include:

- Someone cannot forcibly assault, resist, oppose, impede, intimidate, or interfere with a federal official who is performing their official duties (18 U.S.C. 111)
- Someone cannot kill or attempt to kill a federal official who is performing their official duties (18 U.S.C. 1114)

See Title 18 of the US Code Sections 111 and 1114 for the complete text.

5.4 - Confidential Sources

5.4.1 – Interviewing Confidential Sources

An individual providing useful and credible non-public information is often referred to as a confidential source. (Such a source, while providing useful assistance to the agency, may not necessarily become a party to the actual FDA investigation.)

Refrain from providing your personal information to the confidential source (for example, your personal cell phone and/or e-mail); just use professional/official contact information.

These individuals usually have access to pertinent information or possess a distinct vantage point allowing them to obtain useful information. These sources typically do not want to be identified or take an active part in the investigation, as such, it's important not to divulge the identity of a confidential source of information.

Note, too, that the source individual may, or may not, be reliable for purposes of using information in court. In all situations, the information obtained must be vetted and reliable.

If you believe or suspect the information provided by the source may involve criminal activity, notify your supervisor. In all cases of criminal activity, including fraud, OCI is the primary investigative office for the FDA. If OCI does open a case, OCI will want to be involved or at least notified of any interviews you conducted and documented that may be useful to further the case. (See Section 8.1.5.3 Criminal Investigations).

When faced with a situation involving human sources of information who want to remain anonymous, contact your supervisor and follow the procedures in this subchapter. You should also maintain awareness regarding your safety (see IOM S.3 and 5.3). If your management concurs with the decision to utilize a confidential source who wishes to remain anonymous, it is particularly important that you take the necessary steps to protect the identity of the source and protect any information that could lead to someone determining the identity of the source.

5.4.1.1 - How to Handle the First Contact

When you interview a potential confidential source, you should use the following procedures (See Section 8.1.6.1 Interviews for more):

1. Attempt to schedule an in-person interview with the individual, rather than a telephone interview. A face-to-face interview gives you the opportunity to assess their demeanor, body language, overall presentation, and truthfulness.
2. Allow the individual to choose the place and time of the interview, unless there is a concern for your personal safety. If you are unsure of the safety or privacy of the location the source provides, then you should suggest an alternate location. When you conduct the interview on non-FDA premises, be sure to notify your supervisor of your destination, purpose, and estimated time of return. When the off-site interview has been completed, check-in with your supervisor and alert them to the meeting's conclusion.

5.4.1.2 - Interviewing Methods/Techniques

It is strongly recommended that you have *two* investigators conduct interviews of a confidential source. This allows the lead investigator to conduct the interview, while the second investigator takes notes and acts as a witness to the interview. Some suggestions for a successful interview:

1. Prepare carefully and adequately. The investigators should develop the questions beforehand that they intend to ask the person during the interview, (for example, specific questions that will help "establish motivation"). You should record and number the questions to be asked in your diaries prior to the interview. This preparation assists in documenting the interview process and reduces the amount of note taking needed during the interview. The investigators should also discuss their interviewing strategy, before the meeting, including determining the method by which they will consult with each other during

the interview, and, in the case of extensive interviews, how best to share interviewing and note-taking responsibilities.

2. Direct the interview in a way that will encourage the person to tell the story chronologically. This will help place complex situations or events into logical order.
3. If the person makes allegations, ask him or her how he or she knows the allegations are true. For instance:
   a. How were they able to know?
   b. Did they personally see, hear, or write about the information/incident?
   c. Can they provide proof of the allegations?

5.4.1.3 - Establish Motivation

At the end of the interview ask the person why he or she is divulging this information. This may reveal their motive(s) and help you shed light on the following possibilities:

1. Is the person a disgruntled current or former employee who harbors a grudge?
2. Is the person looking for some type of whistle-blower reward or notoriety?
3. Does the person just want to do the right thing?
4. Is the person involved in actual or prospective litigation about or related to the information?

5.4.1.4 - Anonymity

If the individual is requesting anonymity, inform them that the FDA:

1. Will not divulge their identity, the occurrence of the interview, or the sensitive information provided to the agency if the information could lead to the identity of the person, unless the FDA is required to disclose the information by law. For example, if the investigation leads to a hearing or trial and the individual is required to testify.
2. Will try to corroborate all information provided by the person, to minimize the chances they must later testify. However, testifying remains a possibility.

Ask the person for names of any other persons who might be willing to speak with you about the allegations and corroborate the individual's story.

5.4.1.5 - Protect the Identity of the Source

Obtain sufficient personal information necessary to enable you to contact the person for follow up if needed. However, to maintain the confidentiality of the person, do not include the person's identifier information, such as gender, name, address, and phone number in the memorandum of interview. You should assign the confidential source a code name, or number, and use that identifier in memoranda and other communications relating to the confidential source (see IOM 5.4.1.7 item 2).

5.4.1.6 - Access

Know who is authorized by program division procedure to access the information and restrict access by and to any others accordingly. Share the minimum amount of information necessary to meet the purpose of the disclosure.

5.4.1.7 - Storage Requirements

1. Each program should establish procedures, in addition to those listed below, to properly store confidential information. Use security measures necessary to protect the confidentiality of personal information, whether it is in hard copy or electronic form, held on FDA premises, in an FDA home-based computer, or in any other form. Use whatever means necessary and appropriate to physically safeguard the information, such as storing in a safe, or locked file cabinets, or password-coded computers, etc.
2. When referring to the source in any manner (orally, in writing, electronically, etc.), consider using code to identify the source. For example, use a number rather than the individual's name, to identify the source. Use discreet subject headers in the file labels as appropriate. Personal privacy information should be safeguarded to the extent allowed by law.

3. Remove personal information from a file only after you have noted in the file your name, date, etc. Promptly return that information to the file.

5.4.1.8 - Disclosure

Do not disclose information from or about the source unless the disclosure complies with the law and FDA's procedures. Do not share non-public information outside of the Freedom of Information Act (FOIA) process unless the sharing is done according to our regulations and procedures. Refer any FOIA requests to FDA's Division of Freedom of Information (see item 3 below). See also IOM Subchapter 1.4.

Use the following guidance with regards to disclosures of information from or about a confidential source:

1. Make duplicates of the personal information only to the extent necessary for authorized disclosure (inside or outside of FDA). Do not leave the copy machine unattended.
2. Make only authorized disclosures of the information, regardless of the manner of disclosing (oral, written, etc.). Do not use mobile telephones or leave voicemails containing the information. Avoid transmitting the non-public information by facsimile or e-mail.
3. If you receive a FOIA request for information from or about a source, consult with your supervisor immediately. Disclosure to a non-FDA government official of information from or about a source may be disclosed *only* if permitted by law and FDA procedures, and after consulting your supervisor, Office of Strategic Planning and Operational Policy/DIDP and, if needed, OCI.
4. Immediately retrieve information from or about a source if inadvertently disclosed. Follow FDA's Inadvertent Disclosure SOP.

According to FDA Records Management procedures, you should destroy personal information by shredding physical paper or degaussing electronic media. (Contact the Employee Resource and Information Center (ERIC) support to degauss electronic media.)

If a matter is referred to Office of Chief Counsel (OCC), consult with OCC prior to contacting the source again.

5.5 – Inspectional Activities

The previous subchapter described activities you should consider and do when preparing for an inspection. This subchapter is focused on activities *during* the inspection. It is general in nature and applies to all inspections. Programmatic sections describe specific activities to be done during inspections related to specific programs.

5.5.1 - Notice of Inspection (Form FDA 482)

Upon arrival at the firm, you should first locate the owner, operator, or agent-in-charge of the establishment. This should be the top management official on site, and you should be certain of this individual's status. Introduce yourself by name, title, and organization. Show your credentials to the official and present a properly signed and completed original of the FDA 482, Notice of Inspection or FDA 482d, Request for FSVP Records. The FDA 482 or FDA 482d should reflect the address of the home district of the firm.[2] For FSVP Inspections see IOM 6.8.1.4

The FDA-482, Notice of Inspection, is issued on site prior to the initiation of the inspection. The FDA-482 can be issued in the following ways:

- Physical paper copy with signature. (Be sure the printed version of the signed FDA-482 is legible)
- Electronically with your electronic signature certificate by email as a PDF attachment. If issued electronically, confirmation of receipt should be verified and documented.

Document your method of issuance in your regulatory notes.

[2] For all firms within the state of Arizona, the home district is Denver District. Home district boundaries are identified in Appendix E.

If additional agency personnel accompany you during the inspection, they must also show their credentials to the top management official upon arrival at the site. A new FDA 482 or FDA 482d must be issued. Submit a copy with your EIR.

Next, explain the purpose of your visit. Readily accept any management offer to have a representative accompany you on the inspection.

If non-FDA officials accompany you during your inspection and do not have authority to enter and inspect, you should obtain permission (preferably in advance) from the most responsible individual at the firm. Note, however, that non-FDA officials, and those who do not hold FDA credentials, do not sign the FDA 482 or FDA 482d. (See IOM 5.1.4.2.1)

For multiple occupancy inspections in drug establishments, refer to IOM 5.1.4.3.3. Inspections of multiple firms, which are separate legal entities, should be reported under separate EIRs.

If you are faced with a refusal, or partial refusal of inspection, proceed as outlined in IOM 5.5.2.

Any time an FDA 482 is issued, you should also issue an FDA 484, Receipt for Samples, (at the conclusion of the inspection) if you collect any physical samples at the firm. (See IOM 5.1.4.2.3, and IOM 4.2.1, 4.2.3 and 4.2.4 for instructions for issuance of the FDA 482 in certain sampling situations.)

If you have any questions or concerns regarding when, or when not, to issue the FDA 482, discuss them with your supervisor.

5.5.1.1 – Multiple Date Inspections

If your inspection covers more than one day, advise management at the close of each day you have not finished the inspection and when you will return. Do this each day until you finish the inspection. An FDA 482 or FDA 482d is not required for each day of an inspection, or when different individuals are interviewed. If there will be an extended period of time (say, a week or longer) before you can return to the firm to complete the inspection, be sure to advise management of the delay and discuss with your supervisor whether or not you need to issue another FDA 482 or FDA 482d.

5.5.1.2 – Inspection of Vehicles

If you need to inspect any vehicles on site, owned or leased by the firm being inspected, the inspection of these is covered by the FDA 482, Notice of Inspection, you issued to the firm.
If any vehicles (including trucks, trailers, railroad cars, etc.) which are not owned or leased by the firm are present and inspection is necessary, a separate FDA 482, Notice of Inspection, is required, along with the following steps:

1. Issue the FDA 482 to the driver of the vehicle.
2. If the driver is not present and if, after a diligent search, they cannot be located, issue a separate FDA 482 jointly to the firm being inspected and to the firm whose name appears on the cab. Enter the license number of the vehicle on the FDA 482. Give the original FDA 482 to the firm and leave a copy in the cab of the vehicle.
3. If there is no cab present, prepare a separate FDA 482 modified to read "*** to inspect unattended vehicle ***" and issue it to the firm being inspected as the "agent in charge" of the vehicle. Enter the license number of the vehicle, trailer, or railroad car number, etc., on the FDA 482. Should the firm being inspected refuse to accept the notice, leave it in a conspicuous place in the vehicle. Describe the circumstances in your EIR.

5.5.1.3 – Follow-Up Inspections by Court Order

At times you may be instructed to conduct inspections of firms by authority of an injunction or other court order. This situation provides separate and distinct inspectional authorities involving both the authority of the court order and the authority of Section 704 of the FD&C Act [21 U.S.C. 374], each providing independent courses of action.

When assigned to conduct such inspections, you should first obtain a copy of the injunction or other court order bearing the filing stamp and all relevant signatures. Prior to starting the inspection study, read the order thoroughly for any and all special instructions of the court. Your supervisor will assist you in determining the depth of the inspection necessary to cover these court requirements.

On the day of the pertinent inspection, take a clearly legible copy of the court decree (not necessarily a certified copy) with you to the firm to be inspected. Present your credentials in the same manner as for any other EI. Issue the FDA 482, Notice of Inspection, but modified to read:

"*Notice of Inspection is hereby given under authority of injunction* (add the injunction number and/or other identification) a*gainst the firm and pursuant to Section 704…*".

Show the person to whom the FDA 482 was issued a copy of the Order, and, read the following statement to them:

"*This inspection is being conducted under the authority of injunction [add the injunction number and/or other identification] [or other court order] granted by the United States District Court against this firm on [date]. The inspection will cover all items specified in the decree. In addition to the inspection authority granted in the court decree, I am issuing you a Notice of Inspection under the authority of Section 704 of the Federal Food, Drug and Cosmetic Act which authorizes inspections of firms subject to that Act.*"

If the firm refuses access to records, facilities, or information for which the decree provides inspectional authority, read out loud the pertinent section(s) or portion of the order to the person refusing so there is no misunderstanding as to the requirements of the decree. If the person still refuses, report the facts to your supervisor as soon as possible so the court can be promptly advised of the situation. (See IOM 5.5.2 for more information on handling refusals.)

When you prepare your EIR, describe the sequence of events in detail, including exactly what happened and how you handled the situation. This documentation will help support any charge of violating the court order and/or Section 704 of the FD&C Act [21 U.S.C. 374].

The court order may require a report to the court. Discuss this with your supervisor since the division will normally handle this part of the requirement.

5.5.1.4 – Conducting Regulatory Inspections When the Agency is Contemplating Taking, or is Taking, Criminal Action

If the agency is contemplating taking, or is taking, criminal action against a firm, you should *not* issue a Notice of Inspection to that firm without first discussing the matter with your supervisor. You should also review IOM 8.1.4 before proceeding.

Program division management will obtain guidance from the OCC and will allow, or not allow the inspection to proceed based on considerations related to the criminal investigation. Decisions to inspect under such circumstances should be based on considerations of whether the request is consistent with FDA's responsibility to ensure products are not produced or distributed in violation of the Federal Food, Drug, and Cosmetic Act or other federal law within FDA's jurisdiction. The program division should ensure that these considerations are documented. In no circumstance should an inspection be conducted solely to obtain evidence to support a possible criminal case. However, inspections conducted in accord with our overarching responsibility to protect the public, and limited in scope to the authorizing statute, are lawful, even when criminal action is being considered or pursued.

The Fourth Amendment to the U.S. Constitution prohibits searches without a warrant supported by probable cause. An exception to the warrant requirement is inspection of industries long subject to close supervision and inspection, which are conducted under a statute with no warrant necessary.

Three criteria must be met under this exception from the warrant requirement.

- First, the regulatory scheme authorizing the regulatory inspection must be supported by a substantial government interest.
- Second, regulatory inspections must be necessary to further the regulatory scheme.
- Third, the statute's inspection program, in terms of the certainty and regularity of its application, must provide a constitutionally adequate substitute for a warrant.

Section 704 of the FD&C Act [21 U.S.C. 374] is appropriately designed to allow regulatory inspections within appropriate limits. This provides the authority to inspect at reasonable times, within reasonable limits, and in a reasonable manner, establishments or vehicles being used to process, hold, or transport food, drugs, devices, or cosmetics. (See IOM 2.2.1.1.) FDA's normal inspection procedures provide guidance on what should be considered "reasonable" under Section 704.

Should the evidence obtained during an inspection become material to a criminal case, it is possible a defendant will claim the use of statutory authority to conduct the inspection was a pretext to conduct an unlawful warrantless search. But if the limits of Section 704, and normal establishment inspection procedures are followed, the possibility a court will find the inspection to be pretextual should be minimal. Deviations from these limits will make it more likely a court would find the use of statutory authority to be pretextual and render the evidence obtained to be inadmissible.

Any concerns you may have related to the conduct of an inspection while a criminal investigation is being considered or pursued should be discussed with the OCC.

It is the responsibility of the office generating the inspection assignment to inform the program division if a criminal action is ongoing or contemplated. There may be occasions when neither the office generating the inspection assignment nor the program division conducting the inspection is aware that OCI is conducting a criminal investigation of a firm subject to regulatory inspection. That's because OCI may determine it is not in the interest of the agency to disclose to other components of FDA the existence of its investigation, if OCI is not involved in the agency decision to conduct a regulatory inspection. However, OCI and other components of FDA may also share information. (See also IOM 5.6.2 – When Evidence of Criminal Violation is Discovered in the Course of a Regulatory Inspection)

5.5.2 – Inspection Refusal

A refusal of inspection is refusal to permit entry or other action that prohibits you from obtaining records and information to which the FDA is entitled under the law. Discuss all refusals with the most responsible individual present at the establishment at the time the refusal was made. (See IOM 4.2.3 for information regarding refusal to permit sampling.)

5.5.2.1 – Refusal to Permit Entry

When you are faced with a refusal of entry, call the most responsible individual's attention to the applicable sections of the FD&C Act (that is, sections 301(f) and 704 of the Act [21 U.S.C. 331 (f) and 374] and section 351(c), 360A(a), (b) and (f); 360B(a); and 361(a) of the Public Health Service Act). Applicable sections of these laws are listed on the front and back of the Form FDA 482 for your convenience. If entry is still refused, leave the completed Form FDA 482 with the most responsible individual, exit the premises, and contact your supervisor immediately for further instructions. Document the refusal in your regulatory notes.

Note that in the case of drug and device inspections, refusal to permit entry may cause the product to be adulterated (see IOM 5.5.2.2).

For international inspections, a refusal to permit inspection may result in a recommendation for regulatory action (for example, an import alert, cancellation of Food Facility Registration, etc.). Refusal to permit an international inspection should be reported in a memo uploaded into an *Operation 15 – Foreign Investigation* and should not be reported as a "Washout" in eNSpect.

For international food inspections, section 807(b) of the FD&C Act (21 U.S.C. 384c(b)), authorizes the FDA to refuse admission of a food "into the United States if it is from a foreign factory, warehouse, or other establishment of which the owner, operator, or agent in charge, or the government of the foreign country, refuses to permit entry of United States inspectors or other individuals duly designated by the secretary, upon request, to inspect such factory, warehouse, or other establishment."

5.5.2.2 – Refusals during Inspection

Inspection refusals may take several forms. All refusals to permit inspection must be documented in your regulatory notes and eNSpect and reported in your narrative report under the "Refusals" heading.

For a refusal experienced during an inspection conducted under section 704 of the FD&C Act, the FDA must demonstrate that the inspection was attempted to be conducted at a reasonable time, in a reasonable manner, and within reasonable limits to show you exercised prudence to avoid refusal. You must have also presented your credentials and given the most responsible individual a properly prepared and signed FDA 482, Notice of Inspection, for domestic inspections. (See CPG Sec. 130.100 Inspectional Authority; Refusal to Permit Inspection.).

In the case of drug or device inspections, inspection refusals, as well as delaying, denying, or limiting your ability to conduct the inspection, may cause a drug or device to be deemed adulterated under Section 501(j) of the FD&C Act [21 U.S.C. 351(j)]. (See subsection 5.10.7.9 for drug and device refusals.) The FDA issued a Draft Guidance for Industry entitled: *Circumstances that Constitute Delaying, Denying, Limiting, or Refusing a Drug or Device Inspection*. At this time, this is draft guidance, and the original guidance, *Circumstances that Constitute Delaying, Denying, Limiting, or Refusing a Drug Inspection* remains in effect.

5.5.2.3 – Refusals to Permit Access or Copying of Records

If management objects to the manner of the inspection, or the coverage of specific areas or processes, do not argue the matter but proceed with the inspection. However, if management refuses to permit access to or the copying of any record(s) to which you are entitled under law, call attention to Section 301(e) of the FD&C Act [21 U.S.C. 331] or applicable sections of the Public Health Service (PHS) Act.

If management still refuses, document the refusal, and proceed with the inspection until finished.

In the case of drug or device inspections, if management refuses access to or copying of any record to which you are entitled under law, in addition to Section 301(e) noted above, call attention to Section 501(j) of the FD&C Act [21 U.S.C. 351(j)] (an adulterated drug or device could lead to prohibited acts under 301(a), (b), (c) [21 U.S.C. 331(a), (b), (c)]). (See IOM 5.3.2.2)

Furthermore, if during a drug or device inspection, management delays producing records you request to which you are entitled under law, without giving a reasonable explanation (such as requiring sufficient time to compile a large volume of records or translate the records into English), you may call their attention to 501(j) of the FD&C Act. Similarly, if management limits your access to or ability to copy any record to which you are entitled under law, you may call their attention to Section 501(j) of the FD&C Act. (See subsections 5.10.2 Drug Inspections and 5.12.1.1 Inspection Authority for Medical Devices for further guidance on responding to these situations.)

It is not an inspection "refusal" when management refuses to provide information (for example, formulations, lists of shipments and manufacturing codes, etc.) not specifically required by law or regulation. If the refusal is such

that you cannot conduct a satisfactory inspection, discuss with your supervisor if a Warrant for Inspection should be requested. Inspection Warrants are further discussed in the Regulatory Procedures Manual Chapter 6 and IOM 5.5.3.

5.5.3 – Inspection Warrant

A refusal to permit inspection or a refusal to permit access to or copying of records may invoke criminal provisions of sections 301(e) and 301(f) of the FD&C Act [21 U.S.C. 331(e), (f)]. Furthermore, in the case of drug or device inspections, delaying, denying, limiting, or refusing an inspection may invoke criminal provisions of sections 301(e) and 301(f) [21 U.S.C. 331(e), (f)]. Depending on the individual situation, instances of refusal may be met by judicious use of inspection warrants.

Instructions for obtaining warrants are contained in the Regulatory Procedures Manual, Chapter 6-3. See your supervisor for additional information and instructions.

When you serve an inspection warrant, you are operating as an agent of the court, and so the warrant must be executed expeditiously once served. (See IOM 5.5.2.3 for guidance on how to handle any refusal after obtaining a warrant.)

In situations where a potential problem is anticipated with the service of a warrant, the program division should consider sending a supervisory consumer safety officer, or compliance officer, and a U.S. Marshal with the investigator to assist and supervise the serving of the warrant.

After successfully obtaining an Inspection Warrant, you should return to the firm and:

1. Show your credentials to the owner, operator, or agent in charge.
2. Issue the person a written Notice of Inspection (FDA 482).
3. Show that individual the original, signed Inspection Warrant.
4. Give them a copy (not the original) of the warrant.

The copy you provide need not be signed by the issuing judge, but the judge's name should be typed on the copy.

Follow the procedures of the court, or U.S. attorney involved, if their methods differ from the above.

When an inspection is made pursuant to a warrant, a Return, showing the inspection was completed must be made to the judge (or U.S. commissioner or magistrate) who issued the warrant. The Return, executed on the original warrant, should be made promptly and usually no later than 10 days following its execution.

5.5.3.1 – Refusals after Serving a Warrant

If you have been refused entry, obtained a warrant, tried to serve or execute it, and are still refused entry under the warrant, inform the person that the warrant is a court order, and such refusal may constitute contempt of court. If the warrant is not then immediately honored (entry and inspection permitted), you should leave the premises, and promptly contact your supervisor. Document the facts regarding the refusal in your regulatory notes.

If you have served the warrant, yet during the inspection you encounter partial refusal or resistance in obtaining access to anything the FDA is authorized to inspect by the warrant, you should inform the firm that that aspect of the inspection is part of a court order and refusal may constitute contempt of court. If the warrant is not then immediately honored, you should, again, leave the premises, and promptly contact your supervisor. Document the facts regarding the partial refusal or resistance in your regulatory notes.

5.5.4 – Consumer Complaints

Prior to conducting any inspection, you should review CMS , Firm 360, ORA Complaint Dashboard, and the firm history to become familiar with all FDA complaint/injury records associated with the firm (See IOM 5.2.3).

Be sure to cover areas of the facility or production associated with these complaints with management, without revealing the complainant's name(s). Also handle whistleblower complaints with care to protect the identity of the complainant. Determine if the firm has had similar complaints on the same product.

Determine what action the firm has taken to identify the root cause of the problem and to prevent a recurrence in the future. (See IOM 5.7.3.7.10 for reporting instructions.)

Also, check the Programmatic section in this chapter and QMiS for any specific instructions for follow-up to consumer complaints during inspections.

5.5.5 - Recalls Identified or Initiated during an Inspection

Due to the potential public health impact of recalls, when you identify a situation that may be a potential or actual recall during your inspection, it is imperative to contact and submit any information, including documentation obtained, to your division recall coordinator (DRC) as soon as possible. The division should not have to wait for writing and submission of the EIR or memorandum when sharing recall documents with the DRC. (See IOM 7.2 for more information related to recalls.)

5.5.6 – Signing Non-FDA Documents

Occasionally a firm will request you sign various documents, including:

- A waiver which will exempt the firm from any responsibility or liability should an accident occur, and you are injured on the firm's premises
- Form letters concerning access to confidential information the firm does not want released
- A training form acknowledging that you were briefed on the personnel gowning procedures
- A written version of the information/data you are requesting during the inspection

If you receive any such requests to sign non-FDA documents, inform the firm that you are not authorized to sign such documents, letters, requests, waivers, etc., but will report their request in your EIR. One exception is that all FDA employees are authorized to sign in and sign out at a firm and to comply with security measures employed by the firm, including documenting the removal/replacement of seals to inspect vehicles and containers. (See IOM 4.3.3.3 and 4.7.4.6.) The key issue to remember here is you are not authorized to waive, without supervisory approval, *any* of the FDA's rights to inspect, sample, photograph, copy, etc., or to sign any interstate shipping record document which could suggest the firm could not be prosecuted under the Act.

5.5.6 – Inspection Walk-Through

A walk-through inspection of the premises should be conducted as early as possible to become familiar with the operation and to plan the inspection strategy. A walk-through visual inspection of the manufacturing site is helpful in establishing the depth of the inspection, learning about products and processes, identifying sources of manufacturing records and identifying potential areas of concern. The size of the facility, the number of employees, employee practices, environmental conditions inside and outside the facility, raw materials, manual and automated processes, potential sources of contamination, manufacturing flow, method of data collection are some of the factors to be taken into consideration in establishing the depth of the inspection. A visual inspection of a manufacturing site should also be used to check readily apparent potential problem areas such as, general housekeeping, state of operation for processes and processing equipment, and employee practices. Visual inspections of areas used for failure investigation, product sampling and testing, product reworks, returned goods, and product quarantine areas should also be inspected for obvious potential product problems.

Depending on the product being inspected, some of the general inspectional equipment you should have available may include a digital camera, eye and ear protection, and boots and protective clothing. If you are unsure what inspectional equipment is needed, consult with your supervisor. Some specialized equipment may include radiation or ethylene oxide (EO) monitoring devices, magnifiers, and timing devices. For some domestic and foreign sites, investigators may be required to be inoculated prior to the inspection for protection from potential environmental concerns, such as hepatitis, yellow fever, malaria, and live biological products which may be encountered in vaccine products. (See Chapter S for more.)

5.5.7 – General Inspection Procedures and Techniques

The procedures and techniques applicable to specific inspections for foods, drugs, devices, tobacco products, cosmetics, radiological health, or other FDA operations are found in part in the IOM (inspectional policy/procedure), and the compliance programs (program specific instructions). Some procedures and techniques which may be applicable to overlapping areas or operations are described below.

5.5.7.1 – Candling

Candling is defined as: "to examine by holding between the eye and a light, especially to test eggs in this way for staleness, blood clots, fertility and growth." Like most techniques learned through the food inspection programs, there are uses for this technique in other program areas, such as looking for mold in bottled liquids which could be drugs, devices, or biologics. Candling can also be useful in the examination of original documents to see underneath white-out or to look for over-writing.

Many types of products lend themselves to inspection by some type of candling. For these products, firms may have candling equipment which may be built into the production lines or may be a separate operation. Where checking products by candling, it may be possible to use the firm's candling equipment. All candling is best accomplished when light outside the item being candled is masked, so that the light passes through the object rather than being diffused around it. A heavy paper or cardboard template can be quickly prepared at the time candling is done.

5.5.7.2 – Label Review

Do not undertake a critical review of labels unless instructed by the assignment, program, or your supervisor. Limit your comments to the mandatory label requirements required by the acts. However, if after review of the formula, it is obvious an active ingredient or an otherwise mandatory ingredient statement does not appear on the label, such discrepancy may be called to the management's attention.

If you are asked for other label comments, refer the firm to the appropriate center to obtain a label review.

When the labeling is suspect or when you are requested to collect labels/labeling, collect a copy of all labels and accompanying literature for further review. For medical devices, if there is a question regarding the need for a new 510(k) or Pre-Market Approval (PMA) supplement, it is essential the label and labeling be collected.

See IOM 5.5.11.2 regarding labeling for blood and blood products.

5.5.7.3 – Field Examinations (Field Exams)

A field examination is an on-site examination of a domestic product (or a foreign product in domestic channels of trade) sufficient to determine if the product is in compliance with the acts enforced by FDA. A field exam can be conducted of any commodity in any location. It is important to conduct field examinations during food inspections to detect violations (for example, any undeclared sulfiting agents, certified color additives, and allergens). If the examination does not reveal a violation or the appearance of a violation, a sample of the lot is usually not collected. If your exam reveals a violation or potential violation, you should collect an official sample. Instructions on how to conduct a field exam are contained in FDA's "Inspection Guides" and "Compliance Programs" webpages. The Sample Schedules in Chapter 4 also provide guidance on lot examinations for special situations.

5.5.7.4 – Imported Products

Be alert to imported products whenever you conduct an inspection. During inspections of domestic firms, if you encounter imported products that appear adulterated, misbranded, counterfeit, tampered with or otherwise suspect, attempt to fully identify the product and the source of the imported products. Contact your supervisor and Division of Import Operations (DIO) if necessary.

5.5.7.5 – Import for Export

During the domestic inspection, follow-up on the IFE entry/lines as described below:

1. IFE entry/line information and documentation can be obtained through the "*Import for Export - IFE*" section in OSAR Firm 360 and ORADSS report "*IMP046 Import for Export Entry Lines and Documents".*
2. During the inspection, verify if the IFE articles:
   a. were used to produce an exported product,
   b. were destroyed, or
   c. are still under the firm's control pending disposition. If the articles are pending disposition, verify whether they are the same articles that were offered for entry (per supporting documentation).
3. If the articles were exported or destroyed, request the firm's import, export, and/or destruction records to verify that the imported articles were further processed or incorporated into another product and were exported in accordance with sections 801 (e) or 802 of the FD&C Act [21 U.S.C. 381 (e) or 382] or section 351(h) of the PHSA; or were destroyed. For drug products, an initial owner or consignee may be allowed to retain a sample of the imported article to comply with good manufacturing practices (GMP) regulations concerning sample retention.

Upon completion of the inspection, ensure the following actions are taken:

1. Document the status of the IFE product and if further follow-up is required in the EIR or a memo.
2. If further follow-up actions are needed, schedule a follow-up inspection or discuss with the Office of Import Operations (OIO), Division of Import Operations (DIO), to determine appropriate actions at the import level. If further follow-up is NOT required, document the completed follow-up in the EIR memo.

Any inspections identifying a prohibited act under section 301(w) of the FD&C Act [21 U.S.C. 331 (w)] should be forwarded immediately to the applicable program director (director of investigations branch or director of compliance branch) for regulatory action. (See RPM Chapter 9.) In addition, a copy of the violative inspection findings should be forwarded to fdaimportsinquiry@fda.hhs.gov.

5.5.8 – Inspection of Foreign Firms

Inspectional requirements generally apply to all inspections, including foreign inspections. However, there are some exceptions. For instance, the FDA 482 is not issued during inspections outside the country, unless the firm is a U.S. military facility. Be guided by relevant compliance programs, assignments, and the Guide to International Inspections and HHS Travel Manual for other differences.

5.5.8.1 – Review of Foreign-Language Documents

When reviewing documents in a foreign language, do not use any web and mobile applications' translation tools that have not been authorized by the FDA for this particular purpose. Use of these tools may result in unauthorized disclosure of non-public information. There are two Translation Web Tools available behind the FDA firewall. Details can be found at ORA OIO SharePoint site. A video tutorial using these tools is available here.

If you are confident that manually entering a single word or short phrase into an electronic tool for translation could not possibly jeopardize trade secrets or confidential information, based on the information you are reviewing, you may do so. Be sure that, if all your searches were read together, the combination of searches would not result in any unauthorized disclosure.

5.5.9 – Inspectional Precautions (Dos and Don'ts During Inspections)

You should be alert to criticism or allegations that you may have contributed to, or caused, contamination at a firm. This is especially important in drug firms and high-risk food firms, among others. You must adhere to good sanitary practices to refute any such criticisms. You could also unknowingly introduce or spread disease during inspections of, or visits to, animal production or sale facilities; while conducting environmental investigations at poultry layer facilities or conducting dairy farm inspections; during audits of state activities; while investigating drug residue reports or working in a veterinary bioresearch area; or conducting produce safety inspections, among other situations. See IOM 5.3 and the IOM Safety Chapter for information outlining precautions you should follow.

Exercise caution with all your activities in the firm. Follow the firm's sanitation program for employees; wash and sanitize hands, shoes, vehicles, and equipment as indicated. Restrict unnecessary movement between various areas in facilities, and when possible, complete your activities in one area before moving to the next.

When inspecting areas where sterility is maintained, or sterile rooms are located (especially in infant critical food, pharmaceutical or device firms), follow the firm's guidance. In general, it is unnecessary to enter sterile rooms except in the most extraordinary circumstances. These areas are usually constructed to provide visual monitoring. Also, do not take any nonsterile items with you into sterile areas (including regulatory diary, pens, laptop, iPad, etc.). In this situation, you can record your observations in your regulatory notes immediately after leaving the sterile area.

Always use aseptic techniques, including hand sanitizing, when collecting in-line and raw material samples, as well as finished product samples subject to microbiological examination. (See IOM 4.3.5.)

Do not use or consume a firm's products at any of a firm's facilities. This could be interpreted as accepting a product as being satisfactory and could possibly embarrass you and the agency, both during the inspection and in the future. In general, consuming food products in a manufacturing area is considered an objectionable practice.

When conducting inspections of firms using chemicals, pesticides, etc., ask to review the Safety Data Sheet (SDS) (formerly known as Material Safety Data Sheets (MSDS)) for the products present or involved, to determine what, if any, safety precautions you must take. This could include the use of respirators or other safety equipment. (See IOM S.14 and S.14.4 for more).

5.5.9.1 – Clothing

Practice these clothing precautions, for safety and sterility purposes:

- Wear clean coveralls or other protective clothing as needed by the inspection type and if circumstances dictate, use a clean pair when returning from lunch, or upon entering certain machinery or critical areas.
- Remove all jewelry and secure any items on your person, such as pens, pen caps, etc., so they cannot fall into the product or machinery. Do not depend on clips on pens, etc., to hold these items in your outer pockets.
- Individually wrap, or place into clean plastic bags and tape, any clean protective clothing to protect from contamination. If the package has been sterilized, you should also protect the package from possible contamination or puncture. The package should not be opened until you are ready to use the clothing. After use, clothing should be turned inside out as it is removed, and immediately placed in clean paper or plastic bags to prevent spread of contamination until washed and/or sterilized.
- Use disposable hair and head coverings throughout the inspection and disposable hand and foot coverings in areas where floor tracking or cross contamination may be a factor. Use hard hats and other protective devices where the situation dictates.
- If reusable protective boots are used, wash, and sanitize before each use. Always use sterile disposable boot covers when entering machinery, such as dryers, or where unavoidable contact with product is a factor.
- When discarding contaminated disposable head and boot coverings, it is suggested they be placed with used clothing for proper disposal after leaving the plant area.

(See Exhibit 19 – Biosecurity for protective clothing and equipment necessary when visiting livestock or poultry production areas.)

5.5.9.2 – Basic sanitary practices

You are not required to have a health certificate, take a physical exam, or submit to other external requirements to ensure compliance with sanitary procedures in the performance of your official duties. However, it is critical that you adhere to basic sanitation practices. (See IOM S.8.1 – General Preventive and Protective Measures and Employee Safety & Occupational Health (sharepoint.com), S.17.2– Immunizations, and S.17.3 – Physical Examinations.

Employee health guidance as it pertains to any and all personnel working, inspecting, etc., in foods facilities, is addressed in the FDA Food Code. This general guidance related to employee sanitary practices and can be applied to any FDA-regulated product.

5.5.9.3 – Representatives Invited by the Firm to View the Inspection

While conducting an inspection, you may find that the firm's management has invited individuals who are not directly employed by the firm to view the inspectional process (for example, representatives from the press, trade associations, consumer groups, congressional staff, or other company officials).

Regardless who the firm invites to observe the progress of an inspection, the presence of outside representatives should not disrupt the inspection. You should continue to conduct the inspection in a reasonable fashion. The presence of these individuals should have no impact on the way the inspection progresses, except you should take precautions to preserve the confidentiality of any information you may have obtained as a result of the agency's statutory authority. This is especially true when the firm or their representatives are either video- or audio-recording, or photographing, the inspection. Where applicable, refer to IOM 5.6.8 for procedures on how to prepare your own recording, in parallel with the firm's recording.

It is the agency's position that while the investigator must protect non-public (for instance, confidential) information provided to them during the inspection, it is the firm's responsibility to protect non-public information that may be observed or recorded by those individuals invited by the firm.

5.5.10 – Reports of Observations

The FDA 483, Inspectional Observations (see Exhibit 5-5), FDA 483a, FSVP Observations (see Exhibit 5-18), and the FDA 4056 Produce Farm Inspection Observations (See Exhibit 5-17) are intended to notify the inspected establishment's top management in writing of significant objectionable conditions, relating to products and/or processes, or other violations of the FD&C Act and related acts (see IOM 5.5.11) which were observed during the inspection. However, do not quote regulations when reporting your observations.

These observations are made when in the investigator's *judgement,* conditions or practices observed indicate that any food, drug, device, or cosmetic has been adulterated, or is being prepared, packed, or held under conditions whereby it may become adulterated or rendered injurious to health.

It is your responsibility to maintain the ability to attest in a legal forum that the observations were personally observed in conjunction with the supporting evidence. Inspectional observations should not be influenced, or appear to be influenced, by parties external to the inspection team, which could call into question the validity of the observations. *This should not prevent you from consulting with your supervisor or others, including the Centers, concerning your observations.*

The issuance of written inspectional observations is mandated by law and ORA policy.

Be alert for specific guidance in assignments or compliance programs which may supplement the following general instructions.

5.5.10.1 – General Guidance

All FDA 483s, FDA 483a's, or FDA 4056s should adhere to the following general principles:

- Observations that are listed should be significant and correlate to regulated products or processes being inspected.
- Observations of questionable significance should not be listed but will be discussed with the firm's management so that they understand how uncorrected problems could become a violation. This discussion should be detailed in the narrative report.
- All copies should be legible.

Observations should have the following characteristics to be useful and credible:

- Each observation should be clear and specific.
- Each observation should be significant. (Length is not necessarily synonymous with significance.)
- Observations should not be repetitious.
- Observations should be ranked in order of significance.

If an observation made during a prior inspection has *not* been corrected, or is a recurring observation, it is appropriate to note this on the FDA 483, FDA 483a, or FDA 4056.

You should make every reasonable effort to discuss all observations with the management of the establishment as they are observed, or daily, to minimize surprises, errors, and misunderstandings when the FDA 483, FDA 483a or FDA 4056 is issued. This discussion should include those observations, which may be written on the FDA 483, FDA 483a, or FDA 4056, and those that will only be discussed with management during the closeout meeting. Industry may use this opportunity to ask questions about the observations, request clarification, and inform the inspection team what corrections have been or will be made during the inspection process.

The FDA 483 or FDA 483a should not include specific corrective actions taken by the firm in response to observations noted on the FDA 483, FDA 483a, or during the inspection, except as described in IOM 5.7.3.7.17. These actions should be reported in the narrative report.
Corrective actions not related to a significant observation are noted in the inspection notes and in the narrative report. (For annotations of the FDA 4056, refer to Section 5.5.11.4 - Annotation of the FDA 483 and the FDA 4056.)

Include the results of confirmed positive environmental samples on the FDA 483 or the FDA 4056 if results are known prior to closeout. The investigator should not prolong the inspection if the results are not known prior to close-out of the inspection.

There may be instances where same-day discussion of observations may not be possible due to the volume of documents collected and/or document review reveals observations on a different day than the documents were collected or other circumstances. When this occurs, the lack of a daily discussion of observations, or of any discussion, does not preclude the listing of significant observations on the FDA 483, FDA 483a, or the FDA 4056.

NOTE (for produce safety inspections): Corrective actions observed during a produce safety inspection are noted on the FDA 4056. Corrective actions not related to a significant observation are noted in the inspection notes and in the EIR. (For annotations of the FDA 4056, refer to Section 5.5.11.4- Annotation of the FDA 483 and the FDA 4056.)

5.5.10.2 – eNSpect Electronic Forms

eNSpect is an electronic FDA 483, FDA 483a, or FDA 4056 and EIR reporting system. Use eNSpect to generate the FDA 483, FDA 483a, or FDA 4056 where applicable citations exist. You should be able to write the entire FDA 483, FDA 483a, or FDA 4056 using eNSpect. However, when citations do not exist for *ALL* of the commodity areas for which observations need to be included, eNSpect should not be used. In these instances, create the FDA 483, FDA 483a, or FDA 4056 outside of eNSpect and record this activity in eNSpect.

Use eNSpect for all EIRs, whether your FDA 483, FDA 483a, or FDA 4056 was generated using eNSpect, and when no FDA 483 was issued. (See IOM 5.7.1.)

5.5.10.3 - Preparation of Form FDA 483

It is not necessary to complete all headings of the FDA 483, when multiple page 483s are issued. Complete all headings on the first page and, on subsequent pages, only those necessary to identify the firm and dates inspected. FDA 483s should be issued at the conclusion of the inspection and prior to leaving the premises. However, in preparing some complex FDA 483s, it may be necessary to leave the premises and return later to issue and discuss your inspectional observations. In these cases, you should advise the firm's management that your inspection has not been completed and you will return to issue the FDA 483 and discuss inspectional findings. However, there should be no unreasonable or unwarranted delays in issuing and discussing the FDA 483.

Also note that during the inspection, you should not show the firm's management a draft, unsigned copy of the FDA 483, or an electronic copy of the FDA 483 on your computer screen. You should issue only a signed FDA 483 at the closeout discussion with management.

As noted above, FDA 483s, FDA 483a, and FDA 4056s should be issued in eNSpect unless there are no commodity specific sites in eNSpect, or you encounter technical difficulties, or are addressing certain multiple commodity situations (See IOM 5.5.10).

In these instances, your other options are:

- An electronic (non-eNSpect) version of the FDA 483, FDA 483a, or FDA 4056
- A handwritten FDA 483, FDA 483a, or FDA 4056.

Note that when using a handwritten or electronic (non-eNSpect) version of the FDA 483, FDA 483a, or FDA 4056, the current version must be used.

It is preferred not to identify individuals or firms by name i.e., suppliers and consignees within the FDA 483, FDA 483a, and FDA 4056. Where appropriate to support the FDA 483, FDA 483a, or FDA 4056 observation, identify the individual(s) or firm(s) by substituting other non-specific identifying information as below. Document your evidence in your EIR, fully explaining the relationship(s).

- The lot number for a component received from or shipped to firm "A".
- The invoice number for a shipment from or to firm "A".
- A patient #, record #, etc.
- The study number for a particular Clinical Investigator site.
- Other necessary but non-specific identifying information to show the observation's relationship to a particular firm and/or individual.

5.5.10.4 – Individual Headings, Form FDA 483

District office address and phone number - Legibly print the home district address where the **firm** is physically located, regardless of program area or investigator duty station. Include the district office telephone number and area code. If using eNSpect for the FDA 483, select the home district of the firm. For example, if a firm is located in

Little Rock, Arkansas, then the district office would be the Dallas District Office. (See Appendix E for boundary maps to assist you with this.)

For foreign inspections, the district office address will be provided by your trip planner.

Name and title of individual to whom report is issued - Enter the legal first name, middle initial, last name, and full title, of the person to whom the form is issued.

Firm or farm name - Enter the full, legal name of the firm, including any abbreviations, quotation marks, dashes, commas, etc.

Street address, city, state, and ZIP Code - Enter the street address, city, state, and ZIP Code. (Not a P.O. Box, unless P.O. Box is part of the address, such as on a rural route).

Date(s) of inspection - Enter the actual or inclusive date(s) of inspection.

FDA Establishment Identifier (FEI) number - If the FEI is on the assignment, enter it here. If not readily available, leave blank.

Type of establishment inspected - Enter the types of the establishment, such as bakery, clinical investigator, drug repacker, blood bank, cigarette retailer, or medical device manufacturer.

Employee(s) signature and employee(s) name and title - The names of everyone who participated in the inspection with the issuance of an FDA 482 should be listed on the FDA 483, FDA 483a, or FDA 4056, even if they are not available to sign the document. Each member of an inspection team should sign the FDA 483, FDA 483a, or FDA 4056. However, absence of a team member at the conclusion of an inspection need not prevent issuance of the form. (See IOM 5.2.8.1.) If you use an electronically generated FDA 483, FDA 483a, or FDA 4056, be sure you reserve a copy for the program division files – and note that an unsigned photocopy or printed duplicate is not acceptable. (See IOM 5.5.10.2.)

Additional headings on the FDA 4056:

Name of state and department (*if acting under the commission with FDA*) – If the FDA 4056 is used by a state acting under FDA commission, the name of the agency is listed here. (For an FDA-led inspection, place "N/A" in this box.)

Farm mailing address – Address, city, state, and ZIP code at which the farm receives mail

Farm physical location, if different from mailing address – Location identifiers such as GPS coordinates

Type of inspection –

- Initial – a first inspection of the farm
- Routine – a normal surveillance inspection
- Follow-up – a follow-up to a violative inspection
- For-cause – an inspection to follow-up on a specific issue, such as an outbreak or positive microbiological sample
- Other (please specify) – an inspection that doesn't meet one of the other categories (this category used very rarely)

For an initial inspection, you will check both the initial box and select an additional box (routine, for-cause, or other box) as appropriate for the type of inspection conducted.

Crops observed - List the crops for which some element or aspect of growing, harvesting, packing, and/or holding was observed during the inspection. If the farm grows or handles other crops, but those crops were not observed during the inspection, do not list them.

5.5.10.5 - Signature Policy

Everyone present under FDA inspectional authority at issuance must digitally sign--or if not able to do so, sign the first and last pages of the FDA 483 with initials on each intervening page in the designated signature block.

NOTE: if you are not using the official multi-part FDA 483 form, and a copier is not available, insert carbon paper to reproduce a signed copy of the FDA 483.

NOTE: If issuing the FDA 483 using eNSpect, the lead CSO's signature should appear on all pages of the FDA 483, while the remaining team members' signatures should appear on the last page.

NOTE: For FDA-4056. See Exhibit 5-20 - Produce Inspection Details.

5.5.10.6 - Date Issued

Enter the date the form will be issued to the firm's management.

5.5.10.7 - Observations

Where applicable, when formulating each FDA 483, FDA 483a, or FDA 4056 observation, you should attempt to answer the *Who* (using titles or initials when necessary), *What*, *When*, *Where*, *Why*, *How Much,* and *How Often* questions. You should also challenge each observation by asking "So What?" as a way to vet and affirm, the observation's significance.

Enter your reportable observations succinctly and clearly. Conditions listed should be significant and relate to an observed or potential problem with the facility, or its equipment, processes, controls, products, employee practices, or records. "Potential problems" should have a reasonable likelihood of occurring based upon observed conditions or events. Do not cite deviations from policy or guidance documents on the FDA 483, FDA 483a, or FDA 4056.

As appropriate, FDA 483, FDA 483a, and FDA 4056 observations should include relationship of observations to a given population. For example, "Two out of 50 records examined were ***" or "4 out of 12 bags examined were ***." When appropriate, an FDA 483, FDA 483a, or FDA 4056 observation may refer to "inadequate" conditions or qualities, as long as you provide supporting facts (examples) or explanations as to why the condition, practice, or procedure you have observed is inadequate.

It is preferred that you not identify individuals or firms by name, like suppliers and consignees, within the FDA 483, FDA 483a, or FDA 4056. Where appropriate to support the FDA 483, FDA 483a, or FDA 4056 observation, identify the individual(s) or firm(s) by substituting other non-specific identifying information, as suggested below. But be sure to document your evidence in your EIR, to fully explain the relationship(s).

Non-identifying information may include:

- The lot number for a component received from or shipped to firm "A"
- The invoice number for a shipment from or to firm "A"
- A patient number, or record number. (See IOM 5.5.11.3 item 7)
- The study number for a particular clinical investigator site.
- Other necessary, but non-specific, identifying information to show the observation's relationship to a particular firm and/or individual (for example, a supplier number from the inspected firm's internal supplier database consisting of a five-digit number).

Presently there are three ways to generate an FDA 483, FDA 483a, or FDA 4056:

- eNSpect
- Electronic (non-eNSpect) version
- Traditional hard copy (including handwritten)

When using a traditional hard copy or electronic (non-eNSpect) version of the FDA 483, FDA 483a, or FDA 4056, the current version must be used.

5.5.10.8 - Medical Device Inspections

All FDA 483s state the following before the listed observations:

> "This document lists observations made by the FDA representative(s) during the inspection of your facility. They are inspectional observations, and do not represent a final agency determination regarding your compliance. If you have an objection regarding an observation, or have implemented, or plan to implement, corrective action in response to an observation, you may discuss the objection or action with the FDA representative(s) during the inspection or submit this information to FDA at the address above. If you have any questions, please contact FDA at the phone number and address above."

Medical device inspections, however, require specific additional language that you should insert on the FDA 483 after the above statement:

> "The observations noted in this form FDA 483 are not an exhaustive listing of objectionable conditions. Under the law, your firm is responsible for conducting internal self-audits to identify and correct all violations of the quality system requirements."

5.5.10.9 - Correction of FDA 483, FDA 483a, And FDA 4056 Errors

Special note: *The following procedures do not pertain to any adverse conditions noted and then corrected during an inspection. Observations of this type stand and should remain on the FDA 483, FDA 483a, and FDA 4056.*

Because the Inspectional Observations (FDA 483), Request for FSVP Observations (FDA 483a), and Produce Farm Inspection Observations (FDA 4056) forms are of critical importance to both the agency and regulated industry--and because individual forms, such as the FDA 483, FDA 483a, and FDA 4056 may become public through publishing in industry trade press, FOIA inquiries, headquarters postings, and other means--it is critical that complete and accurate documentation of any corrections made to these official documents occurs.

5.5.10.9.1 - Errors Discovered Prior to Leaving the Establishment (eNSpect)

For corrections to an FDA 483, FDA 483a, or FDA 4056 created in eNSpect:
All corrections/deletions should be made in eNSpect. If there are technical difficulties that prevent you from issuing an amended eNSpect 483, you may handwrite the corrections on the original (maintain a copy for the EIR) and inform the firm representative(s) that you will make corrections and provide them with the corrected eNSpect 483.

- Changes made to correct errors in the text of the observation will show on the face of the final printed FDA 483. Any changed text deletions should remain visible as a strikethrough along with the correction that was made. (For example, to change "lot 1234" to "lot 5678," so that it correctly appears as, "lot ~~1234~~ **5678**" you would select the text to be altered, right click, then select font and select strike-through. Or to add to "lot 1234" so that it includes" lot 5678," you would embolden the additional lot in this way: "lots 1234 **and 5678**".
- If an entire observation is removed, or the underlying citation is changed, incidental text should be used to add the statement, "An observation concerning *** was removed, or the underlying citation was changed based on discussions with management."
- Addition of a new observation or changes to the observation.

5.5.10.9.2 - Errors Discovered Prior to Leaving the Establishment (Non-eNSpect)

For an FDA 483, FDA 483a, or FDA 4056 created outside eNSpect:

- Make handwritten changes to correct the error(s) on the original FDA 483, FDA 483a, or FDA 4056, and initial the changes. Correct errors by striking through the erroneous text and entering the correct information (if any). When possible, retrieve and destroy all uncorrected copies of the FDA 483, FDA 483a, or FDA 4056, either provided to or produced by the establishment.
- If the establishment has photocopying equipment available and will provide you with a copy of the corrected original FDA 483, FDA 483a, or FDA 4056, then obtain a copy of the corrected original document from the establishment.
- If you have an FDA-issued scanner, make a digital copy of the corrected original. If you do not, and the establishment has photocopying equipment available and will provide you with a copy of the corrected original FDA 483, FDA 483a, or FDA 4056, then obtain a copy of the corrected original document from the establishment to attach to the EIR.
- If the establishment has no such equipment or refuses to provide you with a photocopy of the original corrected FDA 483, FDA 483a, or FDA 4056, you should duplicate corrections you made on the original and initial the changes using a carbon copy or other copy of the original form. Retain the corrected copy of the FDA 483, FDA 483a, or FDA 4056 to attach to the EIR.

5.5.10.9.10 - Errors Discovered after Leaving the Establishment

Normally, you should not use the amendment process to issue additional FDA 483, FDA 483a, or FDA 4056 items after the inspection has been closed out and you have left the premises. However, if you think you must, consider the following guidance:

- Regarding eNSpect FDA 483, FDA 483a, or FDA 4056, discuss any errors with your supervisor. Make all corrections/deletions in eNSpect per 5.5.10.9.1.
- Regarding non-eNSpect FDA 483, FDA 483a, or FDA 4056, discuss any errors with your supervisor. If necessary, prepare a revised FDA 483, FDA 483a, or FDA 4056.
- When issuing the corrected FDA 483, FDA 483a, or FDA 4056, you should personally deliver the amended FDA 483, FDA 483a, or FDA 4056 to the firm for discussion. If personal delivery is not practical, then mail the amendment to the firm with a full explanation provided in a cover letter. Include a copy of the original FDA 483, FDA 483a, or FDA 4056, and the amended FDA 483, FDA 483a, or FDA 4056, and cover letter, in the EIR. In addition, you should call the person to whom the original FDA 483, FDA 483a, or FDA 4056 was issued to discuss the change(s). Document this discussion in your EIR.

Special Note: The issuance of an amended FDA 483, FDA 483a, or FDA 4056 in person or via mail does not change the inspectional end date. The inspectional end date remains as the date that the original FDA 483, FDA 483a, or FDA 4056 was issued.

5.5.11 - Reportable Observations

You should cite factual observations of significant deviations from the FD&C Act [21 U.S.C. 301], PHS Act, 21 CFR, and other acts where the FDA has enforcement authority, unless these citations require concurrence, or are specifically prohibited – see IOM 5.5.11.3 Non-Reportable Observations.

However, do not report opinions, conclusions, or characterize conditions as "violative." The determination of whether any condition is “violative” is an agency decision made after considering all circumstances, facts, and evidence.

Examples of reportable observations generally fall into one of two categories, either adulteration or other. See below.

5.5.11.1 – Adulteration Observations

For assistance, review Sections 402, 501, 505(k), 601, and 704 of the FD&C Act [21 U.S.C. 342, 351, 355(k), 361, and 374]. Adulteration observations include specific factual observations of:

- Foods, drugs, devices, or cosmetics consisting in whole, or in part, of filthy, putrid, or decomposed substances.
- Undesirable conditions or practices, bearing on filth or decomposition, which may reasonably result in the food, drug, device, or cosmetic becoming contaminated with filth.
- Insanitary conditions or practices that may reasonably render the food, drug, device, or cosmetic injurious to health.
- Careless handling of rodenticides or pesticides.
- Results of field tests (for example, organoleptic examination of fish, crack-out of nuts, etc.) that reveal adulteration.
- Observations of faulty manufacturing, processing, packaging, or holding, of food, drug, or device products as related to current good manufacturing practice regulations, including inadequate or faulty record keeping.
- Observations of faulty can closures and/or deviations from recommended processing times and temperatures.
- Deviations from the animal proteins prohibited in ruminant feeds requirements (21 CFR 589.2000).
- Results of analytical laboratory findings that reveal adulteration.

5.5.11.2 - Other Observations

You may include other factual observations of significant deviations from the FD&C Act [21 U.S.C. 301], 21 CFR, Government Wide Quality Assurance Program (GWQAP) requirements, and other acts as directed by compliance programs and other agency directives. In some cases, you may cite labeling deviations as directed below. (This list of potential "other observations" is not all- inclusive.)

- Observations indicating non-conformity with commitments made in a New Drug Application, New Animal Drug Application, or in an antibiotic certification or certification exemption form. (See Section 505 FD&C Act, [21 U.S.C. 355].)
- Observations, forming the basis for product non-acceptance under the GWQAP. (See IOM 5.2.3.5.)
- Deviations from blood and blood products labeling requirements, as specified in 21 CFR 606.121 and 21 CFR 640.
- Animal protein products, and feeds containing such products, that are not in compliance with the labeling requirements of paragraphs (c) through (f) of 21 CFR 589.2000. (See Section 403(a)(1) or 403(f) of the FD&C Act [21 U.S.C. 343(a)(1) or 343(f)].)
- Deviations from the applicable labeling regulations for human cells, tissues, and cellular and tissue-based products (HCT/Ps), as specified in 21 CFR 1271 and CP 7341.002.
- Observations indicating drug misuse, failure to maintain proper drug use records, and/or poor animal husbandry practices during drug residue investigations. (See the applicable compliance program(s) for guidance.)
- Observations indicating non-conformity with the post marketing adverse drug experience reporting requirements, as specified in 21 CFR 310.305, 314.80, 314.98, 314.540, or 600.80 or other post marketing requirements, as specified in 21 CFR 314.81 or 600.14. (See Sections 505 and 760 of the FD&C Act [21 U.S.C. 355(k) and 379aa].)
- Observations indicating non-conformity with the Medical Device Reporting requirements as specified in 21 CFR 803 {See Section 519(a) of the FD&C Act [21 U.S.C. 360i].

- Observations of non-conformity to the Medical Devices Reports of Corrections and Removals requirements as specified in 21 CFR 806 {See Section 519(f) of the FD&C Act [21 U.S.C. 360i(f)]} should be verified with the program's division recall coordinator.
- Observations of non-conformity to the Medical Device Tracking requirements, as specified in 21 CFR 821 {See Section 519(e) of the FD&C Act [21 U.S.C. 360i(e)]}
- Observations of non-conformity to the Unique Device Identification (UDI) requirements of 21 CFR 801 Subpart B and 21 CFR 830.
- In general, observations indicating noncompliance with medical device pre-market notification requirements and pre-market approval requirements under FD&C Act sections 510(k) and 515 [21 U.S.C. 360 (k) and 360e] respectively, should be included with the prior concurrence of CDRH and/or CBER.
- Reporting observations noted at a contract facility to the contracting facility is allowed under 21 CFR PART 200.10. But before doing so, consult with your supervisor to determine if appropriate.
- Observations indicating non-compliance with LACF/Acidified food registration and failure to file scheduled processes. Before doing this, verify lack of such, as covered in CP 7303.803A.
- Deviations from the applicable labeling requirements for outsourcing facilities, as specified in Section 503(B)(a)(10) of the FD&C Act.
- Observations at animal food facilities that are not subject to animal food regulations (for example, not required to register as a food facility) indicating food safety noncompliance with the FD&C Act adulteration or misbranding provisions in FD&C Act section 402 and 403. (See Compliance Program 7371.000: COMPREHENSIVE ANIMAL FOOD INSPECTION for more details.)

5.5.11.3 - Non-Reportable Observations

As implied, non-reportable observations should not be reported on the FDA 483. These objectionable conditions fall into three basic categories:

1. Observations of significant deviations from specific laws and/or regulations, as identified in items 1-9 below.
2. Observations of deviations from specific laws and/or regulations that in your judgment are of "questionable significance" and "deemed not to merit inclusion on the FDA 483, FDA 483a, or FDA 4056," but do warrant discussion with management.
3. Observations, based on your judgement, that deviate from official published guidance, but do not deviate from regulations, and warrant discussion with management.

(See IOM 5.5.12 regarding discussions with management at which time other verbal observations may be discussed.)

Do not report observations pertaining to:

1. Label and labeling content, except per IOM 5.5.11.2, items 2, 3, 4, 5, and 12 above.
2. Promotional materials.
3. The classification of a cosmetic, animal-grooming aid, or device as a drug.
4. The classification of a drug as a new drug, or new animal drug.
5. Non-conformance with the New Drug Regulations, 21 CFR 312.1 New Drugs for Investigational Use in Human Beings: Exemptions from Section 505(a)) unless instructed by the particular program or assignment.
6. The lack of registration required by Section 415 and 510 of the FD&C Act. The lack of registration per 21 CFR 1271 Subpart B Procedures for Registration and Listing, promulgated under Section 361 of the PHS Act.
7. Patient names, donor names, etc. If such identification is necessary, use initials, code numbers, record numbers, etc.
8. The use of an unsafe food additive or color additive in a food product.

9. The lack of approval, conditional approval, or indexing for an animal drug

Non-reportable observations and any corrections made related to them must be discussed with management and be described in the narrative report. See IOM 5.7.3.7.17.

5.5.11.3.1 – Reporting

Be sure to follow any program-specific instructions on how to report when using eNSpect.

You may record non-reportable observations on the FDA 483 or FDA 483a in the three categories in IOM 5.5.11.3 as follows:

- Category 1: You should select the appropriate eNSpect cite, verify or set the "Print type" to "Do Not Print," and save the observation in the eNSpect database. This should be done even if there are no other reportable observations (for example, Lack of Food Registration, as covered in IOM 5.8.1.5, is not reportable).
- Category 2: You should always report these observations under the "General Discussion with Management" heading in the EIR, as specified by IOM 5.5.12.4. Additionally, you may select the appropriate citation in eNSpect, enter the "specifically" text regarding the observation, set it to "Do Not Print," save, and it will be automatically entered into the EIR when it is generated.
- Category 3: There are no eNSpect cites for official guidance. These observations are discussed with management and should be entered directly into the EIR under the "General Discussion with Management."

5.5.11.4 - Annotation of the FDA 483 or FDA 4056

Offer to annotate the FDA 483 for all medical device inspections. The program division has discretion to annotate the FDA 483s in other program areas. BIMO inspections are generally excluded from annotations. Annotations of FDA 483s for inspections in other program areas may be done if both the establishment and the investigator/team believe annotation will facilitate the inspection process. When an FDA 483 is annotated it should be done in accordance with the guidance that follows.

Inform the establishment of the annotation process at some point prior to the final discussion with management. Determine from management whether they wish to have their FDA 483 observations annotated. This is voluntary on the part of the establishment. If the establishment does not want one or more observations annotated, you must honor the request.

The actual annotation of the FDA 483 should occur during the final discussion with management. They should appear as succinct comments about the status of the FDA 483 item. The annotations can be made after each observation, at the end of each page of the FDA 483, or at the bottom of the last page of the FDA 483 prior to the investigator's signature. (See IOM 5.5.12 for discussions of FDA 483 observations with management.)

If the establishment chooses to annotate the FDA 483 observations, the FDA 483 should be annotated with one of the following comments, as appropriate:

1. Reported corrected, not verified.
2. Corrected and verified.
3. Promised to correct.
4. Promised to correct by [insert date].
5. Promised to correct within [time interval].
6. Under consideration.
7. Annotation Intentionally Left Blank.

On the FDA 4056, if the produce farm has corrected the item or has committed to correct it, the description section should include one of the following annotations:

1. Reported corrected, not verified.

2. Corrected and verified.
3. Promised to correct.

The term "verified," as used in the above phrases, means "to confirm; to establish the truth or accuracy." In these instances, you are responsible for the verification. In some situations, you will not be able to verify the corrective action unless there is further program division or center review, or until there is another inspection of the establishment.

The establishment's stated objections to any given observation, or to the FDA 483 or FDA 4056, should *not* be annotated on the FDA 483 or FDA 4056. If firm does not wish to annotate the FDA 483, select “No annotation” in eNSpect, or if issued outside eNSpect, do not annotate. The EIR should include the establishment's objections to the observation and the fact that the establishment declined to have the observation annotated.

When an establishment has promised corrections and furnishes a date or timeframe (without a specific date) for completion, then you may add "by x date" or "within x days or months" in the annotation. Where the investigator and the establishment have "agreed to disagree" about the validity of an observation on the FDA 483, you may annotate this observation with "Under consideration," or with no annotation based on the establishment's desire.

All corrective actions taken by the establishment and verified by FDA should be discussed in detail in the EIR.

5.5.11.5 - Government Wide Quality Assurance Program (GWQAP)

A Memorandum of Understanding (MOU) between the FDA and the Department of Defense (DoD) Defense Logistics Agency (DLA) requires the FDA to determine if medical products offered for delivery to the DLA were produced in accordance with the contract requirements. GWQAP staff request these source inspections and provide ORA staff copies of the DLA contract (Form DD1155) with the requirements and specifications agreed by the manufacturer.

When performing product acceptance examinations under the GWQAP, you must discuss all deficiencies with management and report these deficiencies in writing on the FDA 483. This includes all deficiencies related to the FD&C Act, as well as deficiencies in complying with contract requirements that result in non-acceptance. There must be a clear differentiation on the FDA 483 between these two types of deficiencies.

Consult these steps:

1. Enter the FD&C type deficiencies [good manufacturing practice (GMP) deviations, etc.] first on the FDA 483.
2. In eNSpect, you may use incidental text to describe deficiencies in contract provisions.
3. Alternatively, if you are issuing the 483 outside eNSpect, after the FD&C type deficiencies, draw a line across the printed or electronic page and add a heading "The Following Additional Contract Non-Conformances Were Observed."
4. Enter each deficiency, which forms a basis for non-acceptance, followed by the reference to the applicable contract requirement or specification.
5. Describe the GQWAP observations in the EIR under the *Objectionable Conditions and Management’s Response* section.

5.5.11.6 – Issuance of the FDA 483, FDA 483a, or FDA 4056

The FDA 483, FDA 483a, and FDA 4056 should be issued to the most responsible individual available at the close of the inspection, per 5.2.3.1., which states that FDA 483s are to be issued at the conclusion of the inspection and prior to leaving the premises.

A copy should be sent to the top management of the firm, including foreign management, unless the individual to whom you issued the original is the top official of the firm.

The signed FDA 483, FDA 483a, or FDA 4056 can be issued in the following ways:

- Physical paper copy. Be sure printed versions of the signed FDA 483s, FDA 483a, or FDA 4056s are legible.
- Electronically by email as a PDF attachment (onsite, prior to leaving the premises). The FDA 483, FDA 483a, and FDA 4056 must be sent in a manner that protects Trade Secret and Confidential Information.
- Electronic media transfer to the firm (for example, USB or CD/DVD). Follow all IT security policies and procedures when using electronic media, including FDA policy with regards to portable media devices in IOM 5.6.6 and in the FDA Information Systems Security and Privacy Guide).

If the FDA 483, FDA 483a, or FDA 4056 is issued electronically, document your method of issuance and discussions with management in your regulatory notes, per IOM 5.5.12– Discussing Issues with Management.

Upload into eNSpect one copy of any signed, modified, and/or amended FDA 483, FDA 483a, or FDA 4056 issued to the firm.

5.5.12 – Discussing Issues with Firm Management

5.5.12.1 – Communication During the Inspection

During the inspection, it is important to discuss findings you may have with firm management in a timely fashion, where possible, so they can be aware of and have an opportunity to respond to your concerns. At minimum, a meeting should be held once each inspection day with firm management to discuss any findings you believe will lead to an observation on a form FDA 483, or a discussion item, as well as any outstanding items that need to be revisited. During the meeting, you should be prepared to discuss the findings using evidence obtained during your inspection and relate those findings to the applicable laws and regulations. Investigators should refrain from providing advice or consultation during their discussions and should note any firm management feedback related to inspectional findings during the meeting.

5.5.12.2 – Closing Meeting Report of Observations (FDA 483)

Prior to meeting with firm management to conclude the inspection, ensure you have obtained all necessary information to satisfy your assignment, including both a clear understanding of the authority and responsibility of management and evidence to support any objectionable conditions you observed during your inspection.

After the conclusion of the inspection, meet with the most responsible individual (see IOM 5.6.3.1) available to discuss the objectionable conditions that you observed. Objectionable conditions may be identified as reportable (See IOM 5.5.12.3) or non-reportable (See IOM 5.5.12.4).

During the discussion, be direct, courteous, and responsive. Explain the significance of each item and relate both reportable and non-reportable objectionable conditions to the applicable sections of the laws and regulations administered by the FDA. Use care to not appear overbearing or arbitrary in your attitude or actions.

Investigators should also refrain from providing advice or consultation during their discussions. Do not volunteer information about other firms or their practices. Ignore casual exploratory questions or remarks from management about competitors or their processes. Your casual and seemingly innocuous remarks may reveal privileged information. Therefore, remain alert and diligent throughout your conversation and avoid voluntarily, or unknowingly, divulging information, which may be privileged or confidential and possibly compromise the FDA's and your own integrity.

Describe in your narrative report all significant conversations with management or management representatives. In most instances it is not necessary to quote management's response verbatim; paraphrasing the replies is

sufficient. However, if the situation is such that quoting their reply, or replies, is necessary, enclose them in quotation marks.

5.5.12.3 – Reportable Observations

Issue the Form FDA 483, 483a, or FDA 4056 in accordance with IOM 5.5.12.2 at the close of the inspection. Explain the significance of each observation and relate it to the applicable sections of the laws and regulations administered by the FDA.

During the discussion, be direct, courteous, and responsive with management. Do not be overbearing or arbitrary in your attitude or actions. Do not argue if management voices a different view of the observations. Explain, to the best of your judgment, the conditions you observed that may be determined by the FDA, after review of all the facts, to be violations. Make clear that the prime purpose of the discussion is to call attention to objectionable practices or conditions, which should be corrected.

Determine management's intentions regarding correcting objectionable conditions, including time frames. Where applicable, request from the firm whether they intend to annotate the observations (see IOM 5.5.11.4). Advise firm management if the FDA receives an adequate response to the form FDA 483, 483a, or FDA 4056, or other objectionable conditions, within 15 business days of the end date of the inspection, as it may impact FDA's determination of the need for subsequent action. Additional instructions on this response may be provided based on program procedure.

The firm may propose corrections or procedural changes and ask you if this is satisfactory. If this involves areas where your knowledge, skill, and experience are such that you know proposed responses will be satisfactory, you can so advise management. However, do not assume the role of an authoritative consultant. Do not recommend products or services of a particular establishment. If asked to suggest a product or consulting laboratory, refer the inquirer to a classified directory, or trade publications or organizations.

If significant deviations are observed during a domestic inspection, you should inform management during the closeout discussion the conditions you observed that may, after further review by the agency, be considered violations of the FD&C Act or other statutes. Legal sanctions available to the FDA for domestic firms may include seizure, injunction, civil money penalties, and prosecution.

If significant deviations are observed during a foreign inspection, you should inform management during the closeout meeting that significant deviations observed during a foreign inspection could result in a facility's product(s) being detained and potentially refused entry into the United States.

5.5.12.4 – Discussion Items ("Do Not Print" Observations, Other items)

Non-reportable observations are not listed on a form FDA 483, FDA 483a, or FDA 4056, and are provided verbally to the firm at the close of the inspection. (See IOM 5.5.11.3 for a discussion of the different categories of non-reportable observations.)

Regardless of the nature of the non-reportable observation, you should explain the concern(s) clearly and succinctly to firm management. Where the issue may represent a deviation from a regulation, you should refer the firm to that regulation. You may explain to the firm that although the Discussion Items will not be listed on the form FDA 483, FDA 483a, or FDA 4056, they will be documented in the EIR and may be followed up on at the next inspection. For non-reportable observations which potentially represent significant deviations from specific laws/regulations, or as directed by your program division, you may encourage the firm to respond to the matter to the FDA in writing as you would for reportable observations.

As with reportable observations, determine management's intentions regarding correcting observed conditions, including time frames. The firm may propose corrections or procedural changes and ask you if this is satisfactory. If

this involves areas where your knowledge, skill, and experience are such that you know the proposed response(s) will be satisfactory, you can advise management. Do not assume the role of an authoritative consultant, and do not recommend products or services of a particular establishment.

5.5.12.5 – Receipt for Samples

You must issue a Form 484, Receipt for Samples, if you collect any physical sample during an inspection. In general, do not issue the Form 484 prior to concluding the inspection, even if the sample is collected at the start of the inspection, as issuance of the form closes the inspection (See IOM 4.2.5). If a Form 484 is issued before the inspection is completed, issue another Form 482, Notice of Inspection, before resuming the inspection. Also, if the person to whom the Form 482 was issued is not available, give it to someone else who meets the definition of "owner, operator, or agent-in-charge." Submit an exact copy with the EIR. Also, do not comment on the type of examination expected, or promise a report of analysis.

5.5.12.5.1 – Items Requiring a Receipt

Issue an FDA 484 for any food, drug, device, or cosmetic, or portion thereof, physically removed from the establishment.

NOTE: A receipt must always be issued to anyone from whom you obtain Rx drugs. This includes individuals, as well as firms. (See IOM 4.2.5.4 and IOM 4.6.2.40.)

The following are examples of materials also requiring a Receipt for Samples:

- Air filter pads.
- Rodent pellets, nesting material, package cuttings, insects, and insect frass.
- Any other physical evidence physically removed from the plant, including in-line and environmental swabs.

5.5.12.5.1 – Items Not Requiring a Receipt

Do not issue an FDA 484 for:

- Items or materials examined during the inspection but not removed from the establishment (report adverse results of analysis of materials on FDA 483 and FDA 4056 as indicated in IOM 5.5.11.1).
- Labels and labeling, including promotional materials.
- Photographs taken during the inspection.
- Record(s), including production, quality control, shipping, and interstate records.

Firm management may request copies of documents or records you obtain from their firm. There is no objection to supplying them. See IOM 5.6.11.3 for procedures when a firm requests a receipt for records copied during an inspection or investigation.

5.5.13 – Post-Inspectional Contacts

If the firm contacts you after the inspection regarding the inspection or follow-up, you should refer the request to your supervisor, or to the Compliance Branch if a regulatory action is contemplated. You should not respond directly to the firm regarding the adequacy of the firm's response to inspectional observations or any follow-up being planned.

After the inspection is concluded, if you find that a document or other required information is missing, you should discuss the needed information and how to proceed with your supervisor.

5.6 - Evidence Development (Types of Evidence)

5.6.1 – Definition of Evidence

Evidence is defined as information in the form of documentation or verbal statements and the material objects admissible as testimony in a court of law used to obtain a ruling on a controversy. The recognition, collection, and effective presentation of admissible evidence is essential to successful litigation. (See IOM 2.3.)

Evidence is required to support your observations and reports of violative conditions, even if not facing potential litigation. Evidence may take several forms during your inspection, with common ones listed below. See the referenced sections for further information about the collection and maintenance of those evidence types.

- Samples (See IOM 5.6.4).
- Exhibits, including both physical material (also referred to as filth exhibits) obtained from the firm (see IOM 5.6.5) and copies of records obtained from the firm, usually via electronic means (see IOM 5.6.6).
- Photographs or video recordings taken by the investigator (see IOM 5.6.7).
- Observations made by the investigator and captured in Regulatory Notes, including statements made by firm personnel (See IOM 1A.1.4.2).
- Written statements of knowledgeable persons, such as those captured in the form FDA 463a, Affidavit (See IOM 4.4.5).

Although inspectional procedures to detect adulteration and contamination, etc., are described under specific headings in the IOM related to one type of inspection, the same procedures and/or techniques may also apply to other areas. For instance, the procedures to detect contamination from filth, insects, rodents, birds, etc., described in IOM section 5.8.7.2, may also apply to drugs or other products. Your experience and training will help you identify techniques that you can use to detect possible violations during your inspections.

5.6.2 - When Evidence of a Criminal Violation is Discovered During a Regulatory Inspection

There may be occasions where you are conducting a regulatory inspection at a facility and, during the inspection, you discover evidence of a criminal violation. If this occurs, you should continue the regulatory inspection as you would under normal circumstances. (See IOM 5.2.2.4.) Document the observation and notify your supervisor as soon as possible. The program division should refer your observations to OCI for their consideration. Evidence of the observation could be used in a criminal investigation, and the evidence could legally be disclosed to criminal investigators.

If you become aware of an ongoing criminal investigation, notify your supervisor. The program division should follow the Regulatory Procedures Manual (RPM) and notify the appropriate center of any OCI involvement in a center-directed inspection.

The discovery of evidence of a criminal violation may also be relevant to FDA's responsibility to ensure articles are being produced in conformity with the FD&C Act. Additional inspections may be warranted. Such inspections should be planned and documented in accordance with IOM 5.5.1.4 - Conducting Regulatory Inspections When the Agency is Contemplating Taking, or is Taking, Criminal Action.

5.6.2.1 - Use of Evidence Gathered During a Criminal Investigation

The extent to which information gathered during a criminal investigation may be shared with FDA counterparts and partners will vary with each case. Investigators should determine the extent of information sharing in accordance with the following guidelines.

Information and evidence gathered during a criminal investigation may be shared with regulatory personnel, subject to two reservations:

1. Information obtained pursuant to grand jury subpoena or testimony may not be shared. Disclosure of such information to anyone other than individuals identified by the Department of Justice attorney involved could subject the individual making the improper disclosure to sanctions for contempt by the court. Only the court can authorize disclosure beyond these parameters. Information obtained by other means (search warrant, cooperative witnesses, surveillance, etc.) may be shared, subject to the following paragraph.
2. There may be a need to protect the confidentiality of the criminal investigation. For example, disclosure to regulatory investigators might prematurely disclose the existence of the criminal investigation or the identity of confidential informants. However, whenever you are calculating the need to protect the confidentiality of information gathered during a criminal investigation through means other than the grand jury, you must consider whether it will be in the interest of public health to protect the confidentiality of that information.

Criminal investigators should consult their supervisors to determine whether disclosure should be made to regulatory investigators.

5.6.2.2 - Use of Evidence Voluntarily Provided to the Agency

Criminal and regulatory investigators may share information and evidence voluntarily provided to the FDA, without use of the regulatory inspection authority, search warrant, or subpoena. If criminal investigators decide not to share such information because of a need to protect the confidentiality of the criminal investigation, they should consider the potential impact on the public health of protecting the confidentiality of that information.

5.6.2.3 - Concurrent Administrative, Civil, and Criminal Actions

It may be appropriate to seek administrative and/or civil remedies against a firm or individual under investigation for criminal violations. There are many issues involved in determining whether such actions may proceed concurrently, or whether certain actions should proceed first. Each situation must be evaluated on an individual basis. If administrative and/or civil remedies are under consideration against a firm or individual also under investigation for criminal violations, representatives from the center responsible for evaluating the administrative and/or regulatory action should meet with the OCI headquarters staff to discuss issues related to the timing of administrative, civil, and criminal actions. The OCI and other components of FDA may share information subject to the reservations set out above.

5.6.2.4 - Working with a Grand Jury

Finally, if you are assigned to work with a grand jury, you should not participate in a regulatory inspection or other regulatory matter involving the same firm or individual(s). Such participation is contrary to long-standing agency policy, might be unlawful, and could result in sanctions against the investigator and the agency. You should not participate in any regulatory matters that could result in improper disclosure of grand jury information, even after the grand jury investigation is closed. Grand jury proceedings remain secret even after they are concluded. Under no circumstances should you undertake such participation without first obtaining clearance from the DO J attorney or the OCC attorney assigned to the grand jury case. (See IOM 2.8.2) for additional information on grand jury proceedings.)

5.6.3 – Individual Responsibility

Always determine and report the full legal name, title, mailing address, and email address of the top management official(s) to whom FDA official correspondence, including FMD-145 correspondence, should be directed. If an email address does not exist, this should be noted.

Always determine and report the full legal name and title of persons interviewed, who supplied relevant facts and the name, title, mailing address, and email address of top management officials to whom FDA correspondence should be directed. If an email address does not exist, this should again be noted.

Always determine and report the full legal name, title, mailing address, and email address of the responsible individual to whom FMD-145 correspondence should be directed. If an email address does not exist, this should be noted.

Obtain correct names and titles of all corporate officers and/or company officials.

You should also identify and report responsibilities for the following firm representatives:

1. Top management official (TMO), synonymous with the owner, operator, or agent-in- charge of a facility. The TMO holds the ultimate duty, power, and responsibility for the inspected facility and is usually the individual at an inspected facility to whom credentials are displayed and any FDA forms 482, 483, and 484 are issued. The TMO of a facility may not be present during an inspection (for instance, they may be located at the corporate office).
2. In the absence of the TMO, the individual who is the most responsible person present at the time of the inspection, and to whom credentials are displayed and any FDA forms 482, 483, and 484 are issued.
3. Those present for the inspection and who were interviewed and supplied relevant facts. Determine and report the full legal name and title.

5.6.3.1 – Responsible Individuals

The identification of those responsible for violations is a critical part of the inspection, and as important as determining and documenting the violations themselves. Responsibility must be determined to identify those persons to hold accountable for violations, and with whom the agency must deal to seek lasting corrections. (See IOM 2.3.1.4)

Document and fully report individual responsibility whenever:

- It is required by the assignment,
- Inspectional findings suggest the possibility of regulatory action, or
- Background information suggests the possibility of regulatory action.

5.6.3.2 – Duty, Power, Responsibility

Duty – An obligation required by one's position. A moral or legal obligation.

Power – Possession of the right or ability to wield force or influence to produce an effect.

Responsibility – An individual who has the duty and power to act is a responsible person.

Three key questions to consider:

- Who had the duty and power to detect the violation?
- Who had the duty and power to prevent the violation?
- Who had the duty and power to correct the violation?

5.6.3.3 – Inspection Techniques: How to Document Responsibility

Obtain pertinent educational and experience backgrounds, and the duties and powers of the officers and employees in key managerial, production, control, and sanitation positions. Ascertain the experience and training of supervisory personnel, in terms that will describe their qualifications to carry out their responsibilities.

There are numerous ways to establish and document responsibility. Evidence may be obtained during interviews as well as record reviews specifically intended to determine responsibility. Cover and report items such as:

- Organizational charts.
- Statements by individuals admitting their responsibility or attributing responsibility to others.
- Company publications, letters, memos, and instructions to employees.
- The presence or absence of individuals in specific areas at specific, significant times, and their observed activities directing, approving, etc.

The following questions may be useful, to help you establish relationships between violative conditions and those responsible:

- Who had knowledge of the conditions?
- Who should have known of the conditions because of their specific and/or overall duties and positions?
- Who had the duty and power to prevent or detect the conditions, or to ensure that they were prevented or detected?
- Who had the duty and power to correct the conditions, or to ensure that they were corrected? What was done after the person(s) learned of the conditions? Upon whose authority and instructions?
- What orders were issued (When? By whom? To whom? On whose authority and instructions?)?
- What follow-up was done to ensure orders were carried out (When? By whom? On whose authority and instructions?)?
- Who decided corrections were, or were not, complete, and satisfactory?
- What funding, new equipment, new procedures were requested, authorized, or denied in relation to the conditions? Who made the requests, authorizations, or denials?

You should also establish the various duties and powers related to a firm's general operations to help further clarify specific relationships to violations. The following questions may help you ascertain such key details:

- Who decides what processing equipment to buy?
- Who decides what raw materials to purchase?
- Who decides what products to produce and what procedures to follow in production?
- Who authorizes production schedules, including how much to produce, what to make, and when to stop or alter production?
- Who decides what production controls are used?
- Who decides what standards are set for products, raw materials, and processes?
- Who decides how to correct or prevent adverse conditions? How much is spent and who is hired to correct or prevent adverse conditions, including, when to clean up?
- Who decides how products will be labeled e approved, and what products to ship?
- Who decides when to reject raw materials or products? When to initiate a recall? And what acceptable quality levels should exist for products?
- Who decides when to hire or fire personnel?
- Who will accept the FDA 482, Notice of Inspection and FDA 483 Inspectional Observations, FDA 483?; Who refuses an inspection?
- Who designed and implemented the quality assurance plan, and receives reports of Q.A.? Who acts, or should act, upon those reports?
- Who is responsible for auditing other facilities, contractors, vendors, Good Laboratory Practices (GLP) sites, etc.?
- In the firm's business relationships, who signs major contracts, purchase orders, etc.?

In some circumstances, documenting individual responsibility requires investigative techniques that lead to sources outside the firm. These sources may include contractors, consultants, pest control or sanitation services, local health officials, and others. Obtaining copies of documents exchanged between the firm and outside parties may help establish responsibilities. Additionally, do not overlook state officials as another possible source of helpful information.

During the inspection, you may observe persons who hold responsible positions and/or influence in the firm whose abilities or judgment may be affected by an obvious infirmity, or disability. If it is obvious the infirmity adversely

affects the person's responsibilities or duties that are under FDA oversight, describe in your EIR the extent of the infirmity and how it relates to the purported problem or adverse condition.

5.6.4 - Samples

Samples, including Factory Food Samples and packaged finished products collected during inspections, provide the necessary links to establish routes of contamination and/or actual product adulteration (for more on in-lines, see IOM 4.3.6.6.3). Samples also clearly establish the jurisdiction of the FDA over the products and/or operations and form the basis for judicial actions. However, in many cases, collection of the physical product is unnecessary or impractical, in which case a documentary sample, consisting of copies of relevant documents and labeling, may be collected instead (see IOM 4.6.1.3). The type and nature of the sample collected will depend on a variety of factors, including instructions in the applicable Compliance Program for the inspection you are conducting. (Refer to IOM Chapter 4 for more information regarding the collection of samples, including 702(b) portion requirements, which apply to many physical sample types.)

Collect physical samples for laboratory examination only when they contribute to confirming the suspected violation, or when directed by the assignment or your supervisor. Lack of a violative physical sample is not a bar to pursuing regulatory and/or administrative action providing the cGMP deficiencies have been well documented. Likewise, physical samples found in compliance are not a bar to pursuing action under cGMP charges.

If a physical sample is collected during an inspection, ensure that you are familiar with the requirements for issuing the form FDA 484, Receipt for Samples, as outlined in IOM 4.2.5. Remember that the form FDA 484 must be issued at the close of the inspection and prior to departing the firm (see IOM 5.5.12.5).

There will be times when one program division will request that another program division collect surveillance or compliance samples on its behalf. The requesting program division should create an assignment for the sample collection using the Assignment Management Service (AMS), providing as much specificity as possible to assist the investigator in collecting the appropriate material(s).

5.6.5 – Exhibits

Exhibits can be extremely effective and important forms of evidence to establish existence of violative conditions or products. Exhibits may refer to either records or physical material(s) (other than an official sample) which are collected from the firm to demonstrate insanitary conditions contributing, or likely to contribute to, filth in the finished product, or to practices likely to render the product injurious or otherwise violative. Photographs and video recordings taken by the investigator are also considered exhibits and are addressed in IOM 5.6.7.

5.6.5.1 – Records Collected as Exhibits

The type and nature of records obtained to document objectionable conditions will vary greatly depending on the matter being documented. Regardless of the record, you should heed the following guidance:

- Do not remove the firm's only copy of records. If duplicates are not available, whenever possible, scan, photograph, or photocopy
- Review all reproductions or copies to ensure all relevant information is readable
- Obtain all records using appropriate methods, including handling them in a manner to preserve the chain of evidence, such that the content may be attested to later. (Methods for properly obtaining and handling electronic records are provided in IOM 5.6.6.)
- Identify exhibits according to IOM 5.6.11.2
- During inspections, do not accept any records that would be used as Exhibits by email from outside the FDA

5.6.5.2 – Physical Material Collected as Exhibits

Certain physical materials (other than official samples) may be collected to support objectionable conditions. These materials should relate to insanitary conditions contributing, or likely to contribute, to filth in the finished product, or to practices likely to render the product injurious or otherwise violative.

Submit as an investigational or INV sample physical exhibits collected during an inspection (see IOM 4.1.5). Describe each subsample and assign a unique subsample number to each exhibit. Group similar subsamples on one collection report.

When collected during an inspection, describe, and refer to the INV sample(s) in your EIR, relating them to objectionable conditions. Diagrams of the establishment, floor plans, flow charts, and schematics are useful in preparing a clear concise report and in later presentation of testimony. A small compass is useful in describing exact locations of objectionable conditions in the plant, in your diagrams, and locations from which samples were taken, etc.

Examples of physical exhibits include:

- Live and dead insects, insect frass (droppings), webbing, and insect-chewed materials; nesting material of rodents and/or other animals; and other behavioral evidence of the presence of insects, rodents, and other animals.
- Components and finished dosage forms.
- Samples of in-process ingredients, in-process materials, and unpackaged finished products, including Factory Food Samples or "in-lines." Note: Samples of packaged finished products and ingredients are official samples. For details about official samples, see IOM 4.1.1 and 4.1.4.
- Manufacturing and control devices or aids.
- Evidence showing the presence of prohibited pesticide residues. (A method you can consult for swabbing for prohibited pesticide residues can be found in Laboratory Information Bulletin # 1622.

5.6.6 – Electronic Records

Electronic records are defined in 21 CFR 11.3(b)(6) as any combination of text, graphics, data, audio, pictorial, or other information representation in digital form that is created, modified, maintained, archived, retrieved, or distributed by an electronic system. This term applies specifically to records in electronic form that are created, modified, maintained, archived, retrieved, or transmitted, under any records requirements set forth in agency regulations. This also applies to electronic records submitted to the agency under requirements of the FD&C Act and the PHS Act, even if such records are not specifically identified in agency regulations. In both instances, these records should be maintained and handled as identified in IOM 5.6.6.2.3. Electronic data obtained from a firm provides an investigator with a wealth of information that can be used to assess industry's compliance with the FD&C Act and promulgated regulations.

5.6.6.1 - Electronic Databases, Queries, and Records Requests

Firms may use proprietary programs developed in-house, or off-the-shelf programs, to generate and/or store records used to show regulatory compliance. This includes blood bank databases, drug production records, medical device complaints, and/or service records. In addition to accessing individual electronic records (for example, in PDF file format), these programs can often be queried to generate copies of the databases or summary data in alternative commonly used file formats, such as Microsoft Excel. During an establishment inspection you may request and receive copies of data from, or summary data generated by the firm about, their electronic databases. Any methods used must maintain the integrity of the electronic data and prevent unauthorized changes.

Of note: Do not personally access a firm's system to review electronic records, databases, or source data during the course of an inspection, unless it is:

- a bioresearch monitoring inspection which meets the criteria outlined in section 5.14.2.1 or
- a biologics inspection where it is not practical to oversee the firm's personnel while they access their system, (see section 5.13.2.5.1).

When it is necessary to access a firm's data during an inspection, you should:

- Oversee the firm's personnel accessing their system and have them answer your questions.
- Request the firm run queries specific to the information of interest.
- Request the firm provide the parameters used to generate the data.
- Request the firm to transmit the electronic data securely to the FDA or provide it on electronic storage media.

Firm electronic data can be dynamic with real-time updating. Your request may require the firm to develop one or more custom queries to provide the requested information. A custom report query is the method of using the reporting software to pull the specific data requested during the inspection (for example, all complaints from the last 12 months with specific data fields). You must assume the query logic is not validated and take appropriate action to ensure the data is accurate and no data has been omitted due to a programming logic error occurring at the firm.

Do not use the firm's equipment or personnel to perform computerized data manipulation for the purpose of real-time review and analysis. If you perform analysis on the working copy of the data from an electronic database (including sorts, pivot tables, or other reviews) to develop or support observations, you should request the firm conduct the same analysis and provide a copy of this analysis (the firm is under no obligation to do so). This can be done by requesting an electronic file that includes only the information of interest (for example, an Excel spreadsheet of failures of a certain type for a specific time period) or requesting a paper copy of the information of interest.

Before requesting a copy of computerized data or electronic records, you should ascertain the following:

1. Determine the program used by the firm to maintain the data of interest. Programs may be capable of outputting data in one of several file types; it is best to obtain data files in a format compatible with programs currently used by the agency such as PDF or XLSX. Check the program you plan to use to ensure it can handle the file type you will be requesting. If necessary, some file types may have standard, built-in conversion programs to facilitate review, such as converting a Microsoft Word document to an Adobe PDF. Other types of file conversion may be difficult and should not be attempted without the necessary knowledge and availability of conversion-type programs where applicable. If help is needed for file conversion, assistance may be available within the program division.
2. Determine what fields of information are routinely captured by the firm. This can be accomplished by requesting a printout of the data structure of the data file or observing firm personnel inputting data at a computer terminal or workstation. It is common for databases to contain numbers or other coded information requiring translations from look up tables to generate meaningful text. You should determine if information fields contain coded data, and if so, a code breakdown should be obtained. Information about code breakdowns should be in the SOPs for that computerized system. Be aware, in relational databases, there may be linking data fields that exist in other tables that should also be considered in the overall data request.
3. If the files are too large to be securely transmitted or to fit on electronic storage media, file compression can be used. If possible, ask that the firm prepare the data in a compression format that is self-extracting. Self-extracting files are executable files and should be virus-scanned before and after executing. All electronic storage media should be scanned prior to being used on any FDA computer. Whatever compression utility is used, make sure you have the software necessary to obtain the uncompressed files for review.

5.6.6.2 – Receiving and Handling Electronic Records

Refer to your program for approved methods of secure transmittal of electronic records, as well as instructions that can be provided to regulated industry. Secure means of transmittal may include approved cloud file-sharing, or use of FDA Electronic Submissions Gateway. If there are no mechanisms available for a firm to securely transmit the data electronically to the investigator, the data may be provided to the FDA by receiving electronic media from the firm or by providing a clean, preformatted electronic media to the firm. ORA procedures for the use of electronic media will be identical for both domestic and foreign inspections/investigations. Those foreign locations that may present a security challenge will be handled on a case-by-case basis through the foreign trip-planning process and will be discussed with the investigator prior to departing the United States.

Data received on electronic media presents a challenge to both IT security and physical security of the media. The information obtained from the firm may be commercial confidential information (CCI), and as such, must be protected to the greatest extent possible. It is your responsibility to make sure the physical data source remains secure. Likewise, data obtained from extra-governmental sources may contain viruses or malware that may be included with the information provided to the investigator, either on purpose or accidentally. The transfer of electronic data must be evaluated to facilitate safeguarding the security of both FDA and firm information. You should be cognizant of issues that may arise with the use of electronic media and be vigilant while using it.

The Device Control Data Loss Prevention (DLP) tool at the FDA blocks most FDA users from using unauthorized USBs, as this is against FDA security policy (as described in FDA Staff Manual Guide 3251.12, Appendix Z). Certain ORA Investigators have been granted an exception and are permitted “read access” to firm-provided USBs to transfer firm provided data onto their computers. However, they are not permitted “write access,” as FDA data should not be written to a device that is not Federal Information Processing Standard (FIPS) 140-3 compliant and/or approved on the FDA Master Approved Technologies (MAT) list. If you are an investigator and are having problems accessing content on a firm-provided USB, please contact your information system security officer (ISSO).

If you provide the electronic storage media to the firm, use only clean and preformatted media. An additional safeguard is to request the firm reformat the media on their own computer to assure it is usable and “clean.”

There are no guarantees the files provided via secure transmission on electronic storage media will be usable data. It is your responsibility to make a working copy to view the copied files and verify the files both contain the information requested, and that the information is useable to you, prior to closing the inspection.

5.6.6.2.1 - Original Copy

An original copy is an unaltered copy of a source electronic record collected to support observations of potential violations or used as evidence in administrative or judiciary proceedings. Any original copy included in an EIR, memorandum, or C/R, must be stored as to maintain the chain of custody and ensure the records may be verified any time after collection.

When records are received via a secure transmission method, the resulting file made available to the CSO must be treated as the original copy. A working copy of the file should be created, and the original transferred to a secure directory for preservation in accordance with program records management procedures, as it may be used to support observations of potential violations or used as evidence in administrative or judicial procedures.

Any electronic storage media containing electronic records received during an inspection should be considered and handled as the original copy. The original copy (USB, CD, DVD, etc.) of electronic records should be secured to ensure the integrity of the data when used to support observations of potential violations or used as evidence in administrative or judicial proceedings. Handle and prepare the media in accordance with IOM 5.6.6.2.3 below.

5.6.6.2.2 - Working Copy

A copy of an electronic record that is created from the original copy and is used to review and analyze the records, to not alter the original copy. This is an exact copy of the original copy electronic records.

5.6.6.2.3 - Identifying and Securing Electronic Storage Media

When electronic storage media are used to obtain electronic records, you should follow these steps to ensure their proper identification and security:

1. If you provide the disk(s)/USB drives to be used, use only clean and preformatted disk(s)/USB drives.
2. Label each original copy of electronic storage media, accordingly, with:
   a. Firm name.
   b. Date and your initials.
   c. The name of the appropriate software and version to ensure readability of the information.
3. Make a working copy of the electronic storage media
   a. First virus-scan the original storage media by taking the following steps:
      i. Disconnect your machine from the FDA network, the VPN, and the internet.
      ii. Insert the media into your computer (USB drive into USB port or CD/DVD into drive).
      iii. Do NOT click ok on or accept any Windows prompts for driver installations.
      iv. Right Click on the drive of interest.
      v. Select "Scan for threats"
      vi. If any threat (for example, a virus or malware) is detected, do not select “Clean” or “Delete”, as the data may be used as evidence. Instead, keep the computer disconnected from the network and report the incident to ERIC at 866-807-3742 and the FDA Cybersecurity and Infrastructure Coordination Center (CIOCC) at CIOCC@fda.hhs.gov or 855-533-2762. Maintain chain of custody on the electronic media. Alert your supervisor of the issue and the steps taken.
      vii. If the scan detects zero (0) threats, proceed forward.
   b. Copy the original information from the electronic storage media onto a working copy.
   c. Verify the data is useable.
4. Seal any original copy(s) with an FDA-415a in an FDA-525 or similar envelope. Complete blocks 2, 3, 5, 7, and 12 of the FDA-525 and seal with an Official Seal, FDA-415a. If you use a larger envelope, identify the envelope with your name, title, home District and program Division, date, firm name, firm address (include zip code), and description of the contents of the envelope. Mark the FDA-525 or similar envelope as containing electronic storage media, or other media, and document the software type and version(s) required to open the included software (for example, Microsoft Word 2016, Microsoft Excel 2016, or Windows Photo Viewer). The electronic storage media or other media should be stored as part of the hardcopy exhibits in the designated file room. See IOM 5.7.4.1.
5. Prepare electronic record(s) for inclusion in the EIR, Memorandum, or C/R.

5.6.7 – Photographs or Video Recordings

Photos taken during inspections are not investigational samples. They are exhibits. Only use FDA-issued equipment, such as a government-issued camera, to take photographs; use of personal equipment may subject that equipment to preservation and discovery in future litigation.

Since photographs are one of the most effective and useful forms of evidence, every photo should be taken with a purpose. Photographs should only be taken for evidentiary purposes (for instance, to document violations and environmental surface subsample sites). Photographs should be related to insanitary conditions or depict violative conditions.

Safety note: Evaluate the area where you intend to use, or are contemplating using, electronics for any personal or other safety concerns (see IOM S.12.2). Potentially explosive conditions may be present that may **limit or prohibit the use of photography** equipment, including flash photography. These conditions may include dusty areas or other areas where explosive or flammable vapors may be present.

Additionally, the high risk for cross-contamination of manufacturing processes may also warrant the use of alternate equipment or procedures (for example, in certain active pharmaceutical ingredient (API) facilities, in the vicinity of potent compounds, and in penicillin-manufacturing operations). Alternative approaches may include the use of dedicated equipment or requesting firm personnel to take photographs on your behalf. If firm personnel are amenable to the request and take photos on your behalf, those photos should be handled as other electronic records obtained from the firm, per IOM 5.6.6.2. If you should encounter any refusals to permit photography, see IOM 5.6.7.1 below.

Examples of conditions or practices effectively documented by photographs include:

- Evidence of rodent- or insect-infestation and faulty construction or maintenance that contributes to these conditions.
- Routes of potential, as well as actual, contamination of raw materials or finished products.
- Condition of raw materials or finished products.
- Employee practices contributing to contamination or violative conditions.
- Manufacturing processes that may lead to the product being violative.
- Manufacturing and various other records showing errors, substitutions, penciled changes in procedure, faulty practices, deviations from GMPs, NDAs, or other protocols, altered or inadequate assays or other control procedures, and any variation from stated procedure. (See IOM 5.3.8.2 for identification of records.)
- Effluent contamination of water systems. (See IOM 5.6.3.2 for techniques for photographing this type of contamination.)

When photographing labels, make sure your picture will result in a legible label with any text or characters large enough to be read by an unaided eye. With regards to labels or documents that have been whited-out, a suggested technique is to photograph them by holding a flashlight against the whited-out side, and taking a close-up photo of the reverse. This will produce a photo with a mirror image of the whited-out side.

Guidance on maintaining and preserving digital photos/video are provided in IOM 5.6.7.3 and 5.6.7.5. If you use a non-digital (film) photography method, see guidance in Exhibit 21 (Film Photography) and consult your supervisor. Ensure your actions to process and obtain the resulting photographs or video is documented in your notes.

5.6.7.1 - In-Firm Photographs

Take your camera or other FDA equipment for taking photographs into the firm and use it as necessary, just as you use other inspectional equipment. Only FDA equipment is to be used to take photos while conducting official business. Do not request permission from firm management to take photographs during an inspection because taking photographs is part of our agency's authority to conduct inspections, as part of Section 704(a)(1) of the FD&C Act [21 USC 374(a)(1)].

If management objects to taking photographs, explain that photos are an integral part of an inspection and present an accurate picture of firm conditions. You can also advise management that the U. S. Courts have held that photographs may lawfully be taken as part of an inspection. If management continues to refuse, provide them with the following references:

- Dow Chemical v. United States, 476 U.S. 227 (1986): This Supreme Court Decision dealt with aerial photographs by EPA, but the Court's language seems to address the right to take photographs by any regulatory agency. The decision reads in part, "… When Congress invests an agency with enforcement and

investigatory authority, it is not necessary to identify explicitly each and every technique that may be used in the course of executing the statutory mission. …"

- United States of America v. Acri Wholesale Grocery Company, A Corporation, and JOSEPH D. ACRI and ANTHONY ACRI, Individuals, U.S. Division Court for Southern Division of Iowa. 409 F. Supp. 529. Decided February 24, 1976.

If management still refuses, obtain the name and contact information for the firm's legal counsel, and advise your program division management immediately. If the firm does not have legal counsel on retainer, collect the name and contact information for the most responsible individual. Program division management will advise their assigned Senior Enforcement Advisor (SEA) in the Office of Chief Counsel (OCC) of the situation, and OCC will then contact the firm's legal counsel or most responsible individual to discuss FDA's legal right to take pictures during inspections. OCC will relay the results of this conversation to program division management. If you have already taken some photos do not surrender any storage media or film to management, and do not agree to delete any photos. Advise the firm that it can also take photos and obtain copies of the photos taken by the FDA under the Freedom of Information Act. (See IOM 5.6.7.7.)

If management of a drug or device firm does, or will, not give a reasonable explanation for its objection, such as a showing that the chemical properties of products manufactured at the facility are such that taking photographs would adversely affect product quality, you may advise management that the refusal may constitute a limiting of the inspection under Section 501(j) [21 U.S.C. 351(j)] of the FD&C.

5.6.7.2 - Photo/Video Identification and Submission

One of the most critical aspects about photographs or videos is the ability for the agency to provide testimony clearly verifying the authenticity of the conditions depicted in the photograph or video. Regardless of the method used to create the recording, you must create a trail, starting with the taking of the photo or video, confirming its original accuracy and establishing a record describing the chain of custody.

The following action steps help protect authenticity:

- Make sure each photograph or video is described in your regulatory notes in sufficient detail to ensure positive correlation of the photo or video with your inspectional findings.
- Do not delete any photographs taken during an inspection, even if the photograph may be blurry or unusable for the final report, as it may raise questions about missing evidence. Such photographs should be described in your regulatory notes and stored with other photographs from the operation.
- To establish identification for a series of photos, photograph the card with your name, program division address and phone number, prior to beginning to take photographs. This will help identify files and assist in tracking, if any media becomes separated from its identification envelope during processing or storage.

Proper procedures will also allow the agency to provide evidence confirming the authenticity of the photographs or video recording in the event you are not able to testify personally.

Photographs and videos must be identified when included as part of an EIR or sample. If using another technology, consult your supervisor for guidance on identifying the photographs or video for submission.

5.6.7.3 – Digital Photographs or Video Recordings

Many digital cameras can record high resolution images and video with corresponding large file sizes stored initially on the device, often in the form of removable, non-volatile flash memory cards or non-removable flash memory built into the device. This presents a challenge to investigators, since the original digital images, captured at the moment the images are recorded to the device's storage, must later be copied and eventually uploaded into eNSpect or another electronic system. Due to the cost of flash memory cards and the large file sizes we typically deal with, it is not usually feasible to purchase new memory cards for each inspection/investigation and preserve the storage media directly, as investigators did in the past when using photographic film. Instead, we must handle

these files in a way that ensures the accuracy of any subsequent copies. As such, and regardless of the type of technology you use to create photos/videos, you are responsible for collecting, handling, documenting the chain of custody, storing, and submitting your evidence in a manner inconsistent with your ability to testify to its authenticity in a court of law. (See IOM 5.6.7.2)

When the electronic storage media (such as a removable flash media card) containing the "original" photos/videos is not able to be preserved, an "original copy" of the photos/videos must be created in the exact original format to preserve the chain of custody. To do so, you may transfer the "original" photos/videos first, onto either an FDA computer system (for example, the investigator's laptop) or FDA cloud storage system, and then transfer the photos/videos to the final method of preservation to create the "original copy" (for instance, burning to permanent storage media such as a CD-R), so long as the image/video data is not modified during this process.

5.6.7.4 – Glossary of Digital Terminology

Some basic terminology you should be familiar with when referring to digital devices.

5.6.7.4.1 - Original

The file recorded by a digital device on digital storage media at the moment in time when the user takes a picture or makes a recording. This concept is similar to a film camera where the photographic film records the image when exposed by light. The film image negatives produced when the film is developed would be considered the originals and prints would be considered copies.

5.6.7.4.2 – Original Copy

An exact copy of the original file recorded by the digital device (camera, video recorder, etc.). The original copy will retain all the characteristics of the original and the contents of the file are indistinguishable from the original. As this is a copy, some of the metadata (such as the date the file was created) may differ from the original.

5.6.7.4.3 - Permanent Storage Media

An electronic storage media format in which the digital files can be stored for the requisite time prescribed by records schedules, as opposed to temporary storage media which may be used to facilitate the transfer of the files. "Permanent" does not refer to the length of time the data can be stored safely on the media; storage media should be selected based on the length of time storage may be necessary. Examples are CD-Rs, DVD-Rs and other approved media.

5.6.7.4.4 - Time/Date Metadata

Data within the digital photo/video file(s) based on an internal clock within the digital device used to record, indicating when the photo/video was recorded. As the internal clock may or may not be accurate, you should, prior to use, ensure that the internal date/time clock is set for the location/time zone where the photographs or videos are being taken. This time/date may or may not be imprinted visually on the photo/video, as was common in the past for many cameras.

5.6.7.4.5 - Working Copy

Any copy of the original copy used for review, processing into exhibits, and as the basis for any enhancements. Creating a working copy decreases the chance the original copy is damaged during review and processing.

5.6.7.5 - Preparing and Maintaining Digital Photographs/Video as Regulatory Evidence

Protect a digital photo or video's chain of custody (and authenticity) using these procedures:

1. Prior to using the FDA equipment to take digital photos or video, verify that the date and time on the internal clock is correct. If removable storage media is used, reformat/clear it using the device's settings to delete any files not related to the current assignment. If non-removable storage media is used, ensure that the location the files will be saved does not contain any images unrelated to the current assignment.

Depending on your inspection and the capacity of your storage, additional removable media may need to be obtained.

2. Handle your device and any storage media in a manner that protects your evidence and maintains the trail of the "chain of custody" for the evidence you have collected. For example, always keep the camera and removable storage media in your personal possession or hold under lock and key in a secure storage area. Also, keep any additional removable storage media containing images or video in your personal possession until transferred to permanent storage media. For devices which support it, ensure that the device or storage system is encrypted with a strong password. As necessary, document these facts in your regulatory notes or written report (EIR, CR etc.).
3. As soon as it is practical, create an original copy of the digital photos or video by copying all the images/videos from the device/removable storage to permanent storage media, such as an unused CD-R. You will want to verify that the computer you are using is set to the correct date and time, too, prior to creating an original copy. Depending on the permanent storage media used, more than one may be needed to store all photos/videos on hand. Also, each image or video should be transferred in the original file format maintaining the resolution at the time it was captured. If possible, avoid the use of compression when transferring the files to the permanent storage media. For very large files, consult your supervisor if you encounter issues transferring the files to permanent storage media. And prior to making the working copy from the original copy, identify the media containing the original copy. It is important to identify the original copy as soon as possible to prevent possible mix-up of the original copy with any working copies. To do so for EIRs, you should identify the relevant copy with the firm name, FEI, date taken or inclusive dates of inspection, and your initials. For sample collections, you should identify copies with sample number, collection date, and your initials.
   NOTE: If using optical media like a CD-R or DVD-R as the permanent storage media, use a permanent CD-safe marker to identify the original copy CD-R. Do not use ball point pens or similar tipped markers since the optical media may be damaged, and do not use adhesive labels on the media itself. (See National Institutes of Standards and Technology document, "A GUIDE FOR LIBRARIANS AND ARCHIVISTS Care and Handling of CDs and DVDs" for techniques to identify optical media.)
4. Where applicable, document in your regulatory notes the verification and identification of each photographic image comparing them to your regulatory notes, which were recorded at the time the photographs were taken.
5. Make only one working copy from each original copy. Make any additional working copies using the initial working copy, as copying from the original copy should be limited in order to best preserve it. Working copies should be used to print photos, for insertion into an EIR, for cropping and other editing needs, and/or for preparing for submission with the written report.
6. After making the initial working copy, seal the original copy of the permanent storage media in an FDA-525, or similar envelope, until submitted with the written report (for instance, the EIR or C/R). Complete blocks 2, 3, 5, 7, and 12 of the FDA-525 and seal with an Official Seal, FDA-415a. If you use a larger envelope, identify the envelope with your name, title, home program division, date, firm name, firm address (include zip code), description of the contents of the envelope and seal with an Official Seal, FDA-415a. If possible, the investigator (who took the photos and will authenticate them at trial) should securely store the sealed permanent storage media until it is submitted with the written report. (If you should break the seal for any reason, see IOM 4.5.4.5 – Broken Official Seals and "Temporary Seals.")
7. Where applicable, document in your regulatory notes the verification and identification of each photographic image or video, comparing them to your regulatory notes, which were recorded at the time the photograph(s) or video(s) were taken.
8. Document in your report (for instance, the EIR or C/R) and regulatory notes any steps taken for any unusual editing of original photo images and/or video. For example: the need to superimpose over an important area of the image, enhance an image, create composite images, etc.

9. Do not scan the FDA 525, or envelopes containing the permanent storage media, and upload as exhibits. The actual photographs included and described in the EIR are the official exhibit and are maintained in the eNSpect system. The officially sealed permanent storage media should be included with the unlabeled hard copy exhibits and attachments filed in accordance with applicable procedures and accompanied by the following statement (as found in section 5.7.3.7.15 – Additional Information): *"The officially sealed original copy and unsealed working copy discs containing the photographs taken during the inspection are filed with the unlabeled exhibits and attachments."*
10. Using the working copy photographs and video, prepare for inclusion as an exhibit to the EIR following the instructions found in SOP ORA-OO.004, "Using eNSpect to Create, Store, and Preserve Electronic Records Associated with an Establishment Inspection Report."

5.6.7.6 – Inserting Photos into an eNSpect Establishment Inspection Report (EIR)

Digital photos taken during an inspection can be inserted into the body of a report in eNSpect when it is helpful to explain issues observed during your inspection. However, inserting digital photos into the body of the EIR can dramatically increase the file size of the eNSpect document, so should be used judiciously. For each photo inserted in the EIR body, include the following information in close proximity to it: the photo number, the date the photo was taken and by whom, and a brief narrative description of what the photo depicts. If several photos are to be inserted, try the following steps, in Microsoft Word, to minimize file size:

1. After inserting the photo into the EIR and placing it where desired, click to select the photo, then select the "Picture Format" ribbon at the top.
2. Select "Compress Pictures" on the ribbon.
3. Select a resolution appropriate to your needs; generally recommended: "Print (220ppi)."

For any photographs inserted in the body of the EIR, attach an additional copy as an exhibit to the EIR. A narrative description should be placed below the digital photograph. Include the photo number, the date photo was taken and by whom, and a brief description of what the photo depicts.

NOTE: When any digital photos are used in an EIR, either by inserting in the body of the EIR or attaching as an exhibit, follow the steps in IOM 5.6.7.5 – Preparing and Maintaining Digital Photographs as Regulatory Evidence to preserve the original copy.

5.6.7.7 - Photograph Requests

Do not routinely advise firms that they may have copies of photos. However, if management of the firm initiates the request, advise them it is possible to obtain copies of photographs taken in their plant under FOIA. Their request should made online. Direct them to the FDA website and How to Make a FOIA Request. The firm must bear the cost of duplicating the photographs, and since photographs are records in an investigative file, they will not be available under FOIA until the file is closed.

Do not discourage firms from taking their own photographs at the same time and of the same scenes as you are.

5.6.8 – Recordings

Normally, you would not use a recording device during an inspection. However, some firms may record an inspection or close-out meeting using audio or video with or without your knowledge. Because of this, you should always assume that you are being recorded during an inspection. If you are aware an individual is recording you during the closeout meeting, you should advise them that, while we do not object to this procedure, we will also record the discussion using our own tools to ensure the accuracy of our records. Contact your supervisor if you are at all unsure about recording a portion of the inspection.

Occasionally a firm's management may record the serving of an inspection warrant or, in a hostile situation, may want to record everything. In such cases, depending on the circumstances, you may prepare your own recording in parallel with the firm's recording. Do not depend on the firm to provide a duplicate of their recordings.

There are multiple devices that can be used to make recordings. The easiest is to use your government-issued cellular phone or tablet device. Your laptop also has recording capabilities. If you need to make a recording during the inspection, use your best judgment and whatever technology you have available to you--but do not use personal devices, like your personal cellular phone.

It's important that each recording be identified at the beginning of the record, with a statement such as:

"This is Investigator (your name) of the U.S. Food and Drug Administration speaking in the (state location) of (firm name), (address), (city), (state), and (zip code). It is now (time) a.m./p.m. on (date). Present are (list individuals present with title). This discussion is being recorded by both the representative of (firm name) and by me. We are going to discuss the inspectional findings of an inspection conducted at this firm on (inclusive dates)."

At the close of the discussion and prior to leaving the firm, the recording should be verbally identified as follows:

"This is (your name) speaking. It is now (time) a.m./p.m. on (date). This was a recording of the discussion with management at the conclusion of an inspection of (firm name and address) conducted on (dates)."

You should name the file in a way so that you can easily identify what the recording covers, for example "Close-out Meeting on xx-xx-xxxx (date) with (firm)." The file must be transferred to a permanent media device (for example, USB drive or CD).

If the recording covers a different situation, not a conclusionary meeting, for instance, you should modify your descriptive identification accordingly. If the representative of the firm refuses permission to record the discussion, continue with your discussion and report the facts in your EIR.

5.6.10 - Guaranties and Labeling Agreements

Review 21 CFR 7.12, 7.13, 101.100(d), 201.150, and 701.9, for information concerning guaranties and labeling agreements.

5.6.10.1 - Guaranty[3]

Certain exemptions from the criminal provisions of the FD&C Act are provided wherein a valid guaranty exists as specified in Section 303(c) of the FD&C Act [21 U.S.C. 333 (c)]. Obtain a copy of any Food and Drug guaranty that the firm claims to use relating to a violation noted during your inspection. **Note:** No person may rely upon any guaranty unless they have acted merely as a conduit through which the merchandise reached the consumer.

5.6.10.2 - Labeling Agreement

Products regulated by the FDA are normally expected to be completely labeled when introduced into, or while in, interstate commerce. Under certain conditions exemptions are allowed when such articles are, in accordance with trade practices, to be processed, labeled, or repacked in substantial quantity at an establishment other than where they were originally processed or packed. (Sections 405, 503(a) and 603 of the FD&C Act [21 U.S.C. 345, 353(a), and 363] also provide exemptions from complete labeling for products.)

5.6.10.3 - Exemption Requirements

To qualify for this exemption, the shipment must meet one of the following:

[3] The term *Guaranty* as used in the FD&C Act is now commonly written *Guarantee*.

1. The shipper must operate the establishment where the article is to be processed, labeled, or repacked; or
2. If not the operator of the establishment, the shipper must first obtain from the owner a written agreement signed by and containing the post office addresses of such persons and such operator and containing such specifications for the processing, labeling, or repacking of such articles as will ensure that such article will not be adulterated or misbranded within the meaning of the Act, upon completion of the processing, labeling or repacking.

Submit copies and dates of written agreements where unlabeled articles are shipped in interstate commerce.

5.6.11 - Records Obtained

Many types of inspections and investigations require collection of copies of records to document evidence of deviations. In some cases, this may involve voluminous copies of GMP records, commitments made in the pre-approval process, adherence to the requirements of the Low-Acid Canned Food regulations or other areas. Copies of records are also obtained to document interstate commerce, product labeling and promotion, and to identify the party or parties responsible for a variety of actions. Copies of records can be obtained in paper or electronic format. All records become part of the government's case should it go to litigation.

Normally, during litigation proceedings, the best evidence rule prevails in court, whereby the copy of the record in the custody of the government can be authenticated, if the original record is not produced by the custodian of the record.

It is imperative that the government witness (usually the collector of the record(s)) be able to testify where, when, and from whom the copies were obtained, and that the copy is a true copy of the source record, based on their review of the source record.

5.6.11.1 - Verification of Source Records

You must verify the copy of the record(s) you received is an accurate representation of the original or source record(s) so you are able to testify that your copy is an exact duplicate of the original or source record. You should document in your regulatory notes that you have authenticated copies of records and when, where, and from whom copies were obtained.

Other than for identification purposes, do not write on, highlight, or otherwise alter copies of original records obtained from the firm as they will no longer be an accurate representation of the source record. You may write on a second copy of records, provided they include both a copy of the original or source record and their altered copy as exhibits to the EIR. See OHAFO Handling Establishment Inspection Report Related Records Procedure.

5.6.11.2 - Identification of Records Collected

Articles used as evidence in court cases must be identified appropriately and adequately so you can later testify the records entered as evidence are, in fact, the very ones you obtained. This includes all records as noted in IOM 5.6.11, and any others for evidence in administrative or judiciary proceedings. When identifying and filing records, you must ensure the record is complete and no identification method or filing mechanism covers, defaces, or obliterates any data on the record.

You must identify records submitted in support of an inspection or investigation, including records provided in an Establishment Inspection Report (EIR) or narrative memorandum. The identification must positively identify the specific copies you received during your inspection or investigation, which will also help you avoid any filing mix-up. If labels are used to identify records, they must be permanently applied so any removal will be obvious.

Electronic labeling should be used to identify records collected. Identification should include at least the firm name, FEI Number, date(s) of the inspection, the lead CSO's initials, exhibit number, and page number(s). (Refer to ORA-OO.004, "Using eNSpect to Create, Store, and Preserve Electronic Records Associated with an Establishment Inspection Report.") When you collect a sample during an inspection, each page of the copied records will become

part of the collection report and should be identified (as noted in IOM 4.4.2- Identifying Sample Records). Identification of records attached to memoranda is described in 8.1.9.2.

5.6.11.3 – Listing of Records

If management requests a list of the copies of records you obtain, prepare it in duplicate, and leave the original with the firm. Many firms prepare duplicate copies of documents requested during our inspections. In the interests of conserving inspectional time, you may ask the firm to prepare the list of copies concurrently with the photocopying, and you then verify the accuracy. Do not use form FDA-484, Receipt for Samples. Describe the circumstances in your report including the name and title of the individual to whom you gave the list. Submit the duplicate list with your report as an exhibit.

5.6.11.4 – Patient and/or Consumer Identification on Records

During the course of many types of inspections and investigations you will review and collect records that specifically identify (by name) patients or consumers. Under most state privacy laws, this information is confidential. Some firms may mistakenly believe this information is not releasable to the federal government; however, federal laws preempt state laws. With few exceptions, we are entitled to review and copy the complete record, including the identifying patient/consumer names. The agency, for its part, however, is then required to maintain the confidentiality of the records/files, as with any confidential record you collect. Any disclosure of the information contained in the record(s) can only be initiated by law, for instance, via a judge's order, disclosure, Congressional order, etc. If you encounter resistance from the firm in providing patient records, you may refer them to 45 CFR 164.512(b), which explains the exemptions allowing the FDA access to the patient records. (See IOM 8.1.6.2- Medical Records.)

Some general, routine guidance:

1. For records copied related to an injury or complaint investigation, in which you obtain patient identification, the identification should remain intact and stored in the official FDA files. For any inspection/investigation involving a regulation-required Informed Consent, such as clinical investigations, IRBs, bioequivalence testing, etc., patient identification should remain intact and stored in the official FDA files.
2. For most other inspections/investigations--such as MQSA, plasmapheresis, blood donations, etc.--only the patient initials and unique identifier supplied by the firm (such as donor number, donation number, etc.) need be routinely retained in the FDA files.

It is not uncommon for a firm to voluntarily purge the documents of the pertinent identifiers as they are copied. You must verify (by direct comparison to the original document) that you received an accurate reproduction of the original--minus the agreed-to purging--prior to accepting the copy.

As with any inspection, there are times when the specific identifiers must be obtained, copied, and retained, such as if/when further interview of the patient/consumer could be necessary. If in doubt, err on the side of obtaining the data. It is always easier to delete later, than to have to return to obtain the information, especially in cases, while not frequent, where questionable practices may result in the loss of the information.

All documents obtained containing confidential identifiers will be maintained as all documents obtained by FDA containing confidential information, that is, in the official FDA files. Confidential identifiers may be flagged in the official FDA files for reference by reviewers to assure no confidential data are released under FOIA. (See IOM 5.1.5.)

5.7 – Reporting

Following an inspection, you are required to prepare a report of your findings. As soon as possible after the close of the inspection, enter in the start and end date of the inspection in eNSpect. You must also select a suggested “Inspection Conclusion” in eNSpect for each process covered.

Reports must be completed within time frames commensurate with the inspection classification, the current regulatory action time frames for the anticipated regulatory action, applicable FMDs, SOPs, RPM, and/or the assignment deadline, if any.

Your narrative report should be prepared to accurately and concisely communicate the findings of your inspection and be adequate for its intended use. For example, an inspection of a new firm, one that FDA has not inspected previously, should be a comprehensive report (see IOM 5.7.3.5). The resulting report should detail the products manufactured, the processes used to manufacture those products, the conditions of the environment in which products are manufactured or stored, any violations observed, persons responsible for the firm's operations, their actual duties and their responsibility for observed violations, distribution practices, and so on, providing information responsive to each of the required elements.

For establishments that have been previously inspected, you should determine what changes in operations and responsible individuals have occurred since the previous inspection, detail those changes in the narrative report, and report on the areas of concern for the current inspectional outcome. For example, a non-violative inspection may only require a Summary of Findings report with the required information in 5.7.3.3.

The key for you to remember in writing your narrative report is to communicate the findings of your inspection so that the agency is fully equipped to take the appropriate action. Notice that the required elements always include the product, interstate commerce, the violations observed, and responsibility of firm officials. This is to document the elements of proof – Jurisdiction, Interstate Commerce, Violation, and Responsibility (JIVR). Write your EIR with the intended use in mind. Your reports may vary greatly--from a brief summary of an inspection of a firm in a state of compliance with applicable regulations, to documentation of a firm in which the agency must take regulatory action to correct deficiencies.

5.7.1 - Establishment Inspection Report (EIR)

All reports must be written in English per IOM 1A.4.

The Establishment Inspection Report (EIR) consists of the data and summary you enter using eNSpect (eNSpect EIR Coversheet), your narrative report, and any attachments, and exhibits. Regarding the use of checklists that are completed during the inspection (such as the BSE Checklist), the original checklist should be submitted with unlabeled attachments. If you maintain the data in your regulatory notes, instead of entering the data directly on the checklist during the inspection, then a copy of the checklist that was completed using the data from your regulatory notes should be included with the EIR. The signed original narrative report is maintained electronically.

5.7.2 – eNSpect Establishment Inspection Report Coversheet

Per SOP-000051 - OEI Development and Maintenance Procedure, each ORA Program Division and HQ Office is responsible for ensuring that all investigators verify, correct, and enter changes to the Official Establishment Inventory (OEI) (including Profile data for firms that require profiles) on the firm's maintenance screens in eNSpect during each inspection, investigation, and during any OEI update. Consult with your supervisor and your OEI Coordinator to make sure data is accurately updated.

Inspectional accountable time reported into eNSpect consists of the hours devoted to file reviews (operational preparation), actual on-site inspectional time, document preparation (attachments and exhibits), and EIR (narrative) write-up. Do not, however, report travel time in eNSpect. One occasional exception could be when more than one participant prepares and discusses the assignment while they are traveling together.

You should report the actual amount of inspection accountable time. Additional time required to complete the assignment due to giving or receiving training should be reported separately from inspectional time.

5.7.2.1 – Operation/Inspection Basis

The inspection basis is the underlying reason for conducting an inspection. If that basis changes, then the supervisor will update the operation basis in eNSpect to reflect the updated, suitable basis. Reference the Assignment Management System (AMS) and eNSpect User Guide for operation basis definitions and the various available options when creating an assignment.

5.7.3 - Inspection Report

5.7.3.1 – eNSpect Reporting

During an inspection, you will collect and subsequently report information in eNSpect. As you do so, you should make every effort to ensure that this information is accurate, and updated as appropriate, during each inspection.

Assignment tab:

The assignment tab primarily gives general inspection assignment details, specific inspection guidance if needed.

Team information should be reviewed and updated as appropriate to include the FDA and non-FDA participants in the inspection.

Firm Information tab:

Overview and Additional Details should be reviewed and updated to support OEI Maintenance, per SOP-000051, OEI Development and Maintenance Procedure. ORA is responsible for ensuring all investigators verify, correct, and enter changes to the OEI (including Profile data for profilable firms) on the "Firm Information" tabs in eNSpect during each inspection, investigation, and during any OEI update. Consult with your supervisor and your OEI Coordinator to assure data is accurately updated.

Firm Profiling should be reviewed during each inspection and the compliance status for each profile class code associated with the firm's operations and/or products should be updated. Consult with your supervisor to ensure data is accurately updated. (For additional information regarding firm profiling see your programmatic section of Chapter 5.)

Corrective Action Report (CAR) should be utilized to report the firm's corrective actions to written and discussed observations for OHAFO products. A corrective action report should be completed in eNSpect Firm Information tab, or CMS. (See the current version of the eNSpect User Guide for instructions on entering a CAR in eNSpect.)

NOTE: For Food and FSVP inspections, if you annotated an FDA 483 or FDA 4056 with corrections, then you must also document those corrections as discussed above.

Additional fields may be available in eNSpect in addition to those already discussed. These fields should be reviewed and updated as appropriate for the product covered.

Inspection tab:

Details shall be entered for each inspection to include, but not limited to, the inspection date(s), inspection basis, FDA responsible organization, announcement status, inspection refusals, recalls, samples, consumer complaints, and trip number for foreign inspections. As soon as practical after the close of an inspection, you must enter the start and end date in eNSpect.

Consumer Complaints tab must be completed in eNSpect for every inspection. Record your review of the firm's complaint files in the appropriate text box. If FDA complaints require coverage, record the complaint coverage and suggested Follow-up Disposition for each complaint number listed in the assignment.

Inspection Protocols (IP) are questionnaires associated with specific PACs. The inspection may have one or more IP depending on the scope of the inspection and associated PACs. IPs should be completed if applicable for the PACs covered during the inspection.

Observations shall be documented in eNSpect whenever possible and in accordance with IOM 5.5.10. When you are not able to document observations in eNSpect, then the most current version of the FDA 483, FDA 483a, or FDA 4056 must be used.

EIRs should be written in eNSpect. The EIR must be written in accordance with IOM 5.7.3. Exhibits and attachments shall be labeled and uploaded as appropriate.

Coverage and Conclusions shall be entered for each PAC and product covered during the inspection and include the PAC, establishment type, process code, inspection conclusion, and product covered. The "Suggested District Decision" may also be entered by the investigator at the discretion of division management. Enter time spent on each PAC (see IOM 5.7.2).

Endorsements include an "Inspection Summary" and "Endorsement Text." The Inspection Summary highlights key information from the inspection; often this is like the narrative report summary or the supervisory investigator's endorsement text. Endorsement Text will be entered in accordance with IOM 5.7.6.

5.7.3.2 – Narrative Report

NOTE: As each program has specific requirements for the narrative portion of the EIR, please refer to your program's reporting section for guidance. (For FSVP reporting, see Chapter 6.)

The narrative report is the written portion of the EIR which describes the investigator's inspectional findings. The narrative report may be prepared as one of the following: a Summary of Findings, an Abbreviated report, or a Comprehensive report. The format that you choose will depend on the type of inspection, the inspection basis, anticipated inspection classification, and the specific assignment and/or compliance program.

For all reporting formats, include additional information as directed by your assignment, compliance program, and IOM 5.7.3.6 - Additional Reporting Requirements. A checklist of the Food EIR elements required information can be found under *Post-Trip Resources* on the OHAFO SharePoint. It is updated as the IOM changes. It can assist in other programs, but is designed primarily for Food EIRs.

Narrative reports should be generated in eNSpect and will automatically prepopulate with the firm and inspection information in the header and footers. Reports generated outside of eNSpect should include the firm name, the FEI in the header, and the footer should include the page number. Depending on the PACs added to the inspection assignment, eNSpect may trigger the use of tabular EIR and inspection protocols (see the eNSpect User Guide for additional information). All reports should be prepared in or uploaded to eNSpect.
Your EIR should adhere to the following:

1. Be factual, objective, and free of unsupportable conclusions.
2. Be concise and descriptive while covering the necessary aspects of the inspection.
3. Not include opinions about administrative or regulatory follow-up.
4. Not include information that could identify confidential or anonymous informants (See IOM 5.2.9.2)
5. Generally, be written in the first-person using the active voice.
6. Be signed by all FDA and commissioned personnel participating in the inspection. (See IOM section 5.1.2.5.1 when more than one FDA or commissioned person participated in the inspection.)

(If an amendment to an endorsed narrative report is required, refer to IOM 5.11.7.)

5.7.3.3 – Summary of Findings Report

Unless otherwise directed in IOM 5.7.3.4 or 5.7.3.5, or by your supervisor, or the assignment or the Compliance Program Guidance Manual, a Summary of Findings report should be prepared for:

- NAI domestic inspections
- VAI domestic inspections

The Summary of Findings Report may not be written solely in the eNSpect-provided "Inspection Summary" heading. The Summary of Findings report should include:

1. The reason for the inspection
2. The date, final classification, and findings of the previous inspection
3. The actual inclusive dates of the inspection (these may be included as part of a header or in the body of the EIR.)
4. Current registration(s) status or any changes to registration status. (Per CPG section 110.300, do not report the FURLS Registration number.)
5. The name of the person to whom credentials were shown and the FDA-482, Notice of Inspection, or FDA 482d Request for FSVP Records, was issued, and the person's authority to receive the FDA 482 or FDA 482d. Explain here, too, if you were unable to show credentials or issue forms to top management. Include the name of the person to whom the FMD-145 correspondence should be directed to and their email address. If an email address does not exist for this person, then this should be noted.
6. The inspectional approach (comprehensive or directed); the scope of the inspection; a brief description of the business; a description of the products produced; and a brief description of the products, processes or systems covered during the inspection. Indicate which aspects of the firm’s processes or systems you observed, versus those which the firm described to you
7. The manufacturing codes, and, if necessary, their interpretation.
8. Significant changes (for example, to personnel, facilities, products, processes, etc.) since the previous inspection
9. Voluntary corrections completed by the firm
10. Samples collected during the inspection
11. Exhibits collected during the inspection
12. Attachments
13. Your signature

All violative EIR's should, in addition to the information required for non-violative reports, contain the following:

1. The objectionable conditions or practices described in sufficient detail so that anyone reading the report will clearly understand the observation(s) and significance.
2. The objectionable conditions or practices cross-referenced to FDA 483 or FDA 4056 citations, samples collected, photographs, or other documentation, including exhibits attached to the EIR.
3. Information regarding *when* the objectionable conditions or practices occurred, *why* they occurred, and *who* is (or was) responsible., identifying such responsibility up to the highest level in the firm.

5.7.3.4 – Abbreviated Report

An abbreviated report can be prepared in these instances:

- When the inspection is not eligible for a Summary of Findings reporting
- When the FDA has an inspectional history for the firm
- When either no regulatory action is anticipated, or the inspection was conducted as an OAI F/U inspection

Unless a summary of finds report format is used, the abbreviated report format should be used for all inspections, regardless of coverage (comprehensive, directed, etc.) unless otherwise directed.

The abbreviated report format primarily highlights changes in firm operations since the previous inspection. Several report elements listed below are required in a summary report, and the remaining sections require change reporting only. *Change reporting* means information that differs from the previous inspection report, such as changes in management, products produced, manufacturing processes, etc.

OAI follow-up inspections are inspections conducted directly following an OAI-classified inspection to determine whether corrective actions have been implemented, and/or whether significant violations continue. For OAI follow-up inspections anticipated to be classified NAI and VAI, reports should focus on the corrective actions implemented by the firm to correct violative conditions observed during the previous OAI inspection. For OAI follow-up inspections anticipated to be classified OAI, reports should focus on the continuing violations, responsibility for those violations, any corrective actions implemented (or inadequate corrective actions), and a definition of the new scope of violations observed, including the products affected.
Required elements:

5.7.3.7.1 – Summary
5.7.3.7.2 – Administrative data
5.7.3.7.9 – Manufacturing Codes
5.7.3.7.14 – General Discussion with Management
5.7.3.7.12 – Objectional Conditions and Management Response (Only required if an FDA 483 or FDA 4056 was issued)
5.7.3.7.12.1 – Supporting Evidence and Relevance
5.7.3.7.12.2 – Discussion with Management
5.7.3.7.13 – Refusals (Only required if refusals encountered)
5.7.3.7.16 – Samples Collected (Only required if collected)
5.7.3.7.17 – Voluntary Corrections
5.7.3.7.18 – Exhibits Collected (Only required if collected)
5.7.3.7.9 – Attachments (Only required if collected)

Change reporting only:

5.7.3.7.3 – History
5.7.3.7.4 – Interstate (I.S.) Commerce
5.7.3.7.5 – Jurisdiction (Products Manufactured and/or Distributed)
5.7.3.7.6 – Individual Responsibility and Persons Interviewed
5.7.3.7.7 – Firm's Training Program
5.7.3.7.8 – Manufacturing/Design Operations
5.7.3.7.9 – Complaints
5.7.3.7.10 – Recall Procedures
5.7.3.7.15 – Additional Information

5.7.3.5 – Comprehensive Report

A comprehensive report should be prepared for:

- Initial inspections
- Inspections anticipated to be classified OAI that follow a NAI or VAI inspection (not OAI follow-up inspections)
- As directed by assignment, compliance program, or your supervisor
- Most foreign inspections

The comprehensive report format includes all report elements listed below. This represents the minimal information needed to produce an EIR that supports further agency regulatory action, as warranted. You are encouraged to add additional report headings, as needed, to communicate important information about the inspection, relevance of inspectional observations that may impact public health, and to address specific requests from directed assignments.

Required elements:

5.7.3.7.1 – Summary
5.7.3.7.2 – Administrative data
5.7.3.7.3 – History
5.7.3.7.4 – Interstate (I.S.) Commerce
5.7.3.7.5 – Jurisdiction (Products Manufactured and/or Distributed)
5.7.3.7.6 – Individual Responsibility and Persons Interviewed
5.7.3.7.7 – Firm's Training Program
5.7.3.7.8 – Manufacturing/Design Operations
5.7.3.7.9 – Manufacturing Codes
5.7.3.7.10 – Complaints
5.7.3.7.11 – Recall Procedures
5.7.3.7.12 – Objectionable Conditions and Management's Response (Only required if an FDA 483 or FDA 4056 was issued.)
5.7.3.7.12.1 – Supporting Evidence and Relevance
5.7.3.7.12.2 - Discussion with Management
5.7.3.7.13 – Refusals
5.7.3.7.14 – General Discussion with Management
5.7.3.7.15 – Additional Information
5.7.3.7.16 – Samples Collected
5.7.3.7.17 – Voluntary Corrections
5.7.3.7.18 – Exhibits Collected (Only required if collected)
5.7.3.7.19 – Attachments (Only required if collected)

5.7.3.6 - Additional Reporting Requirements

Additional reporting requirements may be required by compliance programs, assignments, or divisions. Report the required information as requested in the source document, or under the most appropriate report heading.

5.7.3.7 – Individual Headings

5.7.3.7.1 – Summary

Provide the following:

1. The reason for the inspection, including if it was announced or unannounced, and other details (for example, its associated compliance program(s), assignment number, trip number, etc.).
2. The inspectional approach (comprehensive or directed), the scope of the inspection (full scope PC, full, or abbreviated) and the type of inspection (preventive controls, seafood HACCP, API, medical gas, etc.).
3. A brief description of the business, a description of processes used, and the products produced.
4. The date, classification, inspectional observations (written observations and discussion items), and other findings from the previous inspection, if applicable.
5. The status of voluntary corrective actions since the previous inspection.

6. A list of the products, systems, and processes covered during the current inspection, and the types of records and documents reviewed. For human drug reports, list all systems the firm has currently employed.
7. A summary of the written observations, discussed observations, and other findings, refusals, samples collected, warnings given to management, and a summary of management's response or voluntary corrections.

5.7.3.7.2 - Administrative Data

1. The firm name, address, phone, website address, and general e-mail address of the firm.
2. Report the names and titles of the investigator(s), analyst(s), non-FDA officials, etc. Report the name of the firm's responsible official who gave permission to non-FDA officials without inspection authority to accompany you during your inspection. (See IOM 5.1.1 and 5.2.2.)
3. The inclusive date(s) of the current inspection, i.e., list the actual dates in the plant.
4. If a team inspection and some individuals were not present during the entire inspection, indicate dates in plant for each team member.
5. For foreign inspections with Locally Employed Staff (LES)/Foreign Service Nation[4]al[1] (FSN) participation include this language:

   This inspection was supported by (name of LES/FSN) during the period of (fill in dates LES/FSN participated), who is a Locally Employed Staff (LES) hired by the United States Embassy and assigned to FDA to work in support of FDA activities. All information, including documents collected during this inspection and any translation from local language to English by (name of LES/FSN) that supports the Form FDA 483, Inspectional Observations, FDA 483a, Form FDA 4056, (if a form was issued) and the Establishment Inspection Report (EIR) was collected in collaboration with the FDA investigator(s).
6. Full names and titles to whom FDA Official Credentials were shown,
7. Full names and titles to whom any FDA forms were issued to or signed by during the inspection (FDA 482, 483, 484, 463, 4056, etc.); where appropriate, explain the reason a form(s) was not issued to or signed by the most responsible individual (this may be reported in the Individual Responsibility and Persons Interviewed heading below),
8. Full name, title, address (if different from the address of the inspected establishment), and email address of the top management official at the inspected firm to whom the FMD 145 letter should be addressed. If an email address does not exist for this person, then this should be noted. If the firm requests an alternate point of contact for FMD-145 correspondence provide their contact information as well.
9. Full names, titles, and addresses (if different from the address of the inspected establishment) of most responsible corporate official(s) to whom other correspondence, e.g., Warning letter, should be addressed (For initial inspections and inspections anticipated to result in regulatory action).
10. If this was a team inspection, who wrote which section of the EIR.
11. Full names and titles of inspectors from other government agencies (to include federal, state, local or foreign) at the facility during the inspection.
12. Full names and titles of who provided translation of foreign language documents.

[1] According to the State Department: *Foreign Service Nationals (FSNs) are employees of the U.S. State Department who provide administrative, technical, fiscal, and other support at posts abroad. They are usually citizens of the same country as the host country but can also be third-country citizens. FSNs are also known as Locally Employed Staff (LE Staff).*

13. If an inspection is conducted at premises also used for living quarters document that you are inspecting a residence and if the owner was agreeable. (IOM 5.1.4.3.1)
14. Full name and title of the individual you provided with guidance documents and list the documents provided.

5.7.3.7.3 - History

1. Report the legal status of the firm (corporation, partnership, limited liability company, sole proprietorship, etc.), and the state and year of incorporation, as applicable.
2. List the parent corporation, corporate address, and any relevant subsidiaries with respective FEIs.
3. Provide a summary of any previous agency actions (for example, issuance of an untitled letter, warning letter, injunction, seizure, and/or import alert) and significant inspection history pertinent to the current inspection.
4. Include any recalls, market withdrawal, etc., since the last inspection.
5. Report the core hours of operation and any seasonal variations.
6. Report all current registration(s) status or any changes to registration status, and describe any inaccuracies identified in the firm's registration(s). (for example, food facility registration, shell egg registration, AF/LACF registration, drug registration and listing, device registration and listing, tobacco registration and listing, radiation safety reports, tissue establishment registration, human cell and tissue establishment registration, blood establishment registration, etc.). For HAF commodities do not report the FURLS Food Facility Registration number (Per CPG section 110.300). Report if the firm is located on tribal land or is owned/operated by a federally recognized Native American tribe or tribal member.

5.7.3.7.4 - Interstate (I.S.) Commerce

1. Report the estimate of the percentage of products shipped outside of the state (or exported to the United States) and the basis of the estimate.
2. Report the firm's general distribution patterns (for example, direct sales to consumers; states, regions, and/or countries shipping to) of the firm and how the products reach the firm customers (for example, firm truck, common carrier truck, rail, vessel, or air freight).
3. If there is an apparent violative product, provide examples of interstate shipments of violative product(s); or if no such shipments, provide examples of interstate shipments of major components of apparent violative products.
4. For foreign inspections, list significant U.S. consignees to whom the firm's products are shipped.
5. For domestic inspections regarding human drugs, list significant consignees to whom the firm's products are shipped.

5.7.3.7.5 - Jurisdiction (Products Manufactured and/or Distributed)

1. Describe or include a list of a representative number of currently marketed products in all program areas subject to FD&C Act or other statute enforced by FDA or counterpart state agency, including any believed violative.
2. Collect appropriate labeling (product and case labels, inserts, brochures, manuals, promotional materials of any type) for those products believed violative or representing any significant new or unusual operation, industry or technology; or as directed by your supervisor.
3. Report the firm's general promotion patterns (for instance, via website, advertisements, trade shows, etc.).
4. Report and document any applicable labeling agreements (and obtain a copy) and statutory guaranty given or received per Sections 301(h) and 303(c)(2) of the FD&C Act [21 U.S.C. 321 (h) and 333 (c)(2)] (IOM 5.3.7.2)

In addition, a product's label, labeling, and promotional materials are a critical part of determining its intended use.

1. In instances where a regulatory action is being considered based on product labels, labeling, and/or other promotional materials (including any information found on websites), you should collect all available documentation. This includes all written, printed, or graphic matter on the immediate container of an article or accompanying the article (the product's label and labeling, see FD&C Act, 201(k) and (m) [21 U.S.C. 321(k) and (m)] and IOM 4.4.9.1). Accompanying labeling could include brochures, pamphlets, circulars, and flyers, as well as copies of audio and video files.
2. A thorough review includes a review of the firms' internet presence. If you are concerned with information on the firm's website, ensure copies of webpages are collected in hard copy and included with the report.
3. In cases where there may be a dispute about whether a product is a drug or a dietary supplement, you should collect all materials which claim a product is intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease.

5.7.3.7.6 - Individual Responsibility and Persons Interviewed

Report with whom you dealt, and in what regard (both during and prior to the start of the inspection):

1. Report the chain of command with names and titles of key operating personnel, to include the top management official. Include an organizational chart, if necessary, to clarify roles.
2. Describe roles and authorities of responsible individuals, including the full names (see IOM 1A.5) and titles of individuals providing you with information.
3. Who accompanied you during the inspection,
4. If the regulatory action is anticipated, report full names and titles of owners, partners, and corporate officers who have the duty, power, responsibility, and authority to prevent, detect, and correct violation(s), and how this is demonstrated and/or documented. See IOM 5.6.3.2
5. For human drug inspection reports, also include the name, title, physical mailing address, phone, fax number and e-mail address for any U.S. agent or broker who represents the company when dealing with the FDA.

5.7.3.7.7 - Firm's Training Program

A firm's training programs are of particular significance when making inspectional findings revealing that people may not be adequately trained. As such, explain the firm's training program(s) as stated in the applicable compliance program, and/or as it correlates to the deficiencies observed during the inspection. You should also consider providing an overview of the firm's new-hire and ongoing refresher training programs as they potentially bear upon any deficiencies observed.

You should also report if the firm is subject to any specific regulatory training requirements (for example, LACF Better Process Controls School, Seafood HACCP, Preventive Controls PCQI, qualified individual) and how the firm is meeting those requirements.

5.7.3.7.8 - Manufacturing/Design Operations

1. Describe the firm's general overall operations, equipment, processes, and products. If necessary, to help illustrate the firm operations, include any relevant schematics, flow plans, photographs, formulations, and diagrams. If previously inspected, report any changes in the firm's general overall operations, including significant changes in equipment, processes, and/or products since the previous inspection.
2. List names and sources of any new or unusual components or raw materials.
3. Report equipment considered new or unusual, unless otherwise directed.

4. Submit pertinent formulas or batch manufacturing records (especially those being manufactured during your inspection) and processing instructions with labeling of suspect products.
5. Indicate which aspects of the firm's processes or systems you observed, versus those that the firm described to you.
6. Describe contractors used and for what purpose, if relevant to observations noted during the inspection.

For human and animal food inspection reports, as applicable, include the following:

1. Unless otherwise directed, choose a product that has not been covered during a previous inspection. Use a risk-based analysis to include consideration of ingredients, processing, and personnel.
2. Describe the product(s) covered and include basic food information, including finished product name, product description with packaging, pertinent ingredients, intended use, and conditions of storage and distribution.
3. Describe the process flow (receiving through distribution) and a description of the process at each step.
4. For full-scope preventive control or HACCP inspections, describe the results of the hazard analysis and the adequacy and implementation of written programs. Describe any deficiencies noted compared to your hazard analysis.
5. Describe the firm's general sanitation procedures.
6. Describe any coverage of additional food safety regulations that apply to the product(s) inspected (for instance, LACF, infant formula, bottled water, etc.).

For human drug inspection reports:

For inspections conducted using CP 7356.002, the EIR should be organized by systems covered during the EI. For pre-approval inspections (PAI) under CP 7346.832, the EIR should be organized by the objectives covered during the inspection. Provide additional details for the system elements found to be deficient, or the subject of an FDA-483 observation.

For medical device inspection reports:

1. Describe manufacturing operations by sub system covered in your inspection (Management Controls, Design Controls, Production and Process Controls, Corrective and Preventive Actions, Material Controls, Facility and Equipment Controls, and Records/Documents/Change Controls). With regards to all Level 2, 3, and "for cause" inspections, for Production and Process Controls, indicate which production processes were covered and reviewed. If a subsystem was not specifically covered during your EI, you do not need to separately describe the general operations of that subsystem.
2. This section should include a description of the manufacturing process flow and identify significant acceptance activity processes associated with products identified on the FDA 483.
3. For all inspections covering CAPA, indicate which data sources were available for review and which were actually reviewed. Also include a brief statement regarding coverage or non-coverage of applicable medical device tracking requirements, MDRs, sterilization, and reports of corrections and removals.
4. If the Design Control system was covered, indicate the design project(s) covered during the inspection. Where design activities occur at a location other than the manufacturing site, list the name, address of the design location, and responsibilities of those personnel performing the design activities.
5. If applicable, identify the name and address of the specification developer, if different from either the manufacturing site or where design activities occur.

5.7.3.7.9 - Manufacturing Codes

Describe the manufacturing coding system (lot, batch, product, etc.), and provide a key to interpretation of codes.

For medical device inspections reports: Where appropriate, include a description of the system used to identify and maintain control of components during the manufacturing process, as well as the codes used for traceability, including the unique device identification (UDI). Ensure the UDI-DI is identified in the Global Unique Device Identification Database (GUDID) (for applicable finished devices).

5.7.3.7.10 - Complaints

Complaints include those reported to the FDA by consumers, health care professionals, industry, etc.; and all complaints received by the firm.

1. Describe the firm's complaint procedure. If the firm has no procedure, describe how complaints are handled by the firm.
2. Report your review of the firm's complaint file(s).
3. If returned goods and/or documents for returned goods are examined, describe findings. If not examined, so indicate.
4. Report your follow-up of FDA-received complaints and action taken by the firm in the complaint coverage box for each FDA complaint. Correlate any consumer/trade complaints, Adverse Event Reports, MDR's, MedWatch reports to specific objectionable conditions observed.
5. Enter the Suggested Follow-up Disposition for each FDA complaint covered during the inspection.

5.7.3.7.11 - Recall Procedures

Describe plans and procedures for removing products from marketing channels if necessary. If these procedures are in written SOP-type format, you may reference any copies obtained to aid in your explanation.

5.7.3.7.12 – Objectionable Conditions and Management's Response

If any observations were provided to management in writing (for instance, via a FDA 483, FDA 483a, or FDA 4056) at the conclusion of the inspection. list each observation. For each observation, provide information organized under the two headings, "Supporting Evidence and Relevance," and "Discussion with Management" below.

NOTE: Observations of a verbal nature (including non-reportable observations and discussion items) should be reported in sufficient detail under "General Discussion with Management." (Correlate any exhibits, samples, etc. to any "verbal" observations).

5.7.3.7.12.1 - Supporting Evidence and Relevance

You should adequately describe the observations, evidence, and their relevance on the FDA 483, FDA 483a, or FDA 4056. And provide any additional information needed to support those observations. For example,

- Identify specific pages of exhibits and/or samples (e.g., procedure title, section, paragraph, sentence), labeling text, interstate shipping records which in your judgment document violations so supervisors, compliance officers, and other reviewers can readily evaluate your evidence.
- Describe verbal statements (verbatim if possible) by firm officials having knowledge, duty, power, and responsibility to detect, prevent, or correct the apparent violation.
- Identify the responsible party for each apparent violation (if known.)
- Identify which team member (if applicable) was responsible for the observation.
- When appropriate explain how this observation relates to the overall situation, for instance, its impact on the product, batches, or lots involved, and any relationships to other products, processes, or other FDA 483 or FDA 4056 observations.
- The duration of the problem.

5.7.3.7.12.2 - Discussion with Management

Discussion with management:

- Report management's response to each specific observation.
- Report, time frames given for corrections and/or corrective action, if provided.
- Report any disagreements with, or refusals, to correct the observation.

Specific to medical device inspection reports:

- For each observation based on sampling of records, indicate which "Sample Table" and level of confidence was used, and the actual number of records sampled.
- If the number sampled is different than the actual number reviewed, so indicate.

5.7.3.7.13 - Refusals

Refusals are documented in eNSpect and should populate in your report. Provide additional details, as necessary, such as, who made the refusal and, if available, why the refusal was given.

In the case of drug and medical device inspections, provide full details of all instances of delaying, denying, limiting, or refusing an inspection.

5.7.3.7.14 - General Discussion with Management

1. Report the names and titles of all individuals present at the close of the inspection, including those present via electronic media. If someone participates via electronic media describe type used.
2. Include the name and title to whom the FDA 483, FDA 483a, or FDA 4056. was issued.
3. Provide additional discussion items not provided in writing at the conclusion of the inspection, such as: questionable labels, labeling and/or labeling practices; commercialization of products covered by IDE or IND; fraudulent health claims; registration/listing deviations; lack of approved PMA, 510(k), NDA, ANDA; etc. These include all verbal observations not included, or meriting inclusion, on the FDA 483, FDA 483a, or FDA 4056 (see IOM 5.2.3).
4. Report all significant conversations with management or management representatives to include descriptions of any warning, recommendation, or suggestion given to the firm, and to whom they were given.
5. Report management's general responses to the inspection and/or to groups of items listed on the report of observations or discussed at the conclusion of the inspection.
6. Report if management was informed of significant observations that may, after further review by the agency, be considered violations of the FD&C Act or other statutes. Legal sanctions available to the FDA may include seizure, injunction, civil money penalties, and prosecution. Significant deviations observed during a foreign inspection could result in a facility's product(s) being refused, or detained upon entry, into the United States.
7. Report if management was advised that if FDA receives an adequate response to the FDA-483, or other objectionable conditions, within 15 business days of the end date of the inspection, it may impact FDA's determination of the need for subsequent action.

5.7.3.7.15 - Additional Information

1. When issues with imported products are encountered during inspections, you should document the product and foreign manufacturer in the EIR. Such examples include rejected APIs due to non-conformance with the USP or applicable compendium, foods without appropriate labeling, etc. Email a copy of the EIR to fdaimportsinquiry@fda.gov and explain the reason for the referral.
2. Report any pertinent facts, which do not fit in another section of the EIR. For example, this might include firm biosecurity requirements, and the documentation of noteworthy travel logistics/issues, like detailed directions to firms that are otherwise difficult to locate, lodging limitations in proximity to the firm, and locations where extensive in-country foreign travel from the firm to the hotel is required.

3. If photographs are taken during the inspection, include the statement, “The officially sealed original copy and unsealed working copy discs containing the photographs taken during the inspection are filed with the unlabeled exhibits and attachments.”
4. If electronic records were received on electronic storage media during the inspection include the statement, “The officially sealed original copy [USB, CD, DVD, etc.] [and unsealed working copy] containing the electronic records provided by the firm during the inspection are filed with the unlabeled exhibits and attachments.”

If electronic records were received via secure transmissions to the FDA, include the statement, “Electronic records provided by the firm during the inspection were obtained via [insert description of secure transmission used] and true copies of these files were stored on FDA servers in accordance with record management procedures.”
*The bracketed information should be edited based on the actual storage devices obtained and if working copies were created.

For Medical device inspection reports:
Include names and addresses of all applicable third-party installers or servicing organizations used by the manufacturer. Include their responsibilities too.

For human drug inspection reports - **PDMA Coverage:**

1. Describe what sample loss, theft, or diversion reports were covered during the inspection.
2. Describe the firm's sample audit and security systems, including a review of the firm's SOPs. Significant problems that may contribute to the firm's inability to adequately monitor sample distribution via sales representative, mail or common carrier should be addressed under “Objectionable Conditions.”

5.7.3.7.16 - Samples Collected

List the sample number(s) and describe each sample collected during the inspection.

5.7.3.7.17 - Voluntary Corrections

1. Provide a brief description of improvements initiated by the firm in response to a previous inspection, report of observations, and/or regulatory actions.
2. Report voluntary destructions, recalls, and similar actions since the prior inspection or during this inspection.
3. Report any follow-up to recalls identified during the inspection (may be by referencing Attachment B recall report).
4. Include recalls to specific objectionable conditions observed.
5. Provide the identity of person(s) responsible for the corrections.
6. Report any appropriate voluntary corrections in FACTS CARS. For human and animal food inspections, report any appropriate voluntary correction in eNSpect CAR.

5.7.3.7.18 - Exhibits Collected

List all exhibits attached. (For assistance, see IOM 5.6.5 - Exhibits.)
Briefly describe or title each exhibit attached and include the number of pages for each exhibit listing in eNSpect.
NOTE: For complex inspections, a cross-reference from the FDA 483, FDA 483a, or FDA 4056 and verbal observations to applicable exhibits and samples can be useful during further review.

5.7.3.7.19 – Attachments

List all attachments. (For assistance, see IOM 5.7.5 - Attachments.)

Briefly describe or title each attachment and include the number of pages for each attachment listing in eNSpect.

After issuance do not number, alter, or label FDA documents (for example, assignment memos) or forms (for example, FDA 463a, FDA 482, FDA 483, FDA 4056).

5.7.3.7.20 - Signature

All participants will sign the final narrative portion of the EIR. (Refer to current eNSpect user guide for guidance on electronic signatures for multiple participants.) In rare situations (for instance, in situations of extended leave, retirement, or deployment) a participant may not be available to sign the EIR. These situations should be documented in the endorsement.

In some cases, electronic signature by all participants is not possible. An example as to how this can be accomplished is to forward an electronic "draft" copy of the EIR for all to review, then followed or accompanied by the original signature sheet. When signed, return to the lead investigator for uploading into eNSpect.

In rare situations (e.g., extended leave, retirement, deployment) a participant may not be available to review and sign the EIR. The supervisor should state in the endorsement “endorser acknowledges the inability of the participant to sign the EIR due to unavoidable circumstances”.

5.7.4 – Exhibits

Exhibits are materials included with the EIR and collected from the firm after the inspection is initiated and before the inspection is closed out. Impressive exhibits are extremely effective and important forms of evidence to establish existence of violative conditions or products.

Collect only records and documents that are relevant to your inspectional findings or are required by the assignment or Compliance Program. Exhibits should contribute to the objective of the assignment, clarify the report, and clearly document any violations. Exhibits include flow plans, labels, schematics, layouts, batch records and procedures, etc. Reference and explain exhibits in your narrative report. Copies of procedures, patient records, etc., which do not serve as evidence of a violation should not be collected unless you are directed to do so. Both electronic or physical materials that are collected from the firm, and are not needed as exhibits, should be destroyed in accordance with FDA Records Management Procedures and program, division, or office policy.

Labeling exhibits should reveal the entire label and must be legible. Generally, one copy of the label is sufficient, but check with the Compliance Program and/or assignment. (See IOM 4.4.7 for exceptions.) In addition, the label, labeling, and promotional materials are a critical part of determining a product’s intended use. As such, you should follow this guidance:

- In instances where a regulatory action is being considered based on product labels, labeling, and/or other promotional materials, including any Internet websites, you should collect all available documentation. This includes all written, printed, or graphic material on the immediate container of an article or accompanying the article (the product’s label and labeling, see FD&C Act, 201(k) and (m) [21 U.S.C. 321(k) and (m)] and IOM 4.4.7). Accompanying labeling could include brochures, pamphlets, circulars, and flyers, as well as audio and video files. Use good judgement in collecting this evidence. If you are unsure, contact your supervisor or compliance branch.
- A thorough review includes a review of the firms’ internet presence. If information found there relates to any violative conditions observed or other concerns you might have, print and collect any hard copies of the relevant webpages and include them with your report.
- In cases where there may be a dispute about whether a product is a drug or a dietary supplement, you should collect all materials claiming a product can be used for the treatment of any disease.

Pertinent portions of exhibits in foreign languages should be translated, especially if they document violations, unless extenuating circumstances prevent such translation, A statement regarding who provided translation on the documents should be included in the "Administrative" section of the report.

For photographs included in the report see IOM 5.6.7.

Exhibits are identified and included with the final EIR. Electronic labeling should be used to identify exhibits submitted with an EIR. Identification should include at least the firm name, FEI Number, date(s) of the inspection, the initials of the lead investigator, exhibit number, and page number(s) (see IOM 5.6.5). (Also refer to ORA-OO-0004 - *Using eNSpect to Create, Store, and Preserve Electronic Records Associated with an Establishment Inspection Report*.)

Exhibits do not include FDA forms, copies of assignments, or information obtained outside of the firm. For example, website downloads using a computer that is not traceable to the U.S. government, printed prior to the start of the inspection, are not exhibits.

Exhibits which include medical records obtained during an investigation or inspection should be handled in accordance with current personal privacy disclosure rules. Such patient records should remain intact and stored in the official files. All external requests should be handled by the Government Information Specialist who handles FOIA requests.

5.7.4.1 - Electronic Records as Exhibits and Attachments

Electronic records included as exhibits or attachments to the EIR should be stored to protect the integrity of the data. (Refer to IOM 5.6.11) Electronic records should be protected from degradation, including preventing exposure of the electronic storage media to extreme temperatures and magnetic fields if necessary. Additional precautions to preserve the electronic records may be required, and you should be guided by your program division procedures for handling electronic storage media. (See IOM 5.7.4 Exhibits and 5.7.5 Attachments)

If electronic records were obtained via electronic storage media, do not scan and upload the FDA 525 or envelopes containing the USB, CD, DVD, or other storage devices containing electronic records to eNSpect. The actual records included on the storage device and uploaded into eNSpect are the official exhibit. The original officially sealed storage device and unsealed working copies should be included with the unlabeled hard copy exhibits and attachments filed in accordance with applicable procedures. The following statement should be included in the Additional Information section of the report: "Electronic records provided by the firm during the inspection were obtained via [insert description of secure transmission used] and true copies of these files were stored on FDA servers in accordance with record management procedures." (See IOM 5.7.3.7.15)

*The bracketed information should be edited based on the actual storage devices obtained and if working copies were created.

For information on handling photographic or video storage media, see IOM 5.6.7.5 – Preparing and Maintaining Digital Photographs/Video as Regulatory Evidence.

5.7.5 – Attachments

Attachments are defined as any materials not provided by the firm during the inspection and referred to in the EIR, such as assignments, Center-provided protocols, website information printed during inspectional preparation, etc. Non-evidentiary materials attached to the narrative portion of the EIR should be identified as "Attachments," in the same way exhibits are (see IOM 5.6.11.2). Documents attached to the EIR may be referred to under the attachments heading, such as a copy of the FDA 463a, the FDA 482, FDA 483, FDA 4056, etc. (in form number order), but such documents/forms may not be numbered, altered from their issued state, bear adhesive identification labels, etc. List and attach copies of associated reports (Recall Attachment B Report, etc.).

5.7.6 – Endorsement

Supervisory investigators evaluate inspection findings, determine the classification of the inspection, and recommend an action, in accordance with applicable compliance programs, assignments, or policies. They also determine or

approve final content of the endorsement of the EIR. However, investigators should prepare proposed endorsements for their supervisor. Endorsements should fit in the available space provided in eNSpect; however, if the endorsement exceeds the character space provided in eNSpect, a separate endorsement should be prepared, fully identifying the firm, with a summary of the endorsement included in eNSpect. The eNSpect endorsement field should indicate that a separate endorsement has been prepared and uploaded to eNSpect. The eNSpect Record will be used as the endorsement and routing document to accompany the EIR. (See also IOM 5.7.3.3.)

The endorsement generally contains the following information:

1. The reason for the inspection (for example, the workplan, or assignment from headquarters). State the subject of the assignment and reference.
2. A brief history of previous findings (for example, relevant FDA 483, FDA 483a, and FDA 4056 observations, and/or discussion items), including classification of previous inspection, any action(s) taken by the program division, and/or corrective action(s) taken by the firm, in response to inspectional observations from the previous inspection.
3. A concise summary and evaluation of current findings and samples collected.
4. Refusals, voluntary corrections, or promises made by firm management.
5. Any FDA-received consumer complaints covered during inspections.
6. Classification and follow-up consistent with inspectional findings and in accordance with applicable compliance program, assignments, or policy. Action may include notification of other program divisions and headquarters as warranted.
7. Distribution consistent with program division policy and the requirements of the specific compliance programs.

Note: When endorsing in eNSpect, include notification to the Division of Import Operations (DIO) at fdaimportsinquiry@fda.gov when any violative, imported products are identified.

Note: In rare situations (for example, in instances of extended leave, retirement, or deployment) a participant may not be available to sign the EIR. The supervisor should state in the endorsement: “endorser acknowledges the inability of the participant to sign the EIR due to unavoidable circumstances.” (See section 5.11.4.3.21)

The existence of Personal Safety Alerts (see IOM 5.3.1.1) or Personal Safety Plans (see IOM 5.3.1.2) pertaining to the firm should be included in the endorsement section only, not in the EIR.

The endorsement should be updated to indicate if an amendment to the EIR (see IOM 5.7.7) or an amended FDA 483, FDA 483a, or FDA 4056 has occurred.

PROFILES: Updating eNSpect with the Compliance Status for each profile class code associated with the firm's operations and/or products is the responsibility of ORA and Center investigators, supervisors, and compliance officers. (See Exhibit 5-14 for more information on profiling CGMP/QS Compliance Status.)

5.7.6.1 – Reporting Verified Corrective Actions

A compliance achievement, also known as a verified corrective action, is the observed repair, modification, or adjustment of a violative condition; or the repair, modification, adjustment, relabeling, or destruction of a violative product when either the product or condition does not comply with the acts enforced by the FDA.

eNSpect should be used to report any verified corrective actions that are not the result of legal actions. See Field Alert 63: Observation and Corrective Action Report and Corrective

Action Report New Expanded Functionality.

5.7.6.2 - Reporting Criteria

There are three criteria for reporting:

1. The detection or identification of the problem. A problem may be observed by the FDA, other federal officials, or by state, local, tribal, and territorial (SLTT) authorities referring them to the FDA; or as a result of an inspection, investigation, sample analysis, or detention accomplished by ORA, or states under contract to ORA.
2. The correction of the problem. The correction is directly attributable to the efforts of ORA or state officials under contract to ORA (involving contract products only) and is unrelated to the filing of a legal action, such as a seizure, prosecution, or injunction.
3. The verification of the correction of the problem. The correction is verified by the FDA, other SLTT authorities and reported in writing to the FDA; and is based on an inspection, investigation, sample analysis, or letter from a firm to FDA certifying the problem has been corrected.

5.7.6.3 - Data Elements

For instructions on entering corrective actions in eNSpect, refer to the user manual.

For instructions on entering corrective actions in FACTS, see Exhibit 5-15.

Only when the corrective action(s) has been verified should a FACTS CARS be reported. The data elements are those entered/coded in FACTS (See IOM Exhibit 5-15) and include the following:

1. PAC. Should there be insufficient space to code all corrections verified on an occasion, record the most significant corrections.
2. PROBLEM TYPE. The problem type is the problem(s) identified during the operation(s). Use the List of Values (LOV) found in this field on the Compliance Achievement Reporting Screen. If “Other” is chosen, you should include an explanation in the “Remarks” field.
3. CORRECTIVE ACTION. The action the establishment took to correct the identified problem. Use the LOVs found in this field on the CARS screen. If "Other" is selected, you should include an explanation in the "Remarks" field.
4. VERIFICATION DATE. Use the date the corrective action(s) is verified, either through an establishment inspection, an investigation, or a letter from the establishment certifying the corrections have been made. Include documentation to verify the action such as repair receipts/plans.
5. CORRECTING ORGANIZATION. The FDA, other federal agency, or state or local authority, which observed the verified correction. Use the LOVs found in this field on the CARS screen.
6. REPORTING ORGANIZATION. The FDA, other federal agency, or state or local authority, which is actually inputting the verified correction. Use the LOVs found in this field on the CARS screen.
7. REASON FOR CORRECTION. The action the FDA took to make the correction happen. Use the LOVs found in this field on the CARS screen. If “Other” is chosen, you should include an explanation in the “Remarks” field.

5.7.7 - Corrections to Endorsed Establishment Inspection Reports

If your EIR requires correcting or clarification after it has been endorsed, an amendment may be prepared at the request of your supervisor. Amendments should only be required for significant errors or omissions, regarding, for instance, dates, names, lot numbers, types of operations, or any grammatical errors that change the intended context of the report.

The amendment will be written using the original EIR as the starting document. The word “Amendment” should be placed after the words “Establishment Inspection Report” in the header. A sequence number should also accompany the word Amendment (example: “Amendment 1”). Ensure any changes you made to correct errors in the text of the EIR remain visible; additionally, embolden all additions made, and strike through all removals made. The amended narrative report should be processed through eNSpect.

The amended operation must be endorsed. At the beginning of the endorsement text, indicate that an amendment has been made to the report with a brief explanation as to why an amendment was necessary and if additional documents were added to the report.

5.8 – Human and Animal Foods

5.8.1 – Human and Animal Foods Inspections

Food inspections are conducted to ensure the safety of our nation's food supply through the evaluation of the firm's compliance with applicable statutory and regulatory requirements.

5.8.1.1 - Inspectional Authority and Records Access Authorities

See IOM subchapter 2.2 for general statutory inspectional authorities, including general inspectional authority and records access authorities in the FD&C Act and the PHS Act. Refer also to RPM Chapter 10-4 INSPECTION OF FOOD RECORDS – SECTIONS 414(a) and 704(a).

If, during an inspection, you believe the FDA has and needs to exercise its authority to access required records, and:

- the firm refuses to provide access to the records, or
- based on experience, the program division anticipates that the firm may refuse to provide access to records, or
- the firm requests that the FDA provide a separate written request for records,

then, notify your supervisor and consult with your program division Compliance Branch.

In addition to the statutory authorities, the FDA has the regulatory authority to obtain records and information in low acid canned food (LACF) and acidified food (AF) facilities:

- 21 CFR 113 requires commercial processors of low-acid foods packaged in hermetically sealed containers to maintain complete records of processing, production, and initial distribution.
- 21 CFR 114 requires the same of commercial processors of acidified foods.
- 21 CFR 108.25(g) and 21 CFR 108.35(h) provide that a commercial processor shall permit the inspection and copying of the records required by 21 CFR 113 and 21 CFR 114 by duly authorized employees of the FDA.

Your demand for these records must be in writing on an FDA 482a, Demand for Records, signed by you, with identification of the records demanded as follows:

"As mandated by 21 CFR 108, 113 and 114 for all LACF and/or ACF products produced by this firm: all documents and records related to all thermal processes, production, and quality control as well as all analytical and maintenance documents and records which may have a bearing on any changes to equipment or thermal processes."

If only a specific record is desired specifically identify it. For example, you may state, "Fill Weight Records for #2 Filling Machine for the period of 4-15-23 through 6-7-23." See IOM Exhibit 5-2.

21 CFR 108.35(c)(3)(ii) states that commercial processors engaged in thermal processing of low-acid foods packaged in hermetically sealed containers shall provide the FDA with any information concerning processes and procedures necessary by the agency to determine the adequacy of the process. 21 CFR 108.25(c)(3)(ii) requires the same of commercial processors of acidified foods. The information in this regulation is the data on which the processes are based. Many processors will not have this information, and, in fact, 21 CFR 113.83 requires only that the person or organization establishing the process permanently retain all records covering all aspects of establishing the process. The processor should, however, have in their files a letter or other written documentation from a processing authority describing the recommended scheduled process and associated critical factors.

You may encounter situations where you believe control of certain factors is critical to the process, yet there is no evidence to document these factors were considered when the process was established (for instance, a change in formulation that could affect consistency). It is appropriate then to issue a written request for a letter or other written documentation from a processing authority, which describes the recommended scheduled process and associated critical factors. This information should be requested using a FDA 482b (Exhibit 5-3). This represents the processing authority's conclusions and should correlate with the filed process. If you believe control of certain factors are critical to the process and are not described in the process authority's recommendation or the filed process, request all available information about the situation as follows:

> *"As mandated by 21 CFR 108: all documents and records relating to or having a bearing on the adequacy of processes for all Low-Acid Canned Food and/or Acidified Canned Food products produced by this firm."*

You may also identify specific products that you need to review. For example, if only one product had a significant formulation change then you may only need to request details about that one product. Include the name of the person or organization who established the process and the specific practices of the firm. This information should be included in your report and forwarded by your program division to LACFTechnical@fda.hhs.gov for review, as soon as possible. If the process establishment data and information is deemed necessary by the center, they will either request it directly from the processor, or will direct the program division to request it.

5.8.1.2 - Preparation and References

Before conducting a food inspection, refer to the following guidance:

- Acquaint yourself with the firm's inspectional, compliance, personal safety, and recall history; open complaints (see IOM 5.2.3); related firms; responsible persons; trademarks; practices; and products. This review may help reveal or identify products you will want to cover because, for instance, they are difficult to manufacture; or they require special handling, processes, techniques, or specific hours of operation, the latter of which may inform a more effective inspection start day/time and decisions regarding environmental sampling, etc. Determine the type of operation (manufacturer, warehouse, own-label distributor, etc.) to be inspected to ensure you apply of the appropriate regulations. ORA has numerous applications available for investigators to use when preparing for an inspection. These include:
- FDA's Online Search and Retrieval System (OSAR), which allows you to quickly perform searches for firm, inspection, remote regulatory assessments, investigations, personal safety, recall, consumer complaint, and citation data in one location. Information accessible through OSAR is curated from multiple ORA systems, including Firm Management System (FMS), Compliance Management System (CMS), Online Reporting Analysis Decision Support System (ORADSS), Field Accomplishments and Compliance Tracking System (FACTS), TurboEIR, eNSpect, Recall Enterprise System (RES), and Documentum. You can access the OSAR User Guide through the help link located at the bottom of the OSAR homepage.
- Firm360, a module of OSAR that provides you with a comprehensive view of information on a specific firm based on the FDA Establishment Identifier (FEI). You can access the most recent Firm360 User Guide through the help link located at the top right in a Firm360 window. This guide provides an overview of the main site features within Firm360. Under each section in Firm360, you can click on the "+ more/- less" button in the detail column to expand or collapse the subsections for additional details. Investigators performing Human and Animal Food (HAF) program domestic inspections should pay particular attention to content found within the following sections of Firm360:
  - **"Snapshot"** – This section provides you with information, including, for instance, if the firm you are assigned to inspect has a personal safety alert (PSA).
  - **"Firm Details"** – Here you can find information such as firm registrations, attestations, aliases, FMS firm comments, and district use codes (for example, dual jurisdiction establishment).
  - **"Samples & Lab Analysis"** – In this section you can quickly sort data using the lab class column to determine if the firm has any recent violative samples or has a history of repeat violative samples.

- **"Inspections"** – Here you'll find the firm's inspectional history, including past final inspection classifications. Use the "+ more/- less" button to find inspection documents. The inspection documents, if available, provide a hyperlink to download the document or select multiple documents to download into a zip file. You can also find a list of FDA citations linked to the inspection and determine if these were written FDA 483 observations (displays as "Normal Printing") or if they were "Do Not Print" additional observations entered into the firm's Corrective Action Report (CAR).
- **"Corrective Action Report"** – CAR data is specific to the HAF program. In this section, you'll find all the firm's CAR enabled observations (can be written FDA 483 observations or do not print observations) from past inspections. The correction status column will help you determine if that particular observation has been entered as corrected, not corrected, pending review, etc. However, Firm360 does not provide all information needed to follow-up on the CAR observations. For this, you will need to access CAR information through CMS (search by the firm FEI) to find the firm's corrective action documents, for example, and any additional notes/comments entered by compliance branch. Also, note that state contract inspection PACs are not currently CAR-enabled.
- **"Investigations"** – Here you'll find the firm's investigational history. For each investigation, you can find details such as the investigation reason, investigation findings, and documents uploaded for the investigation (if available).
- **"Remote Regulatory Assessments"** – While not widely common yet in the HAF program, you should determine if the firm you are assigned to inspect has had a recent RRA conducted. If so, you should review the information.
- **"Consumer Complaints"** – This section provides you with consumer complaints associated with the firm. You can find the complaint number, status, product name, injury/illness, and details on the complaint. Use care when determining which consumer complaints need to be followed up on during your inspection. For example, the complaint status may show "closed," but you will need to use the "+ more/- less" button to confirm that a follow-up disposition, and associated date, has been entered. If you review the prior EIR and note the consumer complaint was followed up on, you should speak with your supervisor to determine next steps. Any consumer complaints with a status of Awaiting Follow-up Disposition should be followed up on during your surveillance/routine inspection. You can search individual complaints in CMS to see full complaint data.
- **"Recalls"** – Here you can find a list of recalls associated with the firm, including recalls not necessarily initiated by it). Any recent recalls, or a history of recalls, can help inform or determine which products and/or processes you will want to cover during your surveillance/routine inspection. For example, if a firm has multiple recalls for undeclared allergens due to incorrect labeling, this should lead you to cover a product containing major food allergens, including determining what steps the firm is taking to ensure the product is packaged with the correct allergens declared on the label.
- **"Compliance Cases"** – Here you can see if the firm you are assigned to inspect has a history of regulatory actions (for example, regulatory meetings, warning letters, untitled letters, injunctions, etc.). Clicking on the "Case ID" hyperlink will take you to the case in CMS. There you can find a wealth of information, including communications between the division, center, and OCC, for example. Firm360 does not provide a list of withdrawn or disapproved compliance cases. However, this information can be found directly in CMS by searching for the firm by FEI.
- **"Compliance Work Activities"** – Here you can find the last five years of work activities for the firm entered in CMS. While CMS is primarily used by division compliance and centers, this system contains information pertinent to investigators too. For example, when you see a "District - Inspection Response (previously District - 483 Response)" work type under this section, click on the "Work ID" hyperlink to be directed to CMS. There, you should have access to the firm's FDA 483 response (for instance, documentation, attachments, and emails sent by the firm to the division) and evaluation of that response by compliance branch and/or others, such as the center. You will also be able to read

any information added to the firm's CAR and associated corrective action documents. **If you are a HAF investigator and do not have access to CMS, request access through your supervisor.**

- In addition to the above data systems, you should also plan to review other content, such as information housed in the FDA Unified Registration and Listing System (FURLS) and hardcopy records found in the division files of the firm to be inspected. Determine the status of the firm's food facility registration, as well as the fulfillment of other applicable requirements, such as Food Canning Establishment (FCE) registration and process filings for acidified and low-acid canned foods.
- Conduct an internet search to obtain additional information regarding the firm's operations, marketing practices, distribution patterns, etc. For example, a review of Secretary of State websites and other applicable business databases may reveal if the firm is no longer in operation, is operating under a different name, has moved to a different address, etc. Review the firm's online presence too, including any websites, social media accounts, multi-level marketing websites, to determine what, if any, promotional claims, or statements are being made about the firm's products. Be aware of claims that can be used on food and dietary supplement labels.
- Become familiar with the relevant Human Food and Animal Food Compliance Programs and Inspection Guides. Become familiar with the applicable Compliance Policy Guides (CPG). In addition, the Resource Library offers a "one-stop shop" for relevant inspection resources for human and animal food investigators.
- Review the inspectional assignment, if one exists, and follow all of its instructions, including arranging any pre-inspectional meetings, following up on any specific issues or concerns, etc.
- Ensure that all necessary training that may be required has been received. Consult your supervisor with questions.
- Consult Exhibit 5-19 for applicable biosecurity measures if you are assigned to inspect a facility, including a private residence, that is engaged in any plant- or animal-related activities, such as the growing of crops or produce, or the housing or transporting of any domestic or wild animals. Accordingly, consult CP 7303.836 (Inspection of Egg for Monitoring Compliance with Egg Safety Rule) for applicable biosecurity measures if assigned to inspect an egg farm or commercial poultry operation.
- Review FD& C Act Chapter 9, Subchapter IV: Food.
- Review and become familiar with the appropriate parts of 21 CFR pertaining to foods. All CFRs can be found here.

Food for Human Consumption	21 CFR 100-190
Animal Drugs, Feeds, and Related Products	21 CFR 500-589
Control of Communicable Disease	21 CFR 1240
Interstate Conveyance Sanitation	21 CFR 1250

- Review implementation dates of regulations to ensure application of the appropriate regulations.
- Review reference materials on food technology and other subjects.
- Review the most current "Food Code" and be trained in its use if you are assigned to inspect retail foodservice establishments associated with a National Special Security Event or other special event. All Retail Food Specialists and some Interstate Travel Program Specialists are standardized in use of the Food Code.
- Be familiar with the Food Chemicals Codex. See IOM 5.8.4.3.
- Review the IOM Safety Chapter as it pertains to your inspection. You should anticipate, recognize, evaluate, and apply control strategies to eliminate or minimize hazardous conditions and unsafe practices that may, even potentially, be encountered.

5.8.1.3 – You've Arrived at the Firm: Now What?

This section provides tips on beginning the inspection and conducting your walk-through of the facility. This information is not meant to be all-inclusive or prescriptive in nature.

When you arrive at the firm to conduct an inspection, introduce yourself, show your credentials, and issue an FDA 482, Notice of Inspection (for domestic inspections only) to the owner, operator, or agent-in-charge (OOAC) at the facility at the time of your arrival. Typically, while introducing yourself and issuing the FDA 482, you will also briefly explain the purpose of your visit (for example, "Good morning, my name is Sidney Rogers. I'm an investigator with the U.S. Food and Drug Administration, and I'm here to conduct a routine inspection of your food manufacturing facility."). When issuing the FDA 482, be sure to use the OOAC's legal name (including their middle initial if they have one). Also, use the firm's legal business name. Do not use an alias or doing-business-as (DBA), for example. Once you have properly displayed your credentials and issued the FDA 482 to the OOAC, your inspection can officially begin.

Usually you'll want to keep your "opening meeting" with the firm brief to expedite proceeding with the "walk-through" of the facility. Topics you choose to cover in the opening meeting will depend on several factors, including if the inspection is a routine, for-cause, compliance follow-up, etc. For newer investigators, many of the inspections will be routine. Initial questions you ask during the opening meeting should help you confirm that the facility is a workload obligation (for instance, is the firm primarily retail?), is subject to FDA jurisdiction (e.g., what are the products handled), what the scope of your inspection will be (e.g., qualified facility, limited scope, etc.), and if there are any other regulators on site. For example, if you determine the firm only manufactures USDA-regulated products, you will collect the information needed by your division to update FMS. Depending on your experience and division practices, you'll then know not to proceed with inspecting the facility. You should confirm with your supervisor before ending the inspection.

Once you confirm the facility is subject to FDA regulation and a workload obligation, you'll want to ask additional questions to ascertain hours of operation, sanitation schedule(s), and what operations are occurring during the time you plan to be in the facility. Depending on the firm's inspectional history and purpose of the inspection, the opening meeting may take additional time. For example, if you are following up on a consumer complaint, you may want to conduct a quick review of complaints or adverse events received by the firm before selecting the product(s) to cover or conducting the walk-through. Typically, the opening meeting should be kept as brief as possible to allow you to proceed with the walk-through and determining the process flow/products to cover.

While there isn't a prescribed approach to conducting your walk-through of a facility, it is common practice to follow the product process from receipt of ingredients (or packaged products in the case of warehouse/distributors) to storage and distribution of products. You'll be observing the firm's processes, manufacturing, procedures, and employee practices as you proceed. There may be situations where your walk-through begins with the "clean" side of the facility, such that the first area you observe would be staging/warehousing of packaged product and the end of your walk-through would be at receipt/storage of ingredients. This may be beneficial, for example, if you are following-up on a sanitation problem in the finished product warehouse, and you prefer to start there rather than at incoming raw ingredients. During your walk-through, you may review written procedures and records and may speak with employees to help determine to what extent processes and procedures are being implemented. You should also remain flexible. Know that you may begin the walk-through with the intent to proceed from "start to finish," but this could change depending on what you observe or learn along the way.

Unless you are directed to follow a specific product(s) or process during the inspection, you'll want to use the opening meeting and walk-through to identify which product(s) you will want to cover during your inspection. For most routine inspections, you'll want to pick the highest risk product/process to cover. For this determination, you'll draw on your knowledge of the regulation(s), compliance program your covering, commodity area, and any

associated hazards. For example, if the firm manufactures both ready-to-eat (RTE) and non-RTE products, in most situations, you'll want to cover an RTE product. Be reassured that if you are a new investigator, or are new to a commodity area, there are numerous resources available to guide you in deciding what products and/or processes are wisest to cover. These resources include, but are not limited to, your supervisor, other investigators, and technical assistance networks/SMEs.

5.8.1.4 - Food Defense Inspectional Activities

Food defense inspectional activities should be conducted during all routine food safety inspections. During the normal course of the inspection be alert to opportunities for improvement or enhancement of the firm's food defense preventive measures, as compared to those recommended in the guidance documents described below. You should not perform a comprehensive food defense audit of the firm or conduct an extensive interview of management or employees to determine the level of adoption of preventive measures listed in the guidance. The goal is to facilitate an exchange of information to heighten awareness about food defense.

5.8.1.4.1 – Food Defense

Inspectional activities related to food defense for routine food establishment inspections should include:

- Discussions with firm management regarding relevant FDA guidance documents including:
  - FDA Firm Resources
  - Human food manufacturing facilities: Draft Guidance for Industry: Mitigation Strategies to Protect Food Against Intentional Adulteration.
  - Retail Food Stores and Food Service Establishments: Guidance for Industry: Food Security Preventive Measures Guidance for Retail Food Stores and Food Service Establishments. (**Note:** FDA does not have food defense requirements for retail food establishments)

  These documents should be used as references during inspections, as appropriate. If firm management does not already have a copy of the relevant guidance documents, provide them with hard copies or information on how to obtain the guidance from FDA's web site.
- Identification of opportunities for improvement or enhancement of the firm's food defense preventive measures, as compared to those recommended in the guidance documents, and encouragement of management to make such improvements or enhancements to their system.

Keep in mind that guidance does not represent mandatory conditions or practices; some of the recommended food defense preventive measures may not be appropriate or practical to the specific operation; and other means of achieving the goals of the preventive measures listed in the guidance may be more suitable for the specific operation than those cited as examples. The important message for management is for them to consider the goals of the food defense preventive measures; evaluate the goals relative to the specifics of their operation; and address those that are relevant to the extent practical.

Food defense observations should not be listed on form FDA 483, Inspectional Observations, unless they likewise constitute deviations from Current Good Manufacturing Practice. Discussions of these observations should be handled discretely and should only involve management of the firm.

The fact that the discussion took place and, if applicable, that a copy of the guidance document(s) was provided, should be recorded in the administrative data section of the EIR. For example, under a section heading titled "Food Defense" you should only state, "A copy of the FSMA Final Rule for Mitigation Strategies to Protect Food Against Intentional Adulteration documents were provided to and food defense issues were discussed with (name of firm official)." The details of inspectional findings should **NOT** be recorded. You should also minimize the quantity and detail of notes taken relative to the firm's food defense program, recording only items needed to serve as a "memory jog" during the discussion with management. If during the course of the inspection or your review of the food defense program, you determine that a reconciliation

exam should be conducted for cause or if directed by the assignment or your supervisor to conduct a reconciliation exam see Exhibit 5-24.

5.8.1.5 - Food Registration

See IOM subchapter 2.10.1 for more information on this topic.

Regulatory submissions (for instance, registrations, process filings, pre-market notifications) are required for certain food-related facilities and firms. You should refer to the relevant CFSAN and CVM Compliance Program and specific Guidance for Industry to help you determine what submissions may be required and what exemptions may exist. See the Registration of Food Facilities and Other Submissions website, which provides guidance and instructions to industry on specific regulatory submission requirements and voluntary submissions.

As covered in 5.8.1.2, you should review FURLS when you are preparing to conduct a food inspection to familiarize yourself with the firm's registrations and listings (for example, its Food Facility Registration, Acidified/Low-Acid Canned Food Registration and Process Filing, and Qualified Facility Attestation).

Beginning January 4, 2020, an owner, operator, or agent-in-charge of a facility must submit their registration to FDA electronically, unless FDA has granted a waiver under 21 CFR 1.245 (see 21 CFR 1.231(a)(2)). If the firm needs to submit a waiver request, inform them that they may obtain a copy of this registration form to complete and submit by mail.. Also encourage the firm to submit the optional information on the registration form to assist and facilitate FDA's future communications with the firm.

If a regulatory submission is required, but the firm is found to be operating without it, provide the firm with the Registration of Food Facilities and Other Submissions website and any relevant Guidance for Industry for information on how to make the required submissions, as well as information about applicable penalties. If you find a firm has failed to submit Food Facility Registration per section 415 of the FD&C Act, or if you find a firm has a current registration but information obtained during the inspection/investigation is different from the information in FFRM, you must send an email to CFSANFoodFacilityRegistration@fda.hhs.gov with the Official Establishment Data Collection Form (FORM-000173) attached, with all the required fields completed (1-32, 42-48). Make sure that the firm's management is aware of the food facility registration requirement to submit an update to the facility's registration within 60 calendar days of any change to any of the required information (21 CFR 1.234(a)).

5.8.2 – Personnel

5.8.2.1 – Management

Follow the guidance described in IOM 5.6.3 when documenting individual responsibility, including obtaining the full name and title of the following individuals:

- Owners, partners, or officers.
- Other management officials or individuals supplying information.
- Individuals to whom credentials were shown and the FDA 482 Notice of Inspection, FDA 482d Request for Foreign Supplier Verification Program (FSVP) Records, and other inspectional forms issued.
- Individuals refusing to supply information or to permit an inspection.
- Individuals with whom inspectional findings were discussed or recommendations made.

Certain regulations require management of an establishment to take reasonable measures and precautions to ensure control of communicable disease, employee cleanliness, appropriate training of key personnel, and compliance by all personnel with the applicable requirements (as found in21 CFR 117.10, 117.4, 112 Subpart C, 113.10, 114.10, and 111 Subpart B).

Determine if adequate employee supervision is provided for critical operations where violations are likely to occur if tasks are improperly performed.

5.8.2.2 – Employees

Improper employee practices may contribute to violative conditions in an otherwise satisfactory plant. Use multiple approaches to determine an employee's duties or work functions. You can observe the employee as they perform their duties, interview the employee to have them explain their duties to you, and review records/documentation that provide direct or indirect evidence of an employee's duties. You should also observe the actions of employees during all phases of the inspection.

Note whether or not employees working in direct contact with food, food-contact surfaces, or food-packaging materials are following appropriate food hygiene and food safety practices while on duty. For example, are the employees…

- wearing outer garments suitable to the operation in a manner that protects against allergen cross-contact and contamination of food?
- maintaining adequate personal cleanliness?
- storing personal items properly?
- eating, chewing gum, drinking beverages, or using tobacco while in areas where food may be exposed or where equipment or utensils are washed?

Determine if hand washing and sanitizing, if necessary, is adequate, and performed at the appropriate times and intervals. Unsecured jewelry and other objects should be removed, covered, or sanitized as appropriate. Gloves, if they are used in food handling, shall be maintained in an intact, clean, and sanitary condition. Hair nets, headbands, caps, beard covers, or other effective hair restraints should be worn, where appropriate, in an effective manner. Determine disease control practices, if there is a reasonable possibility of food, food-contact surfaces, or food-packaging materials becoming contaminated. For example, if employees are shown to have or appear to have an illness; open lesion, including boils, sores, or infected wounds; or any other abnormal source of microbial contamination, they should be excluded from any operations that may be expected to result in contamination.

Special note: Under no circumstance should you swab a sore, touch or remove a bandage from an employee in an attempt to obtain bacteriological evidence. To do so is a violation of personal privacy, possibly hazardous to you and/or the employee, and usually provides little useful data.

Observe employee traffic patterns to determine how they affect possible routes of contamination. (See IOM 5.8.7.2 for additional information on routes of contamination.) During inspections of produce farms, evaluate practices for growing, harvesting, packing, and holding practices of covered produce to prevent contamination of covered produce and food contact surfaces.

Observe and document insanitary employee practices or actions showing employees handling or touching insanitary or dirty surfaces, and then contacting food products or direct food contact surfaces. (See IOM 5.8.7.2 for additional information on how employee practices can become routes of contamination.) Such practices might include employees spitting, handling garbage, placing their hands in or near their mouths, cleaning drains, handling dirty containers, etc., and then handling food product(s) without washing and sanitizing their hands. Observe whether employees comply with plant rules such as, "No smoking," "Keep doors closed," "Wash hands before returning to work," etc.

Be alert to employees handling insanitary objects, then quickly dipping their hands in sanitizing solutions without first washing them. Depending upon the amount and type of filth deposited on the hands during the handling of insanitary objects, such attempts at sanitizing are questionable at best. Note, too, that sanitizers work most effectively on hands that have first been cleaned by washing with soap and water.

Conducting conversations with employees doing the work may provide information on both current and past objectionable practices, conditions, and circumstances. Be sure to document these conversations in your regulatory notes.

Determine employee education and training as appropriate to the regulation you are covering during the inspection. Determine the type, duration, and adequacy of the firm's training programs, if any, to prepare employees for their positions and to maintain their skills.

5.8.3 – Plants and Grounds

The plant and grounds must be kept in a condition that will protect against the contamination of food. Outbuildings and structures used for equipment or storage must be appropriately maintained. Plant employees must have control of their grounds and outbuildings, regardless of the specific food being produced or held, because litter, waste, weeds, and grass can all attract and harbor pests, and the first step for pest control in the plant is to avoid attracting pests. If the plant grounds are bordered by grounds not under the operator's control, care must be exercised in the plant by inspection, extermination, or other means to exclude pests, dirt, and filth that may be a source of food contamination. Environmental factors such as proximity to swamps, rivers, wharves, city dumps, drain fields, runoff, concentrated animal feeding operation (CAFO), compost operations, manure operations, etc., may also contribute to rodent, bird, insect, or other sanitation problems.

Note: Buildings on produce farms may include fully- or partially-enclosed structures (such as structures that have a roof but no walls) and fields. These buildings can be permanent or temporary structures.

5.8.3.1 – Plant Construction, Design and Maintenance

The plant must be suitable in size, construction, and design to facilitate maintenance and sanitary operations for food-production purposes (manufacturing, processing, packing, and holding). Determine the approximate size and construction (for example, brick and concrete block) of building(s) housing the firm and if suitable in size, construction, and design to facilitate maintenance and sanitary operations.

Buildings, fixtures, and other physical facilities must be maintained in a clean and sanitary condition and must be kept in repair adequate to prevent food from becoming adulterated. Check placement of equipment, storage of materials, lighting, ventilation, and placement of partitions and screening to eliminate product contamination by bacteria, birds, vermin, etc. You should determine any construction defects or other conditions (for instance, broken windows, cracked floorboards, sagging doors, gaps/holes to the outside environment), which may permit pest entry or harborage.

Also, determine if drip or condensate from the plant fixtures, ducts, and pipes could potentially contaminate food, food handling areas, or equipment.

Determine who is responsible for buildings and grounds maintenance. Many facilities such as docks, wharves, or other premises are owned and maintained by other firms, municipalities, or individuals for lease for manufacturing operations. Determine who is legally responsible for repairs, maintenance, rodent proofing, screening, etc. Document evidence that demonstrates the mindset and behavior of firm management/employees towards maintenance and cleaning operations. For example, are there procedures in place to routinely monitor the condition of floors, walls, and ceilings? What actions were, or were not, taken in response to needed repairs? If you bring issues to management or the employees’ attention, what is their response?

5.8.3.2 – Waste Disposal

Waste and garbage disposal poses a problem in all food operations depending upon plant location and municipal facilities available.

Check the effectiveness of waste disposal on the premises and ensure it does not cause violative conditions or contribute toward contamination of the finished products. Check for in-plant contamination of equipment and/or product, if its water is supplied from nearby streams, springs, lakes, or wells.

If you suspect the firm is dumping sewage effluent into nearby streams, lakes, or bay waters near water intakes, speak to your supervisor and explain what evidence (for instance, via photographs, documents, statements from firm management/employees) you have indicating the firm could be dumping sewage effluent inappropriately. You may be instructed to conduct a test using water-soluble fluorescein sodium dye for tracking the sewage effluent from the firm to the nearby stream, lakes, etc. If this is the case, you should place approximately two ounces of the water-soluble fluorescein dye, which yields a yellowish red color, into the firm's waste system and/or toilets, as applicable, and flush the system. The discharge area of the effluent becomes readily visible by a yellowish-red color on the surface of the water as the dye reaches it. Take photographs to document the contamination.

Determine collecting or flushing methods used to remove waste from operating areas. If water is used, determine if it is recirculated and thus able to contaminate equipment or materials.

Determine the disposition of waste materials that should not be used as human food such as rancid nuts, juice from decomposed tomatoes, etc.

Determine the disposition of waste, garbage, etc., that contains pesticide residues. Determine how this material is segregated from waste material that contains no residues, and that which may be used for animal feed.

5.8.3.3 – Plant Services

If applicable, check steam generators for capacity and demand. Demand may reach or exceed the rated capacity, which could affect adequacy of the process. Check boiler water additives if steam comes in direct contact with foods. Boiler additives for steam that comes into contact with food must be approved as direct food additives under 21 CFR 173.310.

Check central compressed air supply for effective removal of moisture (condensate) and oil. Determine if any undrained loops in the supply line exist where condensate can accumulate and become contaminated with foreign material or microorganisms.

5.8.4 – Raw Materials

Raw materials and other ingredients must be inspected and segregated or otherwise handled as necessary to ascertain that they are clean and suitable for processing into food. Raw materials must be stored under conditions that will protect against allergen cross-contact as well as microbial, chemical of physical contamination and stored in a manner to minimize deterioration.

List in a general way the nature of raw materials on hand. Itemize and describe those, which are unusual to you, or involved in a suspected violation (copy quantity of contents and ingredient statements, codes, name of manufacturer or distributor, etc.). Be alert for additives and preservatives. Evaluate the storage of materials. Determine the general storage pattern, stock rotation, and general housekeeping. The plant must provide sufficient space for storage of materials as is necessary for the maintenance of sanitary operations and the production of safe food. Thoroughly check ceilings, walls, ledges, and floors in raw material storage areas for evidence or rodent or insect infestation, water dripping or other adverse conditions.

5.8.4.1 – Handling Procedure

Determine if growing conditions relative to disease, insects, and weather are affecting the raw material. Check measures taken for protection against insect or rodent damage. Raw materials may be susceptible to decomposition, bruising or damage, e.g., soft vegetables and fruits delivered in truckload lots. Determine the

holding times of materials subject to progressive decomposition. Review storage practices for ingredients that require time / temperature control such as bulk silos or in-process batters and slurries.

5.8.4.2 – Condition

Evaluate the firm's acceptance examination and inspection practices including washing and disposition of rejected lots. Examine rejected lots and, if you encounter a raw material that is potentially adulterated or misbranded, consider collecting a sample and ensure the information is reported to the appropriate HAF Division. If the documentation shows the product was imported, then you should review FIRM 360 for the product manufacturer to determine if the product is subject to Import Alert and work with Division management to contact your corresponding import division to determine appropriate follow-up.

Determine the general acceptability of raw materials for their intended use and their effect on the finished product. Raw stocks of fruits or vegetables may contribute decomposed or filthy material to the finished product. Be alert for use of low quality or salvage raw materials. Check bags, bales, cases, and other types of raw material containers to determine signs of abnormal conditions, indicating presence of filthy, putrid, or decomposed items. Check any indication of gnawed or otherwise damaged containers, to ascertain if material is violative. Be alert to contamination of raw materials by infested or contaminated railroad cars or other carriers.

Document by photographs, exhibits, or sketches any instances where insanitary storage or handling conditions exist.

5.8.4.3 – Food Chemicals Codex

Any substance used in foods must be food-grade quality. FDA regards the applicable specifications in the current edition of the publication Food Chemicals Codex as establishing food-grade unless FDA publishes other specifications in the Federal Register.

5.8.5 – Equipment and Utensils

By arriving before processing begins, you can evaluate conditions and practices not otherwise observable before plant start-up. This includes adequacy of clean-up, where and how equipment is stored while not in use, how hand sanitizing solutions and food batches are prepared and if personnel sanitize their hands and equipment before beginning work as appropriate.

Dirty or improperly cleaned equipment and utensils may be the focal point for filth or bacterial contamination of the finished product. Examine all equipment and utensils to determine the following: design, materials, workmanship, materials, maintenance, suitability, and ease of cleaning and sanitization. Determine if equipment is constructed or covered to protect contents from dust and environmental contamination. Open inspection ports to check inside only when this can be done safely. Notice whether inspection ports have been painted over or permanently sealed.

Containers and equipment used to convey or hold human food by-products for use as animal food before distribution must be designed, constructed of appropriate material, cleaned as necessary, and maintained to protect against the contamination of human food by-products for use as animal food.

5.8.5.1 – Filtering Systems

Observe the firm's filtering systems and evaluate the cleaning methods (or replacement intervals of disposable filters) and schedules. Check types of filters used. There have been instances where firms have relied on household furnace type filters.

5.8.5.2 – Cleaning and Sanitization of Equipment and Utensils

Cleaning and sanitizing of utensils and equipment must be conducted in a manner that protects against allergen cross-contact and against contamination. Utensils and equipment must be cleaned as frequently as necessary to protect against allergen cross-contact and against contamination of food.

Check the sanitary condition of all machinery used in manufacturing, processing, packing, or holding food. Determine if equipment is cleaned prior to each use and the method of cleaning. Observe how cleaning occurs and if there is a possibility of aerosol contamination of food contact surfaces. For example, the use of high-pressure hoses on one system that is idle may contaminate an adjacent system that is operational. If the firm rents or leases equipment on a short-term basis, report prior cleaning procedures. Equipment may have been used for pesticides, chemicals, drugs, etc., prior to being installed and could therefore be a source of cross-contamination.

5.8.5.3 – Conveyor Belt Conditions

Equipment used to convey, hold, or store raw materials and other ingredients, work-in-process, rework, or other food must be designed / constructed and of such material / workmanship as to be adequately cleanable /maintained to protect against allergen cross-contact and against contamination during manufacturing, processing, packing, and holding.

Inspect conveyor belts for build-up of residual materials and pockets of residue in corners and under belts. Look in inspection ports and hard-to-reach places inside, around, underneath, and behind equipment and machinery for evidence of filth, insects, and/or rodent contamination. Chutes and conveyor ducts may appear satisfactory, but a rap on them with the heel of your hand or a rubber mallet may dislodge static material, which can be examined. See IOM 4.3.6.6.3 for procedure on taking In-line Sample Subs.

5.8.5.4 – Utensils

Determine how brushes, scrapers, brooms, and other items used during processing or on product contact surfaces are cleaned, sanitized, and stored. Evaluate the effectiveness of the practices observed.

5.8.5.5 – Mercury and Glass Contamination

Be alert for improper placement or inadequately protected mercury switches, mercury thermometers, or electric bulbs. Breakage of these could spray mercury and glass particles onto materials or into processing machinery.

5.8.5.6 – UV Lamps

If firm is using ultraviolet (UV) lamps for bacteria control, check if it has and uses any method or meters to check the strength of UV emissions. If so, obtain methods, procedures, type equipment used, and schedule for replacement of weak UV bulbs. Please note that disinfection may no longer occur beyond the manufacturers recommended replacement schedule.

5.8.5.7 – Chlorine Solution Pipes

In plants where chlorine solution is piped, check on type of pipe used. Fiberglass reinforced epoxy pipe has been observed to erode inside through the action of the chlorine solution. This poses a threat of contamination from exposed glass fibers. Pipes made with polyester resin do not deteriorate from this solution.

5.8.5.8 – Sanitation Practices

Overall sanitation must be under the supervision of one or more competent individuals assigned responsibility for this function. Observe sanitizing practices throughout the plant and evaluate their effectiveness, degree of supervision exercised, strength, time, and methods of use of sanitizing agents. Determine the use, or absence of, sanitizing solutions both for sanitizing equipment and utensils as well as for hand dipping. (Note: Not all operations require the use of sanitizer. Check the requirements for the specific regulation you are inspecting under.) 21 CFR

178.1010 describes sanitizing solutions that may be safely used (under the conditions prescribed in this part of the regulation) on food-processing equipment and utensils, and on other food-contact articles. Confirm the firm is following the manufacturer's instructions for use on the sanitizer label or accompanying documentation. If the firm is using, typically a concentration of 50 ppm - 200 ppm free chlorine should be used for equipment and utensils, while a 100-ppm free chlorine will suffice for hand dipping solutions. Many sanitizing solutions rapidly lose strength with the addition of organic material. The strength of the solution should be checked several times during the inspection. Sanitizers including peracetic acid (PAA) and chlorine dioxide may be used in post-harvest agriculture water as a treatment for bacteria in the water. Ensure any sanitizers used are food grade and manufacture's labeled instructions are followed.

5.8.6 – Process and Controls

All operations must be conducted in accordance with adequate sanitation principles. All operations must be conducted under such conditions and controls necessary to minimize the potential for the growth of microorganisms, allergen cross-contact, contamination of food, and deterioration of food. These operations include manufacturing, processing, packing, and holding of food.

Fans and other air-blowing equipment should operate in a manner that minimizes the potential for allergen cross-contact and for contamination.

Where helpful to describe equipment and processes, draw flow plans or diagrams to show movement of materials through the plant. Generally, a brief description of each step in the process is sufficient. List all quality control activities for each step in the process and steps where food safety hazards are controlled or minimized. Provide a full description when necessary to describe and document objectionable conditions, or where the assignment specifically requests it. Observe whether hands and equipment are washed (and sanitized as appropriate) after contact with insanitary objects. For example:

- Workers do general work, then handle the product;
- Containers contact the floor, then are nested or otherwise contact product or table surfaces;
- Workers use common or dirty clothes or clothing for wiping hands; or
- Product falls on a dirty floor or a floor subject to outside foot traffic and is returned to the production line.

Be alert for optimum moisture, time, and temperature conditions conducive to bacterial growth.

Keep in mind that in agricultural practices, some buildings may not be fully enclosed. This is a normal part of operations and may not indicate insanitary conditions. Evaluate the farm's operations including the process controls and cleaning operations.

In industries where scrap portions of the product are reused or reworked into the process (e.g., candy and macaroni products), observe the methods used in the reworking and evaluate from a microbiological standpoint. Reworking procedures such as soaking of macaroni or noodle scrap to soften or hand kneading of scrap material offers an excellent seeding medium for bacteria. Determine if work-in-process and rework materials are handled in a manner to protect against allergen cross-contact, contamination, and growth of undesirable microorganisms.

When a product is processed in a manner which destroys microorganisms, note whether there are any routes of recontamination from the "raw" to the processed product (e.g., dusts, common equipment, hands, flies, etc.).

5.8.6.1 – Ingredient Handling

Raw materials and ingredients must be inspected and segregated or handled so they are clean and suitable for processing and must be stored under conditions that will protect against allergen cross-contact and against contamination and minimize deterioration. Water reused for washing, rinsing, or conveying food must not cause allergen cross-contact or increase the level of contamination of the food.

All food that has become contaminated to the extent that it is adulterated must be rejected, or if appropriate, treated or processed to eliminate the contamination.

21 CFR 117.100(b) further prohibits the mixing of a food containing defects at levels that render that food adulterated with another lot of food. This practice would render the final food adulterated, regardless of the defect level of the final food. Examples of defect action levels that may render food adulterated can be found in the Food Defect Levels Handbook.

Material scheduled for rework must be identified and held to protect against allergen cross-contact and against contamination. This includes holding at proper temperatures and relative humidity and in such a manner as to prevent the food from becoming adulterated.

Observe the method of adding ingredients to the process. Filth may be added into the process stream from dust, rodent excreta pellets, debris, etc. adhering to the surface of ingredient containers. Evaluate the effectiveness of cleaning and inspectional operations performed on the materials prior to or while adding to the process. Determine specific trimming or sorting operations on low quality or questionable material. Observe and report any significant lags during the process or between completion of final process and final shipping. For example, excessive delay between packing and freezing may be a factor in production of a violative product.

5.8.6.2 – Formulas

The Act does not specifically require management to furnish formula information except for human drugs, restricted devices, and infant formulas. Nonetheless, they should be requested especially when necessary to document violations of standards, labeling, or color and food additives. Management may provide the qualitative formula but decline to provide the quantitative formula.

If management declines to provide formula information, attempt to reconstruct formula by observing:

- Product in production,
- Batch cards or formula sheets, and
- Raw materials and their location.

5.8.6.3 – Food Additives

Refer to the food additives programs in CP 7309.006 (page 9) for instructions on conducting establishment inspections of firms manufacturing food additive chemicals. Information is also available in ORA's Guide to Inspections of Manufacturers of Miscellaneous Food Products - Volume II.

On food inspections, direct your evaluation of food additives only to those instances of significant violation, e.g., failure to declare sulfiting agents on finished product labels, when required, or gross misuse.
Routine inspectional coverage will be directed primarily to the following two types of additives:

- Unauthorized and illegal as listed in the Food Additive Status List (safrole, thiourea, et al), and
- Restricted as to amount in finished food.

Because of special problems, exclude the following additives from coverage during routine inspections:

- Packaging materials,
- Waxes and chemicals applied to fresh fruit and vegetables (unless covered under the Produce Safety Regulation),
- Synthetic flavors and flavoring components except those banned by regulations or policy statements (these products will be covered under other programs), and
- Food additives in feeds (these products will be covered under other programs).

Substances Added to Food (formerly The Everything Added to Food in the United States (EAFUS) and the Food Additives Status List (FASL) found on the CFSAN website contains an alphabetical listing of substances, which may be added directly to foods or feeds and their status under the Food Additives Amendment and Food Standards. In addition, a few unauthorized or illegal substances are included.

You may encounter substances not included in the Food Additives Status List (FASL). Such substances will include:

- Safe substances not on the list of items Generally Recognized as Safe (GRAS) which are not published in the regulations, i.e., salt, cane sugar, corn syrup, vinegar, etc.;
- Synthetic flavoring substances because of their indefinite status;
- Substances pending administrative determination, or
- Substances granted prior sanction for specific use prior to enactment of the Food Additives Amendment.

Give primary attention to unauthorized substances. Document and calculate levels of restricted-use additives in finished food only where gross misuse or program violations are suspected as follows:

1. List ingredients, which may be restricted substances or food additives, and determine their status by referring to the current FASL. Document labeling on containers of these substances.
2. Obtain the quantitative formula for the finished product in question.
3. Determine the total batch weight by converting all ingredients to common units.
4. Calculate the theoretical levels in the final product of all restricted or unauthorized ingredients from the formula by using the Food Additives Nomographs. See IOM Exhibit 5-11.
5. Determine probable level of restricted ingredients by observing the weight of each ingredient put into the batch.

5.8.6.4 – Color Additives

Evaluate the status of color additives observed during each establishment inspection by using the Color Additive Status List and the Summary of Color Additives Listed in the United States in Food, Drugs, Cosmetics, and Medical Devices. Both links can be found on the CFSAN or www.fda.gov websites. These lists provide the current status and use limitations of most color additives likely to be found in food, drug, device, or cosmetic establishments.

Determine if certified color additives are declared on finished product labels, when required.

Stocks of delisted and uncertified colors may be found in the possession of manufacturers where there is no evidence of misuse. Advise the firm of the status of these color additives. Note: Delisted colors can be used in lots of food specifically manufactured for export to a country in which its use is legal, provided all the requirements of Section 801(e) of the Act are followed and provided further, that a control system is followed which insures that there is no possibility of diversion by mistake or otherwise to domestic channels, of the food containing the color. If management wishes to voluntarily destroy such colors additives, witness the destruction, and include the facts in your EIR. If the firm declines to destroy the colors additives, determine what disposition is planned (i.e., use in non-food, non-drug, non-cosmetic, or non-medical device products). The validity of certification information can be checked by accessing the Color Certification Lot # Lookup application (also referred to as the Color Certification Database) maintained by CFSAN's Office of Colors and Cosmetics (OCAC). You will be prompted to request access if you do not already have approval to access the database.

If you encounter the following situations, collect a sample of the finished product for color analysis (see bullet #1, 2, and 4 below for documentation, sample collection, and shipping details).

- Unlisted color additive (e.g., FD&C Red #2)
- Improper use of a listed color additive (e.g., food containing D&C Orange #5)
- Use of a color additive that does not conform to the purity and identity specifications of the listing regulation (e.g., cochineal extract with a pH over 5.5 at 25°C)

When color additive information is not consistent with Color Certification Lot # Lookup, such as different color additive or company, then the color additive may be violative and proceed as follows:

1. Collect an official sample consisting of the finished product suspected of containing the violative color additive. Make every effort to collect interstate shipments of the product before attempting to develop a 301(k) or 301(a) case. When regulatory action is an alternative, obtain sufficient interstate records to cover both the color additive and the basic ingredients of the manufactured product. Refer to IOM Sample Schedule, Chart 9 – Sampling Schedule for Color Containing Products for guidance.
2. Document the use of violative color additives. Documentation should include photo of the color additive label, batch formula cards, employee statements, code marks indicating date of manufacture, color certification number, and purchasing, shipping, and receiving documents for the color additive. Presence of a color additive in the finished product will be confirmed by the ORA/ORS servicing laboratory.
3. If the violative color additive(s) where the certification information is not consistent and is available for sampling at the same time as the finished product, email the Branch Chief for OCAC's Color Certification Branch (HFS-107) prior to collecting the color additive. If instructed to collect the color additive, refer to IOM Sample Schedule, Chart 9 – Sampling Schedule for Color Containing Products for guidance.
4. When collecting only the finished product for color analysis, ship the officially sealed sample to the appropriate ORA/ORS servicing laboratory (refer to the LST Dashboard). When collecting the finished product and the color additive, ship the samples as follows:
    a. **It is imperative to link the finished product sample to the color additive sample in FACTS as related samples (see IOM 4.6.2.41).** Identify the finished product sample as the "lead" sample and include in the collection remarks field on each C/R how the samples are related (e.g., sample # [enter sample number] of [name of finished product] is suspected of containing [name of color additive] under sample # [enter sample number].
    b. Ship the officially sealed finished product sample to the appropriate ORA servicing lab for color analysis (refer to the ORA LST Dashboard).
    c. Ship the officially sealed color additive sample to:
    CFSAN Sample Custodian
    ATTN Color Certification Lab
    5001 Campus Drive
    College Park, MD 20740
    d. For the color additive sample, select "CFSAN-LABS" under the physical sample sent to field in FACTS. Also, include the sample is to be analyzed by the Color Certification Lab in the Collection Remarks section.
    e. Email the ORA/ORS servicing lab and CFSAN color certification staff (color.cert@cfsan.fda.gov) to ensure they are aware of how the two samples are related to each other. Provide the shipping information and both sample numbers. Use the following in the email subject line: "Samples shipped to CFSAN (Color Certification Lab) and ORA/ORS for color additive analysis".

5.8.6.5 – Quality Control

Appropriate quality control operations must be employed to ensure that food is suitable for human consumption and that food-packaging materials are safe and suitable. The objective of quality control is to ensure the maintenance of proper standards in manufactured goods, especially by periodic random inspection of the product. Chemical, microbial, or extraneous-material testing procedures must be used where necessary to identify sanitation failures or possible allergen cross-contact and food contamination. Your inspection should determine if the firm's quality control system accomplishes its intended purpose.

The manufacturer, processor, packer, and holder of food must utilize quality control operations that reduce natural or unavoidable defects to the lowest defect action level currently feasible. More information of defect levels can be found here: Food Defect Levels Handbook | FDA.

Establish responsibility for specific operations in the control system. Determine which quality controls are critical for the safety of the finished product. These controls may include process control points, sanitation control points, allergen control points or other controls intended to ensure a safe product is manufactured.

5.8.6.5.1 – Inspection system

Determine what inspectional control is exercised over both raw materials and the processing steps. Such inspection may vary from simple visual or other organoleptic examination to elaborate mechanical manipulation and/or laboratory tests. Determine what inspection equipment is used, i.e., inspection belts, sorting belts, grading tables, ultraviolet lights, etc.

Ascertain its effectiveness, maintenance, or adjustment schedules. Where indicated, determine the name of the manufacturer of any mechanical inspection device and the principles of its operation.

Evaluate the effectiveness of the personnel assigned to inspection operations. Determine if the inspection belts or pick-out stations are adequately staffed and supervised.

Determine the disposition of waste materials, which are unfit for human or animal food purposes.

5.8.6.5.2 – Laboratory Tests

Describe routine tests or examinations performed by the firm's laboratory and the records maintained by the firm. Tests may include in product testing, finished product testing or environmental monitoring. Determine what equipment is available in the laboratory and if it is adequate for the purpose intended. If the firm uses a consulting laboratory, determine what tests are performed and how often. Review laboratory records for the period immediately preceding the inspection.

5.8.6.5.3 – Manufacturing code system

Obtain a complete description of the coding system with any necessary keys for interpretation, or the need of ultra-violet light for visibility. (Specific requirements exist for codes applied to Low Acid Canned Foods (LACF) and Acidified Foods (AF)). Refer to 21 CFR 113.60(c) and 114.80(b)).

5.8.6.6 – Packaging, Labeling, and Packing

Evaluate packaging, packing, and labeling operations. “Packaging” is the processes and procedures used to place product into its immediate container. “Packing” refers to how packages or secondary packages are placed and configured for storage, shipping, and distribution.

Evaluate storage of packaging materials including protection from contamination by rodents, insects, toxic chemicals, or other materials. Appraise the way containers are handled and delivered to the filling areas. Determine if there is likelihood of chipping of glass or denting, puncturing, tearing, etc., of packaging materials. Observe the preparation of containers prior to filling. Consider any washing, steaming, or other cleaning process for effectiveness. Determine, in detail, the use of air pressure or other cleaning devices.

5.8.6.6.1 – Quantity of contents

If slack fill (21 CFR 100.100(a)) is suspected, weigh a representative number of finished packages. See IOM 4.3.8 for net weight procedure. Sets of official weights are available in the division servicing laboratory. These may be used to check the accuracy of firm's weighing equipment.

5.8.6.6.2 – Labeling

Check the sanitary condition of labelers and equipment feeding cans to, and away from, the labeler. Evaluate the firm processes for product label changeover or refilling to ensure the proper labels are used. Check availability of floor drains in the labeling area. Absence of floor drains could indicate infrequent cleaning of the equipment unless it is physically moved to another area for cleaning.

For human food by-products for use as animal food, ensure the labeling that identifies the by-product by the common or usual name is affixed to or accompanies the product when distributed.

Determine what labels and labeling are used. Document any applicable labeling agreements in place. Determine what labeling accompanies and/or promotes the product, including information on the establishment's internet website. Depending upon the claims made in promotional material, a food product may be a dietary supplement or drug product. Consult your supervisor with questions about claims. Obtain specimens of representative labels and labeling including pamphlets, booklets, and other promotional material as necessary.

5.8.6.6.3 – Nutritional and allergen labeling

If the products contain allergens, ensure that the firm has controls in place to accurately identify the label declaration and procedures to ensure proper application to the final packaging. Review product labels to ensure major food allergens are properly declared in the ingredient list or in a "Contains" statement. Check for listing of subingredients that may contain allergens. See Food Allergen Labeling and Consumer Protection Act of 2004 (FALCPA) requirements for guidance.

For products that bear voluntary gluten-free claims, refer to the "Gluten- Free Labeling of Foods" page for guidance. Such claims must meet the requirements in the Gluten-Free labeling of foods regulation (21 CFR 101.91).

Refer to the "Industry Resources on the Changes to the Nutrition Facts Label" and 21 CFR 101.9 to ensure product labels meets the requirement for the Nutrition Facts label as applicable to the firm (does the firm qualify for an exemption).

5.8.6.6.4 – Labeling violations

21 CFR 101 is the primary reference for labeling requirements for conventional foods and dietary supplements. Refer to 21 CFR Part 112 for information on labeling requirements covered under the Produce Safety rule. Collect and review labels as required by a particular assignment. See IOM 4.4.7 for more information on labels and labeling. For routine inspections, collecting labels is not required unless significant violations are noted.

5.8.6.6.5 – Qualified exempt produce labeling

When a food packaging label is required on food that would otherwise be covered produce it must include prominently and conspicuously on the food packaging label the name and the complete business address of the farm where the produce was grown.

When a food packaging label is not required on food that would otherwise be covered produce, it must prominently and conspicuously display, at the point of purchase, the name and complete business address of the farm where the produce was grown, on a label, poster, sign, placard, or documents delivered contemporaneously with the produce in the normal course of business, or, in the case of Internet sales, in an electronic notice.

For additional information on qualified exempt produce and labeling, refer to 21 CFR 112 Subpart A.

5.8.7 – Sanitation

Documented observation of the conditions under which food products are manufactured, processed, packed, or held is essential to the proper evaluation of the firm's compliance with the law. This involves the determination of whether insanitary conditions contribute to the product being adulterated with filth, rendered injurious to health, or whether it consists in whole or in part of a filthy, putrid, or decomposed substance.

Observations that dirt, decomposed materials, feces, or other filthy materials are present in the facility and there is a reasonable possibility these filthy materials will be incorporated in the food are also ways of determining products may have become contaminated.

5.8.7.1 – Sanitary Operations and Sanitary Facilities

Buildings, fixtures, and other physical facilities must be maintained in a clean and sanitary condition and must be kept in repair adequate to prevent food from becoming adulterated.

Substances used in cleaning and sanitizing must be free of undesirable microorganisms and be suitable under the conditions of use. Toxic compounds, e.g., detergents, sanitizers, and pesticides, must be properly stored and used per manufacturer instructions.

Effective measures must be taken to exclude pests from the manufacturing, processing, packing, and holding areas and to protect against the contamination of food on the premises by pests.

Each plant must be equipped with adequate sanitary facilities and accommodations including the following: water supply, plumbing, sewage disposal, toilet facilities, hand washing facilities and rubbish and offal disposal.

Inspect toilet facilities for cleanliness, adequate supplies of toilet paper, soap, towels, hot and cold water, and hand washing signs. Check if hand washing facilities are hidden, or if located where supervisory personnel can police hand washing.

Determine if there is backflow from, or cross connections between, piping systems that discharge wastewater or sewage and piping systems that carry water for food or food manufacturing.

5.8.7.2 – Routes of Contamination

It is not sufficient to document only the existence of insanitary or filthy conditions. You must also demonstrate how these conditions contribute or may contribute to contaminating the finished product. Investigate and trace potential routes of contamination and observe all means by which filth or hazardous substance may be incorporated into the finished product. For example, defiled molding starch in a candy plant may contribute filth to candy passing through it, splash or overspray from cleaning operations may contaminate food and food contact surfaces, or filth in insect or rodent contaminated raw materials may carry over into the finished product. Document evidence of insanitary / filthy conditions, as appropriate, through observations, photographs, and sample collections. IOM Section 4.3.6 contains instructions on sample collection techniques for adulteration violations, including instructions for field exams and sample collections to document evidence of rodent, insect, etc., contaminated lots, and instructions for in-line sampling, including bacteriological samples. Finished product sample sizes for filth and micro collections can be found in the applicable food CPs or Inspection Guides. Consult with your supervisor prior to collecting samples.

5.8.7.2.1 – Insects

Insect contamination of the finished product may result from insect infested raw material, infested processing equipment or insanitary practices, and by insanitary handling of the finished product. When evidence of contamination with insect filth is encountered, broadly identify the type of insects found (e.g., apparent weevils, beetles, moths, etc.), its quantity, location, affected product, and other pertinent information. Explain its significance and potential for product contamination. See IOM Exhibit 4-22 for information on collecting insect evidence.

5.8.7.2.2 – Rodents

Rodent contamination of the finished product may result from using rodent defiled raw materials, exposure to rodents during storage or processing, and by rodent depredation of the finished product. When evidence of rodents is encountered, you should describe the type of contamination (e.g., apparent rodent excreta pellets,

gnaw marks, etc.), its quantity, location, affected product(s), and other pertinent information. Explain its significance and potential for product contamination. See IOM Exhibit 4-22 for information on collecting rodent evidence.

5.8.7.2.3 – Pesticides and Industrial Chemicals

Pesticide and industrial chemical contamination of the finished product may be the result of mishandling of food products at any stage (e.g., growing, manufacturing, storage). The use of pesticides and chemicals in a manner, which may result in contamination, constitutes an insanitary condition. Additional information can be found in 21 CFR as follows:

- Part 117.10(b)(9) – Personnel
- Part 117.20(b)(2) – Plant Construction and Design
- Part 117.35(b) – Sanitary Operations
- Part 117.35(c) – Pest Control
- Part 117.40(a)(2) – Equipment and Utensils

Additional information can be found in 40 CFR Part 180 – Tolerances and Exemptions for Pesticide Chemical Residues in Food administered by the Environmental Protection Agency as follows:

- Part 180.521 – Fumigants for grain-mill machinery; tolerances for residues, and
- Part 180.522 – Fumigants for processed grains used in production of fermented malt beverages; tolerances for residues.

All firms should have Safety Data Sheets for all chemicals used onsite. When evidence of contamination with chemical or pesticides is encountered, you should determine the chemical, quantity used, location, affected product(s), and other pertinent information. In addition, for pesticides determine:

- Who administers the firm's rodent and insect control program,
- responsibility for the careless use of toxic materials,
- Name of exterminator and contract status,
- Name of pesticide,
- Name of pesticide manufacturer,
- EPA registration number,
- Active ingredients, and
- Any significant markings on pesticide containers.

Examples of misuse or possible cross contamination include:

- Possible PCB polychlorinated biphenyls (PCB) contamination. Articles containing PCBs (e.g., transformers, PCB containers stored for disposal, electrical capacitors) must be marked with prescribed labeling to show they contain PCBs. No PCB-containing heat exchange fluids, hydraulic fluids, or lubricants are allowed to be used in food production and storage areas. All PCB storage areas must be marked to show the presence of PCBs. Observe food plant transformers for possible leakage. If observed, determine if food items are stored in the area, and sample for PCB contamination. If PCBs are encountered in a food establishment, immediately advise management this is an objectionable condition and advise your supervisor.
- Possible mix-up of pesticides or industrial chemicals with food raw materials.
- Improperly stored pesticides or industrial chemicals (lids open, torn bags near foods, signs of spillage on floors, pallets, shelves, etc.).
- Incorrect application methods including excessive use. Many pesticide labels give instructions for use and precautions on the container.
- Improper disposal or reuse of pesticide or industrial chemical containers.
- Evidence of tracking powder or improper use of bait stations or baited traps.
- Improper handling of equipment. Movable or motorized equipment used for handling possible chemical contaminants should not be used for handling food products unless they are thoroughly

decontaminated. For example, fork-lifts moving pallets of pesticides should not also be used to move pallets of flour, etc.

- Use of unauthorized pesticides.
- Use of foods treated with pesticides and marked "Not for Human Consumption" (e.g., Treated seed wheat, etc.).
- Noticeable odor of pesticides.
- Careless use of machinery lubricants and cleaning compounds.
- Chemical contaminants in incoming water supply.

Arsenic, lead, mercury, and cadmium, sometimes referred to as heavy metals or toxic elements, may occur naturally in the environment and are often at higher levels from past industrial uses and pollution. When inspecting products with a known potential for contamination with heavy metals, determine whether the firm has evaluated the hazard and if they test for such contamination in raw materials as appropriate for the regulation(s) they must comply with.



If samples are to be collected to document pesticide or industrial chemical misuse, exercise caution to prevent contamination of the immediate area of use, product, or yourself. See Chapter S.14.2-S.14.4.

Please refer to the Compliance Program 7304.019 Toxic Elements in Food and Foodware, and Radionuclides in Food – Domestic and Import and Compliance Program 7304.004 Pesticides and Industrial Chemicals in Food - Domestic and Import for additional information.

5.8.7.1.4 – Other

Contamination of food products by bats, birds, and/or other animals is possible in facilities where food and roosting facilities are available. Birds and other animals are normal in farm operations. Evaluate the farm's wildlife management and their actions if there is any contamination or concerns.

Examine storage tanks, bins, and warehousing areas, as appropriate, to determine condition and history of use. There have been instances where empty non-food use containers were used for food products.

5.8.7.3 – Microbiological Concerns

During the inspection, identify likely sources and possible routes of contamination of the product with pathogenic microorganisms. Identify any vectors of contamination (e.g., birds, rodents, insects, foot traffic, etc.), and describe sources and the routes of contamination from them to the product. Support this with your actual observations.

See IOM sections 4.3.6.6 and 4.3.6.7 for microbiological and viral sampling guidance.

You should become familiar with the flow of the process and determine the potential trouble spots, which may be built into the operation. To document the establishment is operating under insanitary conditions which may result in the presence of pathogens in food, it is necessary to show that the manufacturing process may have or has contributed to the bacterial load of the product. (s)If there are several products being prepared at once, do not try to cover the entire operation during one inspection. Select the product which has the greatest potential for bacterial contamination, or which poses the greatest risk for the consumer.

It is extremely important for each EIR to contain complete, precise, and detailed descriptions of the entire operation. The EIR must be able to stand alone without the analytical results, which serve to support the observations.

Observations made during the inspection must be written in clear and concise language. The EIR will be reviewed in conjunction with analytical results of in-line, environmental, and finished production samples collected. Based on this review and other information which may be available, the program division must then decide if the total package will support a recommendation for regulatory action.

Each inspection/process will be different, but the techniques for gathering the evidence will be the same. However, the critical points in the operation should always be defined and special attention given to these areas.

Depending on the type of product being produced and the process being used, it may be useful to record the time each critical step takes, encompassing the entire processing period from beginning to end, with correlating temperature measurements. This should be done especially for products which may support the growth of microbial pathogens. During the entire inspection, be aware of and document delays in the processing of the product (e.g., temperature of product prior to, during, and after a processing step, and the length of time the product has been delayed prior to the next step). Be aware of and document potential routes of environmental contamination.

Some products receive a thermal process at the end of production, which may reduce bacterial counts to or near zero, although post process contamination is still possible through cross-contamination from the environment. Include detailed observations of heating step, temperature, length of time, controls, and documentation used/not used by the firm. Even in the presence of end-product thermal processing, there is a regulatory significance to insanitary conditions prior to cooking, coupled with increases in bacterial levels demonstrated through in-line sampling.

5.8.7.3.1 – Processing equipment

Document the addition, or possible addition of pathogenic microorganisms from accumulated material due to poorly cleaned and/or sanitized processing equipment. All food-contact surfaces must be cleaned as frequently as necessary to protect against allergen cross-contact and against contamination of food.

Observe and report the firm's cleaning and sanitizing procedures and the condition and cleanliness of food contact surfaces before production starts, between production runs and at the end of the day. Document any residue on food contact surfaces of equipment, especially inside complex equipment not easily cleaned and sanitized. Report firm’s clean-up procedures in depth, since it may lend significance to insanitary conditions of residues on the plant machinery which are left to decompose overnight or between shifts. Where possible, observe equipment both before and after cleaning to assess its adequacy. Observations of residues on plant machinery can dramatically document the addition of pathogenic microorganisms, if present, into the product.

5.8.7.2.2 – Employee practices

Document any poor employee practice and how they have or would provide a route for contaminating the product with microorganisms. For example, did employees (number/time of day) fail to wash and sanitize their hands at the beginning of processing, after breaks, meals, or after handling materials likely contaminated with a microbial pathogen, etc., and then handle the finished product or touch RTE food contact surfaces. Did employees handle product in an insanitary manner (cross contaminating raw product with cooked product, etc., how many, how often).

5.8.7.4 - Storage

Evaluate the storage of finished products in the same manner as for raw materials. Determine if products are stored to minimize container abuse, facilitate proper rotation, and adherence to the storage requirements. This includes refrigeration temperatures, critical temperature tolerance, aging of products, and proper disposition of distressed stock.

During holding, human food by-products that are destined for use as animal food must be accurately identified.

5.8.7.4.1 – Food transport vehicles

FDA’s final rule establishing 21 CFR Part 1, Subpart O (Sanitary Transportation of Human and Animal Food, also known as the Sanitary Transport (ST) rule, created new requirements for the sanitary transportation of human and animal food by motor vehicle and rail vehicle to ensure that transportation practices do not create food

safety risks. Unless excluded or subject to a wavier, the ST rule applies to shippers, receivers, loaders, and carriers who transport food domestically by motor or rail vehicle, whether or not the food is offered for or enters interstate commerce. The rule does not apply to transportation of food by barges, ships, or aircraft. As explained in Compliance Program 7303.040 (Preventive Controls and Sanitary Human Food Operations), HAF divisions will be notified of the need to perform surveillance ST inspections via the annual work plan and Food Safety Modernization Act (FSMA) inventory. However, the Compliance Program also provides a list of circumstances when ST inspections should be performed for-cause.

In addition to the ST rule, there are other FDA regulations covering sanitary transportation of food. For example, 21 CFR 118.1(b) and 118.4(e) established requirements for refrigeration of shell eggs during storage and transportation. For links to existing regulations and guidance documents that address food transportation see FDA's Sanitation & Transportation Guidance Documents & Regulatory Information webpage. In addition, FDA's Guidance for Industry: Sanitary Transportation of Food contains an appendix listing regulations and guidance documents addressing food transportation and provides a list of problem areas where food may be at risk for physical, chemical, or biological contamination during transport.

The type of transportation operations covered will depend on several factors including the type of inspection and food commodity area. Speak to your supervisor if you are unsure what transportation operations to cover. Refer to IOM 5.2.2.2 regarding issuance of FDA 482, Notice of Inspection, while inspecting vehicles. In general inspections of the transportation operations will evaluate for evidence of insanitary conditions, physical defects in the transport vehicle, poor industry handling practices, or conditions which might lead to food adulteration. The type of transport vehicles (both refrigerated and non-refrigerated) covered during your inspection could include railroad boxcars/hopper cars, trucks, and farm vehicles used in covered produce activities. Use extreme caution if it is necessary to inspect tank railcars or tank trucks. Usually, this coverage will be limited to determining what was transported in the tank previously and was the tank cleaned and/or sanitized as necessary between loads.

Regulatory actions are possible if, for example, unfit transportation vehicles are loaded and, because of loading, adulteration occurs. Fully document any violations noted with appropriate evidence such as photographs. When vehicle insanitation is observed, it is imperative to document the carrier's and shipper's responsibility for the food adulteration with appropriate evidence, such as:

- The nature and extent of the conditions or practices.
- The mechanical or construction defects associated with the food transport vehicle.
- Individual responsibility for vehicle or trailer cleaning, vehicle assignments, load assignments, etc.

For the ST rule, CP 7303.40 provides some examples of conditions that may warrant regulatory action, depending on firm history, inherent risk of the food, and corrective action/response to observed conditions.

5.8.7.4.2.1 – Vehicles at receivers

When it comes to inspecting vehicles at receivers, you should refer to the regulation and compliance program you are covering to determine what to evaluate and how in-depth to go. In general, when inspecting receivers of food products, examine the food transport vehicle prior to or during unloading. Make a preliminary assessment of food product condition, then inspect the vehicle after unloading to determine its condition and whether the unloaded food may have been contaminated during shipment. If the food appears to have been adulterated, speak to your supervisor to determine if sample collection is warranted. You may also collect documentary (DOC) samples from the vehicle to substantiate the route of contamination.

5.6.8.4.2.2 – Vehicles at shippers

When it comes to inspecting vehicles at shippers, you should refer to the regulation and compliance program you are covering to determine what to evaluate and how in-depth to go. In general, when inspecting shippers of food products, examine the food transport vehicle just prior to loading to determine its sanitary/structural conditions. If the vehicle has significant sanitation or structural deficiencies, notify the shipper of these conditions and of the possibility of product adulteration. If the shipper loads food aboard the vehicle, alert your supervisor so they can contact the FDA program division where the consignee is located for possible follow-up. You may also collect evidence of the conditions observed.

5.8.8 – Distribution

Report the general distribution pattern (i.e., direct sales to consumer; states, regions, and/or receiving countries) of the firm and how the products reach the firm customers (i.e., firm truck, common carrier truck, rail, vessel, air freight, etc.). Review interstate shipping records or invoices to report shipment of specific lots. If access to invoices or shipping records is not possible, observe shipping cartons, loading areas, order rooms, address stencils, railroad cars on sidings, etc., to determine customer names, addresses and destination of shipments. If no products are suspect, obtain a listing of the firm's larger consignees.

5.8.8.1 – Promotion and Advertising

Determine the methods and patterns used to promote or advertise products (e.g., websites, social media, oral presentations, printed materials, etc.). Determine what promotional materials are used and whether they accompany the products or are distributed under a separate promotional scheme.

5.8.8.2 – Recall Procedure

Determine the firm's recall procedure. Audit enough records to determine the effectiveness of established procedures. Firms that are subject to preventive controls have specific requirements for recall plan. Refer to 21 CFR 117.139, as applicable, for firms subject to 21 CFR 117, Subpart C

Note: Many firms are not required to have a recall procedure, such as produce farms.

5.8.8.3 – Complaint Files

Review the firm’s complaint files Include a summary of each significant complaint in the EIR. During the inspection, identify who reviews complaints and their qualifications. Describe the criteria used by the firm in evaluating the significance of complaints and how they are investigated.

Determine if records are kept of oral and telephone complaints. See IOM 5.5.4 for discussion of complaints with management and IOM 5.7.3.7.10 for reporting of complaints in the EIR.

Complaints may not be filed in one specific file, but may be scattered throughout various files under other subject titles including Product name; Customer name; Injured party name; Adjustment File; Customer Relations; Repair orders, etc.

During the inspection investigate all complaints received by FDA since the last inspections, or that were not covered during the previous inspection. See IOM 5.2.3, 5.5.4 and 5.7.3.7.10. Complaints can be accessed by doing a fast search for the complaint number in CMS, or by clicking the “Firm 360” link in OSAR of the associated firm.

5.8.9 – Other Government Inspection

See IOM Chapter 3 for general procedures on cooperating with other federal, state, and local officials.
During establishment inspections when other government officials are onsite, document their agency, name, and title.

- Federal – See IOM 3.1.3.1 and 3.1.3.2. Information specific to USDA can be found under IOM 3.2.1.
- State and local – See IOM 3.1.2, 3.1.3.3, and 3.3.

5.8.9.1 – Grade A Dairy Plant Inspections

If you are assigned to conduct an inspection or sample collection at a milk plant that is covered under the Grade A Milk program, which has milk and milk products labeled and sold as Grade A, you should verify the need to complete the assignment with your supervisor and a milk specialist. Grade A milk plants, milk, and milk products labeled as Grade A are inspected by state inspectors and check rated by ORA's Office of State Cooperative Programs (OSCP) milk specialists and you should not inspect these Grade A milk and milk products. Milk plants in the Grade A Milk program and covered by the Interstate Milk Shippers (IMS) program are identified in the Interstate Milk Shippers List of Sanitation Compliance and Enforcement Ratings. This reference lists the specific milk plant and each milk and milk product covered under the IMS program. These Grade A milk and milk products are covered by a Memorandum of Understanding (MOU) between the FDA and the states, which places primary inspectional responsibility with the state.

There are situations where you will need to conduct an inspection in a Grade A milk plant and cover products they manufacture which do not carry the "Grade A" designation (such as juices). Prior to conducting an inspection at a Grade A plant, you should contact the FDA milk specialist for the state. A list of the FDA milk specialists can be found on the Interstate Milk Shippers List.

Fluid milk and milk products, cultured/ acidified milk and milk products, eggnog, cream(s), sour cream, and yogurt are all considered Grade A and are required to be labeled as Grade A. The Grade A milk plant may also manufacture milk and milk products which are optional for the Grade A designation, depending upon the state. Cottage cheese is considered a Grade A optional milk product. If the state does not require the Grade A designation for cottage cheese, then the cottage cheese will not be included in the IMS listing of Grade A milk and milk products for that specific milk plant. If the Grade A milk plant is manufacturing condensed or dried milk or milk products or condensed or dried whey or whey products, which are optionally labeled as Grade A, then those milk or milk products must be IMS listed and are covered under the Grade A Milk Program. Note: This same Grade A milk plant may also be manufacturing non-Grade A versions of these condensed/dried milk or milk products or condensed/dried whey or whey products.

5.8.10 – Pesticides

Most farm investigations into pesticide residues are conducted by the states and your first contact should be your state liaison and/or emergency response coordinator via your immediate supervisor. See Exhibit 5-22 (Pesticide Inspections/Investigations) for information on inspection and investigation activities related to pesticides.

5.8.11 – Foreign Supplier Verification Program

See IOM 6.8 Foreign Supplier Verification Program for inspectional instructions.

5.8.12 – Standards of Identity for Food

See Exhibit 5-23 for information on inspection activities related to standards of identity for food.

5.9 – Cosmetics

5.9.1 – Cosmetics Inspections

NOTE: While Subchapter 5.8 refers specifically to food inspections, general guidance concerning sanitation, routes of contamination, etc., can be applied to all commodities. Consumer safety officers conducting cosmetics inspections should be familiar with that subchapter.

Cosmetic inspections are conducted to ensure the safety of cosmetics through the evaluation of the firms' compliance with applicable statutory and regulatory requirements.

See the SharePoint site for the Center for Food Safety and Applied Nutrition (CFSAN) Office of Compliance for the most current resources (e.g., Compliance Programs, field assignments, enforcement bulletins, direct reference authorities). Additional resources can be found at the SharePoint site for CFSAN's Office of Cosmetics and Colors, which is the office responsible for developing guidelines, regulations, and policies for cosmetics and color additives.

There is currently no FDA pre-approval for cosmetic products or ingredients, except for color additives. However, cosmetic firms are responsible for marketing safe and properly labeled products. Inspections can identify adulterated and misbranded cosmetics as defined in Sections 601 [21 U.S.C. 361] and 602 [21 U.S.C 362], respectively, of the FD&C Act. Inspections cover three major areas:

- Control of processes and quality of products – Products are manufactured in an adequate state of control to meet the firm's established quality standards.
- Sanitation, cleanliness, and hygiene – The facility is clean and orderly, sanitary conditions are being maintained and workers are attentive to preventing contamination.
- Labeling – Products are labeled in compliance with regulations and are accurately labeled to reflect contents.

FDA inspections can reveal use of prohibited ingredients, noncompliance with requirements related to color additives, failure to adhere to requirements for tamper-resistant packaging where needed, and violations involving labeling without necessarily performing an on-site inspection. Assurance of cosmetic product safety also depends upon control of microbiological product quality during manufacturing and distribution of products. An on-site inspection is the only means by which FDA can determine if cosmetics are being manufactured under insanitary conditions whereby cosmetics may be contaminated with objectionable microorganisms. (See 5.7.1.3 (Contaminated Cosmetics) and 5.7.1.6 (Specific Types of Cosmetic Safety Concerns))

5.9.1.1 – Preparation and References

Before conducting a cosmetic inspection, refer to IOM 5.8.1.2 (information in bullets 1-3 and 4-8 as applicable) and additional resources below:

- Review FD&C Act Chapter 9, Subchapter VI: Cosmetics, 21 CFR 700-740 (Cosmetics), and the Fair Packaging and Labeling Act .
- Determine if the firm has registered under the Voluntary Cosmetic Registration Program .
- Refer to Compliance Program 7329.001 (Cosmetics – Import and Domestic) and IOM Chapter 5 All Program Sections.
- Additional resources include the Draft Guidance for Industry: Cosmetic Good Manufacturing Practices, the Cosmetics Labeling Guide, import alerts relevant to cosmetics, and cosmetics recalls / alerts.

5.9.1.2 – Documents and Records

While there is no requirement for the firm to provide records for your review, it is important to review documents and records, to determine if the site has adequate procedures and systems for manufacturing and monitoring to ensure production and distribution of safe cosmetic products. Therefore, make a request to review processing records, packaging and labeling records, raw material records, and any records pertinent to the manufacture, packaging, labeling and distribution of the cosmetic product, including finished product testing, batch release, complaints and/or adverse events.

5.9.1.3 – Contaminated Cosmetics

Inspect the firm's methods for preventing and controlling microbial and other forms of contamination and review records that may indicate batches that were manufactured and distributed in violation of any of the cosmetic adulteration provisions of the Act.

Typical causes of product adulteration are manufacturing under insanitary conditions, improper storage conditions, and product design flaws and/or defects (i.e., ingredients, packaging) including use of an ineffective

preservative system (see below). Observe and document when any of the following present a potential cause of insanitary conditions:

- Overall cleanliness of the facility and sanitation practices, including programs and systems for pest control and waste disposal.
- Personal hygiene and employee health, including training of staff and monitoring of employees by supervision.
- Handling of ingredients, materials, and products by employees; including procedures for making transfers, training, and use of Personal Protective Equipment (PPE).
- Microbiological quality of ingredients, including whether ingredient batches received from suppliers are tested by the manufacturer and how ingredients are stored (see next section on raw material quality).
- Water systems, including system design and control and monitoring of microbiological quality.
- Equipment design, including potential for stagnant water.
- Cleaning and sanitization of equipment surfaces contacting process stream or products, including utensils and shared equipment.
- Buildup of previous batches of material on equipment surfaces during prolonged manufacturing campaigns.

Susceptibility of cosmetic products to microbiological growth is governed the by water activity of the formulation. Preservatives are added to mitigate the risk of microbial growth, but each preservative system's capability has unique limitations. As proof of effectiveness of preservation, the formulation can be subjected to microbial challenge testing. Check to see if the manufacturer (or product distributor) has performed and retained documentation of preservative efficacy testing on its cosmetic product formulations. See CP 7329.001 section on adequacy of preservation for more information. Also refer to sections 5.8.7 for more information about documenting routes of contamination and microbiological concerns. While Subchapter 5.8 refers specifically to food inspections, general guidance concerning sanitation, routes of contamination, etc., can be applied to all commodities.

See CP 7329.001 Part V.1.c. for more information on current policy on microbiological quality of cosmetics, including products and levels of concern constituting potential health hazard.

5.9.1.4 – Cosmetic product labels or labeling making drug claims

See CP 7329.001 (Part III.A. and III.B.1) to determine if there is cause to collect evidence supporting that a cosmetic is to be considered a drug. 21 CFR 701 contains information on cosmetic labeling requirements and 21 CFR 740 describes requirements for cosmetic product warning statements. Examples of products marketed strictly as cosmetics but making drug claims include those which claim to promote hair growth, prevent baldness, prevent, or treat dandruff, enhance eyelash growth, and treat skin diseases such as acne.

Collect the following as evidence that could enable FDA to consider such a product an illegally marketed drug:

- Product labels, including outer containers and all inserts.
- Promotional material in written and/or electronic format.

If the product is suspected to contain an active pharmaceutical ingredient associated with drug claims also collect:

- Samples of product.
- Samples of the active ingredient used in the cosmetic and ingredient certificate of analysis.
- Records showing usage of the active ingredient in manufacturing of a cosmetic product batch.

(NOTE: As stated in CP 7329.001 III.A, the Center for Drug Evaluation and Research and CFSAN have concurrent jurisdiction over any product purported as a cosmetic that meets the legal definition of a drug.)

5.9.1.5 – Cosmetic Ingredients

Determine if the manufacturer has suitable procedures for supplier selection and qualification and adequate controls for chemical, microbial, and physical contamination to ensure the ingredients are suitable for use in cosmetics. If the manufacturer uses ingredients that have been reconditioned or reprocessed, determine if there is adequate documentation to justify such use. Determine who (e.g., the firm's quality department, the product distributor) decides to approve suppliers, and accept or reject ingredient batches from suppliers. Determine if ingredients (and packaging materials) are stored and handled properly to prevent mix-up and contamination; and if there are suitable systems to identify and trace ingredients and packaging materials used in cosmetic products.

5.9.1.6 – Specific Types of Product Safety Concerns

You should be aware of certain cosmetic products that CFSAN/OCAC has identified as posing unusual safety hazards due to concerns about the product ingredients. Examples include:

- Tattoo inks.
- Ingredients or products labeled "organic" or "natural".
- Products lacking traditional preservatives.
- Products containing stem cells or human tissue.
- Wet wipes (used by infants/children and adults).
- Cosmetic non-alcohol oral care products.
- Eye area products.
- Potential use by immuno-suppressed or institutionalized individuals.

There are currently no prohibitions on the use of many of these ingredients and FDA's regulatory policy is still in development. OCAC will provide training on these specific topics and others that may emerge in the future. If in doubt about the status of a particular ingredient or type of product you encounter on an inspection, contact CFSAN/OCAC.

5.10 - Drugs

5.10.1 - Drug Inspections

5.10.1.1 - Pre-Announcements

If a program division believes pre-announcing an inspection of an establishment will optimally facilitate the inspection process, then the respective procedures for conducting pre-announcement for drug inspections should be followed. ORA's primary purpose for pre-announcing is to ensure the appropriate records and personnel will be available to us during the inspection. It is not to make an appointment for the inspection, nor should it be referred to as an "appointment" to inspect. When doing a pre-announcement, it is important you communicate to the establishment the purpose of the inspection and a general idea of the records you may wish to review. If you find neither the appropriate personnel, nor records available, note this in your Establishment Inspection Report (EIR). For pre-announced foreign drug inspections, the pre-announcement will be conducted by the Division of Foreign Pharmaceutical Quality Inspections (DFPQI) as part of the inspection planning process.

In the case of drug inspections, if efforts to schedule a pre-announced inspection are met with unreasonable delays by the establishment, including a request for a later start date without a reasonable explanation, it may constitute a delay of an inspection under Section 501(j) of the FD&C Act [21 U.S.C. 351(j)]. The FDA will make reasonable accommodations for potentially interfering local conditions such as weather, holidays, or, where appropriate, manufacturing campaign schedules; however, if faced with an unreasonable delay by the establishment, you may call the responsible person's attention to 501(j) of the Act. Talk with your supervisor to determine whether the length of a particular delay may be considered unreasonable, even in cases in which the

explanation given for the delay may seem reasonable. The program division may use this data in the future when considering whether this establishment should be eligible for pre-announced inspections.

Guidance using eNSpect: In the eNSpect "Pre-Announced / Unannounced to Firm" field, select "Unannounced" when no notification was provided to the firm in advance of arrival at the firm for inspection. Select "Pre-announced" when the firm was notified of the inspection prior to the CSO arrival at the firm for the inspection. See IOM 5.2.6 for general guidance on Pre-Announcement.

5.10.1.1.1 - Basic Premises

Pre-announcement of inspections is to be applied only to establishments that meet specific criteria. Pre-announcement may be considered for establishments that manufacture both drugs and devices or biologics and devices. The eligibility of an individual establishment for pre-announced inspection is at the discretion of the inspecting division using clearly described criteria. (See 5.2.6.1: Criteria for Consideration) The program division does not have the discretion to decide the types of establishments eligible for pre-announcement, but may decide the specific establishments' eligibility because they meet the criteria.

The pre-announcement should generally be no less than five calendar days in advance of the inspection. Should a postponement be necessary, the decision as to rescheduling rests with the investigator/team, but the new inspection date should not be later than five calendar days from the original date. Inspections may be conducted sooner than five calendar days, if requested by or acceptable to the establishment, and if this date is acceptable to the investigator/team.

To participate in a pre-announced inspection, establishments are expected to meet the commitment to have appropriate records and personnel available during the inspection.

Pre-announced inspections should be as thorough as necessary, and, in no way limit an investigator's authority to conduct the inspection.

5.10.1.1.2 – Criteria for Consideration

Certain criteria determine whether an establishment requires or qualifies for a pre-announced inspection (see section 5.2.6.1 Pre-Announcement). Examples include:

- Foreign inspections, unless conducted as part of a "For Cause" assignment or as part of the "foreign un-announced inspection pilot."
- Specific kinds of inspections as instructed by the Compliance Program, assignment, or directive (for example, per 56006P, positron emitting tomography (PET) drug production facilities, unlike other commercial production facilities, generally employ a few operators each of whom must perform certain operations and checks quickly, without disruption, so that the drug product can be distributed promptly to pharmacies and waiting patients. For this reason, Divisions are to schedule PET inspections in advance with the firm to allow the facility time to ensure appropriate staff is available to enable an efficient and complete inspection. When scheduling the inspection with the firm, the investigator may obtain information about the planned times of key operations and time their arrival accordingly. Note that the investigator may also need to accommodate the typical PET establishment's early hours of operation. "For cause" inspections, however, need not be scheduled in advance.
- Inspections conducting during a health emergency crisis, like an epidemic or pandemic.

5.10.1.1.3 - Procedures

Procedures:

1. The investigator or designated FDA official should contact the most responsible individual at the facility. You should leave a message requesting a return call if the most responsible person at the facility is unavailable at the time the call is made. If this is the case, the program division should use good judgment in determining what constitutes a reasonable time frame to await the return call.

2. Keep changes in dates to a minimum. If a change is made, a new date should be provided as soon as possible that still facilitates an effective inspection and accommodates your schedule. The establishment should also provide a valid reason for requesting a change in the start date. (A valid reason should be the same as you would accept if presented with the information during an unannounced inspection.)
3. Inform the establishment as to the purpose, estimated duration, and the number of agency personnel expected to take part in the inspection. The products or processes to be covered should be described if this will facilitate and be consistent with the objectives of the inspection.
4. When appropriate, request access to any relevant specific records and/or personnel at the time the inspection is pre-announced.
5. Be as specific as reasonably possible in your notification, including an exact date for the start of the inspection.
6. If it is a pre-approval inspection, you should notify the pre-approval manager, and CDER's Office of Pharmaceutical Manufacturing Assessment (OPMA), with the inspection dates or altered pre-approval inspection dates.

Special notes regarding the EIR: Include in your report whether or not the inspection was pre-announced, as well as information on any difficulties you experienced in notification, or while accessing records or personnel that should have been freely available as a result of pre-announcing the inspection. Also, if an establishment should become ineligible for pre-announcement, the endorsement of the EIR should reflect this statement. This information will be necessary for making any future determinations regarding pre-announced inspections of the establishment. In addition, you should inform the establishment during the current, and subsequent inspections, of the action(s) that may have caused them to be ineligible for pre-announcement.

5.10.2 - Drug Inspections

As a reminder, our authority for conducting inspections is discussed in IOM 2.2. FD&C Act Sections 501(a) through (d) and 501(j) [21 U.S.C. 351(a) through (d) and 351(j)] describe the ways in which a drug may be or may become adulterated. Section 502 of the FD&C Act [21 U.S.C. 352] does the same, with respect to misbranding. Section 505 of the FD&C Act [21 U.S.C. 355] requires that new drugs be approved by the FDA. With these authorities, laws, and regulations in mind, the purposes of a drug inspection are to execute and fulfill the following:

1. Evaluate a firm's adherence to the concepts of sanitation and good manufacturing practices, such that production and control procedures take into account all reasonable precautions needed to ensure the identity, strength, quality, and purity of the finished products and active pharmaceutical ingredients.
2. Identify deficiencies that could lead to the manufacturing and distribution of products in violation of the Act, (for example, non-conformance with Official Compendia, super/sub potency, or substitution).
3. Determine whether a firm is distributing drugs that lack required FDA approval, including counterfeit or diverted drugs.
4. To obtain correction to identified deficiencies.
5. Determine if drugs are manufactured by the same procedures and formulations as specified in the associated Drug Application documents.
6. Determine the drug labeling and promotional practices of the firm.
7. Ensure the firm is reporting NDA field alerts as required by 21 CFR 314.81, and Biological Product Deviation Reports (BPDRs) for therapeutic biological products as required by 21 CFR 600.14;
8. Determine if the firm is complying with the requirements of the Prescription Drug Marketing Act (PDMA) and associated regulations.
9. Determine the disposition of Drug Quality Reports (DQRS) received from the Drug Surveillance and Data Reporting Branch (DSDRB)/CDER.

10. Determine if the firm is complying with any relevant post-market Adverse Drug Experience reporting requirements, as required by 21 CFR sections 310.305 (prescription drugs without approved NDA/ANDA), 314.80, 314.98, and 314.540 (application drug products), 514.80 (applicable for animal adverse events) and 600.80 (therapeutic biological products); Section 760 of the FD&C Act (non-application nonprescription products) [21 U.S.C. 379aa];. and Section 503B (b)(5) [21 U.S.C. 353b(b)(5)] of the FD&C Act (registered outsourcing facilities).
11. Determine, for pharmacy compounding inspections, if compounded drug products meet the conditions of section 503A or 503B of the FD&C Act.

5.10.2.1 - Preparation and References

During your preparation for an upcoming assignment, you should become familiar with current programs related to drugs. You should also determine the nature of the assignment, for instance, does it relate to a specific drug problem? Or is it a routine inspection?). If necessary, consult other program personnel, such as chemists, microbiologists, and other subject matter experts, or center personnel, such as office of compliance staff, to aid your understanding. You should also review the establishment program files of the firm to be inspected, including, any:

- Establishment Inspection Reports
- Inspection Coversheets
- Firm Profiles
- OTC monographs and other pertinent references for non-application products
- Drug Applications (new, abbreviated and investigational) and the Knowledge Transfer Memo, if the Center has provided it for a specific pre-approval inspection
- Therapeutic Biologics License Applications
- Sample results, where applicable
- Complaints and Recalls
- Regulatory files
- CMS Files/FEI Information
- Drug Quality Reports (DQRs), NDA Field Alert Reports (FARs), and Biological Product Deviation Reports (BPDRs)
- Drug Registration and Listing
- Inspection Protocols (NIPP) and their questions where appropriate
- Facility Dossier, where applicable
- Inspection Assignment memo, where applicable.

During your review of these documents, you should also pay special attention to and identify products that:

- Are difficult to manufacture
- Are complex dosage forms
- Require special tests or assays, or cannot be assayed
- Require special processes or equipment
- Are new drugs and/or potent low dosage drugs
- Are misbranded, unapproved, fraudulent, or are compounded human drug products that do not meet the conditions of section 503A or 503B of the FD&C Act
- Are manufactured for vulnerable populations (such as, pediatric or geriatric)

You should also review the factory jacket, FACTS OEI and registration/listing data, CMS, OSAR, and all complaint reports that are marked follow-up next inspection. These complaints are to be investigated during the inspection and discussed with management. (See IOM 5.7.3.7.14.)

Become familiar with current regulations and programs relating to drugs, CP 7356.002, and similar resources. When preparing for CGMP inspections, discuss with your supervisor the advisability of consulting a microbiologist, analyst, engineer, or other subject matter expert to aid in evaluating those areas of the firm germane to their expertise. Review the FD&C Act, Chapter V, Drugs and Devices. Review parts of 21 CFR 210/211/212 applicable to the inspection involved and Bioavailability (21 CFR 320).

In the case of APIs, review FD&C Act section 501(a)(2)(B) [21 U.S.C 351(a)(2)(B)] and the ICH industry's"Q7 Good Manufacturing Practice Guidance for Active Pharmaceutical Ingredients."

Review the current editions of the United States Pharmacopeia (USP), and Remington's Pharmaceutical Sciences for information on specific products or dosage forms. (See IOM 2.2.3 Authority to Inspect and 2.10 Regulatory Submissions for special regulatory information by product category.)

Review 21 CFR 203 "Prescription Drug Marketing," 21 CFR 205 "Guidelines for State Licensing of Rx Drug Distributors," and CP 7356.022, Enforcement of the Prescription Drug Marketing Act (PDMA).

Before conducting drug pre-approval inspections (CP 7346.832), it is important to be familiar with the application, and coordinate accomplishment of Center goals as communicated by (1) Division Preapproval Manager, (2) inspectional memos, (3) pre-inspection briefings, and/or (4) Center participation on the inspection team.

The Office of Manufacturing Quality (OMQ) in CDER has established two digital resources for you to obtain technical assistance before, during, or after an inspection:

1. The OMQ SharePoint site, which contains organizational charts, names, and phone numbers of OMQ individuals identified as technical specialists in various areas.
2. The Questions and Answers on Current Good Manufacturing Practices for Drugs forum, which is intended to provide timely answers to questions about the meaning and application of CGMPs for human, animal, and biological drugs, and to share these widely. Questions and answers found here generally clarify statements of existing requirements or policies.

Section 704(a)(4) of the Act provides for a records request or other information in advance of an inspection. This section will not discuss the legal aspects of in lieu of an inspection but addresses in advance of an inspection. The issuance of a 704(a)(4) request must follow established procedures. Please see QMiS DIR- 000087 for OPQO procedures.

5.10.2.2 - Inspectional Approach

Review and follow Compliance Program Guidance Manual (CPGM) 7356.002 and others as appropriate when conducting drug CGMP inspections. The in-depth inspection of all manufacturing and control operations is usually not feasible or practical, as such, a risk-based systems audit approach is recommended in which higher-risk, therapeutically significant, medically necessary, and difficult-to-manufacture drugs are covered in greater detail during an inspection. (Note: The status of a drug as “medically necessary” is determined by CDER. For more information, contact Office of Compliance/Recalls and Shortages Branch at cderrecalls@fda.hhs.gov) This group of drugs includes, but is not limited to, time-release and low-dose products, metered-dose aerosols, aseptically processed drugs, and formulations with components that are not freely soluble. If the inspection is conducted for a CDER-led combination product, see also IOM 5.16 Combination Products.

CPGM 7356.002 incorporates the systems-based approach to conducting an inspection and identifies six systems in a drug establishment for inspection: Quality, Facilities and Equipment, Materials, Production, Packaging and Labeling, and Laboratory Control. The full inspection option includes coverage of at least four of the systems; the abbreviated inspection option covers at least two systems. In both cases, CPGM 7356.002, indicates the Quality System be selected as one of the systems being covered. During your evaluation of the Quality System, it is important to determine if top management makes science-based decisions and acts promptly to identify, investigate, correct, and prevent manufacturing problems likely to, or have led to, product quality problems.

When inspecting drug manufacturers that market a number of drugs meeting the earlier-mentioned risk criteria, consider doing the following to help you identify suspect products:

1. Review the firm's complaint files early in the inspection to determine relative numbers of complaints per product.
2. Inspect the quarantine, returned, reprocessed, and/or rejected product storage areas to identify rejected products.
3. Identify those products that have process control problems and batch rejections by reviewing processing trends and examining reviews performed under 21 CFR 211.180(e).
4. Review summaries of laboratory data (for instance, laboratory workbooks), OOS investigations, and laboratory deviation reports.

5.10.2.3 - Drug Registration & Listing

Keep in mind the following requirements and other information regarding registration and listing:

- Registration and listing is required whether or not interstate commerce is involved. (See Exhibit 5-12 and IOM 2.10.2.1 for additional information.)
- Two or more companies occupying the same premises and having interlocking management are considered one establishment and usually will be assigned a single registration number. (See IOM 5.1.4.3.3 - Multiple Occupancy Inspections for additional information.)
- Independent laboratories providing analytical or other laboratory control services on commercially marketed drugs must register.
- FACTS FMS, eDRLS, and CMS will indicate if the establishment is registered for the current year. If you determine registration and listing is required, advise your supervisor. After checking for past registration, cancellation, etc., the program division will provide the firm with the proper forms and instructions.
- Each establishment is required to list with the FDA every drug in commercial distribution, whether or not the output of such establishment or any particular drug so listed enters interstate commerce. During the establishment inspection, you should remind the firm of its responsibilities for ensuring its drug listing accurately reflects the current product line, and updating its listing as necessary to include all product changes, NDC changes, and discontinuations in accordance with 21 CFR 207. If registration and listing deficiencies are found, document it in your EIR, collect a documentary sample and/or contact your supervisor.
- During foreign inspections, the investigator should verify the information for the U.S. agent. A U.S. Agent is a person residing or working in the Unites States who is designated as such by a foreign establishment registered for drugs. A U.S. agent is responsible for: 1) reviewing, disseminating, routing, and responding to all communications from the FDA; 2) responding to questions concerning those drugs that are imported or offered for import to the United States; 3) assisting the FDA in scheduling inspections; and 4) if the FDA is unable to contact a registered foreign establishment directly or quickly, the agency may provide the information and/or documents to the U.S. agent, who is considered equivalent to providing the same information and/or documents to the registered foreign establishment (21 CFR 207.69). This information is critical to ensure the safety of the supply chain and to ensure that the FDA has appropriate contact information for any emergency or recall situations.

5.10.3 - Counterfeit Drug Authority

Section 702(e) of the FD&C Act [21 U.S.C. 372(e)] contains certain authorities relating to counterfeit drugs including the authority to seize ("confiscate") counterfeit drugs and containers, counterfeiting equipment, and all other items used or designed for use in making counterfeit drugs prior to the initiation of libel proceedings. This authority has been delegated, with certain restrictions, to holders of official credentials consistent with their authority to conduct enforcement activities. Additional authorities in 702(e), to make arrests, to execute and serve arrest warrants, to carry

firearms, and to execute seizure by process under Section 304 of the FD&C Act [21 U.S.C. 334], have not been delegated.

The agency does intend to utilize the authority contained in Section 702(e) to execute and serve search warrants, but such use does not require delegation from ORA's Associate Commissioner for Regulatory Affairs.

Section 702(e)(5) contains authority for such delegated persons to confiscate all items which are, or which the investigator has reasonable grounds to believe are, subject to seizure under Section 304(a)(2). Items subject to seizure, and thus to confiscation under Section 702(e)(5), includes most things associated with counterfeit drugs. Confiscation authority does not, however, extend to vehicles, records, or items (for instance, profits) obtained as a result of counterfeiting.

5.10.3.1 - Scope

Under this delegation, with supervisory concurrence and prior to the initiation of libel proceedings, investigators and inspectors are authorized to confiscate:

1. Any counterfeit drug
2. Any container used to hold a counterfeit drug
3. Any raw material used in making a counterfeit drug
4. Any labeling used for counterfeit drug
5. Any equipment used to make a counterfeit drug including punches, dies, plates, stones, tableting machines, etc.
6. Any other item which you have reasonable grounds to believe is designed or used in making a counterfeit drug.

NOTE: You and your supervisor must remain vigilant regarding the potential dangers involved in confiscating property from individuals. Special care should be taken to ensure your safety. Refer to IOM S.3 for information on personal safety and speak to your supervisor about creating a personal safety plan. Arranging for teams of investigators to conduct the investigation, or arranging for assistance by local police, or other agencies with police powers, should be considered in planning the confiscation of counterfeit materials.



5.10.3.2 - Inspectional Guidance

Guidance provided for implementing the authority to confiscate drug counterfeits is as follows:

1. The authority is not to be utilized unless there has been an agency determination that the drug to be confiscated is a counterfeit and is a drug that "without authorization, bears a trademark, *** or any likeness" of a legitimate product. The determination usually is based upon evidence supplied by the firm whose product is being counterfeited. A written agency determination will issue to the Program Division Director from the Office of Enforcement and Import Operations (OEIO), in conjunction with CDER or CVM.
2. When engaged in counterfeit investigations, you should proceed as follows when encountering items to be confiscated:
   a. Evaluate your safety needs and check the physical location to ensure it is safe to proceed. Do not attempt to remove an item by force. If it appears there will be resistance, contact the local police, or other agencies with police powers, for backup, if not already done in advance. (Refer to IOM S.3 for information on personal safety and speak to your supervisor about creating a personal safety plan.)
   b. Inventory the items to be confiscated.
   c. Prepare a written receipt and offer it to the person in charge.
   d. Remove the items, if possible, from the premises (if they cannot be removed, secure them under seal).
   e. Place all items removed, under lock, at a secure location. In most cases, confiscated items will be stored at the program division or resident post office until they are seized.

5.10.3.3 - Follow Up Guidance

After items are confiscated, certain actions must be taken to bring confiscated items under the control of the court. You should proceed as follows:

1. Immediately notify your supervisor after an item has been confiscated.
2. Supervisors must then notify the appropriate compliance units of the items confiscated.
3. Compliance units should initiate seizure proceedings against any items confiscated.
4. Office of Medical Products and Tobacco Program Operations (OMPTO) should be advised of any action utilizing this authority.

5.10.3.4 - Search Warrants

Section 702(e)(2) contains authority to execute and serve search warrants. Proceed as instructed by your program division after a search warrant has been obtained.

5.10.4 - Promotion and Advertising

5.10.4.1 - Promotion and Advertising

The jurisdiction of FDA drug promotion and advertising falls to two regulatory agencies: the FDA and the Federal Trade Commission.

If you should come across any drug advertisement or promotional labeling that is potentially a violation of the FD&C Act, collect that labeling or advertisement for further review. Collect, or document, the drug advertisement and promotional labeling as a photo, screenshot, or PDF. Keep in mind that any hyperlinks associated with a drug or firm website are often temporary and may not capture changes made to the website after the potential violation was observed. Your intent should be to capture labeling of potential misbranding/unapproved new drug adulteration violations. Once collected, that evidence, with your supervisor's approval, should be sent to compliance for evaluation.

(For more important information about how a drug is promoted, see section 21 CFR 201.128, which defines the intended use of the drug product.)

5.10.5 - Labeling

See section IOM 4.4.7 for the definition of product labeling and the method of collection.

Product labeling includes the product labels (the label on the immediate product container and packaging or outer box) that describes the intended use of a drug product and lists active and inactive ingredients and concentration of each active ingredient. The product label may also reference website(s) for additional information for the intended use (such as treatment of a medical condition). OTC drug manufacturers may also manufacture dietary supplements and cosmetics. Information on the product label differentiates whether a product is an OTC drug product, a dietary supplement, or a cosmetic product. (See 21 CFR 201.66 OTC Drug Labeling.)

During GMP inspections of OTC drug manufacturers, you should collect and review product labeling (product label and internet website) of each drug product to determine conformance with the OTC drug monographs found in 21 CFR 310.519 - 548 (negative monograph or new drugs) and 21 CFR 331 - 358 (final monograph) in order to consider whether any unapproved new drug and misbranding charges apply to the firm's OTC products. Please ensure that photocopies or photographs of all sides of the product label show legible texts. You should also document interstate shipment(s) of the distributed OTC product to support an unapproved new drug charge. (See CPGM 7361.003 OTC Drug Monograph Implementation for inspectional guidance.)

5.10.6 – Guaranties and Labeling Agreements

You should determine the firm's policies relative to receiving guaranties for raw materials and issuing guaranties on their products. Also determine firm's practices regarding shipment of unlabeled drugs under labeling agreements. (See IOM 5.6.10.2.)

5.10.7 - Other Inspectional Issues

5.10.7.1 - Intended Use

Please see the discussion of jurisdiction in section IOM 5.7.3.7.5.

5.10.7.2 - Drug Approval Status

You should ascertain whether the drugs manufactured by the firm are covered by an NDA, ANDA, NADA, ANADA, OTC monograph, or marketed under a claim of DESI or another exemption status.

5.10.7.3 - Drug Status Questions

If you have questions about misbranding, new drug status, API/finished drug product status, drug/cosmetic, or drug/food (dietary supplement) status, contact the Office of Unapproved Drugs and Labeling Compliance (OUDLC) in CDER's Office of Compliance at 301-796-3100 or CDEROUDLCPMTRACK@CDER.FDA.GOV.

If you have questions about the status of compounded human drugs products, contact the Office of Compounding Quality Compliance in CDER's Office of Compliance at 301-796-3100 or Compounding@fda.hhs.gov.

5.10.7.4 - Verification of Compliance with PDMA Requirements

You should ascertain whether a manufacturer uses samples of prescription drugs to market its products. If so, it must be in compliance with the regulations at 21 CFR 203 Subpart D – Samples. (Refer to CP program 7356.022, Enforcement of the Drug Sample Distribution Requirements of the Prescription Drug Marketing Act (PDMA).) If you have questions concerning this portion of an inspection, contact Office of Compliance at 301-796-3100 or DrugSupplyChainIntegrity@fda.hhs.gov.

5.10.7.5 - Drug/Dietary Supplement Status

In instances where the drug/dietary supplement status of a product is unclear, you should collect all related labeling and promotional materials, including pertinent websites. Such labeling, promotional materials, and websites are often useful in determining the intended use of a product, as they may, for example, contain or advertise disease claims, that can be used to determine the intended use of a product and, therefore, if it is a dietary supplement or a drug and an unapproved new drug. (See 21 CFR 201.128).

5.10.7.6 - Approved Drugs

Check the current programs in your CPGM, Section 505 of the FD&C Act [21 U.S.C. 355] and 21 CFR part 314 for required information. You may also ask your designated pre-approval manager for CMC information of the targeted drug application. Document and report all deviations from representations in the NDA or ANDA, even though they may appear to be minor. You can access applications through the Lorenz docuBridge application.

5.10.7.7 - Investigational Drugs

Follow the instructions in pertinent programs in your CPGM, or as indicated in the specific assignment received.

5.10.7.8 - Clinical Investigators and/or Clinical Pharmacologists

Inspections in this area will be on specific assignment previously cleared by the agency. Follow guidance in the CPGM or assignment.

5.10.7.9 - Delaying, Denying, Limiting or Refusing Drug Inspections

Use reasonable discretion when discerning whether action taken by a drug firm during an inspection constitutes delaying, denying, limiting, or refusing a drug inspection. If you are unsure whether an action taken by a firm constitutes delaying, denying, limiting, or refusing drug inspection, consult with your supervisor.

As needed, refer to the Guidance for Industry – Circumstances that Constitute Delaying, Denying, Limiting, or Refusing a Drug Inspection, for examples of firm actions that may cause a drug to be deemed adulterated under FD&C Act section 501(j). Remember, however, that these examples are not exhaustive, and that guidance documents do not establish legally enforceable rights or responsibilities and are not legally binding on the firm or the agency. (See IOM 2.2.3.2)

5.10.8 – Drug Inspection Reports

See IOM 1A.4 – English Language Requirement, the requirements in IOM 5.7.3.7 and any applicable CP, as well as New Inspection Protocol Project (NIPP), can be used to help you prepare your report.

Guidance here does not cover the reporting requirements for a directed inspection with a narrow focus, such as a complaint follow-up or investigation into a recall. In those cases, use your judgment and the guidance found in IOM 5.7.3.2 about the depth of reporting required. And follow the instructions and format for a human drug inspection report as contained in IOM 5.7.3.7.

The human drug inspection report does not require full and detailed narratives for every area for every inspection. The firm's state of compliance, the previous inspectional report and information, complexity of operations, type of inspection, and other aspects all are determinants in how much reporting will be necessary. In many cases, brief summaries addressing the format areas will be sufficient.

5.11 - Animal & Veterinary

5.11.1 - CVM Website

The Center for Veterinary Medicine (CVM) website contains a listing of current and planned Guidance Documents, on-line access to the Animal Drugs FDA Database listing new animal drug approvals, and a variety of current information regarding medicated and nonmedicated animal feed and pet food. It also hosts a "search" feature allowing you to search for documents containing various words or phrases. The website also contains organizational information for CVM and an explanation of the various laws and regulations that the Center enforces. Information on the website can provide guidance for inspectional efforts related to CVM obligations.

5.11.2 - Veterinary Drug Activities

CVM is responsible for work-planning inspections of therapeutic and production drugs, and Active Pharmaceutical Ingredients (APIs). Therapeutic drugs are used in the diagnosis, cure, mitigation, treatment, and/or prevention of disease. Production drugs are used for economic enhancement of animal productivity and include drugs that address such industry issues and objectives as, growth promotion, feed efficiency, and increased milk production.

Pre-approval inspections are conducted pursuant to pending NADA or ANADA applications. (CVM's Compliance Program 7368.001 addresses: New Animal Drug Applications (NADA), Abbreviated New Animal Drug Applications (ANADA) Investigational New Animal Drug (INAD) Applications, Generic Investigational New Animal Drug (JINAD) Applications and Conditional New Animal Drug Applications (CNADA).)

Post-approval inspections of veterinary drugs are conducted to determine compliance with the Current Good Manufacturing Practices (CGMPs) for Finished Pharmaceuticals under 21 CFR Part 211. These cGMPs apply to both human and veterinary drugs. Information on approved veterinary drugs can be found in the "Green Book" database accessed through CVM's website.

APIs are active pharmaceutical ingredients. Many of the APIs used to manufacture dosage-form drugs are imported from foreign countries. The intended source for an API must be indicated in NADA/ANADA submissions for new animal drug approvals. Any change in a source for an API would require a supplement to the application.

The goal of CVM's Compliance Program 7371.001 – Animal Drug Manufacturing Inspection is to minimize animals' exposure to adulterated drugs and human exposure to adulterated food resulting from animals treated with adulterated drugs. This includes APIs and finished-dose form (sterile and non-sterile) animal drugs.

The CGMPs for Type A Medicated articles are found under 21 CFR Part 226 and can also be found in the "Green Book." CVM's Compliance Program 7371.005 – Type A Medicated Articles provides guidance for implementing the strategies and explains risk-based inspectional requirements for Type A Medicated Article drug manufacturing.

Extra-label drug use refers to the regulations in 21 CFR Part 530 codified as a result of the Animal Medicinal Drug Use Clarification Act (AMDUCA) of 1994. These regulations set forth the requirements that veterinarians must meet to prescribe extra-label uses of FDA-approved animal and human drugs. The regulations also define what constitutes a valid veterinary-client-patient relationship, as well as what is considered illegal extra-label use. 21 CFR Part 530 addresses issues regarding extra-label use in non-food as well as food-producing animals. 21 CFR 530.41 contains a list of drugs that cannot be used in an extra-label manner in food-producing animals. During an inspection or investigation, if you encounter any situations relating to suspected illegal extra-label use of any FDA approved animal or human drugs, or those prohibited for extra label use in food animals, you should contact CVM's Division of Drug Compliance (HFV-210).

21 CFR Part 530 also addresses compounding of products from approved animal or human drugs by a pharmacist or veterinarian. The regulations clearly state compounding is not permitted from bulk drugs. This would include APIs. CVM has an existing GFI-256 which addresses Animal Drug Compounding. The Division of Drug Compliance (HFV-210) has issued assignments to conduct inspections of firms, including internet pharmacies, who may be engaged in the practice of manufacturing under the guise of pharmacy compounding.

ORA drug investigators should send their correspondence about general pharmacy compounding issues to oracompounding@fda.hhs.gov (ORA-Compounding) for proper response and routing. ORA-Compounding should contact the Division of Drug Compliance (HFV-210) at cvmcompounding@fda.hhs.gov to report instances of animal drug compounding, or to seek guidance on inspectional issues, or regulatory and enforcement policies relating to animal drug compounding.

5.11.3 - Animal Food Activities

Animal food is defined under Section 201(w) of the FD&C Act [21 U.S.C. 321 (w)] as "food for animals other than man intended for use as a substantial source of nutrients in the diets of the animal, this includes raw materials and ingredients used to manufacture animal food." As such, CVM is responsible for oversight of the following animal food programs:

- Medicated animal feed
- CGMP and Preventive Controls for animal foods
- Pet foods and treats
- Feeds containing Veterinary Feed Directive (VFD) drugs
- Prohibited Materials in Ruminant Animal Food (BSE)
- Sanitary Transportation Requirements (Directed Only)

The regulations for these programs can be found here:

CGMPs for medicated feed	21 CFR Part 225
CGMPs/PC for non-medicated feed and pet food	21 CFR Part 507
VFD Requirements	21 CFR Part 558.6

BSE Requirements	21 CFR Parts 589.2000 and 589.2001
Medicated Feed Mill Licensure	21 CFR Part 515
Sanitary Transportation	21 CFR Part 1, Subpart O

Your inspections of animal food facilities should include an evaluation of all activities performed at a facility such that you can determine compliance with all animal food regulatory requirements that may apply. CVM's Comprehensive Animal Food Inspection Compliance Program, 7371.000 lays the framework for conducting a comprehensive animal food inspection and provides additional guidance on topics that are ancillary to these inspections (including registration, feed mill licensing, VFD distributor notifications, etc.). The comprehensive inspectional approach serves two purposes: (1) to implement a systems-based approach to evaluate whether a facility is implementing practices necessary to meet all the animal food safety regulatory requirements that apply at their facility; and (2) to efficiently utilize inspectional resources.

Appropriate training must be obtained prior to conducting any animal food inspections.

If you have questions concerning any of the animal food programs, you should contact CVM/Division of Food Compliance at CVMAnimalFoodPrograms@fda.hhs.gov.

(The regulations for animal food labeling are found in 21 CFR Part 501. Guidance on pet food labeling requirements can be found on CVM's website www.fda.gov/animal-veterinary/animal-food-feeds/pet-food.)

5.11.4 - Biosecurity Procedures for Inspections at Poultry Facilities and Farms

Biosecurity continues to be a high priority when conducting animal food inspections. Given our experiences with pathogenic animal viruses, such as porcine epidemic diarrhea virus (PEDV) and highly pathogenic avian influenza (HPAI), we expect everyone conducting animal food inspections on FDA's behalf to observe simple, routine, biosecurity precautions for all routine animal food inspection work. In addition to FDA's biosecurity guidance and procedures, you should:

1. Follow the biosecurity plan for the facility being visited if it has one.
2. Plan your daily activities and movements so that you do not carry contamination from one location to another. As much as possible, plan to work from the cleanest to the dirtiest site on a given day, whether this is within a single facility, or across multiple facilities.
3. Wear clean shoes and clothes and use clean equipment.
4. Practice good personal hygiene, such as handwashing and bathing.
5. Change or clean your shoes between inspection sites if they get dirty or soiled or wear disposable shoe coverings.
6. Avoid making contact with animals during on-farm feed inspections, a practice generally not required in most situations anyway, unless it becomes necessary.
7. Be cognizant of any recent contact with livestock, poultry, or pet birds owned by you or others, including during activities/hobbies such as hunting.
8. As much as possible, avoid going from one farm to another on a single day. If you need to do so, consider changing clothes and/or shoes, and showering.
9. Make an appointment to conduct routine on-farm inspections.
10. Review and be familiar with all appropriate field alerts and field bulletins.

This information is summarized from Exhibit 5-19, - Biosecurity it is important that you follow biosecurity procedures – during the inspection planned for a given site, as well as for work that may be planned for several days following – and that you are prepared to practice these measures. Therefore, CVM suggests that all routine assigned work (covered in the work-plan or an assignment) involving on-farm animal food inspections be pre-announced. This gives the CSO the opportunity to ask about biosecurity procedures beforehand, including requesting and gaining assurance that someone will be present onsite so that the inspection can be conducted. Regarding for-cause

inspections/investigations, pre-announcement is not necessary, but it is essential that you be prepared to address any biosecurity needs and issues you may encounter.

5.11.5 - Drug Residues

The presence of violative drug residues in food from slaughtered animals is a human health concern. Drug residue inspections are performed in response to reports of violative drug residue levels found in tissue sampled at slaughter by the USDA's Food Safety Inspection Service (FSIS).

Drug residues are commonly caused by medicating animals prior to marketing and a failure to follow the drug's approved label directions. When a new animal drug is approved, the approval is very specific in how the drug should be used, the dosage it should be given, route of administration, frequency of use, and reason for use. A drug manufacturer conducts studies to determine withdrawal times, and these times must be followed. Established tolerances for drug residues of new animal drugs in food can be found in 21 CFR Part 556.

Drug residue investigations are unique in comparison to other fieldwork we conduct. Although your investigation may begin at the USDA slaughter establishment, or at a facility for a person named on the USDA/FSIS "Violation Notification Letter", you may inspect and/or visit additional sites as part of your overall investigation. For instance, you may also need to visit an auction barn, dealer, trucker, veterinarian, drug supplier, slaughter facility (USDA firm management or state personnel), etc., as one or more of these establishments may be responsible for the drug residue. As a result, each establishment's activities may warrant a recommendation for regulatory action, such as a Warning Letter, Injunction, etc., where involvement with residue violations is documented.

Upon receipt of a FACTS assignment from CVM to conduct a drug residue follow-up investigation, the program division may also create additional operations, linked to the original CVM assignment, to encompass all operations required to complete the CVM assignment. This could include multiple inspections, sample collections, and/or investigations. In fact, you may not be aware of all the establishments you will need to visit prior to beginning your investigation. This also means you will need to add, or delete, applicable operations to or from the program division assignment as you proceed with the investigation. Be mindful, too, that each site visit is unique, and produces its own set of unique documents and evidence requiring individual reporting by an establishment. Practice diligence and good judgment during case development to assure you document your investigation thoroughly. Explain the full chain of events and evidence, from the initial drug residue report to any other establishments, and how they were all involved. Collect DOC samples as appropriate (DOC samples are generally only required for violative cases where judicial action is being sought). Consult regularly with your supervisor and/or compliance branch during these operations to ensure all evidence needed to develop a quality case is obtained and submitted in an appropriate format.

Following completion of all operations, you should prepare a Memo of Investigation, referencing the FACTS assignments, for your supervisor's endorsement to the program division Compliance Branch, with a copy to the originating CVM office. This memo should summarize each site visit (EI or Investigation), sample(s) collected, and relevance to the overall CVM assignment. A copy of the memo will be routed to each appropriate factory file. The individual operations will then stand alone, and/or may be used together to build one or multiple cases. For example, a site visit to a slaughter facility may yield information about an animal according to USDA inspection personnel on site, as well as verification from management that the establishment ships in interstate commerce. Information obtained at the slaughter facility or other establishments may be documented in an affidavit from each individual providing salient information. A site visit to a veterinarian is required when the drug(s) causing the violative residue was/were prescribed by the veterinarian. When there is reason to believe extra-label use or other activities have occurred, which may warrant a recommendation for regulatory action, an establishment inspection should be conducted, and your evidence included with your report. (Refer to the Compliance Program 7371.006, "Illegal Residues in

Meat, Poultry, Seafood and other Animal Derived Foods" (https://www.fda.gov/media/74810/download) for in depth instructions on how to conduct a drug residue inspection.)

For more information on drug residue violations and activities, contact the CVM/Division of Food Compliance (HFV-236) CVMAnimalFoodPrograms@fda.hhs.gov.

5.11.6 - Veterinary Devices

Medical devices for animal/veterinary use are not subject to the premarket approval requirements like human medical devices. Once an animal use device is marketed the Center is concerned with safety and efficacy of the veterinary device. CVM often recommends firms use the human device GMPs in controlling the manufacturing of animal use devices. CVM also suggests labeling be sent in for review by the Division of Drug Compliance (HFV-210) (ASKOCS@fda.hhs.gov) to avoid misbranding. Regulatory questions for veterinary/animal use devices should be directed to the CVM/Division of Drug Compliance (HFV-210) (ASKOCS@fda.hhs.gov.)

5.11.7 - Animal Grooming Aids

Grooming aids for animals formulated and labeled only to cleanse or beautify the animal are not cosmetics within the meaning of Section 201(i) and not subject to the Federal Food, Drug, and Cosmetic Act. Where animal grooming aids are labeled to contain an active drug ingredient or otherwise suggest or imply therapeutic benefit, they may be considered to be drugs and/or new animal drugs as defined by Section 201(v) of the Act (see CPG 653.100).

Questions on labeling and regulatory concerns should be directed to the Division of Compliance (HFV-230) at 240-276-9200.

5.11.8 – Products Intended for Control of Fleas and Ticks

Products for animal use intended for control of fleas and ticks may be regulated as drugs by FDA under the Federal Food, Drug, and Cosmetic Act or pesticides by the Environmental Protection Agency (EPA) under the Federal Insecticide, Fungicide, and Rodenticide Act. Products registered with EPA as pesticides must have an EPA registration number listed on the label. Questions regarding whether a product intended for control of fleas and ticks is regulated by FDA or EPA should be directed to CVM, Division of Drug Compliance at CVMCompliance@fda.hhs.gov. Questions regarding EPA-registered pesticide products should be referred to EPA at pesticidequestions@epa.gov or Environmental Protection Agency, Office of Pesticide Programs, 1200 Pennsylvania Ave., Washington, DC 20460.

5.12 - Medical Device and Electronic Radiation Product Controls (EPRC)

5.12.1 - Medical Device Inspections

Medical device inspections will be conducted as assigned and in accordance with applicable Compliance Program(s), for instance, CP 7382.845 Inspection of Medical Device Manufacturers and 7383.001 Medical Device Premarket Approval and Postmarket Inspections. Types of inspections include routine assignments, such as Abbreviated or Baseline Quality Systems Inspections, and directed assignments, such as Compliance Follow-Up, For-Cause, Premarket Approval (PMA), and Post-Market inspections. Inspections may also be assigned as combinations of these different types.

If the inspection covers EPRC requirements, see also IOM 5.12.2. If the inspection is conducted for a combination product, see also IOM 5.16.

CAUTION: Investigators should be on the alert for, and avoid contact with, manufacturing materials and hazards associated with the manufacturing of many types of devices, which may present a threat to health, including ethylene oxide, high-voltage electricity, pathogenic biomaterials, etc. (See IOM Chapter S, including S.15.2- Radiation Hazards, S.12.6.3 - Ethylene Oxide (EtO), and S.15.1.3 - Energy Hazards.)



5.12.1.1 – Inspection Authority for Medical Devices

The term "device" is defined in Sec. 201(h) of the FD&C Act [21 U.S.C. 321 (h)]. In-vitro diagnostics (21 CFR 809) are also devices, as defined in 201(h) of the Act [21 U.S.C. 321 (h)], and may also be biological products, subject to Section 351 of the PHS Act.

The FDA has distinct authority under section 704(e) of the FD&C Act [21 U.S.C. 374 (e)] to inspect and copy records required under section 519 or 520(g) of the FD&C Act [21 U.S.C. 360i or 360j (g)]. Investigators should only collect copies of documents as necessary to support observations or to satisfy assignments. Note that manufacturers who have petitioned for and obtained exemption from the QSR are *not* exempted from FDA authority to review and copy complaints and records associated with investigation of device failures and complaints. (See IOM 2.2 for discussion of statutory authority to enter and inspect.)

Provisions in the FD&C Act pertaining to FDA review of records are:

1. For restricted devices, the FD&C Act in Section 704(a)(1)(B) [21 U.S.C. 374 (a)(1)(B)] extends inspection authority to records, files, papers, processes, controls, and facilities bearing on restricted medical devices. (See FD&C Act Sec. 704 [21 U.S.C. 374] for a full explanation and for a list of the items, for instance, financial data, which are exempt from disclosure to the FDA.) (Restricted devices, per CFR 807.3(i), are devices for which a requirement restricting sale, distribution, or use has been established by regulation, such as prescription devices.)
2. For all devices, including restricted devices, refer to Section 704(e) of the FD&C Act [21 U.S.C. 374 (e)], which provides for FDA's access to, copying, and verification of certain records.
3. Section 519 of the FD&C Act [21 U.S.C. 360i] requires manufacturers, importers, or distributors of devices intended for human use to maintain such records and provide information as the Secretary may by Regulation reasonably require.
4. Section 520(g) of the FD&C Act [21 U.S.C. 360j (g)] covers the establishment of exemptions for devices for investigational use and the records which must be maintained and open for inspection.

Records showing compliance with the QSR must be maintained by the firm for a period of time equivalent to the design and expected lifespan of the device, but not less than two years from the date the device is released for commercial distribution per 21 CFR 180(b).

5.12.1.2 - Medical Device Single Audit Program (MDSAP)

The FDA works with other global regulators within the International Medical Device Regulators Forum (IMDRF) for the purposes of leveraging work performed for other medical device regulators to meet FDA inspection obligations. The Medical Device Single Audit Program (MDSAP) allows an MDSAP-recognized Auditing Organization to conduct a single regulatory audit of a medical device manufacturer that satisfies the relative requirements of the regulatory authorities participating in the program. Currently, five countries participate in MDSAP: the United States, Australia, Brazil, Canada, and Japan.

The FDA uses MDSAP audit reports as a substitute for surveillance inspections for firms that volunteer to participate in the MDSAP program. MDSAP audit reports submitted by MDSAP Auditing Organizations, that include the United States as a jurisdiction, are reviewed and classified by the FDA.

Inspections that are conducted "For Cause" or "Compliance Follow-up" by the FDA will not be affected by this program. Moreover, this MDSAP program does not apply to any preapproval or post approval inspections for Premarket Approval (PMA) applications or to decisions under Section 513(f)(5) of the FD&C Act [21 U.S.C. 360c(f)(5)] concerning the classification of a device. Firms with activities related to the Electronic Product Radiation Control (EPRC) provisions of the Act continue to be subject to FDA inspections for the EPRC activities.

You should verify a firm's active status and participation in the Medical Device Single Audit Program (MDSAP) by accessing the MDSAP Master List before conducting any surveillance medical device inspections. You can do so by

searching the list for FEI, firm name, and address. Note that firm participation is based on facility/site, so a firm with multiple sites may or may not be participating in MDSAP for all sites. If additional verification or other information is required, contact the MDSAP program via MDSAP@fda.hhs.gov.

When planning an inspection at a firm participating in MDSAP, you should alert CDRH of the planned inspection by sending an e-mail to MDSAP@fda.hhs.gov *prior to scheduling* the inspection if possible, *but no later than five business days* before the scheduled inspection. The e-mail should include the name, address, and FEI of the firm, the type of inspection that will be performed, the estimated inspection dates, and any additional information pertinent to the situation, such as a request for the MDSAP report or a reference number for a Warning Letter, etc.

If the reason for an inspection at an MDSAP-participating firm is related to a specific assignment, generated by either ORA or CDRH, the ORA Division should email ORA's OMDRHO Operations at ORADeviceInspectionPOC@fda.hhs.gov *at least ten days prior* to initiating the inspection. The email should contain the name, address, and FEI of the firm, planned dates of inspection or investigation, nature of the complaint or quality issue, and any other relevant firm/device information or history, prior to ORA investigators conducting the inspection or investigation. In these situations, a teleconference between the CDRH MDSAP SMEs and ORA may be needed to discuss the scope of any planned inspection or investigation and allow additional information to be exchanged between CDRH and ORA.

5.12.1.3 - Pre-inspectional Activities for Medical Device Inspections

Refer to IOM Section 5.2 for general pre-inspection activities applicable to all inspection types.

5.12.1.3.1 - Assignment Information

The assignment details in eNSpect should be reviewed to determine the scope of the inspection and general information about the firm, Operation Type, PAC, Assigned and Target Date, Priority, and assignment. Foreign trip assignment information is communicated to the traveler via the Foreign Inspection, Planning and Scheduling System (FIPSS).

5.12.1.3.2 - Firm Information

You should review the history of the establishment prior to the start of a medical device inspection. You should also review the previous EIR, inspectional findings, and subsequent correspondence between the establishment and the FDA. Additionally, you should check for and review any consumer complaints where follow-up has not occurred, or recalls, since the last inspection.

You may obtain this information via Firm360, CMS, ORA's Online Search and Retrieval (OSAR), and the Online Reporting Analysis Decision Support System (ORADSS). Firm 360 provides a comprehensive history of the firm to include firm registration and listing, previous inspections with exhibits and attachments, ORA consumer complaints, recalls, compliance cases, and import alerts. ORADSS extracts data from various FDA systems, and in preparation of an inspection, can be used to query, run canned reports, and analyze retrieved data, such as import activities related to foreign and/or domestic firms.

5.12.1.3.3 - Medical Device Reports (MDRs)

As part of pre-inspectional preparation, you should review the firm's MDR data. MDRs can provide data to assist in determining potential problem areas in the manufacturing process, issues with the design of the device, specific lot/batch issues, and/or adverse events.

MDR information can be accessed through the Manufacturer and User Facility Device Experience (MAUDE) database or Total Product Lifecycle (TPLC). (Additional information about Medical Device Reporting requirements may be found in Compliance Program 7382.845, Inspection of Medical Device Manufacturers.)

5.12.1.3.4 - Registration & Listing

You should review the firm's Registration and Listing information through a resource such as the FDA Establishment Registration and Listing page, to identify the firm's establishment types, device listings, device product codes and regulation numbers, device classifications, Marketing Authorizations, and firm contact information.

5.12.1.3.5 - Marketing Authorizations

510(k) and PMA submission data can also assist you in determining what devices the establishment is manufacturing and whether any devices have been newly designed or changed since the last inspection. This data can also help you identify higher risk devices, for example, Class II or III versus Class I. One way to determine device submissions is to review registration and listing data. If needed, you may also request and obtain additional documents related to the submissions via CDRH.

5.12.1.3.6 – Unique Device Identification

You should review the firm's UDI records found through a resource such as Access GUDID or GUDID to confirm the firm has all devices with required UDI information in those databases.

5.12.1.4 - Pre-announcement of Medical Device Inspections

As a result of the FDA Reauthorization Act of 2017 (FDARA), the FDA published a guidance document outlining processes and standards for device establishment inspections, including a standardized process for pre-announcement. Certain types of medical device inspections are required to be pre-announced to the owner, operator, or agent-in-charge under this process, while the FDA retains its authority to continue to conduct unannounced for-cause inspections.

The purpose of pre-announcement is to notify the establishment's management of the date and time the investigator will be arriving at the establishment to conduct the inspection. For domestic inspections, preannouncement is *not* a request to schedule an inspection. See IOM section 5.12.1.4.2 for considerations if a firm requests a change in start date.

5.12.1.4.1 - Criteria for Consideration

You will need to determine whether an establishment requires pre-announcement prior to inspection. Inspections where pre-announcement is appropriate include:

- Quality System Inspection Technique (QSIT) based surveillance inspections
- Pre-market and post-market inspections (PMA, 510(k))
- Foreign inspections
- When instructed, by directive, procedure, compliance program, or assignment
- Where logistical concerns indicate preannouncement would be beneficial to the inspection, with supervisory concurrence.

5.12.1.4.2 - Procedures

1. Pre-announcement of domestic firms should be no less than five calendar days in advance of the inspection; pre-announcement of foreign firms is generally more than five calendar days due to the requirements for country clearances.
2. For domestic inspections, the investigator designated to conduct the inspection will contact the owner, operator, or agent-in-charge at the facility by phone to pre-announce. Should that person be unavailable at the time the call is made, a message requesting a return call should be left. The program division should use good judgment as to what is a reasonable time frame to await the return call. If after several attempts, acknowledgement of pre-announcement by the owner, operator, or agent-in-charge cannot be obtained, the inspection may proceed as planned.

3. During pre-announcement planning, you should inform the establishment as to the start date, the type/nature of the inspection, estimated duration (to include working hours during which the inspection is likely to take place), and the number of agency personnel expected to take part in the inspection. To the extent possible, you should also provide advance notice of some records that may be requested during the inspection (for instance, certain procedures and any associated records).
4. Changes in dates should be kept to a minimum. Should a postponement be necessary, the decision as to rescheduling rests with the investigator/team, but the new inspection date should not be later than five calendar days from the original date. If an establishment requests a change in start date, it must also provide a valid reason for the request. A valid reason should be the same as an investigator would accept if presented with the information during an unannounced inspection.
5. Include in the EIR whether the inspection was pre-announced, and if not pre-announced, describe briefly in the EIR why not.

5.12.1.5 - Conducting Medical Device Inspections

Medical Device inspections should be conducted in accordance with assignment instructions, Compliance Program Guidance, and Program Inspection Guidelines/Techniques. Specifically, you should be attentive to:

1. Specific instructions in the assignment, if any.
2. The applicable Compliance Program, such as CP 7382.845 Inspection of Medical Device Manufacturers.
3. The Quality System Inspection Technique (QSIT), which provides a roadmap for review of the firm's Quality System by subsystems and satellites.
4. Guidance documents specific to the firm's operation type(s) and product(s) being reviewed.
5. Guidance from your supervisor.

Brief information is provided in sections 5.12.1.5.1 to 5.12.1.5.4 on regulations commonly reviewed during Medical Device Quality System inspections; however, this list is not exhaustive. Refer to the applicable compliance program(s) for further background and instructions on coverage.

5.12.1.5.1 - Quality System Regulation (QSR)

The regulation promulgated under 21 CFR 820 establishes minimum requirements applicable to finished devices, as defined in 820.1(a). This regulation does not generally apply to manufacturers of components or parts of finished devices. In some special cases, such as components that have been classified as finished devices (for instance, dental resins, dental alloys), components may be subject to the QSR. Consult with your supervisor if you should have any questions about applicability of this regulation.

The preamble to the final rule for the QSR includes FDA's response to the public comments that were received and explains the agency's thinking on application of the regulation. See preamble and QSR.

The medical device QSR does not prescribe in detail how a firm must manufacture a particular device. The regulation provides a framework, with which all manufacturers must comply, to develop and follow procedures that are appropriate to the manufacture of a given device. Use your good judgment in determining compliance with the QSR, keeping in mind that all requirements may not apply or be necessary. You should also not insist that a manufacturer meet non-applicable requirements. (Refer to IOM Exhibit 5-13 for types of establishments that are required to comply with the QSR.)

5.12.1.5.2 - Medical Device Reporting (MDR)

The first Medical Device Reporting (MDR) regulation was published on December 13, 1984. Undergoing several changes over time, the latest version of MDR regulation under 21 CFR 803 includes reporting requirements for manufacturers, user facilities, and importers. This regulation generally requires manufacturers of medical devices, including in vitro diagnostic devices, to report to the FDA whenever the manufacturer or importer receives, or otherwise becomes aware of, information that reasonably suggests that one of its marketed devices: (1) may have caused or contributed to a death or serious injury or, (2) has malfunctioned and the

device, or any other device marketed by the manufacturer or importer, would be likely to cause or contribute to a death or serious injury if the malfunction were to recur.

Guidance on the application of this regulation may be found in the guidance document Medical Device Reporting for Manufacturers published in November 2016, and in Compliance Program 7382.845 Inspection of Medical Device Manufacturers.

5.12.1.5.3 - Recalls, Corrections and Removals

The Corrections and Removal regulation, 21 CFR Part 806, took effect on May 18, 1998. The regulation generally requires that device manufacturers and importers promptly report to the FDA any correction or removal of a device undertaken to: (1) reduce a risk to health posed by the device; or (2) remedy a violation of the act caused by a device which may present a risk to health. Device manufacturers and importers are also required to keep records of all corrections and removals they make, including those not required to be reported to the FDA.

Medical device recalls are usually conducted voluntarily by the manufacturer under 21 CFR 7. In rare instances, where the manufacturer or importer fails to voluntarily recall a device that is a risk to health, the FDA may issue a recall order to the manufacturer under 21 CFR 810, Medical Device Recall Authority.

Guidance on the application of this regulation may be found via the Recalls, Corrections and Removals (Device) page on FDA.gov, and in Compliance Program 7382.845 Inspection of Medical Device Manufacturers.

5.12.1.5.4 - Unique Device Identification (UDI)

The FDA established the Unique Device Identification (UDI) system to adequately identify medical devices sold in the United States, from manufacturing through distribution, under regulations promulgated in 21 CFR 801 (Subpart B) and 21 CFR 830. Device labelers (typically, manufacturers) are generally required to: 1) include a UDI, issued under an FDA-accredited issuing agency's UDI system, on device labels, device packages, and in some cases, directly on the device; and 2) submit device information to the Global Unique Device Identification Database (GUDID).

Guidance on the application of this regulation may be obtained from The Unique Device Identifier System: Frequently Asked Questions, Vol. 1, and in Compliance Program 7382.845 Inspection of Medical Device Manufacturers.

5.12.1.5.5 - Policy on Record Review

Per the Quality System Inspection Technique (QSIT) Guide and CP 7151.02 (CPG Manual Subchapter 130.00), FDA personnel are prohibited access to a firm's audit results. Under the Quality System Regulations (QSR), this prohibition extends to review of supplier audit reports and management reviews. Accordingly, investigators' reviews of these aspects of the firm's Quality System should be limited to review of procedures and documents which show conformance with 21 CFR 820.50 (purchasing controls), 21 CFR 820.20(3)(c) (management reviews), and 21 CFR 820.22 (quality audits). Investigators, with CDRH concurrence, may seek written certification from firm management that such audits and inspections have been implemented, performed, and documented, and that any required corrective action(s) have been taken.

Note that corrective and preventive actions and related documentation are not excepted from inspectional review. Per the preamble to the QSR, comment 160, "FDA will review the corrective and preventive action procedures and activities performed in conformance with those procedures without reviewing the internal audit reports."

(For additional information on this topic including exceptions to these prohibitions, see CPG 7151.02 (CPG Manual Subchapter 130.300).)

5.12.1.5.6 - Considerations for Establishment Types

When preparing for, or during the conduct of, an establishment inspection, you may have questions as to the appropriate areas for inspectional coverage based on the types of operations being conducted at the facility. In these instances, refer to IOM Exhibit 5-13 SUBSTANTIALLY EQUIVALENT MEDICAL DEVICES for guidance. The table includes a list of medical device operation types and indicates whether each operation type is subject to compliance with the Quality System Regulation (QSR). Where not all QSRs are applicable to a particular operation type, the table identifies those regulations that should be considered for coverage.

Special Considerations for Specific Operation Types

1. Contract manufacturers. These manufacturers do not meet the definition of a finished device manufacturer per 21 CFR820.3(l), (for example, component manufacturers or subassemblers) and distribute only to the finished device manufacturer. Assignments to conduct inspections of this facility type are not typical but may be requested by CDRH as part of a premarket approval (PMA) inspection assignment. In such cases, FDA-483 observations are not issued for identified deficiencies, and instead, the finished device manufacturer is responsible for ensuring components are manufactured under QSRs. The QSR includes Purchasing Controls, 21 CFR 820.50; Receiving, In-process and Finished Device Acceptance, 21 CFR 820.80; and Traceability, 21 CFR 820.65, that requires finished device manufacturers to exercise control over the components they use in their devices. The preamble of the QSR states: "Since FDA is not regulating component suppliers, FDA believes that the explicit addition to the CGMP requirements of the purchasing controls...is necessary to provide the additional assurance that only acceptable components are used." And "...inspections and tests, and other verification tools, are also an important part of ensuring that components and finished devices conform to approved specifications." It further states: "...traceability of components must be maintained so potential and actual problem components can be traced back to the supplier."
2. Initial importers/distributors (except where distribution is retail only). Per IOM Exhibit 5-13, facilities conducting this operation type are required to comply with certain QSRs (for example, 807.3(d), 820.198, 820.100 and 820.200, etc.). If on initiation of the inspection, firm management states that they do not have primary responsibility for complaint-handling and medical device-reporting activities, you should verify that the firm has a Quality Agreement in effect (signed and dated by both parties) delineating each parties' responsibilities, including record-keeping and record accessibility requirements.

5.12.1.5.7 – Annotations for Form FDA 483

At the close of the inspection, you should meet with the most responsible person and discuss the observations made during the inspection, if any. For all medical device inspections, whenever reportable observations are issued on a Form FDA 483, Inspectional Observations, the firm must be offered the opportunity to annotate those observations. Annotations are succinct comments about the status of the Form FDA 483 item and include the following selections:

- Reported corrected, but not verified
- Corrected and verified
- Promised to correct
- Promised to correct by [insert date]
- Promised to correct within [time interval; the number of days, weeks, or months]
- Under consideration
- Annotation Intentionally Left Blank

The term "verified" means "to confirm; to establish the truth or accuracy." In this case, the investigator is the one who must do the verification. In some situations, corrective actions cannot be verified unless there is

further program division or Center review, or until there is another inspection of the establishment. All corrective actions taken by the establishment and verified by FDA should be discussed in detail in the EIR.

When performing the annotation process, you should ensure that…:

- the firm understands and is offered the opportunity to annotate any Form FDA 483 observations during the final discussion with management.
- the firm understands the annotation process is voluntary.
- the firm is aware that it can annotate each observation differently and is not required to annotate all observations (see below for more information).

When the firm does not wish to annotate the Form FDA 483, the option “no annotation” is selected in eNSpect; if issued outside eNSpect, annotation is not performed. The establishment's stated objections to any given observation, or to the Form FDA 483 as a whole, should not be annotated on the Form FDA 483. Instead, the EIR should reflect the establishment's objections to the observation and the fact that it declined to have the observation annotated.

When an establishment has promised corrections and furnishes a date or timeframe, you should enter the appropriate information after the applicable selection (date or time interval) in the annotation. In instances when you and the establishment disagree about the validity of an observation on the Form FDA, and the establishment is not promising actions to correct the observation, the observation may be annotated as "Under consideration" or with no annotation (Annotation Intentionally Left Blank) based on the establishment's request.

Whether the Form FDA 483 is issued hardcopy or electronically (see IOM 5.5.11.4), you should ensure that the individual to whom the form is addressed receives a copy with all annotations.

5.12.1.5.8 - Form FDA 483 Response Instructions

For inspections in which a Form FDA 483 is issued, you should provide instructions to the firm regarding their options for submitting a voluntary written response through use of one of the following handouts:

- FORM-000299 Inspectional Handout OMDRHO Div 1
- FORM-000300 Inspectional Handout OMDRHO Div 2
- FORM-000302 OMDRHO Div III Inspectional Handout
- FORM-001247 OMDRHO FDA 483 Responses to Foreign Inspections Handout
- FORM-001676 OMDRHO Mandarin Translation FDA 483 Response for Foreign Inspections

5.12.1.6 - Banned Devices

Section 516 of the FD&C Act [21 U.S.C. 360f] provides authority for banning by regulation a device for human use (21 CFR 895) if it presents substantial deception or an unreasonable and substantial risk of illness or injury. You should become familiar with this regulation. If during an inspection or investigation you discover that banned devices are being distributed, you should document their distribution, manufacture, etc., as you would any other violative product and refer them for potential regulatory action(s).

5.12.2 - Electronic Product Radiation Controls (EPRC) Inspections

The Radiation Control provisions of the FD&C Act are located in sections 531 through 542 (see IOM 2.2.3). These authorities apply to any manufactured or assembled product--or component, part, or accessory of such product--which when in operation (i) contains or acts as part of an electronic circuit and (ii) emits (or in the absence of effective shielding or other controls would emit) electronic product radiation. Regulations promulgated to implement the requirements in this portion of the act are contained in 21 CFR 1000 through 1050. These sections of the Act and regulation are referred to as the Electronic Product Radiation Control (EPRC) provisions, and the products subject to these requirements as EPRC products.

All EPRC manufacturers must comply with applicable requirements in 21 CFR 1000, 1002, 1003, 1004 and 1005. If a mandatory radiation safety performance standard applies to a manufacturer's product, then the manufacturer must also comply with 21 CFR 1010, and the product must comply with the requirements of the specific standard found in 21 CFR 1020 – 1050.

EPRC products may be either medical (that is, they also meet the definition of a medical device under the Act) or non-medical. Examples of each:

- Medical: diagnostic x-ray or ultrasound imaging devices, microwave or ultrasound diathermy devices, laser coagulators, x-ray or electron accelerators, sunlamps, ultraviolet dental curing devices
- Non-medical: microwave ovens, televisions receivers and monitors (video displays), entertainment lasers, industrial x-ray systems, laser CD players

5.12.2.1 - Inspection Authority for EPRC products

See IOM Section 5.1.4.3.2 for specific information on the authority to inspect facilities subject to ERPC requirements. As EPRC inspections have authorities separate from section 704 of the FD&C Act, should you encounter a refusal to permit the planned inspection, discuss with your supervisor how best to proceed, depending on the type of assignment and the firm's operations.

Records required by the Radiation Control provisions of the Act must be maintained for five years. 21 CFR 1002(b) requires that upon reasonable notice, manufacturers shall permit inspection of any books, records, papers, and documents relevant to determining whether the manufacturer has acted, or is acting, in compliance with federal standards. Firms may retain records in electronic or photocopy form, provided the copies are true and accurate reproductions.

5.12.2.2 - Pre-inspectional Activities for EPRC Inspections

Prior to inspecting a facility manufacturing an EPRC product, it is important for you to determine whether the firm also manufactures medical devices, or if the product of interest also appears to be a medical device (for example, a medical x-ray, fluoroscopy, or medical laser). If the firm manufactures medical devices, or the product of interest is also a medical device, it is recommended that a joint EPRC/Medical Device inspection be planned. If Medical Device coverage is anticipated during the inspection, see additionally the pre-inspectional activities outlined within IOM 5.12.1. Guidance for preparing for EPRC inspections is provided based on the product type in the Compliance Programs listed in IOM 5.12.2.3.

Certain required submissions by these firms, such as Annual Reports and Accidental Radiation Occurrences, may also be obtained from queries in the Center Tracking System (CTS).

EPRC inspections, whether or not in conjunction with a medical device inspection, should only be conducted by individuals with appropriate training and experience. Those not trained to conduct EPRC inspections may participate as part of a team with an EPRC-trained investigator. Notify your supervisor prior to pre-announcement if, during preparations, you have questions regarding the training required to complete the operation.

Radiation-emitting devices and substances present a unique hazard and risk potential. Every effort should be taken to prevent any undue exposure or contamination. You should use monitoring devices whenever radiation exposure is possible; for these types of inspections, that may mean bringing along and using more than one dosimeter. To be added to the dosimetry program and obtain appropriate monitoring equipment in advance of an inspection, contact the ORA Dosimetry Program.

If the inspection will be covering medical device requirements, pre-announcement may be required, depending on the nature of the assignment (see IOM 5.12.1.4 to clarify which inspections require pre-announcement). Note that if only EPRC coverage is planned, pre-announcement is not required, but is generally recommended. Such pre-announcement may help facilitate the inspection, ensuring you have access to necessary personnel and records, as

well as knowledge, beforehand, of any relevant safety protocols for preventing unintended exposure during the operation. Consult your supervisor if you believe pre-announcement is not warranted for an EPRC inspection.

5.12.2.3 - Inspection of EPRC Facilities

Inspections of facilities manufacturing EPRC products may vary depending on the product type and the nature of the assignment. Guidance for coverage of these operations is provided in these CPGM, accordingly:

Laser Products (Medical and Non-Medical) – 7386.001 Inspection and Field Testing of Radiation-Emitting Electronic Products

Sunlamps – 7386.001 Inspection and Field Testing of Radiation-Emitting Electronic Products

Medical X-Ray Products – 7386.003a Inspection of Domestic and Foreign Manufacturers of Diagnostic X-ray Equipment

Non-Medical X-Ray Products - 7386.001 Inspection and Field Testing of Radiation-Emitting Electronic Products

If during the inspection of a medical device manufacturer, you determine that one or more of their devices emits radiation and is subject to EPRC, consult with your supervisor on whether expansion of the inspection, to include coverage of those requirements, is appropriate.

Significant issues developed during coverage of EPRC requirements should be documented on the Form FDA 483, Inspectional Observations. If both EPRC and medical device observations are being issued on a Form FDA 483, Inspectional Observations, they should be grouped separately on the form using text subheadings.

5.12.3 - Technical Assistance

Each program division has engineers and radiological health personnel available for technical assistance and consultation. Do not hesitate to contact them for further assistance. A list of contacts relevant to types of inspections are located in the associated Compliance Programs.

5.12.4 - Sample Collection During Inspection

Due to the relatively high cost of device samples, you should consider, in consultation with your supervisor, the following factors before collecting a physical sample of a device:

1. Whether or not the sampling, as part of a follow-up to a Quality System observation, demonstrates the issue and/or a defective product. Documentary Samples may be more suitable for Quality System Inspection purposes.
2. The likelihood of the analysis showing the device is unfit for its intended use.
3. The possibility for physical or biological hazards to be present in the collected devices (for instance, returned devices from a patient that may be a biohazard).

Collect the firm's test methods and document the standards used by the firm for any analysis that the FDA will attempt to duplicate.

(Refer to CPGM 7382.845, Inspection of Medical Device Manufacturers, and IOM Chapter 4 for guidance regarding device sample collections.)

5.13 - Biologics

5.13.1 - Definition

A "biological product" means a virus, therapeutic serum, toxin, antitoxin, vaccine, blood, blood component or derivative, allergenic product, protein (except any chemically synthesized polypeptide) or analogous product, or arsphenamine or derivative of arsphenamine (or any other trivalent organic arsenic compound), applicable to the

prevention, treatment, or cure of a disease or condition of human beings (Public Health Service Act Sec. 351(i)). Additional interpretation of the statutory language is found in 21 CFR 600.3. Biological products also meet the definition of either a drug or device under Sections 201(g) and (h) of the FD&C Act.

Additionally, veterinary biological products are subject to the Virus-Serum-Toxin Act, which is enforced by the USDA (21 U.S.C. 151-158).

5.13.2 - Biologics Inspections

The periodic CGMP inspections of licensed biological drug products, that include plasma fractionated products, allergenic products, vaccines, and gene and cell therapy products are led by investigators from ORA's Office of Biological Products Operations, Biological Products Inspection Staff (OBPO/BPIS). OBPO Investigation Branch investigators lead inspections of blood and blood components, human cells, tissues, and cellular and tissue-based products (HCT/Ps), source plasma, licensed in-vitro diagnostic devices for donor screening, 510k/PMA, CBER-regulated medical devices (for example, blood establishment software, and NDA/ANDA drug products regulated by CBER.) See IOM 2.2 for a discussion of statutory authority. Generally, CBER maintains the lead for pre-licensing and most pre-approval inspections of biological products, while ORA customarily leads PMA/510(k) and NDA/ANDA inspections.

5.13.2.1 - Authority

Biological products are regulated under the authority of Section 351 of the Public Health Service Act and under the FD&C Act, as drugs or devices, with the exception of certain human cells, tissues, and cellular and tissue-based products (HCT/Ps) regulated solely under Section 361 of the Public Health Service Act (see 21 CFR 1271.10). Blood and blood products for transfusion are prescription drugs under the FD&C Act. Under the Act, source plasma and recovered plasma may have the legal identity of either a drug or device depending on their intended use. Section 351(a) of the PHS Act provides for licensure of biological products and inspection of the products covered in 351(d). Most biological drugs are licensed. The investigational new drug application regulations (21 CFR 312) also apply to biological products subject to the licensing provisions of the PHS Act. However, blood grouping serum, reagent red blood cells, and anti-human globulin in-vitro diagnostic products may be exempted (21 CFR 312.2(b)).

5.13.2.1.1 - Blood and Source Plasma Inspections

For blood bank and source plasma establishment inspections (CP 7342.001 & 7342.002), use the CGMPs for Blood and Blood Components (21 CFR 606), as well as the general requirements for biological products (21 CFR Part 600), the general biological product standards (21 CFR Part 610), and the additional standards for human blood and blood products (21 CFR Part 640.) This would generally be Parts 606 and 640 of the regulations in the case of blood bank and source plasma establishments. The drug GMPs (21 CFR 210/211) also apply to biological drugs. In the event it is impossible to comply with both sets of regulations, the regulation specifically applicable to the product applies.

5.13.2.1.2 - Human Tissue Inspections

21 CFR Part 1271 contains six subparts and associated topics:

1. Subpart A of part 1271 – general provisions
2. Subpart B of part 1271 – registration
3. Subpart C of part 1271 - screening and testing of donors to determine eligibility
4. Subpart D of part 1271 - provisions on CGTP
5. Subpart E of part 1271 - certain labeling and reporting requirements
6. Subpart F of part 1271 - inspection and enforcement provisions

The subparts apply as follows:

Subparts A through D apply to all HCT/Ps, described in Sec. 1271.10 and regulated solely under section 361 of the PHS Act, and to those regulated as drugs, devices, and/or biological products. Subparts E and F, which pertain to labeling, reporting, inspection, and enforcement, apply only to those HCT/Ps described in Sec.

1271.10 and regulated solely under section 361 of the PHS Act. However, subpart D, with the exception of two provisions (Sec. 1271.150(c) and 1271.155), and subpart E are not being implemented for reproductive HCT/Ps described in 21 CFR 1271.10 and regulated solely under section 361 of the PHS Act.

HCT/Ps subject to the provisions of 21 CFR Part 1271 include, but are not limited to, bone, ligaments, skin, dura mater, heart valve, cornea, hematopoietic stem/progenitor cells derived from peripheral and cord blood, manipulated autologous chondrocytes, epithelial cells on a synthetic matrix, and semen or other reproductive tissue.

For HCT/P inspections, use the CP 7341.002, "Inspections of Human Cells, Tissues, and Cellular and Tissue-Based Products."

If the HCT/P does not meet the criteria set out in 21 CFR 1271.10(a), and the establishment that manufactures the HCT/P does not qualify for any exceptions in 21 CFR 1271.15, the HCT/P will be regulated as a drug, device, and/or biological product under the FD&C Act, and/or section 351 of the PHS Act and applicable regulations, including 21 CFR 1271. A premarket review, biologics license application (BLA) or an NDA/ANDA will be required.

5.13.2.2 - Donor Confidentiality

Blood bank, source plasma, and human tissue establishments are typically sensitive about maintaining confidentiality of donor names, though the mere reluctance to provide records is not considered a refusal. The FDA, however, has the authority, under both the PHS and the FD&C Acts, to make inspections, with 21 CFR 600.22(g) and 1271.400(d) providing for copying records during an establishment inspection. For prescription drugs, section 704 of the FD&C Act specifically identifies records, files, papers, processes, controls, and facilities as being subject to inspection.

If you encounter problems accessing records, explain FDA's authority to copy these records. IOM 5.5.2 should be followed if a refusal is encountered. When donor names or other identifiers are necessary, they may be copied, but the information must be protected from inappropriate release. (See IOM 5.6.11.4.)

5.13.2.3 - Inspectional Objectives

The inspectional objective for biological products is to assure the products are safe, effective, and contain the quality and purity they purport to possess and are properly labeled (see IOM 5.13.1). The inspectional objective for HCT/Ps regulated solely under 361 of the PHS Act is to assure that HCT/Ps are recovered, processed, stored, labeled, packaged, and distributed, and the donors are screened and tested, in a way that prevents the introduction, transmission, or spread of communicable diseases.

Facilities will be inspected for their conformance with the following:

1. Provisions of the PHS Act and/or FD&C Act
2. Applicable regulations in:
   - 21 CFR 210-211
   - 21 CFR 600-680, and
   - 21 CFR 820
3. HCT/P regulations in 1271.
4. FDA policies, which include guidance to the industry, and the Compliance Policy Guides Chapter 2.

5.13.2.4 - Preparation

As part of your preparation, review the program division files and OSAR of the facility to be inspected, and familiarize yourself with its operation and compliance history. You should also review:

1. Appropriate Compliance Programs and related Compliance Policy Guides (CPG), Chapter 2.
   NOTE: Federal Cooperative Agreements Manual; MOU with the Department of Defense, and MOU with the Centers for Medicare and Medicaid Services (CMS) on transfusion services
2. Correspondence from the firm depicting any changes since the last inspection
3. Firm's registration and product listing information
4. Biological Product Deviation Reports, Adverse Reaction Reports, complaints, recalls, and ECMS, as applicable
5. Consumer Complaints

5.13.2.5 - Inspectional Approach

Consult the Compliance Program (CP) for inspectional instructions and applicable regulations. Give special attention to biological products deviation reports indicative of problematic areas or processes, adverse reactions, transfusion- or donation-associated fatalities, and hepatitis and HIV "lookback" procedures. The follow-up investigations to such reports should also be covered.

- For blood banks and source plasma establishments, refer to CP 7342.001 and 7342.002.
- For HCT/P establishments, refer to CP 7341.002.
- For Biological Drug Products, refer to CP 7345.848.
- For Licensed In-vitro Diagnostic Devices Regulated by CBER, refer to CP 7342.008.
- For 510k/PMA devices regulated by CBER, refer to CP 7382.845 (PACs 42845A, 42845B, 42845C)
- For NDA/ANDA drug products regulated by CBER, refer to CP 7356.002A (PACs

At each inspection, you should provide the current FDA contact information found in the OBPO Domestic or Foreign Inspection Handouts, which includes the post-inspectional correspondence e-mail ORABIOInspectionalCorrespondence@fda.hhs.gov.

QMiS links to the OBPO Domestic and Foreign Inspection Handouts:

- Domestic Inspectional Handout (FORM-000467)
- Foreign Inspectional Handout (FORM-000468)

5.13.2.5.1 - Access of Electronic Databases and Queries

Providing oversight of firm personnel while they access their system for data/records you are requesting is not always practical. For this reason, if *all* the following criteria are met, OBPO investigators are permitted, when necessary, to access a firm's records using a read-only account, dummy terminal, or comparable mechanism:

- Responsible management at the firm is agreeable to allowing read-only access to electronic systems and/or databases;
- Access to electronic systems/databases is read- only and will not permit you to change or alter data or programming in any manner;
- The firm has a representative that will be available to initially describe and review the layout of their records, and make themselves available throughout the inspection as additional information or copies of records are needed; AND
- You document this read-only access in your regulatory notes, EIR, or investigational memorandum, accordingly.

5.13.2.6 - Regulations, Guidelines, Recommendations

Guidance documents for industry are made available to the public in accordance with good guidance practice regulations found at 21 CFR 10.115. The contents of most of these documents are incorporated into the establishment's SOPs and/or license applications or supplements.

Deviations from guidance documents must not be referenced on an FDA 483. However, since these documents are often related to specific GMP requirements, in most cases, deviations can be referenced back to the corresponding GMP. If a deviation is observed during an inspection and the investigator relates it to the regulations or law, then

the item may be reported on the FDA 483. In addition, during the discussion with management, the relationship of the deviation to the regulation or law, should be clearly explained.

If an establishment indicates it is not aware of any of these documents, provide them the guidance document(s) or direct them where to find these documents on www.fda.gov. Provide the firm with this email address to obtain additional information from CBER at industry.biologics@fda.hhs.gov.

If a firm claims approval for an alternative procedure, verify this by reviewing the firm's written approval letter. Approved alternative procedures may also be verified by contacting CBER/Division of Blood Applications, or the appropriate CBER product office.

5.13.2.7 - Technical Assistance

National Experts and Program Experts in ORA/OMPTO/OBPO are available to assist you, by telephone and/or on-site consultation, with regards to challenges and problem areas you may encounter.

5.13.2.8 - Biologics Establishment Inspection Reports

(See IOM 1A.1.4.1) You should write your EIR following the guidance found in IOM 5.7.3.2, 5.7.3.3, 5.7.3.4, and 5.7.3.5. Section headings can be added to address the needs of a specific Compliance Program referenced in conducting the inspection. Where applicable, and per the CP, the report should state the levels of the inspection and systems that were covered. The reasoning for the level and systems covered should also be reported, as directed in the CPs. The report should also include a summary, the FDA 482, the FDA 483 (if issued), and the required eNSpect record in OSAR.

The scope of the reporting should reflect requirements and regulations for each area, the firm's state of compliance, previous inspectional report(s) and information, complexity of operations, and other aspects that may affect the reporting that will be necessary.

For directed inspections with a narrow focus, include information to appropriately cover the assignment. Follow specific assignment instructions included in any associated assignment memorandum or included in the eNSpect assignment details (Program Directives and Background).

5.13.3 - Registration, Listing and Licensing

5.13.3.1 - Registration and Listing

See IOM 2.10.6.1 for registration and listing requirements for Human Blood and Blood Products and for Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/PS).

Facilities manufacturing biological drug products regulated by CBER must register as a human drug facility, see IOM 2.10.2.1.

Facilities manufacturing medical devices regulated by CBER must register as a device establishment, see IOM 2.10.4.1.

5.13.3.1.1 – Transfusion Services

Transfusion services may be exempt from registration under 21 CFR 607, except for firms that conduct operations as described in section Part II, C. 7. of the CP. This includes facilities that are certified under the Clinical Laboratory Improvement Amendments of 1988 (42 U.S.C. 263a) and 42 CFR Part 493 to perform the FDA-required tests on blood or has met equivalent requirements as determined by the Centers for Medicare and Medicaid Services and are engaged in the compatibility testing and transfusion of blood and blood components, but which neither routinely collect nor process blood and blood components.

Note that all VA Blood Banks and Hospital Transfusion Services must register with FDA since they are not inspected by CMS.

5.13.3.1.2 - HCT/Ps

Establishments manufacturing HCT/Ps (human cells, tissues, or cellular or tissue-based products) as defined in 21 CFR 1271.3(d) must register and list using form FDA 3356. Examples of HCT/Ps include, but are not limited to, bone, ligament, skin, cornea, hematopoietic stem cells derived from peripheral and cord blood, manipulated autologous chondrocytes, and semen or other reproductive tissue.

Establishments that only manufacture investigational HCT/Ps under an IND or IDE are not required to register and list until the HCT/P has been licensed, approved, or cleared by the FDA. Establishments manufacturing HCT/Ps regulated as drugs and/or biological products must register and list with the FDA pursuant to 21 CFR 207. Establishments manufacturing HCT/Ps regulated as medical devices must register and list with the FDA pursuant to 21 CFR 807.

5.13.3.1.3 - Military Blood Banks

Inspection of military blood banks is an ORA responsibility. These facilities are required to meet the same standards as other blood banks, although military emergencies may require deviations from the standards. A separate license is held by each branch of the service; and while each individual establishment may be licensed or unlicensed, all are required to register. Program divisions should notify the appropriate military liaison(s) 30 days before inspection of a military facility.

For additional information on inspection of government establishments, see Compliance Program Guidance Manual 7342.001, the Federal Cooperative Agreements Manual, and the MOU with Department of Defense Regarding Licensure of Military Blood Banks.

Special notes: Foreign notification of Military Blood Banks is done by the Trip Planner in preparation of the international trip. Field Management Directive 92, Agency Establishment Registration and Control Procedures, details the registration process within the agency. It's best practice to ensure that the firm's current registration forms reflect actual operations.

5.13.3.2 - MOUs

Under the 1983 Memorandum of Understanding (MOU) between the FDA and the Centers for Medicare and Medicaid Services (CMS, formerly Health Care Financing Administration - HCFA), CMS agreed to survey those facilities that engage in minimal manufacturing to minimize duplication of effort and reduce the burden on the affected facilities while continuing to protect transfusion recipients. However, no transfer of statutory functions or authority is made under the MOU and the FDA retains legal authority to inspect these unregistered transfusion services whenever warranted. When appropriate, program divisions should conduct inspections jointly with the CMS regional liaison. If you determine during a routine inspection an establishment is a CMS obligation under the MOU, you should terminate the inspection and report the status to the OBPO OEI Coordinator. (See Federal Cooperative Agreements Manual – FDA/HCFA MOU.)

5.13.3.3 - Biologics License

See IOM 2.10.6.2. A biologics license application (BLA) shall be approved only after inspection of the establishment(s) listed in the application and upon a determination that the establishment complies with the standards established in the BLA and the requirements prescribed in applicable regulations (21 CFR 601.20(d)). CBER maintains the lead for pre-license (PLI) and pre-approval (PAI) inspections of biological products. These inspections are part of the review of a BLA or BLA supplement. CBER identifies the scope of the inspection and invites ORA to participate in, or, in some instances, may request ORA lead the PLI or PAI.

Copies of CBER's PLI and PAI inspection reports are forwarded to the Program Divisions and are stored in the firm's eCMS file. You can also find these inspection reports in eNSpect and OSAR.

5.13.3.4 - Approval of Biological Devices

There must be a pre-approval inspection (PAI) of the establishment for compliance with the QS/GMP regulation and the firm's PMA. For licensed devices, CBER conducts the pre-license inspection (PLI). Devices used in the collection and testing of blood for transfusion are approved/cleared through the PMA/510(k) authorities. ORA OBPO Investigators customarily inspect the CBER-regulated devices, which are subject to PMA/510(k) applications.

5.13.4 - Other Inspectional Considerations

5.13.4.1 - Testing Laboratories

Blood bank, source plasma, and HCT/P establishments may use outside testing laboratories to perform required testing.

Laboratories conducting testing for licensed blood banks are usually licensed. CBER may approve the use of a non-licensed laboratory to do required testing, provided the lab is capable of performing the tests and the lab registers with CBER prior to CBER approving the licensing arrangement.

Laboratories performing required testing for source plasma manufacturers must either be:

- licensed, or
- certified to perform such testing on human specimens under the Clinical Laboratory Improvement Amendments of 1988 (42 U.S.C. 263a) and 42 CFR part 493 or have met equivalent requirements as determined by CMS.

Instructions for inspecting testing laboratories are included in the appropriate CP. You should coordinate the inspection of non-registered laboratories with CMS regional office contacts. If a testing laboratory is located outside of the program division, request an inspection by the appropriate program division office, where appropriate.

(See updated information on: Donor Screening Assays for Infectious Agents and HIV Diagnostic Assays; and HCT/P donors for Relevant Communicable Disease Agents at FDA.gov.)

5.13.4.2 - Brokers

Blood establishments may use brokers to locate buyers for products such as recovered plasma or expired red blood cells. These articles are used for further manufacturing into products, such as clinical chemistry controls and in-vitro diagnostic products not subject to licensure. Fractionators also use brokers to locate suppliers of plasma under the short supply provisions (21 CFR 601.22). During your inspections, you should determine if the facility is selling products to any brokers. If brokers are used, determine if the brokered products are shipped to a facility operated by the broker, or directly to the consignee.

Brokers who take physical possession of blood products and engage in activities considered manufacturing or labeling are required to register and are included in the OEI for routine inspection under the blood bank compliance program. Brokers who only arrange sales of, or store, blood and blood components, but do not engage in manufacturing activities, are not required to register.

5.14 - Bioresearch Monitoring (BIMO)

Inspectional activities in the bioresearch monitoring (BIMO) program involve all product areas and centers. Types of establishments inspected include: Sponsors, Monitors, Contract Research Organizations, Clinical Investigators, Sponsor-Investigators, Institutional Review Boards, Radioactive Drug Research Committees, In Vivo Bioavailability/Bioequivalence Clinical and Analytical Sites, and Nonclinical Laboratories. BIMO inspections also include

Postmarketing Adverse Drug Experience (PADE) reporting and Risk Evaluation and Mitigation Strategies (REMS) reporting, both of which are post approval activities. BIMO inspections are conducted to determine the reliability of data submitted in support of premarket and pre-license applications, as well as to ensure the rights and safety of research subjects are protected.

5.14.1 - BIMO Establishment Type Definitions

Clinical Investigator – A person who conducts a research study (that is, recruits study subjects, administers the investigational product to humans or animal subjects or uses a device on subjects, prepares and maintains case history reports, etc.).

Contract Research Organization (CRO)- A person/entity that assumes, as an independent contractor with the sponsor, one or more of the obligations of a sponsor, for example, the design of a protocol, selection or monitoring of investigations, evaluation of reports, and preparation of materials to be submitted to the FDA. When operating under a written agreement for transfer of regulatory obligations, the CROs are subject to the same regulatory actions as sponsors for any failure to perform any of the obligations assumed. The medical device regulations do not define responsibilities for CROs; therefore, device sponsors are held responsible for any regulatory noncompliance by a CRO.

Monitor – An entity employed or contracted by sponsors or CROs to oversee the progress of an investigation. A monitor is not a regulated entity unless the regulatory obligations have been transferred from the sponsor in writing. In such case, the monitor is regulated as a CRO. However, device sponsors are held responsible for any regulatory noncompliance by a CRO.

Institutional Review Board – Also known as "Institutional Review Committee for Human Studies and Ethics Committee" internationally. An IRB reviews protocols for studies and evaluates informed consent documents and risk/benefit decisions made regarding study procedures. An IRB may or may not be affiliated with an institution such as a hospital.

In Vivo Bioavailabilty/Bioequivalence Clinical Site – A facility or individual involved in the screening and/or dosing of human subjects for obtaining biological specimens (for example, blood, saliva, urine, feces) for analysis of investigational product content to define absorption, distribution, metabolism, and/or elimination characteristics of the investigational product, or to establish its equivalency with a defined standard.

In Vivo Bioavailability/Bioequivalence Analytical Site – A laboratory involved in the analytical testing of human biological specimens for levels of investigational product content, or the in vitro testing of investigational products to establish equivalency with a defined standard. These facilities may be integrated with, or separate from, clinical sites obtaining human specimens.

Nonclinical Laboratory – A laboratory that conducts in vivo or in vitro experiments in which investigational products are studied prospectively in test systems under laboratory conditions to determine their safety. Nonclinical studies do not include studies utilizing human subjects or clinical studies or field trials in animals. Nonclinical studies also do not include basic exploratory studies carried out to determine whether an investigational product has any potential utility, or to determine physical or chemical characteristics of an investigational product.

Sponsor – A person or establishment that initiates, supports, and usually monitors an investigational study on FDA-regulated products, but who does not actually conduct the study.

Sponsor-Investigator – An individual who both initiates and conducts an investigational study. This person has the responsibilities of both a sponsor and a clinical investigator.

Postmarketing Adverse Drug Experience (PADE) – PADE inspections are conducted at pharmaceutical establishments, which may be the manufacturing site, but most often are at a corporate headquarters facility. The inspection is conducted where the complaint=handling unit/department responsible for evaluating and reporting adverse drug

events is located. The purpose of the inspection is to ascertain whether the firm is complying with the evaluation and reporting requirements.

Risk Evaluation and Mitigation Strategies (REMS) - A (REMS) is a required risk management plan that uses tools, as specified in the FDA Amendments Act of 2007 (FDAAA), beyond routine professional labeling (the package insert) necessary to ensure that the benefits of a drug outweigh its risks. The purpose of a REMS inspection is to verify the REMS is implemented and functioning in accordance with the FDA-approved REMS and to verify information in the REMS assessment report.

Radioactive Drug Research Committee (RDRC) –An Institutional Review Board subcommittee or branch, which is FDA approved, who reviews and approves certain research uses of radioactive drugs that are generally recognized as safe and effective (GRASE).

5.14.2 - BIMO Assignments

Assignments are issued by the product centers to ORA. These assignments are primarily issued to conduct inspections of entities engaged in nonclinical or clinical research and were involved in studies submitted as part of an application for approval of a new product. Typically, inspections are conducted well after a nonclinical or clinical study has been completed. Inspections may also be conducted of ongoing research. Assignments may also be issued for-cause, for allegations of potential noncompliance and to conduct investigations and sample collections.

Each assignment will identify the establishment type to be inspected. In BIMO, the Compliance Programs are based upon the establishment type, so they will provide instruction on what you should cover during your inspection. The areas of coverage relate to the specific regulatory requirements of each establishment type.

Centers prepare assignments using a template that was harmonized across all centers for the BIMO program. This assignment memo identifies the following: type of establishment to be inspected, the relevant Compliance Program, the Program Assignment Code, background information, general instructions, and any special instructions for inspectional coverage. Assignments are issued to ORA HQ, reviewed, and then assigned to the appropriate division. Assignments are received by the Director, Investigations Branch and then disseminated to the appropriate supervisory group for assignment to an investigator.

Occasionally, center personnel will participate in inspections with field investigators, serving as subject matter expert on products and/or processes that are the focus of nonclinical or clinical research. In these cases, the ORA investigator will serve as the lead investigator. (See IOM 5.2.8 – Team Inspections.)

Assignments in BIMO are usually associated with specific background materials, which will be available to you via a link to Enterprise Content Management Server/System (ECMS). Background materials may include the protocol for the study you are assigned to inspect; certain line listings of data included in the application, such as reported adverse events and measurements taken during the study; and the assignment memo. If there are specific areas to focus on during the inspection, the assignment memo will discuss these areas too. There may also be specific data included in the background materials for you to verify during your inspection.

Centers have final classification authority for inspections in the BIMO program. When inspections are completed and the EIR reviewed by your supervisor, an initial inspection classification will be assigned through eNSpect. The centers will then determine and assign the final classification for the inspection after they complete their review of the EIR and all evidence collected.

5.14.2.1 - Read-Only Access to Electronic Databases During Bioresearch Monitoring Inspection Assignments

Clinical and non-clinical trials are increasingly moving toward 100 percent electronic data capture--including electronic case report forms, medical records, patient-reported outcomes, informed consent systems and other

electronic study records. It is necessary for bioresearch monitoring investigators to have access to these electronic systems and databases to perform inspections effectively and successfully. Overseeing the firm's personnel while they access their electronic systems is not always practical in BIMO inspections.

- Access to electronic systems/databases is to be read-only and not permit you to change or alter data or programming in any manner.
- The firm should have a representative that will be available to initially describe and review the layout of their records. They should be available throughout the inspection as additional information or copies of records are needed.
- Document that you had read-only access in your establishment inspection report or investigational memorandum accordingly.

While you may complete a form needed by the firm to obtain read-only access, such as an account request form, you *will not* sign such form as per IOM section 5.5.6. You may acknowledge by email that you have completed any required training necessary for access. When signing in to access a system, you may check a box and/or enter your name to acknowledge or accept the user agreement.

5.14.2.2 -Electronic Regulatory Notes For BIMO Operations

As per section 1A.1.4.3, regulatory notes may be either handwritten in a bound notebook or in electronic format. eNSpect will be used for all electronic regulatory notes in the BIMO program.

5.14.3 - BIMO Compliance Programs

BIMO Compliance Programs are posted on the internet. Compliance Programs in BIMO are designed to focus on the establishment type, as clinical and nonclinical research crosses all product areas.

- 7348.003 In Vivo Bioavailability-Bioequivalence Studies– Clinical
- 7348.004 In Vivo Bioavailability-Bioequivalence Studies– Analytical
- 7348.007 Inspection of Nonclinical Laboratories Conducting Animal Rule-Specific Studies
- 7348.808 Good Laboratory Practice (Nonclinical Laboratories)
- 7348.808A Good Laboratory Practice Program (Nonclinical Laboratories) EPA Data Audit Inspections
- 7348.809 Institutional Review Board
- 7348.809A Radioactive Drug Research Committee
- 7348.810 Sponsors and Contract Research Organizations
- 7348.811 Clinical Investigators and Sponsor- Investigators
- 7353.001 Postmarketing Adverse Drug Experience (PADE) Reporting Inspections
- 7353.001C Risk Evaluation and Mitigation Strategies (REMS) Reporting Inspections

5.14.4 - Postmarketing Adverse Event Reporting Inspections

Section 760 of the FD&C Act [21 U.S.C. 379aa] and 21 CFR sections 310.305, 314.80, 314.98, 314.540, and 329.100 require reporting of adverse events associated with the use of human drug products, and section 600.80 requires reporting of adverse events associated with the use of biological products (including therapeutic biological products). Responsible firms include holders of applications (NDAs, ANDAs, or BLAs) and manufacturers, packers and distributors that are named on the labels of all FDA approved drug products, all prescription drug products, and OTC monograph drug products. Both foreign and domestic firms are required to develop written procedures and to maintain records related to adverse events. Firms must evaluate adverse event data to determine if the event has had a serious outcome--such as death, disability, hospitalization, or was life-threatening--and if the event was expected (labeled) or unexpected (unlabeled) for the product. Responsible firms must also submit adverse event information to the FDA in expedited or periodic reports in an electronic format as described in the regulations. This information should be complete and accurate based on the data received.

(Refer to the Compliance Program (CP) 7353.001 and the assignment for the description of the program and for detailed instructions for conducting inspections.)

5.14.5 - Risk Evaluation and Mitigation Strategies (REMS) Reporting Inspections

Section 505-1 of the FD&C Act [21 U.S.C. 355-1] gives the FDA the authority to require Risk Evaluation and Mitigation Strategies (REMS) for certain drugs to ensure that the benefits outweigh the risks. REMS are required risk management plans that use risk minimization strategies, beyond the professional labeling, to ensure benefits of certain prescription drugs outweigh their risks. An applicant may be required to establish a REMS as part of the approval process (or when new safety data for an approved product arises), and an inspection will focus on the applicant's adherence to the REMS. Each REMS is unique, can be used for a single drug or class of drugs, and may include one or more of the following: a medication guide, communication plan, elements to assure safe use (ETASU), and implementation plan. REMS must also include a timetable for submission of assessments.

REMS are subject to inspection and are enforceable under section 505 (o) of the FD&C Act as amended by the FDAAA.

REMS inspections are conducted to verify that the REMS is implemented and functioning according to the FDA-approved REMS document and to verify the information provided to the agency in the REMS assessment report. Since every REMS program varies, the detailed instructions for conducting inspections will be given to the investigator prior to each inspection. (Refer to the Compliance Program (CP) 7353.001C and the assignment for the description of the program and for detailed instructions for conducting inspections.)

5.14.6 - BIMO Establishment Inspection Reports (EIRs)

In general, refer to IOM 5.7.3 for reporting requirements following BIMO inspections, with a few exceptions as follows.

- The Summary of Findings format is not to be used for BIMO EIRs.
- For foreign inspections where the firm has been previously inspected and the current inspection will be classified NAI, an abbreviated report may be used as per section 5.7.3.4 Abbreviated Report, as outlined below.
- Domestic BIMO EIRs and EIRs for foreign inspections not meeting the above criteria will utilize the Standard Narrative Report format but must also include content required by compliance programs and specific assignment instructions. This content should be included by adding the headings that are listed in the compliance program, for example, Authority and Administration, Protocol, Institutional Review Board, Subjects' Records, etc. would be added for a clinical investigator inspection report.

There are a few section headings that may be deleted as they are not generally applicable to BIMO inspections. If you are creating your report in eNSpect and the system does not allow you to delete the heading, simply insert "N/A" within that section of the report. Headings that may be deleted for BIMO EIRs include:

- Manufacturing/Design Operations
- Manufacturing Codes (*although may be applicable for Bioequivalence)
- Recall Procedures

All other headings should be included. If they do not apply to your inspection (for instance, Sample Collection and Refusals), simply insert "N/A" into that section, but do not delete it.

For foreign inspections where the firm has been previously inspected and the current inspection will be classified NAI, the abbreviated report should include the information as required in section 5.7.3.3- Abbreviated Report (to include change reporting), as well as the following:

BIMO program-specific information (that is the data requested in post-inspection email summaries provided to center points of contact, with additional details that may add value to the review process):

- Protocol – including name, number, and sponsor

- Number of Subjects Screened/Consented/Enrolled/Randomized/Completed (use most appropriate descriptions)
- Records Reviewed (including Subjects) and Recordkeeping Practices
- Adverse Events
- Primary Endpoints
- Discussion Items (including minor protocol deviations and/or recordkeeping issues)

5.14.7 - BIMO Complaints

Complaints related to the BIMO program may be received from various sources such as sponsors, Institutional Review Boards, study subjects, and other firms. BIMO complaints are evaluated by the Center responsible for review of the product that is the subject of the complaint. The Center may issue a for-cause inspection assignment to follow-up on a complaint. CSOs may also be assigned to interview complainants or confidential sources, and to report coverage/follow-up of any complaints, including any associated complaint number(s) in the EIR or a memorandum. If you receive a complaint involving an FDA-regulated product directly, contact your supervisor so that the complaint can be routed to the appropriate Center/Office. (See also IOM 5.5.4 (Consumer Complaints) and IOM 5.4.1 (Interviewing Confidential Sources and Informants).)

5.15 - Tobacco Products

5.15.1 - Definitions

The term "tobacco product" is defined in Section 201(rr) of the FD&C Act [21 U.S.C 321] and means any product made or derived from tobacco, or containing nicotine from any source, that is intended for human consumption, including any component part, or accessory of a tobacco product (except for raw materials other than tobacco used in manufacturing a component, part, or accessory of a tobacco product.) The term "tobacco product" does not mean an article that is a drug under section 201(g)(1) of the FD&C Act, a device under section 201(h) of the FD&C Act, or a combination product described in section 503(g) of the FD&C Act. The term ‘‘tobacco product’’ does not mean an article that is a food under section 201(f) of the FD&C Act, if such article contains no nicotine, or no more than trace amounts of naturally occurring nicotine.

The definition of certain tobacco products can be found in the FD&C Act under section 900.

5.15.2 - Tobacco Inspections

(See IOM 2.2 for discussion of statutory authority.)

Inspections involving tobacco product(s) at manufacturing facilities are led by ORA’s Tobacco Operations Staff (TOS) within the Office of Medical Products and Tobacco Operations and are conducted pursuant to assignments issued by CTP. These assignments are issued to conduct inspections of entities engaged in the manufacture, preparation, compounding, or processing of tobacco products. Inspections may also be conducted to support the pre-market and post-market review process. Assignments may also be issued to conduct investigations and sample collections. CTP Subject Matter Experts may accompany ORA’s Tobacco Operations Staff during such inspections. Additional guidance on deemed tobacco products can be found on CTP's Deeming webpage. https://www.fda.gov/tobacco-products/rules-regulations-and-guidance/fdas-deeming-regulations-e-cigarettes-cigars-and-all-other-tobacco-products

5.15.3 - Retail Compliance Check Inspection Contracts

The FDA issues contracts to assist with compliance check inspections of tobacco retail establishments to help determine a retailer's compliance with federal laws and regulations, including the FD&C Act, as amended by the Tobacco Control Act, and associated regulations. The FDA has a goal of establishing a contract, where feasible, with every U.S. state and territory, to support such compliance, but some states and territories, for a variety of reasons, have been unable to do so. Therefore, the agency has awarded contracts to third-party entities that are able to hire

commissionable inspectors to conduct compliance check inspections of tobacco retailers in those states and territories where the FDA has been unable to contract with a government agency. The FDA has further expanded this program by awarding retail inspection contracts to American Indian and Alaska Native tribes to conduct retail inspections within their jurisdictions. In addition, the FDA may, at any time, also conduct inspections using its own personnel.

5.15.4 - Guidance, Compliance & Regulatory Information

The https://www.fda.gov/about-fda/fda-organization/center-tobacco-products CTP website contains resources for legal, regulatory, and policy issues related to tobacco products and information for small business assistance (SmallBiz.Tobacco@fda.hhs.gov)

5.16 – Combination Products

5.16.1 – Combination Product Inspections

Combination products are defined in 21 CFR 3.2(e). The term combination product includes:

- A product comprised of two or more regulated components, i.e., drug/device, biologic/device, drug/biologic, or drug/device/biologic, that are physically, chemically, or otherwise combined or mixed and produced as a single entity;
- Two or more separate products packaged together in a single package or as a unit and comprised of drug and device products, device and biological products, or biological and drug products;
- A drug, device, or biological product packaged separately that according to its investigational plan or proposed labeling is intended for use only with an approved individually specified drug, device, or biological product where both are required to achieve the intended use, indication, or effect and where upon approval of the proposed product the labeling of the approved product would need to be changed, e.g., to reflect a change in intended use, dosage form, strength, route of administration, or significant change in dose; or
- Any investigational drug, device, or biological product packaged separately that according to its proposed labeling is for use only with another individually specified investigational drug, device, or biological product where both are required to achieve the intended use, indication, or effect.

These articles retain their regulatory identity when they become constituent parts of a combination product., Accordingly, the authority for inspections of combination products arises from the authorities for drug, device, and biological product inspections as described in IOM 5.10, 5.12, and 5.13, respectively.

All combination products are subject to at least two sets of CGMP requirements. In 21 CFR part 4, subpart A, section 4.3 identifies a streamlined approach to demonstrate compliance with the drug CGMPs (21 CFR part 210 & 211) and the device Quality System (QS) Regulation (21 CFR part 820) for single-entity and co-packaged combination products that contain a drug or biological product constituent part and a device constituent part. This allows a combination product manufacturing facility to comply either with the drug CGMPs and specific called-out provisions from the device QS regulation (drug CGMP-based streamlined approach, see 21 CFR 4.4(b)(1)) or with the device QS regulation and specific provisions from the drug CGMPs (device QS regulation-based streamlined approach, see 21 CFR 4.4(b)(2)).

Regardless of whether a streamlined approach is used, in addition, for a combination product that includes a biological product, the manufacturer must demonstrate compliance with all applicable CGMP requirements for biological products (including standards) that are found within 21 CFR Parts 600 through 680 (21 CFR 4.3(c)). For a combination product that includes any HCT/P, the manufacturer must demonstrate compliance with all applicable regulations in 21 CFR Part 1271.

5.16.1.1 – Preparation

Identify the combination products manufactured at the facility and, if not already known, identify the lead center. The lead center is the medical product center (e.g., CBER, CDER, or CDRH) that has primary jurisdiction for a

specific combination product's review and regulation. Questions on which center is lead for a combination product should be directed to combination@fda.hhs.gov. Typically, the application type for the combination product is aligned with the lead center (for example, generally, PMA and 510(k) products are CDRH-led, and NDA/ANDA products are CDER-led). The lead center serves as the primary point of contact before, during, and after the inspection. For a CDER-led combination product inspection, review IOM 5.10. For a CDRH-led combination product inspection, review IOM 5.12. For CBER-led combination product inspection, review IOM 5.13.

Obtain the following information before the inspection whenever possible:

- The CGMP operating system in use at the facility. Although most combination product manufacturers choose to follow a streamlined approach that aligns with the lead center/ application type (e.g., a facility manufacturing a combination product approved under a PMA follows a device QS regulation-based streamlined approach), they may choose to follow either of the streamlined approaches or full compliance with both sets of regulations.
- Information about the facilities involved in the manufacturing (including design activities) for the combination product and the scope of CGMP responsibilities of the facility to be inspected.
- For pre-announced inspections, confirm that documentation to enable review of compliance with called out provisions will be available or accessible at the site being inspected.
    - Pre-announcement will typically apply to pre-approval inspections for ANDA/NDA/PMA combination products, consistent with the ORA inspectional process for the lead center.
    - Pre-licensing inspections for CDER-led BLAs are also typically preannounced.
    - Pre-announcement will apply to surveillance inspections, as appropriate, consistent with the process for the base (Lead Center) compliance program.
    - For non-application combination products concerns, if needed, request a consult for respective lead center via your supervisor.

5.16.1.2 – Inspectional Approach

For combination product CGMP inspections for CDER-led or CDRH-led single-entity or co-packaged combination products, follow Compliance Program 7356.000 and associated commodity-specific compliance programs for pre-approval, post-approval, surveillance, for cause, and other risk-based inspections. For surveillance inspections where combination product coverage is conducted, prioritize combination products recently approved, cleared, or significantly changed (in terms of design) or those that include complex technology or manufacturing considerations. This applies unless there are indicators that there are safety and effectiveness concerns with other products. For CBER-led combination product inspections, contact OBPO supervisory staff and CBER for assistance.

5.16.1.3 – Registration and Listing

Combination products are generally registered and listed with the lead Center only. However, they may also be registered with a secondary Center. In both instances, the listing should reflect that the product is a combination product. If potential problems related to registration and listing are identified, contact the lead center for assistance.

5.16.1.4 – Combination Product Establishment Inspection Report

A single EIR and, when applicable, FDA-483 should be used to document all observations made during an inspection at a combination product manufacturer.

ORA investigators conducting a combination product inspection should mark the Combination Products as "Yes" from the drop-down menu in eNSpect (Inspection /Coverage and Conclusion).

5.16.1.5 – Limitations on Inspection

The limitations on the agency's ability to access audit results (see IOM 5.12.1.5.5) also apply to an inspection of a combination product manufacturer.

5-1 FORM FDA 482 NOTICE OF INSPECTION

DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION	1. DISTRICT OFFICE ADDRESS & PHONE NO. 1431 Harbor Bay Parkway Alameda, CA 94502 (510)337-6700

TO	2. NAME AND TITLE OF INDIVIDUAL Helen E. Castro, President	3. DATE 07/28/13
	4. FIRM NAME ABC Bread Company	5. HOUR 7:30 a.m.
	6. NUMBER AND STREET 579 Main Street	p.m.
	7. CITY AND STATE & ZIP CODE Richmond, CA 94805	8. PHONE NO. & AREA CODE (510)123-4567

Notice of Inspection is hereby given pursuant to Section 704(a)(1) of the Federal Food, Drug, and Cosmetics Act [21 U.S.C. 374(a)][1] and/or Part F or G, Title III of the Public Health Service Act [42 U.S.C. 262-264][2]

As a small business that is subject to FDA regulation, you have the right to seek assistance from the U.S. Small Business Administration (SBA). This assistance includes a mechanism to address the enforcement actions of Federal agencies. SBA has a National Ombudsman's Office that receives comments from small businesses about Federal agency enforcement actions. If you wish to comment on the enforcement actions of FDA, CALL (888) 734-3247. The website address is www.sba.gov/ombudsman.

FDA has an Office of the Ombudsman that can directly assist small business with complaints or disputes about actions of the FDA. That office can be reached by calling (301) 796-8530 or by email at ombuds@oc.fda.gov.

For industry information, go to www.fda.gov/oc/industry.

9. SIGNATURE(S) *(Food and Drug Administration Employee(s))*	10. TYPE OR PRINT NAME(S) AND TITLE(S) *(FDA Employee(s))*
Sidney H. Rogers	Sidney H. Rogers, Investigator

[1] **Applicable portions of Section 704 and other Sections of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 374] are quoted below:**

Sec. 704(a)(1) For purposes of enforcement of this Act, officers or employees duly designated by the Secretary, upon presenting appropriate credentials and a written notice to the owner, operator, or agent in charge, are authorized (A) to enter, at reasonable times, any factory, warehouse, or establishment in which food, drugs, devices, tobacco products, or cosmetics are manufactured, processed, packed, or held, for introduction into interstate commerce or after such introduction, or to enter any vehicle being used to transport or hold such food, drugs, devices, tobacco products, or cosmetics in interstate commerce; and (B) to inspect, at reasonable times and within reasonable limits and in a reasonable manner, such factory, warehouse, establishment, or vehicle and all pertinent equipment, finished and unfinished materials, containers, and labeling therein. In the case of any person (excluding farms and restaurants) who manufactures, processes, packs, transports, distributes, holds, or imports foods, the inspection shall extend to all records and other information described in section 414, when the standard for records inspection under paragraph (1) or (2) of section 414(a) applies, subject to the limitations established in section 414(d). In the case of any factory, warehouse, establishment, or consulting laboratory in which prescription drugs, nonprescription drugs intended for human use, restricted devices, or tobacco products are manufactured, processed, packed, or held, inspection shall extend to all things therein (including records, files, papers, processes, controls, and facilities) bearing on whether prescription drugs, nonprescription drugs intended for human use, restricted devices, or tobacco products which are adulterated or misbranded within the meaning of this Act, or which may not be manufactured, introduced into interstate commerce, or sold, or offered for sale by reason of any provision of this Act, have been or are being manufactured, processed, packed, transported, or held in any such place, or otherwise bearing on violation of this Act. No inspection authorized by the preceding sentence or by paragraph (3) shall extend to financial data, sales data other than shipment data, pricing data, personnel data (other than data as to qualifications of technical and professional personnel performing functions subject to this

(Continued on Reverse)

Act), and research data (other than data relating to new drugs, antibiotic drugs, devices, and tobacco products and subject to reporting and inspection under regulations lawfully issued pursuant to section 505 (i) or (k), section 519, section 520(g), or chapter IX and data relating to other drugs, devices, or tobacco products, which in the case of a new drug would be subject to reporting or inspection under lawful regulations issued pursuant to section 505(j)). A separate notice shall be given for each such inspection, but a notice shall not be required for each entry made during the period covered by the inspection. Each such inspection shall be commenced and completed with reasonable promptness.

Sec. 704. (a)(2) The provisions of the third sentence of paragraph (1) shall not apply to (A) pharmacies which maintain establishments in conformance with any applicable local laws regulating the practice of pharmacy and medicine and which are regularly engaged in dispensing prescription drugs or devices, upon prescriptions of practitioners licensed to administer such drugs or devices to patients under the care of such practitioners in the course of their professional practice, and which do not, either through a subsidiary or otherwise, manufacture, prepare, propagate, compound, or process drugs or devices for sale other than in the regular course of their business of dispensing or selling drugs or devices at retail; (B) practitioners licensed by law to prescribe or administer drugs, or prescribe or use devices, as the case may be, and who manufacture, prepare, propagate, compound, or process drugs, or manufacture or process devices solely for use in the course of their professional practice; (C) persons who manufacture, prepare, propagate, compound, or process drugs, or manufacture or process devices solely for use in research, teaching, or chemical analysis and not for sale; (D) such other classes of persons as the Secretary may by regulation exempt from the application of this section upon a finding that inspection as applied to such classes of persons in accordance with this section is not necessary for the protection of the public health.

Sec. 704. (a)(3) An officer or employee making an inspection under paragraph (1) for purposes of enforcing the requirements of section 412 applicable to infant formulas shall be permitted, at all reasonable times, to have access to and to copy and verify any records (A) bearing on whether the infant formula manufactured or held in the facility inspected meets the requirements of section 412, or (B) required to be maintained under section 412.

Sec. 704(b) Upon completion of any such inspection of a factory, warehouse, consulting laboratory, or other establishment, and prior to leaving the premises, the officer or employee making the inspection shall give to the owner, operator, or agent in charge a report in writing setting forth any conditions or practices observed by him which, in his judgment, indicate that any food, drug, device, tobacco product, or cosmetic in such establishment (1) consists in whole or in part of any filthy, putrid, or decomposed substance, or (2) has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health. A copy of such report shall be sent promptly to the Secretary.

Sec. 704. (c) If the officer or employee making any such inspection of a factory, warehouse, or other establishment has obtained any sample in the course of the inspection, upon completion of the inspection and prior to leaving the premises he shall give to the owner, operator, or agent in charge a receipt describing the samples obtained.

Sec. 704. (d) Whenever in the course of any such inspection of a factory or other establishment where food is manufactured, processed, or packed, the officer or employee making the inspection obtains a sample of any such food, and an analysis is made of such sample for the purpose of ascertaining whether such food consists in whole or in part of any filthy, putrid, or decomposed substance, or is otherwise unfit for food, a copy of the results of such analysis shall be furnished promptly to the owner, operator, or agent in charge.

Sec. 704(e) Every person required under section 519 or 520(g) to maintain records and every person who is in charge or custody of such records shall, upon request of an officer or employee designated by the Secretary, permit such officer or employee at all reasonable times to have access to and to copy and verify, such records.

Section 704 (f)(1) An accredited person described in paragraph (3) shall maintain records documenting the training qualifications of the person and the employees of the person, the procedures used by the person for handling confidential information, the compensation arrangements made by the person, and the procedures used by the person to identify and avoid conflicts of interest. Upon the request of an officer or employee designated by the Secretary, the person shall permit the officer or employee, at all reasonable times, to have access to, to copy, and to verify, the records.

Section 512 (l)(1) In the case of any new animal drug for which an approval of an application filed pursuant to subsection (b) is in effect, the applicant shall establish and maintain such records, and make such reports to the Secretary, of data relating to experience, including experience with uses authorized under subsection (a)(4)(A), and other data or information, received or otherwise obtained by such applicant with respect to such drug, or with respect to animal feeds bearing or containing such drug, as the Secretary may by general regulation, or by order with respect to such application, prescribe on the basis of a finding that such records and reports are necessary in order to enable the Secretary to determine, or facilitate a determination, whether there is or may be ground for invoking subsection (e) or subsection (m) (4) of this section. Such regulation or order shall provide, where the Secretary deems it to be appropriate, for the examination, upon request, by the persons to whom such regulation or order is applicable, of similar information received or otherwise obtained by the Secretary.

(2) Every person required under this subsection to maintain records, and every person in charge or custody thereof, shall, upon request of an officer or employee designated by the Secretary, permit such officer or employee at all reasonable times to have access to and copy and verify such records.

[2] Applicable sections of Parts F and G of Title III Public Health Service Act [42 U.S.C. 262-264] are quoted below:

Part F – Licensing – Biological Products and Clinical Laboratories and* * * * * *

Sec. 351(c) "Any officer, agent, or employee of the Department of Health and Human Services, authorized by the Secretary for the purpose, may during all reasonable hours enter and inspect any establishment for the propagation or manufacture and preparation

(Continued on Page 3)

of any virus, serum, toxin, antitoxin, vaccine, blood, blood component or derivative, allergenic product, or other product aforesaid for sale, barter, or exchange in the District of Columbia, or to be sent, carried, or brought from any State or possession into any other State or possession or into any foreign country, or from any foreign country into any State or possession."

Part F – * * * * * *Control of Radiation.

Sec. 360 A (a) "If the Secretary finds for good cause that the methods, tests, or programs related to electronic product radiation safety in a particular factory, warehouse, or establishment in which electronic products are manufactured or held, may not be adequate or reliable, officers or employees duly designated by the Secretary, upon presenting appropriate credentials and a written notice to the owner, operator, or agent in charge, are thereafter authorized (1) to enter, at reasonable times any area in such factory, warehouse, or establishment in which the manufacturer's tests (or testing programs) required by section 358(h) are carried out, and (2) to inspect, at reasonable times and within reasonable limits and in a reasonable manner, the facilities and procedures within such area which are related to electronic product radiation safety. Each such inspection shall be commenced and completed with reasonable promptness. In addition to other grounds upon which good cause may be found for purposes of this subsection, good cause will be considered to exist in any case where the manufacturer has introduced into commerce any electronic product which does not comply with an applicable standard prescribed under this subpart and with respect to which no exemption from the notification requirements has been granted by the Secretary under section 359(a)(2) or 359(e)."

(b) "Every manufacturer of electronic products shall establish and maintain such records (including testing records), make such reports, and provide such information, as the Secretary may reasonably require to enable him to determine whether such manufacturer has acted or is acting in compliance with this subpart and standards prescribed pursuant to this subpart and shall, upon request of an officer or employee duly designated by the Secretary, permit such officer or employee to inspect appropriate books, papers, records, and documents relevant to determining whether such manufacturer has acted or is acting in compliance with standards prescribed pursuant to section 359(a)."

* * * * * *

(f) "The Secretary may by regulation (1) require dealers and distributors of electronic products, to which there are applicable standards prescribed under this subpart and the retail prices of which is not less than $50, to furnish manufacturers of such products such information as may be necessary to identify and locate, for purposes of section 359, the first purchasers of such products for purposes other than resale, and (2) require manufacturers to preserve such information Any regulation establishing a requirement pursuant to clause (1) of the preceding sentence shall (A) authorize such dealers and distributors to elect, in lieu of immediately furnishing such information to the manufacturer to hold and preserve such information until advised by the manufacturer or Secretary that such information is needed by the manufacturer for purposes of section 359, and (B) provide that the dealer or distributor shall, upon making such election, give prompt notice of such election (together with information identifying the notifier and the product) to the manufacturer and shall, when advised by the manufacturer or Secretary, of the need therefore for the purposes of Section 359, immediately furnish the manufacturer with the required information. If a dealer or distributor discontinues the dealing in or distribution of electronic products, he shall turn the information over to the manufacturer. Any manufacturer receiving information pursuant to this subsection concerning first purchasers of products for purposes other than resale shall treat it as confidential and may use it only if necessary for the purpose of notifying persons pursuant to section 359(a)."

* * * * * *

Sec. 360 B.(a) It shall be unlawful–

(1) * * *

(2) * * *

(3) "for any person to fail or to refuse to establish or maintain records required by this subpart or to permit access by the Secretary or any of his duly authorized representatives to, or the copying of, such records, or to permit entry or inspection, as required or pursuant to section 360A."

* * * * * *

Part G - Quarantine and Inspection

Sec. 361(a) "The Surgeon General, with the approval of the Secretary, is authorized to make and enforce such regulations as in his judgment are necessary to prevent the introduction, transmission, or spread of communicable diseases from foreign countries into the States or possessions, or from one State or possession into any other State or possession. For purposes of carrying out and enforcing such regulations, the Surgeon General may provide for such inspection, fumigation, disinfection, sanitation, pest extermination, destruction of animals or articles found to be so infected or contaminated as to be sources of dangerous infection to human beings, and other measures, as in his judgment may be necessary."

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

1. DISTRICT ADDRESS AND PHONE NO.
6751 Steger Dr.
Cincinnati, OH 45237
(513)679-2700

TO

2. NAME AND TITLE OF INDIVIDUAL
Michael A. Weston, Plant Manager

3. DATE OF REQUEST
06/20/12

4. FIRM NAME
ABC Food Company

5. TIME OF REQUEST
8:30 ☑ A.M. ☐ P.M.

6. NUMBER AND STREET
3114 Mapleleaf Avenue

7. CITY AND STATE
Cincinnati, OH

8. ZIP CODE
45213

Written demand for examination and/or copying of the records required by 21 CFR 113.100, 21 CFR 114 and 21 CFR 500.23 is hereby given, pursuant to 21 CFR 108.25(g), 21 CFR 108.35(h) and 21 CFR 500 for the records described below in order to verify the pH, adequacy of processing, the integrity of container closures, and the coding of the products processed by your firm.

9. RECORDS NECESSARY

All thermal process, production, and quality control / analytical records and maintenance records which may document any changes to the equipment, or the thermal process mandated by 21 CFR 108, 113, and 114 [*choose appropriate regulation, 113 LACF or 114 acidified*] for all low acid canned foods and/or acidified food products [*or specify product*] which were produced by this firm since the last FDA inspection.

10. SIGNATURE *(Food and Drug Administration Employee(s))*	11. TITLE FDA EMPLOYEE
Sidney H. Rogers	Investigator

FORM FDA 482a (6/11) PREVIOUS EDITION IS OBSOLETE. **DEMAND FOR RECORDS**

PSC Publishing Services (301) 443-6740 EF

5-2 - FORM FDA 482a

5-3 FORM FDA 482b

DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION	1. DISTRICT ADDRESS AND PHONE NO. 6751 Steger Dr. Cincinnati, OH 45237 (513)679-2700

TO		
	2. NAME AND TITLE OF INDIVIDUAL Michael A. Weston, Plant Manager	3. DATE OF REQUEST 06/20/12
	4. FIRM NAME ABC Food Company	5. TIME OF REQUEST 8:30 ☑ A.M. ☐ P.M.
	6. NUMBER AND STREET 3114 Mapleleaf Avenue	
	7. CITY AND STATE Cincinnati, OH	8. ZIP CODE

Written request is hereby given pursuant to 21 CFR 108.25(c)(3)(ii), 21 CFR 108.35(c)(3)(ii) and 21 CFR 500.23 for the information described below, concerning processes and procedures, which is deemed necessary by the Food and Drug Administration to determine the adequacy of the processes for products processed by your firm.

9. RECORDS NECESSARY

All documents and records mandated by 21 CFR 108 relating to or having a bearing on the adequacy of processes for all low acid canned foods and/or acidified food products [*or specify product*] that were produced in this firm since the last FDA inspection.

10. SIGNATURE *(Food and Drug Administration Employee(s))*	11. TITLE FDA EMPLOYEE
Sidney H. Rogers	Investigator

FORM FDA 482b (6/11) PREVIOUS EDITION IS OBSOLETE. **REQUEST FOR INFORMATION**

PSC Publishing Services (301) 443-6740 EF

5-3 INSTRUCTIONS FOR COMPLETING THE FDA 482b, REQUEST FOR INFORMATION

Block 1 – Enter the district address where the firm is physically located, regardless of program area or investigator duty station. Include the district office commercial telephone number and area code.

Block 2 – Enter the complete name and official title of the individual to whom you issue the FDA 482b.

Block 3 – Enter date on which you are requesting the records.

Block 4 – Enter the firm's legal name. This should be the firm's legal name and not the DBA (doing business as), trade name, or alias.

Block 5 – Enter the time of the request.

Block 6, 7, and 8– Enter the number, street, city, state, and zip code of the firm.

Block 9 – Enter a brief description of the processing records and other relevant documents. See example language in the completed FDA 482b below. If specifying the product involved, include the product name and form, container size, and processing method.

Block 10 and 11 – Enter your signature and title.

Once completed, issue the original FDA 482b to the same person to whom the FDA 482, Notice of Inspection, was issued. Submit an exact copy with your EIR.

5-5 FORM FDA 483

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT OFFICE ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
#1 Industry Information: www.fda.gov/oc/industry	#2
	FEI NUMBER #3

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED

TO: #4

FIRM NAME	STREET ADDRESS
#5	#6
CITY, STATE AND ZIP CODE	TYPE OF ESTABLISHMENT INSPECTED
	#7

THIS DOCUMENT LISTS OBSERVATIONS MADE BY THE FDA REPRESENTATIVE(S) DURING THE INSPECTION OF YOUR FACILITY. THEY ARE INSPECTIONAL OBSERVATIONS, AND DO NOT REPRESENT A FINAL AGENCY DETERMINATION REGARDING YOUR COMPLIANCE. IF YOU HAVE AN OBJECTION REGARDING AN OBSERVATION, OR HAVE IMPLEMENTED, OR PLAN TO IMPLEMENT CORRECTIVE ACTION IN RESPONSE TO AN OBSERVATION, YOU MAY DISCUSS THE OBJECTION OR ACTION WITH THE FDA REPRESENTATIVE(S) DURING THE INSPECTION OR SUBMIT THIS INFORMATION TO FDA AT THE ADDRESS ABOVE. IF YOU HAVE ANY QUESTIONS, PLEASE CONTACT FDA AT THE PHONE NUMBER AND ADDRESS ABOVE.

DURING AN INSPECTION OF YOUR FIRM (I) (WE) OBSERVED: #8

#9

Add Continuation Page

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	EMPLOYEE(S) NAME AND TITLE *(Print or Type)*	DATE ISSUED
	#10	#11	#12

FORM FDA 483 (9/08) PREVIOUS EDITION OBSOLETE **INSPECTIONAL OBSERVATIONS** Page 1 of 1

COMPLETION OF THE FORM FDA 483

Presently there are three ways to generate an FDA 483.

- eNSpect
- Electronic (non-eNSpect) version
- Handwritten hard copy

Where possible, you should be creating, issuing, and signing the Form FDA 483 via the eNSpect method. Many of the fields in the form are either partially or fully automated when using this method.

When using an electronic (non-eNSpect) or handwritten hard copy of the FDA 483, the current version must be used.

The sections of the Form FDA 483 are identified below, with numbers corresponding to the preceding blank version of the form.

1 - District Office Address and Phone Number - Legibly print the home District address where the **firm** is physically located, regardless of program area or investigator duty station. Include the district office commercial telephone number and area code. If using eNSpect for the FDA 483, select the home district of the firm.

For example, if a firm is located in Little Rock, Arkansas, then the district office would be Dallas District Office. See Appendix E for boundary maps.

For foreign inspections, the address to be used for this box will be provided as part of the assignment.

2 - Date(s) of inspection - Enter actual or inclusive date(s) of inspection.

3 - FEI Number - If the FDA Establishment Identifier is on the assignment, enter it here. If not readily available, leave blank.

4 - Name and Title of individual to whom report is issued - Enter legal first name, middle initial and last name and full title of the person to whom the form is issued.

5 - Firm Name - Enter full, legal name of the firm, including any abbreviations, quotation marks, dashes, commas, etc.

6 - Street address, city, state and Zip Code-Enter Street address, city, state, and Zip Code. (Not P.O. Box unless P.O. Box is part of the address such as on a Rural Route).

7 - Type of establishment inspected - Enter the type of the establishment, such as bakery, cannery, wholesale warehouse, drug repacker, salvage warehouse, contract manufacturer, specification developer, or medical device manufacturer.

8 – **Medical Device Specific Text** – For inspections of medical device firms, the following language should be inserted on the FDA 483 after the paragraph explaining how the firm may contact FDA and immediately above the statement "During an inspection of your firm (I)(We) Observed":

"The observations noted in this form FDA 483 are not an exhaustive listing of objectionable conditions. Under the law, your firm is responsible for conducting internal self-audits to identify and correct any and all violations of the quality system requirements."

9 - Observations – See IOM 5.5.11 for information about what observations are considered "reportable" and may be listed on the Form FDA 483. Enter your reportable observations succinctly and clearly. Conditions listed should be significant and relate to an observed or potential problem with the facility, equipment, processes, controls, products, employee practices, or records. "Potential problems" should have a reasonable likelihood of occurring based upon observed conditions or events. Do not cite deviations from policy or guidance documents on your FDA 483.

Where applicable, when formulating each FDA 483 observation, answer Who (using titles or initials when necessary), What, When, Where, Why, How Much and How Often? Challenge each observation by asking "So What"? (regarding its significance).

As appropriate, FDA 483 observations should include relationship of observations to a given population, for example, “Two out of 50 records examined were * * *” or “4 out of 12 bags examined were ***.” When appropriate, an FDA 483 observation may refer to inadequate situations as long as you provide supporting facts (examples) or explanation as to why the condition, practice or procedure observed is inadequate.

It is preferred not to identify individuals or firms by name (e.g., suppliers and consignees) within the FDA 483. Where appropriate to support the FDA 483 observation, identify the individual(s) or firm(s) by substituting other non-specific identifying information as below. Document your evidence in your EIR, fully explaining the relationship(s).

a. The lot number for a component received from or shipped to firm “A”.
b. The invoice number for a shipment from or to firm “A”.
c. A patient #, record #. See IOM 5.2.3.3 item 7.
d. The study number for a particular Clinical Investigator site.
e. Other necessary but non-specific identifying information to show the observation’s relationship to a particular firm and/or individual.

10 - Employee(s) signature

Everyone present under FDA inspectional authority at issuance signs the FDA 483. However, absence of a team member at the conclusion of an inspection need not prevent issuance of the form (see IOM 5.1.2.5.1). If signing the FDA 483 digitally using eNSpect, the lead CSO’s signature will appear on all pages of the FDA 483 and the remaining team members’ signature will appear on the last page. When it is necessary to use pen to sign the form (e.g., when issuing a handwritten hard copy version), each person signs the first and last pages of the FDA 483 and initials each intervening page in the signature block.

When using eNSpect to sign the Form FDA 483, the system will retain a copy of the digitally signed form automatically. If you do not use eNSpect to digitally sign the document, assure you retain a digitally signed copy. If using a pen to sign the form, make a photocopy or carbon copy of the signed form. An unsigned photocopy or printed duplicate is unacceptable to maintain with the division’s files. See IOM 5.2.3.6.2.

11 - Employee(s) name and title

The names of everyone who participated in the inspection with the issuance of an FDA 482 should be listed on the FDA 483, even if they are not available to sign the document.

12 - Date Issued - Enter the date the form is actually issued to the firm’s management.

The observations of objectionable conditions and practices listed on the front of this form are reported:

1. Pursuant to Section 704(b) of the Federal Food, Drug and Cosmetic Act, or

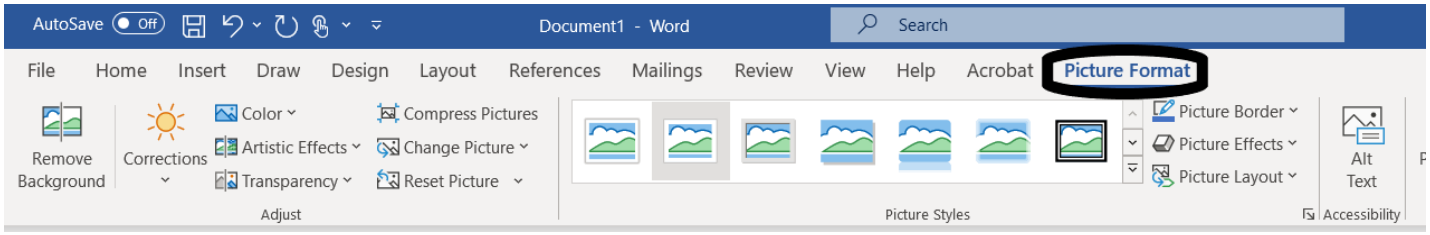
2. To assist firms inspected in complying with the Acts and regulations enforced by the Food and Drug Administration.

Section 704(b) of the Federal Food, Drug, and Cosmetic Act (21 USC 374(b)) provides:

"Upon completion of any such inspection of a factory, warehouse, consulting laboratory, or other establishment, and prior to leaving the premises, the officer or employee making the inspection shall give to the owner, operator, or agent in charge a report in writing setting forth any conditions or practices observed by him which, in his judgement, indicate that any food, drug, device, or cosmetic in such establishment (1) consists in whole or in part of any filthy, putrid, or decomposed substance, or (2) has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health. A copy of such report shall be sent promptly to the Secretary."

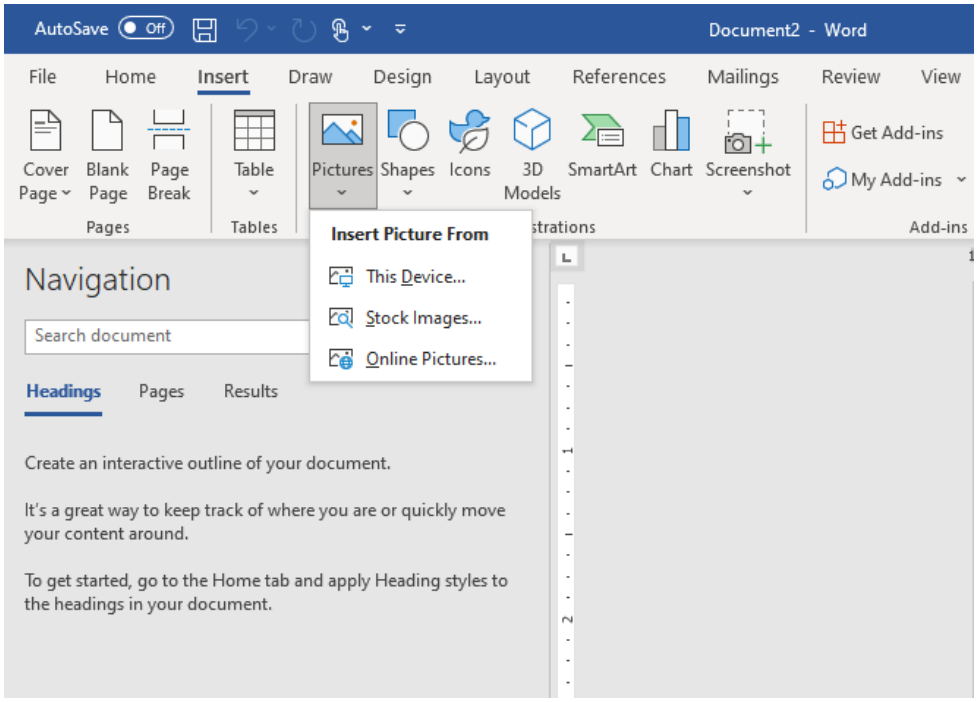
FORM FDA 483 (9/08)

5-6 INSERTING DIGITAL PHOTOS INTO eNSpect (RESIZE PHOTO)

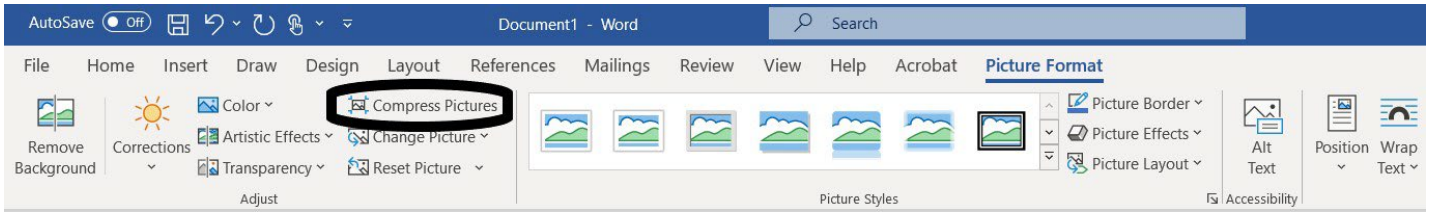


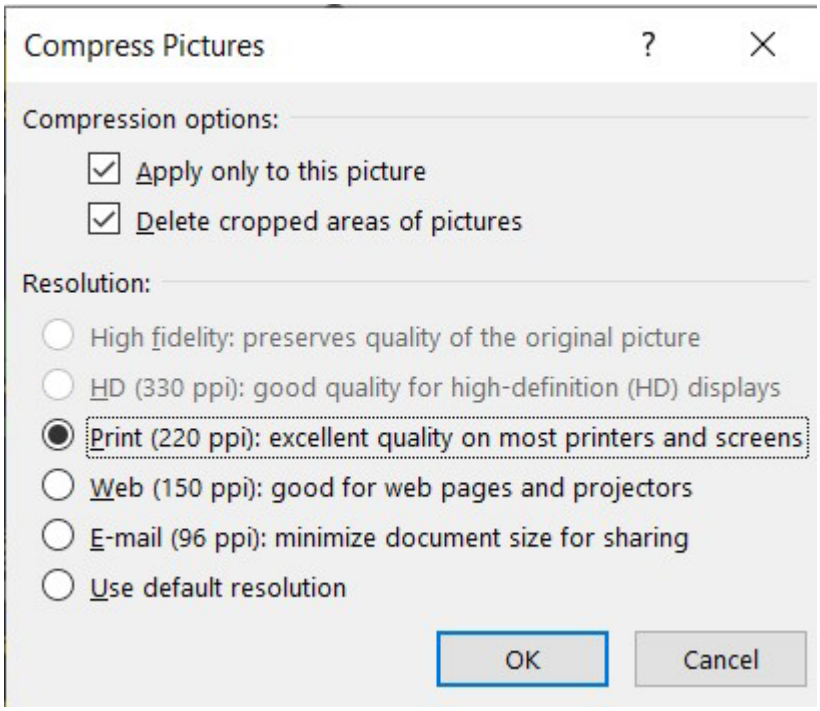
5-7 INSERTING DIGITAL PHOTOS INTO eNSpect (INSERT PHOTO)

Inserting a resized picture into Microsoft Word.

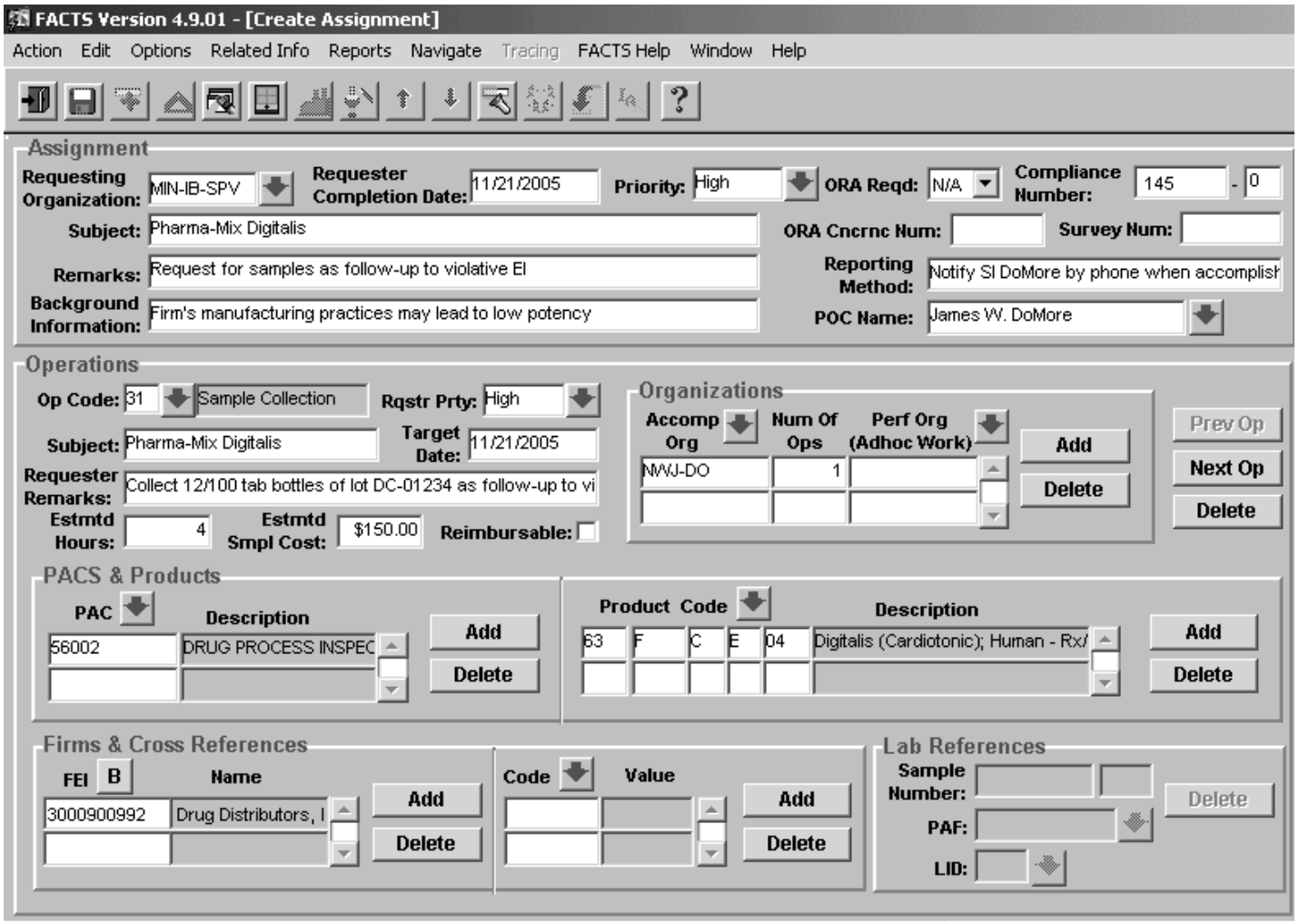


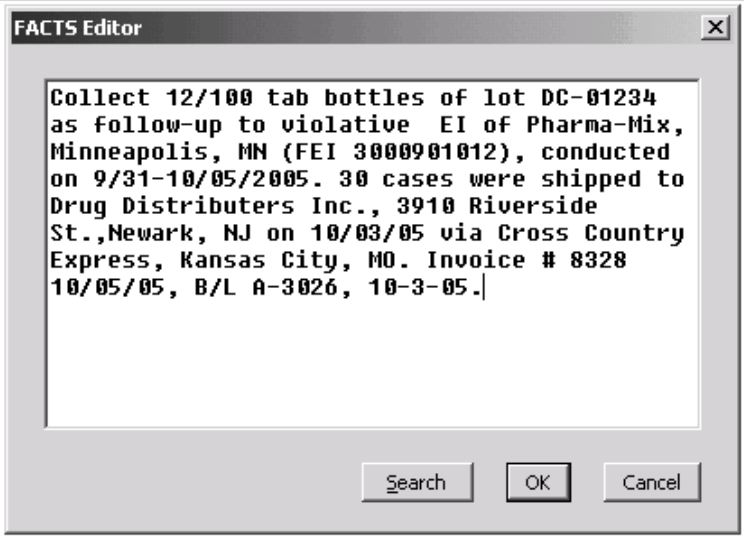
5-8 INSERTING DIGITAL PHOTOS INTO eNSpect (RESIZING USING MS WORD)





5-9 FACTS CREATE SAMPLE ASSIGNMENT SCREEN-





5-10 FORM FDA 482c NOTICE OF INSPECTION - REQUEST FOR RECORDS

DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION		1. DISTRICT OFFICE ADDRESS & PHONE NO.
TO	2. NAME AND TITLE OF INDIVIDUAL	3. DATE
	4. FIRM NAME	5. HOUR a.m. / p.m.
	6. NUMBER AND STREET	
	7. CITY AND STATE & ZIP CODE	8. PHONE # & AREA CODE

Notice of Inspection is hereby given pursuant to Section 704(a)(1) of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 374(a)(1)][1]. Written request is hereby given to access and/or copy the records described below, pursuant to the Federal Food, Drug and Cosmetic Act, Section 414(a) [21 U.S.C. 350c][2] and Title 21 Code of Federal Regulations, Section 1.361[3].

9. SIGNATURE *(Food and Drug Administration Employee(s))*	10. TYPE OR PRINT NAME AND TITLE *(FDA Employee(s))*

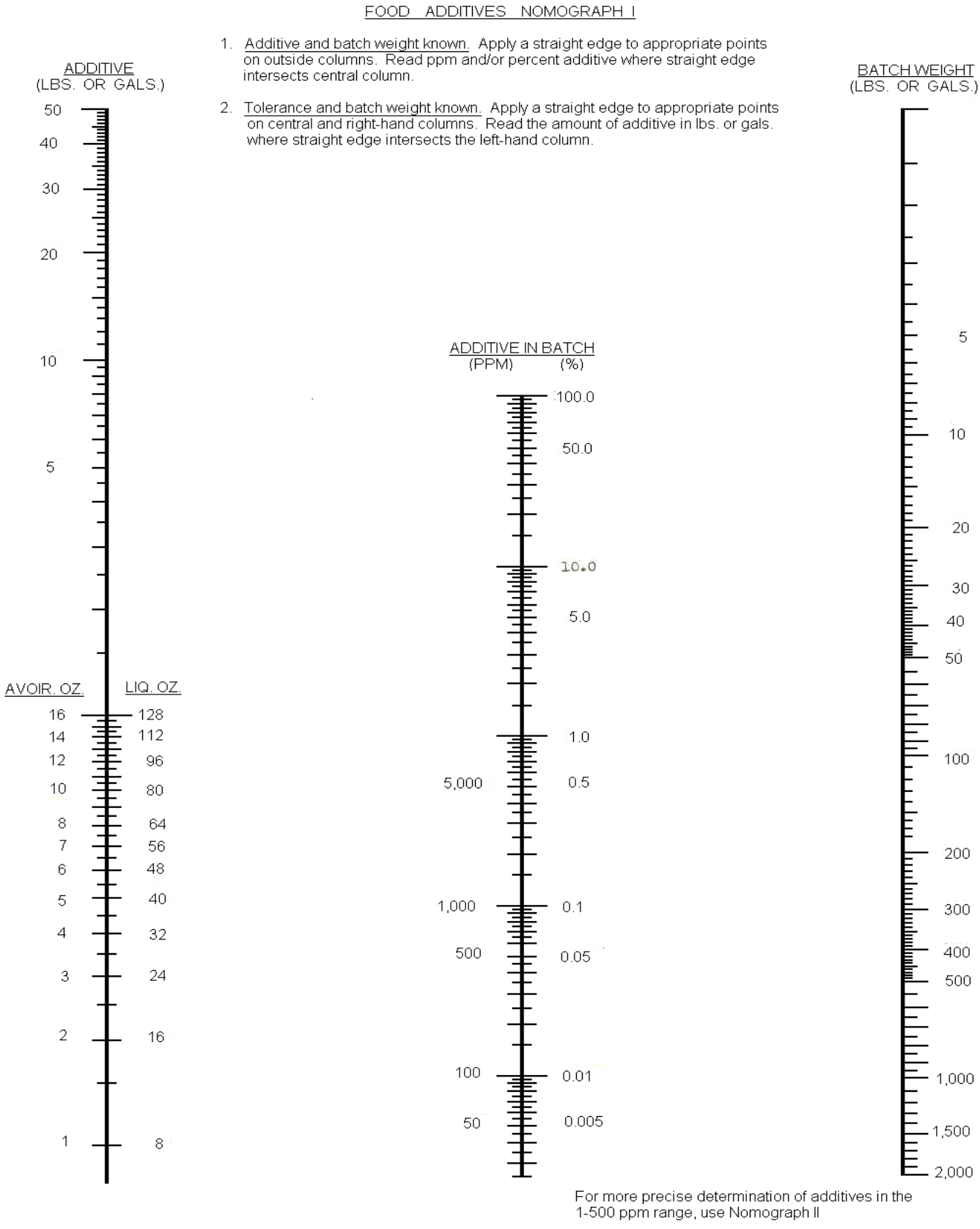
Applicable portions of Sections 704 and 414 of the Federal Food, Drug and Cosmetic Act (21 U.S.C. 374 and 350c) and Title 21 of the Code of Federal Regulations, are quoted below:

[1]Sec. 704.(a)(1) For purposes of enforcement of this Act, officers or employees duly designated by the Secretary, upon presenting appropriate credentials and a written notice to the owner, operator, or agent in charge, are authorized (A) to enter, at reasonable times, any factory, warehouse, or establishment in which food, drugs, devices, or cosmetics are manufactured, processed, packed, or held, for introduction into interstate commerce or after such introduction, or to enter any vehicle being used to transport or hold such food, drugs, devices, or cosmetics in interstate commerce; and (B) to inspect, at reasonable times and within reasonable limits and in a reasonable manner, such factory, warehouse, establishment, or vehicle and all pertinent equipment, finished and unfinished materials, containers and labeling therein. In the case of any person (excluding farms and restaurants) who manufactures, processes, packs, transports, distributes, holds, or imports foods, the inspection shall extend to all records and other information described in section 414, when the standard for records inspection under paragraph (1) or (2) of section 414(a) applies, subject to the limitations established in section 414(d). In the case of any factory, warehouse, establishment, or consulting laboratory in which prescription drugs, nonprescription drugs intended for human use, or restricted devices are manufactured, processed, packed, or held, the inspection shall extend to all things therein (including records, files, papers, processes, controls, and facilities) bearing on whether prescription drugs, nonprescription drugs intended for human use, or restricted devices which are adulterated or misbranded within the meaning of this Act, or which may not be manufactured, introduced into interstate commerce, or sold, or offered for sale by reason of any provision of this Act, have been or are being manufactured, processed, packed, transported, or held in any such place, or otherwise bearing on violation of this Act. No inspection authorized by the preceding sentence or by paragraph (3) shall extend to financial data, sales data other than shipment data, pricing data, personnel data (other than data as to qualifications of technical and professional personnel performing functions subject to this Act), and research data (other than data, relating to new drugs, antibiotic drugs and devices and, subject to reporting and inspection under regulations lawfully issued pursuant to section 505(i) or (k), section 519, or 520(g), and data relating to other drugs or devices which in the case of a new drug would be subject to reporting or inspection under lawful regulations issued pursuant to section 505(j). A separate notice shall be given for each such inspection, but a notice shall not be required for each entry made during the period covered by the inspection. Each such inspection shall be commenced and completed with reasonable promptness.

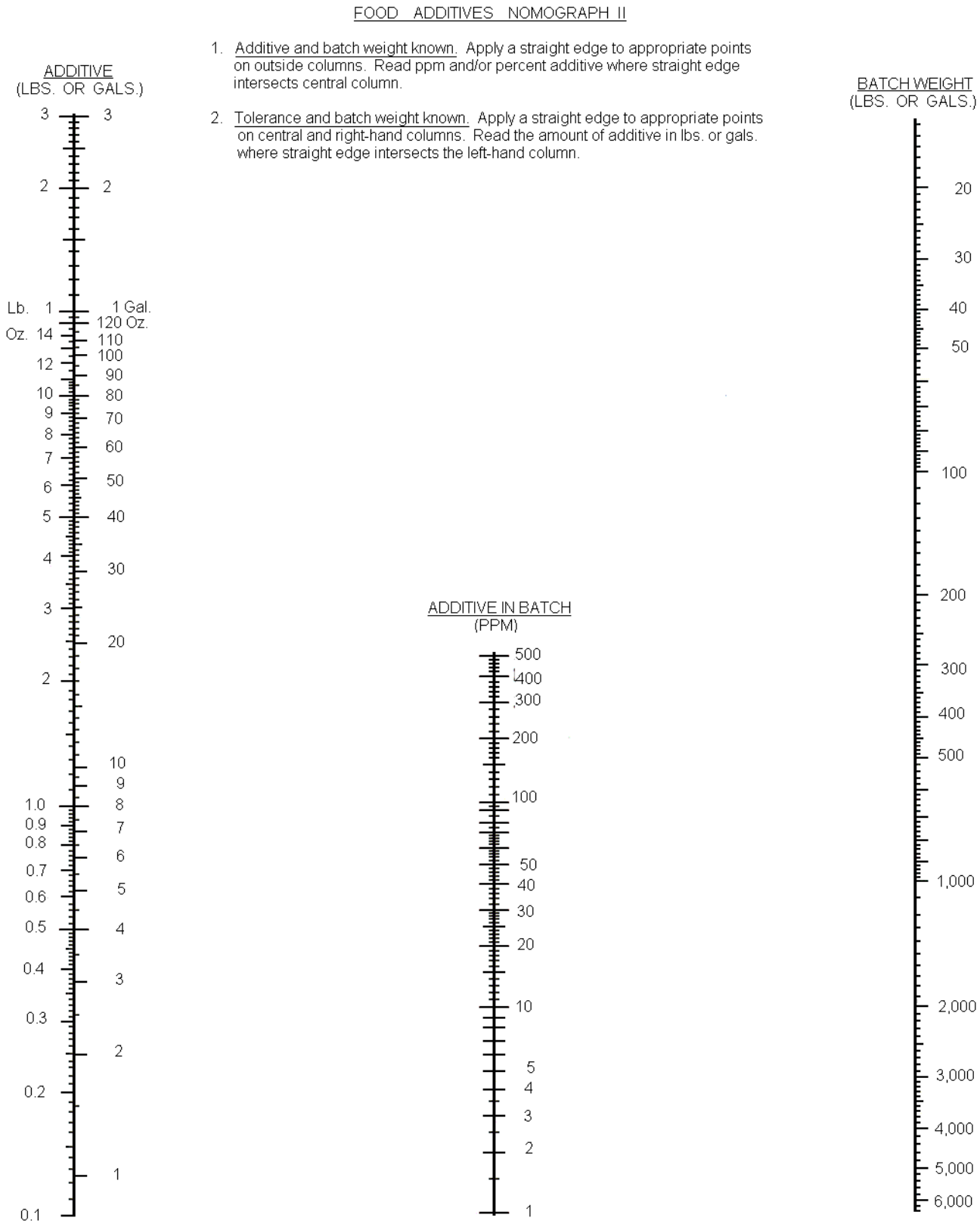
[2]Sec. 414(a) RECORDS INSPECTION. - (1) ADULTERATED FOOD. - If the Secretary has a reasonable belief that an article of food, and any other article of food that the Secretary reasonably believes is likely to be affected in a similar manner, is adulterated and presents a threat of serious adverse health consequences or death to humans or animals, each person (excluding farms and restaurants) who manufactures, processes, packs, distributes, receives, holds, or imports such article shall, at the request of an officer or employee duly designated by the Secretary, permit such officer or employee, upon presentation of appropriate credentials and a written notice to such person, at reasonable times and within reasonable limits and in a reasonable manner, to have access to and copy all records relating to such article, and to any other article of food that the Secretary reasonably believes is likely to be affected in a similar manner, that are needed to assist the Secretary in determining whether the food is adulterated and presents a threat of serious adverse health consequences or death to humans or animals. (2) Use of or exposure to food of concern. --If the Secretary believes that there is a reasonable probability that the use of or exposure to an article of food, and any other article of food that the Secretary reasonably believes is likely to be affected in a similar manner, will cause serious adverse health consequences or death to humans or animals, each person (excluding farms and restaurants) who manufactures, processes, packs, distributes, receives, holds, or imports such article shall, at the request of an officer or employee duly designated by the Secretary, permit such officer or employee, upon presentation of appropriate credentials and a written notice to such person, at reasonable times and within reasonable limits and in a reasonable manner, to have access to and copy all records relating to such article and to any other article of food that the Secretary reasonably believes is likely to be affected in a similar manner, that are needed to assist the Secretary in determining whether there is a reasonable probability that the use of or exposure to the food will cause serious adverse health consequences or death to humans or animals. (3) Application.--The requirement under paragraphs (1) and (2) applies to all records relating to the manufacture, processing, packing, distribution, receipt, holding, or importation of such article maintained by or on behalf of such person in any format (including paper and electronic formats) and at any location.

[3]321 CF CFR 1.361 What are the record availability requirements? When FDA has a reasonable belief that an article of food is adulterated and presents a threat of serious adverse health consequences or death to humans or animals, any records and other information accessible to FDA under section 414 or 704(a) of the act (21 U.S.C. 350c and 374(a)) must be made readily available for inspection and photocopying or other means of reproduction. Such records and other information must be made available as soon as possible, not to exceed 24 hours from the time of receipt of the official request, from an officer or employee duly designated by the Secretary of Health and Human services who presents appropriate credentials and a written notice.

5-11 FOOD ADDITIVE NOMOGRAPH I



5-11 FOOD ADDITIVE NOMOGRAPH II



5-12 SUMMARY OF REGISTRATION AND LISTING HUMAN PHARMACEUTICALS

SUMMARY OF REGISTRATION AND LISTING REQUIREMENTS FOR THE MANUFACTURE OR DISTRIBUTION OF HUMAN PHARMACEUTICALS			
TYPE OF FIRM	**REGISTRATION STATUS**	**LISTING STATUS**	**FACTS CODE**
Manufacturer [including homeopathic & controlled drugs]	yes	yes	M
Contract Manufacturer	yes	yes	M
Own Label Distributor	no	yes	L
Wholesale Distributor (no manufacturing or distribution under own name and label)	no	no	W-*
Own Label Repacker	yes	yes	R
Own Label Relabeler [including recirculizer]	yes	yes	Y
Contract Relabeler	yes	yes	Y
Contract Testing Laboratory [dosage forms & active ingredient release]	yes	no	C
Contract Testing Lab [doing non-release tests]	no	no	C
Contract Sub-Manufacturer	yes	yes	M
IND Manufacturer [Clinical Drugs]	no	no	M
NDA and ANDA Manufacturer	yes	yes	M
Sponsor/Monitors/Clinical Investigator	no	no	4, 5, 6, 7
Contract Sterilizer	yes	yes	0
Fulfillment Packager [adding substantive labeling]	yes	yes	Y
Mail Order House [adding insubstantial labeling]	no	no	D
Printing House	no	no	None
Medical Gas Transfiller	yes	yes	MG
First Aid/Rescue Squad [transfilling for own use]	no	no	MG
Medical Gas Transfiller [operating out of a van]	yes	yes	MG
Contract Assembler	yes	no	M
Active Drug Substance Manufacturer	yes	yes	M
Excipient Drug Manufacturer	no	no	M
Manufacturer of Research Drugs	no	no	M
Drug Importer	no	no	A
Foreign Drug Manufacturer	yes	yes	M
Methadone Clinic	no	no	T
Retail Pharmacy	no	no	D
Salvage Operation	yes	no	X
Biopharmaceutical Clinical Facility	no	no	2
Outsourcing Facility	yes	no	OF

*Includes W, WA, WF, WR, and/or WZ

5-13 SUBSTANTIALLY EQUIVALENT MEDICAL DEVICES

	Operation	Submit 510(k)	Register	List	COMPLY W/GMP	UDI Records Required
1.	Manufacture and distribute device	YES: 807.81(a)	YES 807.20(a)	YES 807.20(a)	YES	YES
2.	Contract manufacturer who commercially distributes device for specifications developer	NO: 807.81(a)	YES if domestic: 807.20(a)(2), YES if foreign 807.40(a)	YES if domestic 807.20(a)(2), YES if foreign 807.40(a)	YES	YES
3a.	Contract manufacturer who meets the definition of finished device manufacturer per 21 CFR 820.3(l).	NO	YES 807.20(a)(2)	YES 807.20(a)(2)	YES	YES, IF THEY DISTRIBUTE THE DEVICE UNDER THEIR NAME
3b.	Contract manufacturer who does not meet the definition of finished device manufacturer per 21 CFR 820.3(l) (e.g., component manufacturer, subassembler)	NO	NO	NO	NO	NO
4.	Manufacturer modifies device or new intended use and distribute	NO: preamble no. 17 & 18 FR 8/23/77 YES: 807.81(a)(3) with signif. change in device or use	YES 807.20(a)	YES 807.20(a)	YES	YES
5.	Located in US and distribute US made device. No specification initiation (domestic distributor)	NO: 807:85(b)	NO: 510(g)(4) of act, 807.20(c)	NO 807.20(c)	NO	YES, IF THE DEVICE IS DISTRIBUTED UNDER THEIR NAME
6.	Specification initiator and distribute only	YES: 807.81(a)	YES: 807.20(a)(1)	YES: 807.20(a)(1)	YES: 820.181, etc.	YES
7.	Specification consultant only; no distribution	NO	NO:	NO	NO	NO
8	Relabeler or repacker: change labeling or packaging in manner other than adding own name	YES	YES: 807.20 (a)(3)	YES. 807.20(a)(3)	YES 820.3(w), 820.3(o) and Preamble Comment 28, FR 52610	YES
9.	Relabeler or repacker: distribute under own name	NO: 807.85(b): no change to device or existing labeling and another person has a cleared premarket notification application	NO	NO	NO	YES
10.	Kit assembler using prelabeled & prepackaged devices only	NO: no change in device or existing labeling other than adding dist. name & address 807.81(a)(3)	YES: 807.20(a)	YES: 807.20(a)	YES	YES IF THEY DISTRIBUTE THE KIT UNDER THEIR NAME, SEE UDI GUIDANCE
11.	Kit assembler changes intended use (801.4) of prepackaged/prelabeled devices	YES: 807.81(a)	YES: 807.20(a)(3)	YES: 807.20(a)(3)	YES: 820.120, 820.130, etc.	YES
12.	Kit assembler changes prepackaged/prelabeled devices	NO: if no significant change to labeling or device:	YES: 807.20(a)(3)	YES: 807.20(a)(3)	YES	YES

		otherwise YES: 807.81(a)(3)(i)				
13.	Manuf. Accessory, component and package & label for health purpose to end user.	YES: 807.81(a)	YES: 807.20(a)(6)	YES: 807.20(a)(6)	YES	YES
14.	Manuf. Components & dist. Only to finished device mfr.	NO: 807.81(a)	NO: 807.65(a)	NO	Use as guide: 820.1	NO
15.	Contract mfr. Of subassembly or component (see no. 13, accessory)	NO	NO	NO	Primary mfr. must see that GMP is met 21 CFR 820.50	NO
16.	Contract packager or labeler	NO	YES	YES	Yes 820.2(a)(1) 820.3(o)	NO, UNLESS DISTRIBUTES DEVICE UNDER THEIR OWN NAME
17.	Contract Sterilizer	NO	YES if domestic 807.20(a)(2), YES if foreign 807.40(a)	YES if domestic 807.20(a)(2), YES if foreign 807.40(a)	YES	NO
18.	Manufacture custom device (domestic or foreign)	NO: 807.85(a)(1)&(2)	YES 807.20(a)	YES 807.20(a)	YES: also see 520(b); 520(f)	NO
19.	U.S. Establishment who manufactures for export only	NO	YES 807.20(a) and 807.25(g)(5)	YES 807.20(a) and 807.25(g)(5)	YES	NO
20.	Foreign manufacturers and all foreign establishments	YES: 807.81	YES, 807.40(a)	YES 807.40(a)	YES	YES
21.	Initial distributor/importer of device	YES: 807.81(a) or 807.85(b) unless 510(k) has been filed by foreign manufacturer or another init. Dist	YES: 807.20(a)(5)	NO:Must identify foreign manufacturer(s) or device(s) imported)	YES: 807.3(d), 820.198, 820.100, 820.200, etc.	NO
22.	Installer-mfr.'s agent	NO	NO	NO	YES: 820.170	NO
23.	Installer-user	NO	NO	NO	NO: for x-ray see 1020.30(d) report	NO
24.	Device being investigated under ide	Exempt: 812.1(a)	NO	NO: 807.40(c)	Exempt per 812.1(a), except for Design Control per 820.30	NO
25.	Mfr. Buys manufacturing rights for device (see no. 4)	NO: preamble 18 FR 8-23-77 only if same type of manuf. equip. is used and no signif. change to device	YES: 807.20(a)	YES 807.40(a)	YES	NO
26.	Reprocessor of single use device	YES	YES: 807.20(a)(4)	YES: 807.20(a)(4)	YES	YES, IF THEY REDISTRIBUTE THE DEVICE UNDER THEIR NAME
27.	Foreign exporter of device (device manufactured in foreign country)	YES: (original manufacturer's 510(k) maybe used)	YES: 807.40 (a)	YES: 807.40 (a)	YES 820.1(a)(2) YES	NO

5-14 eNSpect PROFILE - COMSTAT

PROFILING A FIRM'S CGMP/QS COMPLIANCE STATUS

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Table 5-14.1 Quick Reference Guide

Review Status	Profile Status	Data Entry Role	Remarks Field	Remarks *Status* Field	Purpose
Initial	Further Action Indicated	IB	Review and date Ex: "Referred to CB mm/dd/yy"		EI is potentially OAI
	Acceptable	IB	Usually no Remarks required.		EI is NAI or VAI.

In Review	Pending	CB	Recommended enforcement or alternative action; with date as well as review and date. Ex: "Recommend WL; Under review by [CB/Center]"		Enforcement or alternative action recommended.
Final	Other	IB/CB	Enter the action firm is operating under Ex: "Consent Decree (CD) for CGMP (Current Good Manufacturing Practices)/QS (Quality Systems) violations signed on mm/dd/yy." If the CD includes a sunset clause/date, add to Remarks. or "AIP invoked on mm/dd/yy."	When the firm is operating under CD/Injunction/AIP (Application Integrity Policy) and the CGMP/QS EI is: NAI or VAI, then "Acceptable (AC)"; or the inspection is OAI and further enforcement action is taken, then the Remarks Status is "Unacceptable (UN)."	Firm is operating under a CD or AIP, and a subsequent CGMP EI has occurred. Enforcement Action may involve medically necessary products or be process or product specific. In this case, such conditions should be reflected in Remarks field (see 3.10 & 3.11(2)).
	Acceptable	IB/CB	No outstanding OAI inspections, no compliance actions.		NAI and VAI inspections; or OAI inspections where no enforcement action was taken and/or was downgraded to VAI.
	Unacceptable	CB	Enter regulatory action taken and date. Ex. WL issued 1/1/18. UTL issued 3/10/18. Reg meeting held 4/10/18.		Only **after** an enforcement action occurred as a result of a CGMP/QSIT EI.

Table 5-14.2 Example of a Maintain Profiles Screen

5-14.1 Introduction

Firm profiles provide a snapshot of the firm's compliance status with CGMP or QS regulations. Profile status is monitored for domestic and foreign firms that manufacture, repack, label/relabel, sterilize, or test drug, medical device, or biological products.

5-14.2 Purpose

Firm profiles provide the compliance status as well as an inventory of product categories covered during a CGMP/QS inspection and are used to support:

- The Government Wide Quality Assurance Program (GWQAP).
- External users such as state and local regulatory authorities and foreign government agencies.
- Other FDA operations such as drug product approvals, export certificates and imports.

5-14.3 Instructions

5-14.3.1 Pre-Inspection Preparation

To obtain a comprehensive history of the firm you are going to inspect, go to ORADSS Domestic Reports folder named Establishment History Report and select EHR101 Firm Info and run the report entering the FEI you want reported. Make sure that a final status has been entered for all Profile Classes (PCs) for the previous inspection. If you find that one or more PCs have an initial status but not a final status, bring this to the attention of your supervisor and finalize prior entering any updates.

5-14.3.2 Firm's Operations

For profile purposes, the firm's operation type can be either as a single entity or in combination with other operations. Look at all the possibilities in the drop down menu before making a selection. Some selections allow for multiple operations. See below for examples:

a. Specification Developer Only versus Specification Developer Also.

   When a firm is a specification developer and they do not manufacture any medical products onsite, select profile class code, SPD, and the Operation Type, "Specification Developer Only."

   When a firm is a specification developer and they do onsite manufacturing of medical products which are not the subject of the specifications developed, select SPD with the Operation Type "Specification Developer Also" **and** select the appropriate profile class of the products they manufacture with Operation Type "Manufacturer."

b. Veterinary Drugs Also versus Veterinary Drugs Only. When a firm manufactures both veterinary and human drugs, select the appropriate profile class code(s) that defines its operation then select the Operation Type Veterinary Drugs Also. When a firm manufactures veterinary drugs only, select the appropriate profile class code(s) that defines its operation then select the Operation Type Veterinary Drugs Only.

5-14.3.3 Maintain Profiles Screen

When entering profile information, it is important to access the Maintain Profiles screen properly as accessing a profile screen incorrectly will result in data quality errors.

The correct way for Field Offices and Centers to access the Profile screen is to use eNSpect, accessed from the eNSpect App link found on the Inside. FDA's ORA Production Applications page. From the menu toolbar, enter the FEI or eNSpect Operation and once the inspection record is selected, click the left-hand side Firm tab then select the Firm Profiling tab. You are now ready to enter/update the profile status.

5-14.3.4 Previous Inspection Profile

It is important that the profile for the previous inspection be complete with a final profile status for each PC before updating the profile for the current inspection. If this is not done, a banner will appear saying "Initial data already exists," and it will not be possible to close the current inspection in eNSpect on the Firm Profiling screen.

5-14.3.5 Firm Information

The Firm Overview, Additional Details, and the Firm Profiling screens should agree in firm name, address, and FEI number. For questions, contact the GWQAP staff gwqap@fda.hhs.gov.

5-14.3.6 Inspection Coverage of Profile Class Codes

When a CGMP/QS systems-based inspection is performed, coverage should reflect the overall state of control for the firm's operations. For this reason, the PCs should reflect all product classes produced by the firm as well as those covered during the inspection.

When a firm manufactures more than one commodity, e.g., drugs and devices, and the inspection covers only the drug systems, then only update the PCs that represent the drug commodity. See 5-14.7 for more information about profile classes and codes.

5-14.3.7 Discontinue and Delete Buttons

Proper use of the Discontinue and the Delete buttons*:

Discontinue button – The PCs should be discontinued if a firm goes out-of-business or no longer manufactures a drug, device, or biologic product.

Delete button - PCs and data entered in error can and should be deleted **prior** to clicking the save button and exiting the screen.

NOTE: If you save incorrect data before realizing it and you cannot delete it, contact the GWQAP Team for assistance. See 5-14.4 for Contact Information.

5-14.3.8 CGMP Inspection and Other Toggle Buttons

The CGMP Inspection toggle button is automatically activated when the Profile Required field is checked on the Maintain Inspection Results screen. The *Other* radio button should not be used for profiling purposes.

5-14.3.9 Initial, In Review, and Final

As reflected in Table 5-14.1 above, profile status should be entered as follows:

Initial: Normally entered by the Investigator. Potentially OAI inspections should be immediately entered as FAI and NAI/VAI as AC.

In Review: Pending should be entered by the Compliance Officer as soon as the record is received for review.

Final: AC should be entered by the Supervisor for NAI/VAI inspections; UN should be entered by the Compliance Officer for OAI inspections when a regulatory action has been taken.

NOTE: The Status Date automatically records the date that the information is entered or updated in Initial, In Review, and Final Profile Status. It is important to maintain the integrity of the profile information by not changing this date.

Foreign firms: The Divisions enter the initial status only and the appropriate Center enters the final profile class status.

For inspections covering CDER-regulated products the Office of Pharmaceutical Quality Operations (OPQO) will be the business unit entering the profile decision (Initial-Final) for domestic and foreign NAI and VAI inspections with the exception of for-cause assignments issued by CDER.

For inspection classifications of OAI and for NAI/VAI for-cause assignments issued by CDER, OPQO staff will be entering the Initial and in-Review status and CDER will enter the final profile decision.

5-14.3.10 Final Profile Status

It is important for the Field and Centers to understand that final profile status should be promptly entered when a final agency decision has been made. Profiles should not be held in Pending status if the Division or Center decides that the course of action is to not take enforcement action as defined by FMD-86, and, instead, re-inspect.

5-14.3.10.1 Other Status

Other should be entered as the final profile status for all profile class codes when a firm is operating under a consent decree (CD) or Application Integrity Policy (AIP). See Tables 5-14.1 & 5-14.2 above for more information.

5-14.3.10.2 Acceptable Status

AC should be entered as the final profile status when an inspection is classified as NAI or VAI and the firm is not operating under a CD or AIP. See Table 5-14.1 above for more information. If an OAI is not supported by an enforcement action, it is entered as AC as defined in Field Management Directive (FMD)-86.

5-14.3.10.3 Unacceptable Status

UN should be entered as the final profile status when there is an outstanding OAI inspection.

5-14.3.10.3.1 Continuation of Unacceptable Status

A UN status along with the regulatory action taken may be carried forward from one inspection to the next when the follow-up inspection reveals the firm had not addressed the violations identified in the original OAI inspection or an enforcement action. In this case, it is important that the Remarks field note this condition. See 5-14.3.11 Remarks field for more information.

5-14.3.10.3.2 Changing from Unacceptable to Acceptable Status

A UN status may be changed to AC when the agency's review of the firm's response to a warning letter reveals the firm's corrective actions adequately address the violations identified, a re-inspection for verification may or may not be warranted. The Remarks field must note the reason for the change.

5-14.3.11 Remark Status Field

The Remark Status field is used mainly to indicate the compliance status of a current inspection while the firm operates under a CD or AIP. See Tables 5-14.1 & 5-14.2 for more information and examples.

It may also be used to indicate an exception to the general compliance status. The profile status when under a CD will be "Others." The Remarks Status Field will show the current compliance inspection status (AC/UN). The Remarks Field will note that the firm is operating under a CD (include date and any information required concerning the current inspection.

5-14.3.12 Remarks Field

The Remarks field is a narrative field that is to be used as often as needed to:

1. Track the status of any potential or completed enforcement or alternative action with dates. This may include an explanation for a continuation of an UN final profile status from one inspection to the next when the follow up inspection reveals the firm's corrective actions were found inadequate. See Table 5-14.1 above or 5-14.4 below for more information and accessing the ORA/OISM/DSS/ESB intranet site, respectively.
2. Indicate when a firm is operating under a CD or AIP with date. Note when there are specific conditions such as product(s) subject to the CD or AIP. This information must remain in Remarks for each PC until the CD/AIP is vacated or revoked.
3. Indicate the regulatory action and date regulatory action was issued.
4. Identify product(s) covered when using the catch all PCs MIS for devices, BMI for biologics and NEC for drugs; and
5. Indicate where a sterilization process(es) takes place such as onsite at the manufacturer, or offsite by a contract sterilizer. If offsite, include the name, address, and FEI of the contract sterilizer.

NOTE: After entering the information once, a copy and paste method can be used to update the Remarks field for each profile class involved as follows:

a. Highlight the narrative text by clicking in the Remarks field.

b. Select CTRL C to copy.

c. Select CTRL V to paste.

5-14.3.13 Out-of-Business Firm

When a profiled firm goes out of business, changes operations, or discontinues production of FDA regulated products, record the appropriate information in the eNSpect Application. From the Offline Field Client select the Firm Information tab followed by the Firm Profiling tab to discontinue each profile class code then select Save.

Navigate to the Assignment Details Page and select the **Convert to Investigation** followed by selecting the **OOB (Out of Business)** Washout Reason and confirm the selection. Synchronize to upload data to eNSpect Online.

From the Online Application select the assignment and Navigate to the Firm Overview tab. Select the Work Obligation as **N No** from the drop-down and select the **Save Assignment** button.

Once the Investigation is complete, the Out of Business data will get synched with the Firm Management Services and will update the firm's operational status to **Out of Business** and Work Obligation to **No**.

For assistance, contact the GWQAP Team. See 5-14.4

below for contact information.

5-14.3.14 Firm Merge

Before attempting to merge two or more firm records, always check to ensure all profile class codes have been finalized. Do not attempt to merge if the profile status is left in Initial or In Review. Merging firms where the profile classes are not finalized will cause problems that can only be resolved by GWQAP staff. See 5-14.4 below for contact information.

5-14.3.15 Troubleshooting

Troubleshooting information may be found at the GWQAP intranet site. See 5-14.4 for intranet site location.

5-14.4 Contact Information

To reach the Government Wide Quality Assurance Program select http://inside.fda.gov:9003/ORA/Offices/OPOP/ISM/DSS/ucm557080.htm. To contact the GWQAP Team email

gwqap@fda.hhs.gov.

5-14.5 Data Quality Assurance Projects

Our GWQAP stakeholders, including the Department of Veterans Affairs (VA), the Defense Logistics Agency (DLA), as well as several Local, State, and Foreign Governments, use an external view of eNSpect profiles.

through the COMSTAT application to help them make procurement decisions for medical products. Since these stakeholders can view only the latest acceptable or unacceptable final profile status, profile classes **must** be finalized.

Each Division and Center is responsible for management of firm profiles specific to it by entering profile information and providing a profile status as soon as a final Agency decision is made. The GWQAP Team in the Division of Systems Solution/Enforcement Systems Branch (DSS/ESB) is responsible for monitoring the Divisions and Centers profile entries and communicating with the same on profile issues when profile information is incomplete, incorrect, or missing. To accomplish this, on a quarterly basis, an Online Reporting Analysis Decision Support System (ORADSS) program is run. Duplicate entries and non-finalized profile entries are addressed and a follow up is made with the Divisions and Centers when incomplete entries and/or errors are found. This data is maintained in an Excel program. It is the responsibility of the GWQAP Team to assure that eNSpect and COMSTAT views are accurate, complete, and current.

Accessing and Running an ORADSS Report

1. From Inside. FDA select IT Applications located under Services.
2. Select ORA Applications and click the ORADSS link.
3. Select Folders in the lower left corner.
4. Select the + Public Folders.
5. Select + Domestic Reports.
6. Select Firms.
7. Select FIR034_Profiles by Division.
8. A dialog box will appear to enter information
    a. From the top of the dialog box, select the appropriate Home District.
    b. Select GMP Insp Date (Start) by entering xx/xx/xxxx into the window that appears.
    c. Select GMP Insp Date (End) by entering xx/xx/xxxx.
    d. Select Enter to Run Query.
9. Saving the Report in Excel
    a. From the toolbar, select the down arrow of Export.
    b. Click Export Document as and select Excel.
    c. Excel will open with the imported data.
10. Removing Duplicate Entries in eNSpect
    a. Contact the GWQAP Team.

    Under this procedure:

    1. Profile Monitors are responsible for running quarterly reports from January 1- December 31.
    2. The GWQAP Team is responsible for conducting quarterly work group meetings and to follow-up with each Division to ensure profiles are up-to-date.

5-14.6 Establishment Profile Criteria

Table 5-14.6.1 Device, Biologic, Drug, and Veterinary Establishments TO Profile

Manufacturer	Makes a new or a changed product from one or more ingredients.
Remanufacturer	Processes, conditions, renovates, repackages, restores, or performs any other act to a finished device that significantly changes the device's

	performance or safety specifications or intended use.
Reprocessor	Performs remanufacturing operations on a single use device.
Packer/ Repacker	Packs a product or products into different containers without making any changes in the form of the product.
Labeler/Relabeler	An establishment which affixes the original labeling to a product or changes in any way the labeling on a product without affecting the product or its container.
Contract Sterilizers	Performs sterilization or irradiation of products or components of products regulated by FDA on a contract basis.
Control Testing Laboratories	Performs production quality control work related to products regulated by FDA on a contract basis.
Assemblers of Medical Device Kits	Responsible for assembling finished devices into medical device kits.
Specification Developer	Initiates or develops specifications for a device that is distributed under the establishment's own name but is manufactured by a second person.
HCT/P Establishment	Manufactures licensed/approved HCT/Ps that are regulated under the FD&C Act, PHS 351, 21 CFR 1271 and the drug (CGMP), medical device (QSR) or biological product regulations, i.e., “351 HCT/Ps”

Table 5-14.6.2 Establishment and Operations NOT to Profile

Blood Banks
Methadone Clinics
Manufacturers of "Research Use Only" Products
Pharmacies (including pharmacy compounders) and Retail firms
Distributors
Plasmapheresis Centers
Custom Device Manufacturers
Veterinary Medical Device Firms
X-ray Assemblers
Mammography Clinics
Manufacturers of General Purpose Articles (Devices)
Physicians Offices, Hospitals and Clinics
Laser Light Shows/Television and Microwave Oven Manufacturers
Sun tanning Establishments
Device Component Manufacturers
Clinical Investigators/Bioresearch Monitoring
Any Non-GMP Inspection
HCT/P establishments that manufacture products regulated solely under PHS 361 and 21 CFR 1271, i.e., “361 HCT/Ps”
HCT/P establishments that manufacture unlicensed/unapproved products that are regulated under the FD&C Act, PHS 351, 21 CFR 1271 and the drug (CGMP), medical device (QSR) or biological product regulations, i.e., “351 HCT/Ps”

5-14.6.3 Pre-Approval Inspections

Pharma product specific Pre-Approval and Post Approval Inspections should not be profiled unless the inspection is the initial inspection of a new profile class and the inspection results in an approval recommendation (VAI or NAI). Withhold recommendations for initial profile classes (the EI is classified as OAI) are not profiled, this assures the product cannot be marketed in the U.S. until a follow-up inspection verifies implementation of appropriate corrective actions or until corrections are substantially verified through other appropriate means.

Device Pre-Approval (PMA) inspections that cover the firm’s systems should be treated like any other QS inspection. In all cases the initial profile status should be entered by the Investigator.

5-14.7 Profile Classes and Codes

The profile system is based upon product categories or classes and is not product specific. Select the most appropriate profile class(es) to describe the product(s) the firm manufactures or otherwise processes.

When describing devices, often more than one class is needed to describe the operations/assembly involved in the device. A rule of thumb is to think of the composition of the device and then select the profile classes that define the make-up of that device and its assembly. For example, a catheter and needle unit is profiled as MTL (metal fabrication and assembly) and PRF (plastic or rubber fabrication and assembly). A Cutter, orthopedic cast, 110 volt AC-DC, is profiled as MTL, PRF and ELE (electrical) For devices that have software and are operated by computer, codes COS (software) and COH (computer hardware) should be added.

SPD (specification developer) should be used if a firm only develops the design and specifications and has the device manufactured by someone else. Do not include other profile classes unless the firm also manufactures other medical products on-site.

When describing combination product (see IOM 5.12.1) multiple profile codes may be needed. (e.g., for a combination product CGMP inspection of a facility manufacturing a sterile- filled prefill syringe, use profile codes SVS-Sterile-filled small valume parenteral drugs and IDD-injectable delivery device (syringes, auto injectors/pens)).

Catch-all codes: MIS for devices, NEC and CRU for drugs, and BMI for biologics can be used when product does not fit into any product class identified by the list of PCs. When using these codes, identify the type of product in the Remarks field for that code. If the product is a sterile product, don't forget to include the appropriate sterilization.

5-14.7.1 Profile Class Codes

For more information, contact your Division Profile Monitor or the GWQAP team. See 5-14.4 for contact information.

Table 5-14.7.1.1 Biologics

BIOLOGICS	
Profile Class Code	**Definitions**
AEV	ANTITOXINS AND ANTIVENINS
AFP	ANIMAL DERIVED FRACTIONATION PRODUCTS
ALP	ALLERGENIC PRODUCTS
BBP	BLOOD AND BLOOD PRODUCTS UNLICENSED
BGR	BLOOD GROUPING REAGENTS
BMI	BIOLOGICAL PRODUCTS NOT OTHERWISE CLASSIFIED (Blood collection bags with anti-coagulant, plasma volume expanders, Limulus Amebocyte Lysate (LAL) test kit, etc.; Note specific product(s) in *Remarks* field)
CBS	COMPUTER BIOLOGICAL SOFTWARE
CGT	CELL AND GENE THERAPY PRODUCTS
HFP	HUMAN DERIVED FRACTIONATION PRODUCTS
LBI	LABORATORY, BIOLOGICAL TESTING
RBD	RECOMBINANT ANALOGUES OF BLOOD DERIVATIVE PRODUCTS
TIS	HUMAN TISSUE REGULATED BY FDA
VBP	VACCINE BULK PRODUCT
VFP	VACCINE FINISHED PRODUCT
VIV	IN VIVO DIAGNOSTICS
VTK	VIRAL MARKER TEST KIT

Table 5-14.7.1.2 Devices

DEVICES	
Profile Class Code	**Definitions**
AMP	ADDITIVE MANUFACTURING PROCESS (incl. 3D printing, additive manufacturing medical products)
CCR	CLINICAL CHEMISTRY REAGENTS (including diagnostic tapes, sticks, etc.)
COH	COMPUTER HARDWARE
COS	COMPUTER SOFTWARE (Devices only)
CSP	CHEMICAL STERILIZATION
CTD	CONTROL TESTING LABORATORIES "ALSO"

	(Device manufacturer that is also a contract testing lab.)
DKA	DEVICE KIT ASSEMBLER (Ex: lumbar puncture kit, anesthesiology kit, suture removal kit)
ELE	ELECTRICAL ASSEMBLY
FSP	FILTRATION STERILIZATION
GLA	GLASS OR CERAMIC FABRICATION AND ASSEMBLY
GSP	GAS (ETO, PROPYLENE OXIDE STERILIZATION)
HCP	HEMATOLOGY AND COAGULATION PRODUCTS
HSP	DRY HEAT STERILIZATION
HTD	HUMAN TISSUE DEVICES
IDD	INJECTABLE DELIVERY DEVICE (syringes, auto injectors/pens)
MED	MEDIA (including microbiological and tissue culture, growth media and accessories, and ingredients)
MIS	NOT ELSEWHERE CLASSIFIED (Note specific product(s) in *Remarks* field)
MSO	METERED SPRAY OTHER (incl. nasal sprays, sublingual sprays)
MTL	METAL FABRICATION AND ASSEMBLY
OID	ORALLY INHALED DELIVERY (incl. MDIs, DPIs, sprays)
OPT	OPTIC FABRICATION AND ASSEMBLY (Optical products or parts, e.g., eye glass lenses, intraocular lenses, contact lenses, lens portion of a laser, etc.)
PAT	PATCH (incl. conventional patches, micro needles)
PBM	PROCESSED BIOLOGIC MATERIAL (Only animal or plant material used as a device)
PRF	PLASTIC OR RUBBER FABRICATION AND ASSEMBLY
RIP	RADIOIMMUNOASSAY PRODUCTS
RSP	RADIATION STERILIZATION
SIP	SEROLOGICAL AND IMMUNOLOGICAL PRODUCTS (Including bacterial typing, rheumatoid factors, pregnancy kits, IVD other than VIRAL marker test kits, etc.)
SOL	DEVICE SOLUTIONS AND GELS (Including contact gels, dialysis solutions, dental pastes, adhesives, etc.)
SPD	SPECIFICATION DEVELOPERS (Note in *Remarks* field where finished product testing is conducted.)
SSP	STEAM STERILIZATION
TSP	FRACTIONAL TYNDALLIZATION STERILIZATION
TXT	TEXTILE FABRICATION AND ASSEMBLY
WOD	WOOD FABRICATION AND ASSEMBLY
WSP	WATER STERILIZATION

Table 5-14.7.1.3 Drugs and Veterinary

DRUGS	
Profile Class Code	**Definitions**
ADM	AEROSOL DISPENSED MEDICATION
CBI	RECOMBINANT/NON-RECOMBINANT PROTEIN DS OF BIOLOGIC ORIGIN
CEX	STARTING/INTERMEDIATE DERIVED FROM PLANT/ANIMAL EXTRACTION
CFN	NON-STERILE API BY FERMENTATION
CFS	STERILE API BY FERMENTATION
CHG	CAPSULES, PROMPT RELEASE
CRF	DRUG SUBSTANCE INTERMEDIATE (FERMENTATION)
CRU	DRUG SUBSTANCE INTERMEDIATE (CHEMICAL SYNTHESIS)
CRX	STERILE STARTING/INTERMEDIATE/NEC (not Plant/Animal)
CSG	CAPSULES, SOFT GELATIN
CSN	NON-STERILE API BY CHEMICAL SYNTHESIS
CSS	STERILE API BY CHEMICAL SYNTHESIS
CTR	CAPSULES, MODIFIED RELEASE

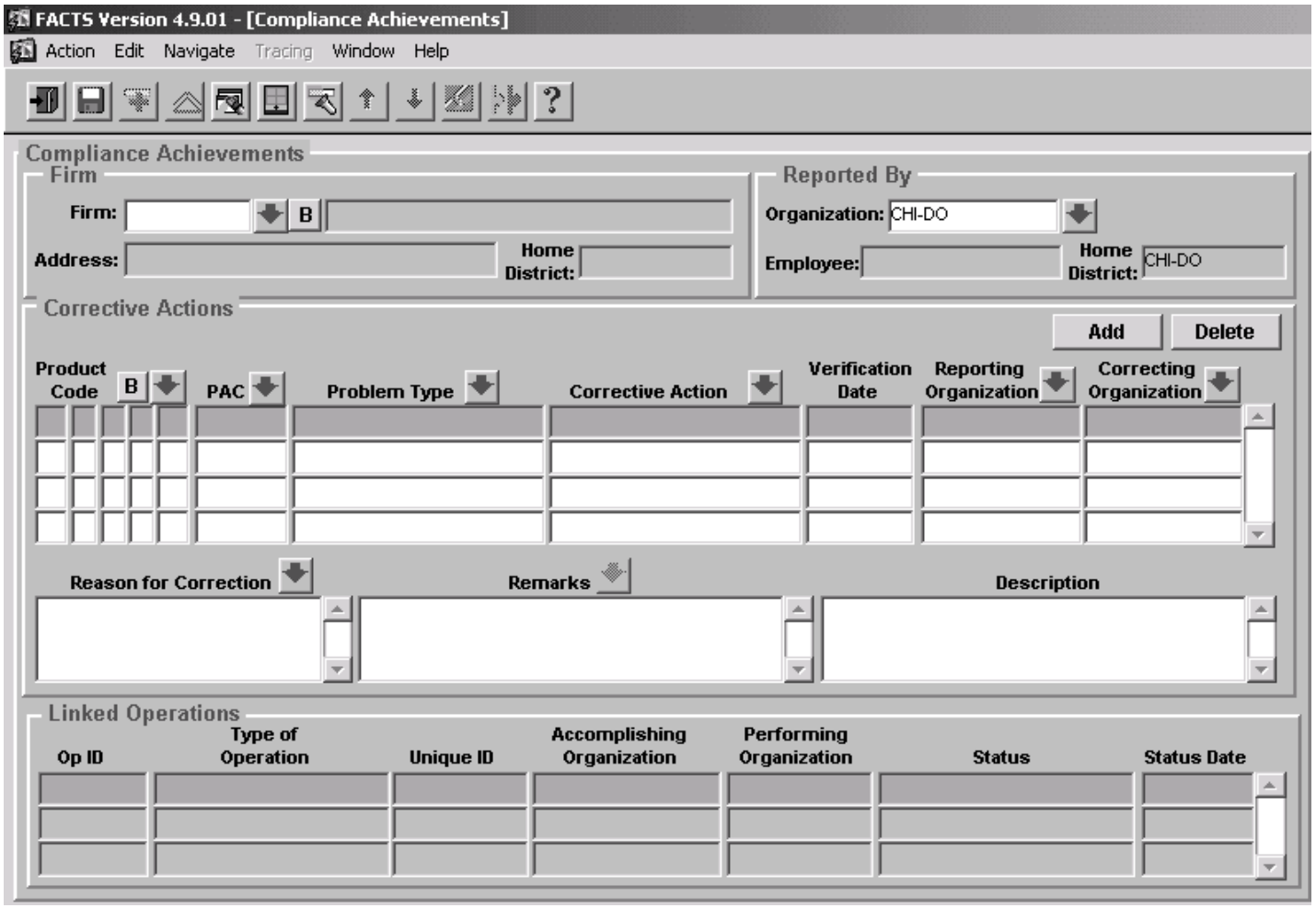
CXA	PURIFIED API DERIVED FROMPLANT/ANIMAL EXTRACTION
EXC	EXCIPIENT (also referred to as inactive ingredient)
GAS	MEDICAL GAS (includes liquid oxygen)
HMA	HOMEOPATHIC API/drug substance/tinctures
HMF	HOMEOPATHIC FINISHED DRUG PRODUCTS
LCP	LABORATORY, CHEMICAL/physical testing
LIQ	NON-STERILE LIQUID (other than suspensions & emulsions)
LMN	LABORATORY, MICROBIOLOGICAL-non-sterility testing
LMS	LABORATORY, MICROBIOLOGICAL-sterility testing
LVP	LARGE VOLUME PARENTERALS
PTC	PATCH (incl. conventional patches, no micro needles)
NEC	NOT ELSEWHERE CLASSIFIED FINISHED DRUG
OIN	OINTMENT, NON-STERILE (includes cream, jelly, paste)
PET	POSITRON EMISSION TOMOGRAPHY
POW	NON-STERILE POWDERS (Includes oral and topical)
SES	SUSPENSIONS AND EMULSIONS (NON-STERILE)
SLQ	STERILE LIQUID (other than suspensions & emulsions)
SON	STERILE OINTMENT
SPW	STERILE POWDER
SSE	STERILE SUSPENSIONS AND EMULSIONS (NON PARENTERALS)
SUP	SUPPOSITORIES
SVL	SMALL VOLUME PARENTERALS (Lyophilized)
SVS	STERILE-FILLED SMALL VOLUME PARENTERAL DRUGS
SVT	TERMINALLY STERILIZED SMALL VOLUME PARENTERALS
TCM	TABLETS, PROMPT RELEASE
TCT	TABLETS, DELAYED RELEASE
TDP	TRANSDERMAL PATCHES
TTR	TABLETS, EXTENDED RELEASE

NOTE: API - Active Pharmaceutical Ingredient is sometimes referred to as Drug Substance.

Table 5-14.7.1.4 Special Veterinary

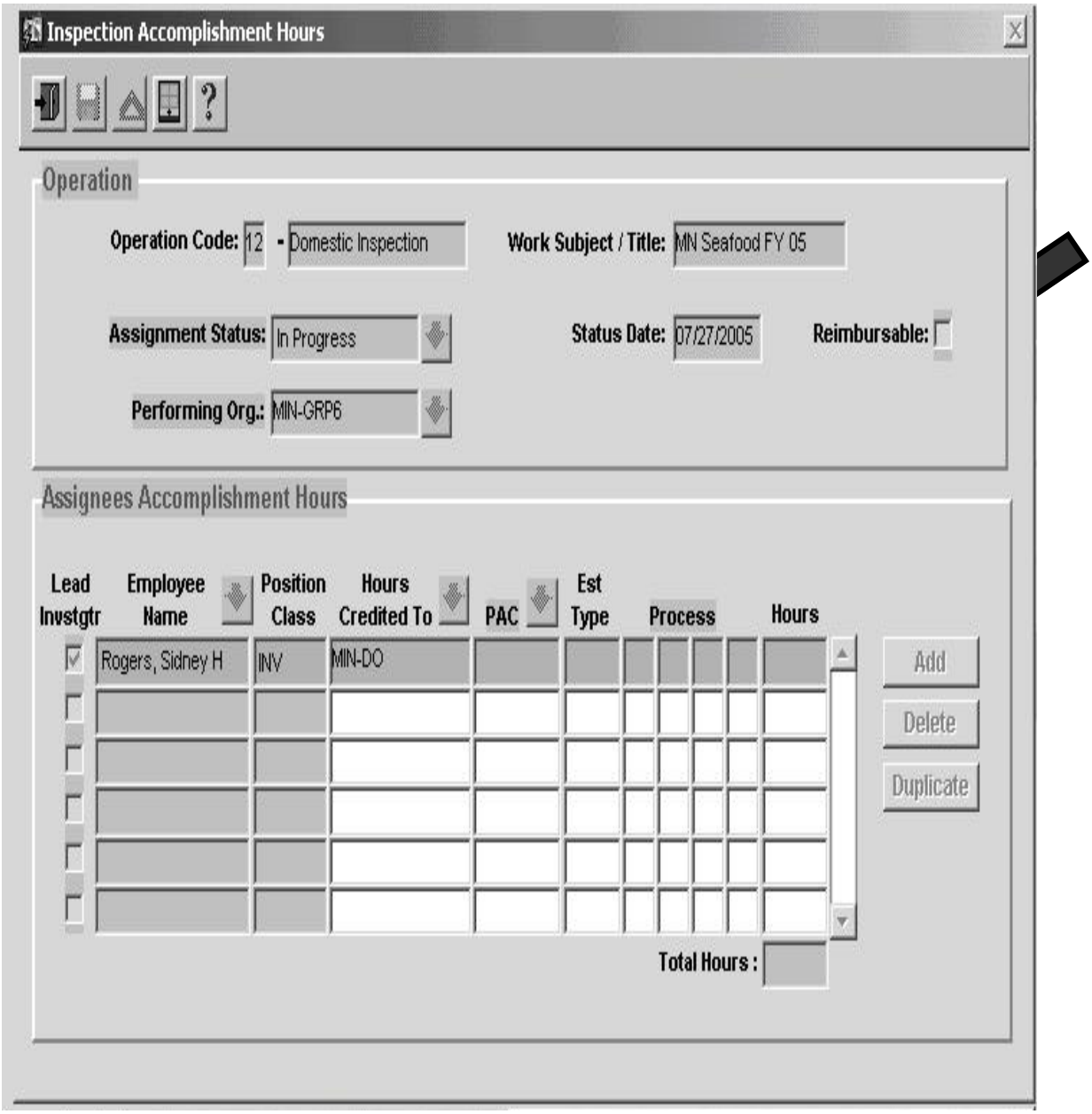
Profile Class Code	Definitions
IMN	IMPLANT NON-STERILE
IMS	IMPLANT STERILE
TAM	TYPE A MEDICATED ARTICLE

5-15 COMPLIANCE ACHIEVEMENT REPORT



5-16 FACTS REIMBURSABLE CHECK BOX

Screenshot showing location of Reimbursable check box:



5-17 FORM FDA 4056 – PRODUCE FARM INSPECTION OBSERVATIONS

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

PRODUCE FARM INSPECTION OBSERVATIONS

FDA

Name of State and Department *(if acting under commission with FDA)* #1	DISTRICT OFFICE ADDRESS #2	
DISTRICT OFFICE PHONE NUMBER #3	DATE(S) OF INSPECTION #4	FEI NUMBER #5

LAST NAME, FIRST NAME, MIDDLE INITIAL AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED *(Most responsible individual present)* TO: #6

FARM NAME *(include business name, if different)* #7

OWNER/OPERATOR #8

FARM MAILING ADDRESS #9	FARM PHYSICAL LOCATION, IF DIFFERENT FROM MAILING ADDRESS (*e.g., location identifiers such as GPS coordinates)* #10
TYPE OF INSPECTION: ☐ Initial ☐ Routine ☐ Follow-up ☐ For-cause ☐ Other *(please specify)* #11	CROPS OBSERVED DURING INSPECTION #12

This form lists factual observations made by the FDA representative(s) during the inspection of the farm's operation.

This is not a final FDA determination of compliance, or non-compliance, with the Produce Safety Rule *(21 CFR Part 112)* or any other legal requirement.

Representatives of the regulatory agency should record their observations on this form as clearly and specifically as possible and should order their observations by significance within each area (most important first). In some cases, an observation may relate to more than one topic area. Representatives of the regulatory agency should record observations in the topic area listed below that, in the representatives' judgment, is the most appropriate topic. Not all topic areas may be applicable in every situation. In addition, representatives of the regulatory agency may not examine every aspect of the farm's operation during an inspection, so a topic area left blank should not be interpreted to mean the farm is in compliance, or not in compliance, with requirements related to that topic area.

Representatives of the regulatory agency should discuss all observations with the management of the farm or their representative as they are observed, or on a daily basis, to minimize surprises, errors, and misunderstandings when this form is issued. Discussion should include those observations which may be written on the form and those that will only be discussed with management during the closeout meeting. This form should be issued during the exit conference of all produce inspections, including when no observations have been recorded.

The farm may use this opportunity to ask questions about the observations or to request clarification. If the farm has implemented, or plans to implement, corrective action in response to an observation, this may be discussed with the representatives of the regulatory agency during the inspection. Representatives of the regulatory agency should annotate the form, as applicable, with any completed or promised corrections discussed during the inspection. FDA representatives are encouraged to verify the farm's completed corrective actions during the inspection as long as the verification does not unreasonably extend the duration of the inspection. Inclusion of annotations regarding corrective actions does not signify any conclusion by the regulatory agency regarding the sufficiency of the actions.

FARM NAME *(include business name, if different)*

DATE(S) OF INSPECTION	FEI NUMBER

If you have any questions, please contact the regulatory agency at the phone number and address above.

Representatives of the regulatory agency should record observations consistent with procedures established for conduct of inspections, including additional instructions that appear in Chapter 5 of the IOM, available at https://www.fda.gov/ICECI/Inspections/IOM.

REPORTABLE OBSERVATIONS MADE DURING THE INSPECTION

Representatives of the regulatory agency should check one of the following options. As noted above, this is not a final FDA determination of compliance, or non-compliance, with the Produce Safety Rule (21 CFR Part 112) or any other legal requirement.

#13

☐ During an inspection of the operation (I) (we) did not observe any conditions and/or practices to be reported on this form.

☐ During an inspection of the operation (I) (we) observed the following conditions and/or practices as described below.

Personnel Qualifications and Training *(21 CFR Part 112, Subpart C)*

1. §§ 112.21 and 112.22: Qualifications and training for personnel who handle (contact) covered produce or food contact surfaces
   ☐ Observation ☐ Corrective action taken
   Description:

2. § 112.23: Assignment or identification of supervisors
   ☐ Observation ☐ Corrective action taken
   Description:

3. § 112.30: Record-keeping
   ☐ Observation ☐ Corrective action taken
   Description:

Health and Hygiene *(21 CFR Part 112, Subpart D)*

4. § 112.31: Measures to prevent ill or infected persons from contaminating covered produce with microorganisms of public health significance
   ☐ Observation ☐ Corrective action taken
   Description:

5. § 112.32: Hygienic practices of personnel
   ☐ Observation ☐ Corrective action taken
   Description:

FARM NAME *(include business name, if different)*

DATE(S) OF INSPECTION	FEI NUMBER

6. § 112.33: Measures to prevent visitors from contaminating covered produce and food contact surfaces with microorganisms of public health significance

☐ Observation ☐ Corrective action taken

Description:

Agricultural Water *(21 CFR Part 112, Subpart E)*

7. § 112.41: Quality of agricultural water

☐ Observation ☐ Corrective action taken

Description:

8. § 112.42: Agricultural water sources, water distribution system, and pooling of water

☐ Observation ☐ Corrective action taken

Description:

9. § 112.43: Treating agricultural water

☐ Observation ☐ Corrective action taken

Description:

10. § 112.44: Microbial quality criteria applicable to agricultural water used for certain intended uses

☐ Observation ☐ Corrective action taken

Description:

11. § 112.45: Corrective measures if agricultural water does not meet requirements of § 112.41 or § 112.44.

☐ Observation ☐ Corrective action taken

Description:

12. §§ 112.46 and 112.47: Testing agricultural water that is subject to the requirements of § 112.44.

☐ Observation ☐ Corrective action taken

Description:

13. § 112.48: Water that is used during harvest, packing, and holding activities

☐ Observation ☐ Corrective action taken

Description:

14. § 112.50: Record-keeping

☐ Observation ☐ Corrective action taken

Description:

FARM NAME *(include business name, if different)*

DATE(S) OF INSPECTION	FEI NUMBER

Biological Soil Amendments of Animal Origin and Human Waste *(21 CFR Part 112, Subpart F)*

15. § 112.52: Handling, conveyance, and storage of biological soil amendments of animal origin
☐ Observation ☐ Corrective action taken
Description:

16. § 112.53: Use of human waste
☐ Observation ☐ Corrective action taken
Description:

17. §§ 112.51, 112.54, 112.55, and 112.56: Determining status of biological soil amendment of animal origin; acceptable treatment processes; applicable microbial standards for such treatment processes; and, application requirements and minimum application intervals for biological soil amendments of animal origin
☐ Observation ☐ Corrective action taken
Description:

18. § 112.60: Record-keeping
☐ Observation ☐ Corrective action taken
Description:

Domesticated and Wild Animals *(21 CFR Part 112, Subpart I)*

19. § 112.83: Measures related to grazing animals, working animals, or animal intrusion
☐ Observation ☐ Corrective action taken
Description:

Growing, Harvesting, Packing, and Holding Activities *(21 CFR Part 112, Subpart K)*

20. § 112.111: Measures related to growing, harvesting, packing, or holding both covered and excluded produce
☐ Observation ☐ Corrective action taken
Description:

21. § 112.112: Measures to be taken immediately prior to and during harvest activities
☐ Observation ☐ Corrective action taken
Description:

22. § 112.113: Handling harvested covered produce
☐ Observation ☐ Corrective action taken
Description:

FARM NAME *(include business name, if different)*

DATE(S) OF INSPECTION	FEI NUMBER

23. § 112.114: Disposition of dropped covered produce
☐ Observation ☐ Corrective action taken
Description:

24. § 112.115: Measures related to packaging covered produce
☐ Observation ☐ Corrective action taken
Description:

25. § 112.116: Measures related to food-packing (including food-packaging) material
☐ Observation ☐ Corrective action taken
Description:

Equipment, Tools, Buildings, and Sanitation *(21 CFR Part 112, Subpart L)*

26. § 112.123: Equipment and tools
☐ Observation ☐ Corrective action taken
Description:

27. § 112.124: Instruments and controls used to measure, regulate, or record
☐ Observation ☐ Corrective action taken
Description:

28. § 112.125: Equipment used in the transport of covered produce
☐ Observation ☐ Corrective action taken
Description:

29. § 112.126: Buildings
☐ Observation ☐ Corrective action taken
Description:

30. § 112.127: Domesticated animals in and around a fully-enclosed building
☐ Observation ☐ Corrective action taken
Description:

31. § 112.128: Pest control in buildings
☐ Observation ☐ Corrective action taken
Description:

FARM NAME *(include business name, if different)*

DATE(S) OF INSPECTION	FEI NUMBER

32. § 112.129: Toilet facilities
☐ Observation ☐ Corrective action taken
Description:

33. § 112.130: Hand-washing facilities
☐ Observation ☐ Corrective action taken
Description:

34. § 112.131: Control and disposal of sewage
☐ Observation ☐ Corrective action taken
Description:

35. § 112.132: Control and disposal of trash, litter, and waste
☐ Observation ☐ Corrective action taken
Description:

36. § 112.133: Plumbing
☐ Observation ☐ Corrective action taken
Description:

37. § 112.134: Control of animal excreta and litter from domesticated animals
☐ Observation ☐ Corrective action taken
Description:

38. § 112.140: Record-keeping
☐ Observation ☐ Corrective action taken
Description:

Sprouts *(21 CFR Part 112, Subpart M)*
☐ Check here if entity does not engage in growing, harvesting, packing, and/or holding of sprouts

39. § 112.142: Seeds or beans used to grow sprouts
☐ Observation ☐ Corrective action taken
Description:

40. § 112.143(a): Fully-enclosed buildings
☐ Observation ☐ Corrective action taken
Description:

FARM NAME *(include business name, if different)*

DATE(S) OF INSPECTION	FEI NUMBER

41. § 112.143(b): Cleaning and sanitizing food-contact surfaces
☐ Observation ☐ Corrective action taken
Description:

42. §§ 112.144(a), 112.145, and 112.146: Environmental monitoring for *Listeria* species or *L. monocytogenes* (written environmental monitoring plan, collection and testing, corrective actions)
☐ Observation ☐ Corrective action taken
Description:

43. §§ 112.144(b) and (c), 112.147 and 112.148: Testing spent irrigation water or in-process sprouts for pathogens *(written sampling plan, collection and testing, corrective actions)*
☐ Observation ☐ Corrective action taken
Description:

44. § 112.150: Record-keeping
☐ Observation ☐ Corrective action taken
Description:

Records *(21 CFR Part 112, Subpart O)*

45. § 112.161 – 112.167: General record-keeping
☐ Observation ☐ Corrective action taken
Description:

Other Observations

46. Other
☐ Observation ☐ Corrective action taken
Description:

FDA REPRESENTATIVE SIGNATURE	FDA REPRESENTATIVE(S) NAME AND TITLE *(Print or Type)*	DATE ISSUED
#14	#15	#16

FARM NAME *(include business name, if different)*

DATE(S) OF INSPECTION	FEI NUMBER

Continuation Sheet

Additional Observations and/or Comments

#17

Continue

FARM NAME *(include business name, if different)*

DATE(S) OF INSPECTION	FEI NUMBER

The observations of conditions and practices listed on this form are reported:

1. Pursuant to Section 704(b) of the Federal Food, Drug, and Cosmetic Act, or
2. To assist firms inspected in complying with applicable laws and regulations.

Any reference to this report in labeling, advertising, or other sales promotion by any person is prohibited under Section 301(n) of the Federal Food, Drug and Cosmetic Act.

COMPLETION OF THE FORM FDA 4056

Presently there are three ways to generate an FDA 4056.

- eNSpect
- Electronic (non-eNSpect) version
- Handwritten hard copy

Where possible, you should be creating, issuing, and signing the Form FDA 4056 via the eNSpect method. Many of the fields in the form are either partially or fully automated when using this method.

When using an electronic (non-eNSpect) or handwritten hard copy of the FDA 4056, the current version must be used.

The sections of the Form FDA 4056 are identified below, with numbers corresponding to the preceding blank version of the form.

1 – Name of State and Department - if the FDA 4056 is used by a state acting under FDA commission, the name of the agency. For an FDA led inspection, place "N/A" in this box.

2 - District Office Address - Legibly print the home District address where the **firm** is physically located, regardless of program area or investigator duty station. If using eNSpect for the FDA 4056, select the home district of the firm.

For example, if a firm is located in Little Rock, Arkansas, then the district office would be Dallas District Office. See Appendix E for boundary maps.

For foreign inspections, the address to be used for this box will be provided as part of the assignment.

3 – District Office Phone Number - Legibly print the district office commercial telephone number and area code.

4 - Date(s) of Inspection - Enter actual or inclusive date(s) of inspection.

5 - FEI Number - If the FDA Establishment Identifier is on the assignment, enter it here. If not readily available, leave blank.

6 – Last Name, First Name, Middle Initial and Title of individual to whom report is issued - Enter legal name and full title of the person to whom the form is issued.

7 - Farm Name - Enter full, legal name of the farm, including any abbreviations, quotation marks, dashes, commas, etc.

6 – Owner/Operator - Full legal name of the person or corporate entity that owns and operates the farm. If the farm owner and operator are different, include both names

9 - Farm Mailing Address - Address, city, state, and zip code at which the farm receives mail

10 - Farm Physical Location, If Different from Mailing Address-Enter Street address, city, state, and Zip Code. (Not P.O. Box unless P.O. Box is part of the address such as on a Rural Route).

11 – Type of Inspection –

Initial – first inspection of the farm

Routine – normal surveillance inspection

Follow-up – follow-up to a violative inspection

For-cause – inspection to follow-up on a specific issue, such as an outbreak or positive sample

Other (please specify) – inspection that doesn't meet one of the other categories (will be used very rarely)

For an initial inspection, you will check both the initial box and select an additional box (routine, for-cause, or other box) as appropriate for the type of inspection conducted.

12 – Crops Observed During Inspection – List the crops for which some element of growing, harvesting, packing, and/or holding were observed during the inspection. If the farm grows or handles other crops but those crops were not observed during the inspection, do not list them.

13 - Observations – See IOM 5.5.11 for information about what observations are considered "reportable" and may be listed on the Form FDA 4056. Enter your reportable observations succinctly and clearly. Conditions listed should be significant and relate to an observed or potential problem with the facility, equipment, processes, controls, products, employee practices, or records. "Potential problems" should have a reasonable likelihood of occurring based upon observed conditions or events. Do not cite deviations from policy or guidance documents on your FDA 4056.

Where applicable, when formulating each FDA 4056 observation, answer Who (using titles or initials when necessary), What, When, Where, Why, How Much and How Often? Challenge each observation by asking "So What"? (regarding its significance).

As appropriate, FDA 4056 observations should include relationship of observations to a given population, for example, "Two out of 50 records examined were * * *" or "4 out of 12 bags examined were ***." When appropriate, an FDA 4056 observation may refer to inadequate situations as long as you provide supporting facts (examples) or explanation as to why the condition, practice or procedure observed is inadequate.

It is preferred not to identify individuals or firms by name (e.g., suppliers and consignees) within the FDA 4056. Where appropriate to support the FDA 4056 observation, identify the individual(s) or firm(s) by substituting other non-specific identifying information as below. Document your evidence in your EIR, fully explaining the relationship(s).

f. The lot number for a component received from or shipped to firm "A".
g. The invoice number for a shipment from or to firm "A".
h. A patient #, record #. See IOM 5.2.3.3 item 7.
i. The study number for a particular Clinical Investigator site.
j. Other necessary but non-specific identifying information to show the observation's relationship to a particular firm and/or individual.

14 - Employee(s) signature

Everyone present under FDA inspectional authority at issuance signs the FDA 4056. However, absence of a team member at the conclusion of an inspection need not prevent issuance of the form (see IOM 5.1.2.5.1). If signing the FDA 4056 digitally using eNSpect, the lead CSO's signature will appear on all pages of the FDA 4056 and the remaining team members' signature will appear on the last page. When it is necessary to use pen to sign the form (e.g., when issuing a handwritten hard copy version), each person signs the first and last pages of the FDA 4056 and initials each intervening page in the signature block.

When using eNSpect to sign the Form FDA 4056, the system will retain a copy of the digitally signed form automatically. If you do not use eNSpect to digitally sign the document, assure you retain a digitally signed copy. If using a pen to sign the form, make a photocopy or carbon copy of the signed form. An unsigned photocopy or printed duplicate is unacceptable to maintain with the division's files. See IOM 5.2.3.6.2.

15 - Employee(s) name and title

The names of everyone who participated in the inspection with the issuance of an FDA 482 should be listed on the FDA 4056, even if they are not available to sign the document.

16 - Date Issued - Enter the date the form is actually issued to the firm's management.

17 – Additional Observations and/or Comments - EXACT LANGUAGE PER OHAFO REQUIREMENTS

5-18 – FORM FDA 483a

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

DISTRICT OFFICE ADDRESS AND PHONE NUMBER	DATE(S) OF REVIEW OF YOUR FSVP RECORDS
#1	#2
	FEI NUMBER #3
Industry Information: www.fda.gov/oc/industry	

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED
#4

FIRM NAME	STREET ADDRESS
#5	#6
CITY, STATE AND ZIP CODE	E-MAIL ADDRESS #7

This document lists observations made by the FDA representative(s) during the review of your Foreign Supplier Verification Program (FSVP). They are observations, and do not represent a final agency determination regarding your compliance. If you have an objection regarding an observation, or have implemented, or plan to implement corrective action in response to an observation, you may discuss the objection or action with the FDA representative(s), including by submitting this information to FDA at the address above. If you have any questions, please contact FDA at the phone number and address above.

During a review of your Foreign Supplier Verification Program I (we) observed:

#8

ADD Continuation Page

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	EMPLOYEE(S) NAME AND TITLE *(Print or Type)*	DATE ISSUED
	#9	#10	#11

FORM FDA 483a (2/16) **FSVP OBSERVATIONS** **Page 1 of 2**

PSC Publishing Services (301) 443-6740 EF

COMPLETION OF THE FORM FDA 483a

Presently there are three ways to generate an FDA 483a.

- eNSpect
- Electronic (non-eNSpect) version
- Handwritten hard copy

Where possible, you should be creating, issuing, and signing the Form FDA 483a via the eNSpect method. Many of the fields in the form are either partially or fully automated when using this method.

When using an electronic (non-eNSpect) or handwritten hard copy of the FDA 483a, the current version must be used.

The sections of the Form FDA 483a are identified below, with numbers corresponding to the preceding blank version of the form.

1 - District Office Address and Phone Number - Legibly print the home District address where the **firm** is physically located, regardless of program area or investigator duty station. Include the district office commercial telephone number and area code. If using eNSpect for the FDA 483a, select the home district of the firm.

For example, if a firm is located in Little Rock, Arkansas, then the district office would be Dallas District Office. See Appendix E for boundary maps.

For foreign inspections, the address to be used for this box will be provided as part of the assignment.

2 - Date(s) of Review of Your FSVP Records - Enter actual or inclusive date(s) of review.

3 - FEI Number - If the FDA Establishment Identifier is on the assignment, enter it here. If not readily available, leave blank.

4 - Name and Title of individual to whom report is issued - Enter legal first name, middle initial and last name, and full title of the person to whom the form is issued.

5 - Firm Name - Enter full, legal name of the firm, including any abbreviations, quotation marks, dashes, commas, etc.

6 - Street address, city, state, and Zip Code - Enter street address, city, state, and Zip Code. (Not P.O. Box unless P.O. Box is part of the address such as on a Rural Route).

7 – E-Mail Address – Enter the e-mail address for the firm.

8 - Observations – See IOM 5.5.11 for information about what observations are considered “reportable” and may be listed on the Form FDA 483a. Enter your reportable observations succinctly and clearly. Conditions listed should be significant and relate to an observed or potential problem with the facility, equipment, processes, controls, products, employee practices, or records. “Potential problems” should have a reasonable likelihood of occurring based upon observed conditions or events. Do not cite deviations from policy or guidance documents on your FDA 483a.

Where applicable, when formulating each FDA 483a observation, answer Who (using titles or initials when necessary), What, When, Where, Why, How Much and How Often? Challenge each observation by asking “So What”? (regarding its significance).

As appropriate, FDA 483a observations should include relationship of observations to a given population, for example, “Two out of 50 records examined were * * *” or “4 out of 12 bags examined were ***.” When appropriate, an FDA 483a observation may refer to inadequate situations as long as you provide supporting facts (examples) or explanation as to why the condition, practice or procedure observed is inadequate.

It is preferred not to identify individuals or firms by name (e.g., suppliers and consignees) within the FDA 483a. Where appropriate to support the FDA 483a observation, identify the individual(s) or firm(s) by substituting other non-specific identifying information as below. Document your evidence in your EIR, fully explaining the relationship(s).

k. The lot number for a component received from or shipped to firm “A”.
l. The invoice number for a shipment from or to firm “A”.
m. A patient #, record #. See IOM 5.2.3.3 item 7.
n. The study number for a particular Clinical Investigator site.
o. Other necessary but non-specific identifying information to show the observation’s relationship to a particular firm and/or individual.

9 - Employee(s) signature

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10 - Employee(s) name and title

The names of everyone who participated in the inspection with the issuance of an FDA 482 should be listed on the FDA 483a, even if they are not available to sign the document.

11 - Date Issued - Enter the date the form is actually issued to the firm’s management.

5-19 – Biosecurity

Routine Biosecurity Procedures for Visits to Facilities Housing or Transporting Domestic or Wild Animals

This section is FDA's guidance when you visit any type of facility where any domestic or wild animals are housed or transported. If a firm has more restrictive controls, follow those in addition to the controls cited below as long as they do not interfere with your assignment needs. The controls and procedures are intended to prevent you from becoming a vector or carrier of animal diseases, to prevent the spread of animal disease, and to set a good example for stockmen, growers, and industry servicemen. A number of chronic diseases, such as Johne's Disease, bovine virus diarrhea (BVD) and others exist in domestic animals which you can unknowingly spread. Any inspectional contact with herds of livestock (including poultry) or non-domesticated animals exposes you to potential claims of introducing or spreading disease. This could occur between sections of a single site, such as poultry houses, or between different sites or farms. The potential also exists for the introduction of disease from an animal processing plant, such as a slaughterhouse or renderer to a live animal facility. You can prevent this by following appropriate cleaning and disinfection steps between facilities. Generally, a break of 5 days or more between sites is sufficient to eliminate concern about transmission of infectious agents.

These precautions, biosecurity measures, are necessary in two types of situations. The first is when there is no known disease present and your actions are precautionary. This section primarily addresses those kinds of activities. The other situation involves known or suspected disease outbreaks or more notorious disease conditions such as salmonella in eggs, infectious Laryngotracheitis, foot and mouth disease, vesicular stomatitis, and blackhead which can be highly contagious and spread from one group of animals to another by movement of people and objects between infected and non-infected groups. In these cases, special precautions must be taken to make sure you are not an unknowing vector for the spread of disease.

Biosecurity on a produce farm is a set of preventive measures designed to protect the farm, including crops and livestock, from bacterial, fungal, and viral diseases and agricultural pests. When conducting a produce safety inspection, you should abide by the farm’s policies. During the pre-inspection call and prior to entering the growing area, you should ask if the farm has implemented biosecurity practices. You should follow these animal and phytosanitary practices and procedures requirements.

If you will only be inspecting an office or house away from areas where animals are housed or kept, clean and suitable street attire may be sufficient. Be aware if you visit any area of a facility where animals have been, you should always sanitize, clean, or change footwear and it may be necessary to change outerwear before visiting another animal site to prevent any possibility of transmission of disease.

Your vehicle may also transport infection if you drive through contaminated areas and may require frequent cleaning between sites.

Pre-Inspection Activities

When you know you are going to visit or inspect any animal production or holding facility, consider contacting the State Veterinarian and/or the Regional APHIS office to determine if there are any areas in

the state under quarantine or special measures to control animal diseases. APHIS office locations can be found on their website. The State Veterinarian will be listed under Government Listings in your phone book and is listed at this website. Milk Specialists frequently working with State counterparts in the Interstate Milk Shippers program should contact these sources at least quarterly for updates. Ask for any special controls or procedures they recommend. Follow any guidance they offer in addition to the precautions in this section. You should also consider pre-notification of the facility unless your assignment does not allow pre-notification. If you elect to pre-announce the inspection, in addition to the normal contact, ask to speak with the person at the facility responsible for their biosecurity measures and find out what they require of employees and visitors. If their requests do not interfere with your ability to do your job, follow their requests as we do when inspecting sterile manufacturing facilities.

Make sure your vehicle is clean and has been recently washed. Commercial car washes are adequate as long as you check to make sure any dirt, manure or other debris, which may be present from a previous site, has been removed. Some facilities may require additional disinfection of tires upon entry to the premises. Ensure tires and floor mats are clean. Consider designating places in your vehicle for storage of clean, unused supplies and dirty or used supplies.

In addition to your normal inspectional tools, obtain the following equipment and supplies from your program division:

- Laundered or disposable coveralls or smocks (coveralls are suggested because they give better coverage). If you are going to visit multiple facilities in one day or trip, obtain sufficient quantities so you can change into clean or unused clothing between each site.
- Disposable plastic gloves, rubber boots, which can be sanitized, and disposable shoe/boot covers. Rubber boots over which you place disposable shoe/boot covers are preferred.
- Reusable cloth or plastic laundry bag(s) for clothing to be laundered. (Disposable bags can be used.)
- Soap, water and disposable or freshly laundered individual hand (or paper) towels.
- Sanitizing solution(s) and equipment (brushes, bucket, tray, measuring devices, etc.) to permit you to properly sanitizing hands, boots, equipment, and your vehicle. Most disinfectants will require removing organic matter before use and good brushes are essential to remove dirt from boots and other objects.

Make sure any equipment you take with you has been thoroughly cleaned and sanitized as necessary. Clip boards, briefcases, flashlights, inspectional sampling tools, coolers, brushes, buckets, and other objects should be cleaned between uses as necessary and between visits to any suspected infected facilities. Disposable equipment should be used to the fullest extent possible.

Additional information for produce safety inspection staff to follow is in the Standardized Approach to Produce Farm Inspections document.

Maintain copies of any applicable Material Safety Data Sheets (MSDS) for disinfectants with you in your vehicle. If the firm's management requests information on the disinfectants you are using, they may read or copy these MSDS. Be familiar with the instructions and precautions concerning use of disinfectants. Any disinfectant should be effective against known or suspected microbiological agents.

In the event of a foreign animal disease, contact the USDA, APHIS Veterinary Services area Veterinarian in Charge for additional precautions and procedures to follow. (See 5.2.10.3)

General Inspection Procedures

Always begin each day with a clean vehicle free from any visible dirt or debris. During the day, take precautions to minimize contamination of your vehicle. If your vehicle becomes obviously dirty with adhering mud or manure, clean it before visiting another animal facility. When you arrive at a facility where animals are located, check to see if there are designated parking spots or pads for visitors. If so, park your vehicle there unless directed otherwise by the firm. If there is no guidance, park well away from all areas housing animals. When you arrive, inquire about or reconfirm any biosecurity measures the firm employs. Confirm your actions are suitable and follow expectations of the facility when this does not interfere with your inspection ability. Follow steps requested by the firm to remove contamination from vehicles, which may include troughs or pools of disinfectants for tires or other control measures. Avoid driving through manure, mud, or wastewater at these sites.

In general, entry to animal housing or feeding areas, corrals, calf pens, hospital pens or special treatment facilities should be avoided unless the assignment requires their inspection or there are specific reasons requiring entry. If you must visit the feeding area occupied by livestock or birds, first determine if any groups are infected with disease. Arrange to visit the known non-disease areas first. Do not handle any animals unless official duty requires such contact. Before leaving the area where you parked your car, put on protective clothing as described and proceed with the purpose of your visit; sanitizing hands (and gloves if worn) and boots as necessary during the visit or inspection.

General procedures:

- Wear rubber boots or other suitable footwear, which you disinfect upon arriving at the site and prior to departure. It is preferable to also place disposable foot coverings over your footwear, regardless of the type, after you have disinfected them. If the firm has footbaths, use them. Boots and footwear should be disinfected with any of the agents identified at the end of this subsection using a good brush. Clean and disinfect the brush(es) and bucket you use for these activities.
- Wash your hands with soap and water. If you are visiting a facility where a known animal disease is present or the firm's biosecurity protocol requires, wear disposable gloves.
- Wear disposable or freshly laundered coveralls, when appropriate. Some facilities may provide disposable coveralls and require visitors to shower in and shower out at their facilities. If requested by the firm and facilities are provided, you should follow those requests.
- Wear appropriate head coverings, as necessary. If you wear a head covering, clean and disinfect between facilities or use disposable head coverings.
- Minimize any materials you carry with you such as notebooks, flashlights, etc. to what is required. Consider keeping these things in clean plastic bags or containers between uses. Disinfect any of these types of items as best you can between visits to facilities or between different animal-housing areas.
- If you are visiting production units with animals of multiple ages, always try to work from the youngest to the oldest.

- Avoid direct contact with livestock or wild animals, bodily fluids or animal byproducts when visiting facilities.
- Milk Specialists, Milk Safety Branch and State Training Team staff frequently working with State counterparts in the Interstate Milk Shippers program shall follow any biosecurity measures the firm employs, any biosecurity measures the State employs, and as a minimum shall follow the coded memoranda issued by CFSAN Milk Safety Branch on this subject.

Upon completing your assignment in a given animal area, return to the same area where you donned protective clothing. Remove disposable shoe/boot covers and gloves, if applicable, and place them in a disposable paper or plastic bag. Clean and sanitize boots/footwear. Remove the protective clothing, if applicable, by peeling it off inside out. (This keeps the surfaces exposed to contamination on the inside.) Unless the firm's biosecurity plan prohibits removal of waste from their premises, all waste should be disposed of by the investigator as follows: Place all disposable items in a disposable, nonporous bag for appropriate disposal according to State and/or local regulations. Place reusable coveralls or other reusable protective clothing in a separate bag for disposition at the office.

Follow guidance on biosecurity provided in the applicable Compliance Program or "Guide to the Inspection of "***" in addition to precautions in this Section.

Repeat these procedures for each separate location visited or inspected.

Purchase commercially available solutions for disinfecting objects or consult with your servicing laboratory. Commercial products such as Nolvosan, Efersan, One Stroke Environ or Virkon-S may be used as long as they are registered by EPA for the intended purpose. Lye or chlorine based cleaners and disinfectants may also be used.

The following formula for household bleach may be used. Mix 3/4 cup (6 oz) of liquid bleach (5.25%) in one gallon of water (128 oz). This solution will be approximately 1:20 dilution. Formulations of household bleach, which are more concentrated than 5.25% are commercially available. Dilute accordingly to these directions. A more concentrated 1:10 solution (1-oz bleach to 9-oz water) may be used with decreased contact time required. Dilutions should be prepared fresh daily and protected from light.

You should read the label and be familiar with directions and precautions, such as removing any organic matter from objects to be disinfected, for any disinfectant you use. In the absence of directions or for chlorine solutions you prepare: 1. Remove visible dirt from the object (boots, tools, tires, etc.). 2. Wipe, brush or scrub surfaces with the solution and keep wet for 2 minutes. 3. Allow to air dry or dry with previously sterilized toweling.

Special Situation Precautions

If you are required to inspect or visit a facility known or suspected to be involved in a contagious animal disease an outbreak or otherwise identified as having diseased animals, contact the Center for Veterinary Medicine and/or Center for Food Safety and Applied Nutrition for additional precautions which may be necessary before you visit these sites. Your activities may be limited to visiting a single site in a day, taking extra-ordinary decontamination steps, ensuring you do not visit or inspect another facility for 5 or more days following the visit to the contaminated site or other steps. APHIS may have

special restrictions or precautions for you to follow. The State Veterinarian may also request you follow additional requirements. During inspections of poultry operations where salmonella contamination is known or suspected, you should make sure you contact CFSAN directly for specific procedures to follow. Additional decontamination steps will be required.

Standard Operating Biosecurity Procedures for Egg Farm Inspections/ commercial Poultry Operations

Classification of Farms

Program divisions should categorize inspections according to risk with farms providing out-door access being considered the highest risk to HPAI. Large farms (those with ≥ 50,000 layers should be inspected first, followed by small farms (those with between 3,000-49,999 layers) and farms with outdoor access (regardless of the number of birds at the farm) should be inspected last. For example, if a program division is assigned 15 inspections as part of an Egg Assignment, and 5 of those firms provide outdoor access, the 10 farms that do not provide outdoor access should be inspected first and the 5 with outdoor access should be inspected last. Of the first 10 of these inspections the largest farms (from a number of layers at the farm perspective) should be inspected first and then in descending order as the number of layers decreases (a farm with 1 million layers would be inspected before a farm with 750,000 layers, even though both are classified as large farms).

Biosecurity Practices

These practices should be followed on every egg farm inspection. It is the responsibility of the lead investigator to brief his/her inspectional team on these practices prior to arrival at the farm.

Pre-Inspection Measures

1. Contact the State Veterinarian to check for quarantines. No egg inspections should be initiated without first contacting the state veterinary office and checking for quarantines. Investigators should ask if there is any type of quarantine and follow that up with a question specifically about HPAI-related quarantines. If quarantines are in place, investigators should ask how long they are expected to continue. If the state veterinarian or official designated by the state indicates that inspections should not continue, those instructions should be followed, and no inspections should be conducted until state clearance is given. If an extended quarantine is expected (longer than 2 weeks), the program division should organize a follow up meeting to include the program division, State Veterinary Office or designated state official, ORA-OFFO, CFSAN-OFS, and CFSAN-OC (see contacts at the end of this document). The purpose of these meetings will be to establish a channel of communication between FDA and the State to ensure state concerns are addressed while ensuring FDA's inspectional obligations are met.
2. Following clearance from the state veterinarian's office, the lead investigator should conduct a cross reference check of the inspection location against the HPAI Current Avian Influenza findings on the USDA/APHIS web page. The Current Avian Influenza findings can be found at the following web address:

https://www.aphis.usda.gov/aphis/ourfocus/animalhealth/nvap/NVAP-Reference-Guide/Poultry/Avian-Influenza

3. During the cross check, investigators should check the state and county from the USDA/APHIS webpage against the location of the farm to be inspected. If the farm is in the same county as a confirmed HPAI occurrence, the program division should cancel the inspection and set up a follow up meeting to include the program division, ORA-OFFO, CFSAN-OC and CFSAN-OFS (see contacts at the end of this document). During this meeting, the following information will be considered: the confirmation date of the occurrence (how far removed from the time HPAI was detected to when the current inspection is scheduled), the relative locations of the HPAI infected site and the farm to be inspected (the infected, buffer, and surveillance zone criteria established by APHIS will be considered), and other pertinent information. After all pertinent information is considered, a decision will be made to either cancel the inspection or reschedule it for a more appropriate time.
4. The mandatory minimum wait time between different farms is 72 hrs. However, many farms have increased the wait period to longer than 72 hrs. in response to lessons learned from the 2015 HPAI outbreak. If the wait time established by the producer is longer than 72 hrs., that specified wait time should be adhered to. In situations where the farm to be inspected includes outdoor access for the birds (this information should be established during the pre-inspection call) the minimum wait time between farms increases to 1 week. Contact with specific bird populations could also result into mandatory one week minimum wait times. Bird populations should be categorized into two broad categories. Population 1 includes birds that are under a biosecurity plan as specified in 21 CFR 110 118.4(b)(1) through (5) (this populations most often will refer to only those birds at commercial farms, i.e., those to be inspected). Population 2 includes all other birds, including but not limited to backyard flocks, duck or geese or other bird populations at municipal parks, avian species at zoological gardens, chicks, or ducklings at feed stores, etc. If an investigator only has contact with Population 1 AND if the farm to be inspected has an established wait time of less than 1 week, that time requirement should be followed. If an investigator has contact with Population 2, they MUST wait 1 week before conducting an inspection.
5. When possible, program divisions should send separate inspectional teams on egg farm inspections such that the time between separate farm visits for any one inspectional team is maximized. For example, rather than sending Inspectional Team A to conduct inspections at Farm 1, Farm 2 and Farm 3, every attempt should be made to instead send Inspectional Team A to conduct the inspection at Farm 1, Inspectional Team B to conduct the inspection at Farm 2 and Inspectional Team C to conduct the inspection at Farm 3. The goal being to increase the length of time that any of the three inspectional teams have to visit the next farm up for inspection.
6. Vehicles to be used during inspections should be washed a maximum of 24 hours before and after each egg inspection. Given that HPAI is highly susceptible to detergents, high temperatures and desiccation, cars washes where hand held nozzles are available should be used when possible. Initially, a cycle should be conducted where a high-pressure rinse is used to remove all organic matter (e.g., mud, dirt and debris) with specific care taken to address the wheel wells, tires, vehicle undercarriage, and vehicle body. This should be followed by a cycle where a scrub brush with a detergent is used on the whole vehicle

including the wheel wells, tires, and vehicle body. Subsequently, a high-pressure rinse that includes the wheel wells, tires, vehicle undercarriage and vehicle body should be completed. The interior of the vehicle should then be vacuumed thoroughly to remove organic matter and floor mats sprayed with a disinfectant aerosol spray. The vehicle should then be allowed to dry thoroughly in a sunny area (as opposed to a shaded garage). After the vehicle has dried, disinfectant should be applied to the wheel wells, tires, and undercarriage (See item #11 below for appropriate disinfectant selection). The vehicle body does not have to be disinfected.

When necessary or during inclement weather, drive-through car washes may be substituted for manual car washes provided that the cycle includes an undercarriage wash, application of a detergent and a high-pressure rinse. The interior should still be vacuumed and disinfected following the car wash. After the vehicle dries, the tires, wheel wells and undercarriage should be disinfected as described above.

During-Inspection Measures

- Follow the farm's own biosecurity program to the extent that it does not interfere with investigators conducting the inspection.
- Do not enter or inspect houses where birds are known to have disease, including but not limited to, SE.
- FDA personnel participating in the inspection cannot be bird owners. Ownership of birds disqualifies that investigator from participation in all egg farm inspections.
- Always change all Personal Protective Equipment (PPE) between houses. PPE includes disposable body coverings, boot covers, hair bonnets, sterile gloves, respirators, eye, and hearing (in areas where loud machinery is in use) protection. The use of disposable PPE and respirators is preferred to eliminate the need for disinfection between poultry houses. In situations where permanent eyewear is worn it must be cleaned and disinfected between each poultry house.
- Investigators should wash hands thoroughly before donning gloves for entry into the house. Where available, use soap and water; if not available, use hand sanitizing gels. It is the responsibility of the team lead to ensure that all members of the team are adhering to protocol. This should be done at both the clean and dirty areas established at the farm, prior to entry into any poultry house.

Selection of disinfectants:

- Ethanol should be used to disinfect the lids of evaporated milk cans, scissors and can openers used during sampling within a poultry house.
- Phenolic or quaternary ammonium-based sanitizers should be used on wheel wells, tires, and vehicle under carriage. The vehicle body should not be disinfected, as the detergent from the car wash is sufficient and some sanitizing compounds can damage the vehicles finish.
- Lysol or equivalent based aerosol spray should be used on floor mats and soles of shoes.
- Purell or equivalent hand gel should be used for hand disinfection.

In situations where reusable respirators are used, they must be cleaned and disinfected in accordance with manufacturer's recommendations. Selection of the appropriate disinfectant is critical; for questions

or assistance with disinfectant selection please contact ORA-OO-ORS (see contacts at the end of this document).

- No item which has been in a layer house may be brought into a different house without a complete cleaning and disinfection or replacement with a new one. This includes all items, e.g., pens, supply tubs, scissors. Replacement of items is more effective than disinfection and lessens the workload on site; therefore, all efforts should be made to replace items rather than transfer between houses.
- Plan carefully prior to inspections and pack inspection kits on a per house basis so as to eliminate the need to share equipment between houses. Aside from permanent eyewear and "egg pad" tablets, there should not be a need to share equipment/items between houses.
- Use disposable cameras, when possible. Otherwise, digital cameras are to be placed within plastic bags prior to entry into the house.
- Double bag all garbage; specifically, one bag is to be left at the vehicle and the other taken into the house to be inspected. When the garbage is removed, it is placed into the bag left at the vehicle, so as to assure that the bag which went into the layer house never touches the vehicle interior.
- Houses should be inspected from the cleanest areas to the dirtiest areas and from the youngest to oldest birds.
- Do not wear jewelry in poultry houses.
- Where possible, wear clothing that has not been on another egg farm and ensure the clothing is laundered. If possible, use the hot water cycle to launder clothing that will be used during an egg inspection.
- If possible, park the car at the beginning of the driveway or outside the farm and carry all of their equipment onto the farm. Investigators should coordinate with farm management to determine the best parking spot for the vehicle.
- Eyeglasses should be cleaned and disinfected with disposable decontamination wipes.

Items listed below represent either direct or indirect contact with Population 2 as described in the pre-inspection measures above. A minimum of 1 week, preferably longer, prior to participating in an FDA egg farm inspection, all investigators involved in the inspections should:

- Not come in contact with bird feeders or bird baths for a minimum of 1 week prior to participating in an egg farm inspection.
- Stay away from family members, friends or acquaintances that are pet bird owners or have backyard poultry flocks of any type.
- Not visit fairs where poultry or birds are shown or exhibited.
- Not visit live bird markets of any type, or gatherings where live birds may be present.
- Not visit flea markets, trade shows, or swap meets where live poultry or birds of any type may be present.
- Not visit zoos, theme or amusement parks where live birds maybe present.
- Not visit known nesting grounds or resting place for wild birds, such as natural preserves or refuges, known breeding grounds or bird sanctuaries.

- Not attend birthday parties or functions where a petting zoo that includes poultry is part of the event, e.g., baby chicks, pet ducks or geese, are present.
- Not come in contact with birds, such as ducks or geese, at municipal, state or other types of parks. e.g., where ducks, geese or pigeons and other birds are local inhabitants and people congregate to feed them.
- Not visit an ocean side town where you may come in contact with shorebirds, e.g., gulls.
- Not visit feed stores or other retail establishments where live poultry may be sold, e.g., baby chicks, turkey poults, ducklings, etc.
- Not go hunting for wild fowl or handle wild fowl. If you have family members or friends who hunt fowl, do not come in contact with them for a least the week prior to the inspection.
- Not meet with other known bird owners either as part of your work (e.g., meeting another producer at a location away from their farm) or meet with other known bird owners in your social circle.

Post-Inspection Measures

- Wash the vehicle used during the inspection as specified in item #5 in the pre-inspection procedures of this directive.
- Clean and disinfect the sampling kit(s), e.g., tubs, scissors, can openers
- Clean and disinfect respirators in accordance with manufacturer's recommendations.

Contacts

CFSAN-OC:

Doriliz De Leon, email: doriliz.deleon@fda.hhs.gov, phone: 240-402-2772

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CFSAN-OFS

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Gerardo A Ramirez, email: gerardo.ramirez@fda.hhs.gov, phone: 713-293-1418

ORA-DDHAFO/HAFPOB

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ORA-ORS

Michelle Markley, email: michelle.markley@fda.hhs.gov, phone: 301-796-8178

Kenneth Crombie, email: Kenneth.crombie@fda.hhs.gov, phone: 240-402-5346

5-20 - Produce Inspection Details

Produce Inspection Details

Produce Farm Pre-Announcement

The Produce Safety Network (PSN) should follow instructions in the Produce Safety Inspections Compliance Program Guidance Manual (CPGM) for inspection pre-announcement. Follow guidance in the Produce Safety Inspection Protocol for reporting in the Produce Farm Inspection Report (PFIR) when inspection pre-announcement does not occur.

Produce Farm Corrective Actions

Corrective actions observed and/or discussed during a produce safety inspection are annotated on the FDA 4056 as described in IOM 5.2.3.1.1 under Reportable Observations Made During the Inspection. Corrective actions not related to a significant observation are noted in the inspection notes and in the PFIR or the inspection report summary.

Form FDA 4056:

Name of State and Department (if acting under commission with FDA) – If the FDA 4056 is used by a state acting under FDA commission, the name of the state agency. For an FDA led inspection, place "N/A" in this section.

District Office Address –

- Domestic: the mailing address of the District Office where the farm is located. See Appendix E for boundary maps.
- Foreign: the mailing address for ORA/DFHAFO (12420 Parklawn Dr, Rm 2037 HFC-130, Rockville, MD 20857).
- State under FDA commission: the state agency office mailing address.

District Office Phone Number - Area code and phone number of the District Office for the inspected location, or of the state agency, if applicable.

Date(s) of Inspection - Enter actual date(s) of inspection. If multiple consecutive days, dates can be represented as an inclusive date range. If there is insufficient space, enter the first and last dates of inspection as a date range followed by an asterisk: "[MM/DD/YYYY] – [MM/DD/YYYY] *". In the Continuation Sheet, enter "*DATES OF INSPECTION" followed by the full listing of actual dates of inspection.

FEI Number – Enter the FDA Establishment Identifier as per the Official Establishment Inventory (OEI). States under FDA commission can enter either the FEI number (if known) or the farm's state ID number.

Last Name, First Name, Middle Initial and Title of Individual to Whom Report is Issued (Most responsible individual present) To - The legal name (listed as last name, first name, middle initial) and full title of the person to whom the form is issued. If the person does not have a middle initial, enter "NMI" for no middle initial.

Farm Name (include business name, if different) - The full, legal name of the farm, including any abbreviations, quotation marks, dashes, commas, etc. If the farm uses another name for business purposes (i.e., a "dba"), include the other name also.

Owner/Operator – Full legal name of the person or corporate entity that owns and operates the farm. If the farm owner and operator are different, include both names.

Farm Mailing Address – Address, city, state, and zip code at which the farm receives mail.

Farm Physical Location, If Different from Mailing Address (e.g., location Identifiers such as GPS coordinates) - Street address, city, state, and zip code where the farm is located. Do not use a P.O. Box unless P.O. Box is part of the address such as on a Rural Route. Include GPS coordinates of the main farm building, if available.

Type of Inspection -

- **Initial** – first Produce Safety Rule inspection of the farm. "Initial" is not a standalone selection. All initial inspections are at a minimum either Routine or For-cause in addition to Initial.
- **Routine** – normal surveillance inspection.
- **Follow-up** – follow-up to a violative inspection; this would include an inspection of a farm completed after the state or FDA took a compliance or enforcement action.
- **For-cause** – inspection in response to a specific issue, such as an outbreak or violative sample, recall, complaint, or previous inspection findings (i.e., expedited next inspection).
- **Other (please specify)** – use if additional explanation of the Type of Inspection is needed. Other should be selected with "Limited" when a full inspection was not performed, such as when "N/A" is entered under Crops Observed During Inspection or otherwise per assignment or compliance program guidance.

Examples of selections:

- Initial, Routine
- Initial, For-cause
- Routine
- Follow-up, For-cause
- For-cause
- For-cause, Other – Limited
- Initial, For-cause, Other – Limited

Crops Observed During Inspection - List the crops for which some element of growing, harvesting, packing, and/or holding were observed during the inspection. If the farm grows or handles other crops but those crops were not observed during the inspection, do not list them. Produce Safety Rule inspections should be conducted when covered activities on covered produce can be observed. As an exception, such as during an active outbreak response, enter "N/A" when no crops are observed.

Reportable Observations Made During the Inspection – The form has two checkboxes:

1. During an inspection of the operation (I) (we) did not observe any conditions and/or practices to be reported on this form.

2. During an inspection of the operation (I) (we) observed the following conditions and/or practices as described below.

One box will be checked during each inspection. If the first box is checked, indicating no reportable observations, the rest of the form will be left blank except for page headers, the Sprouts checkbox (if applicable; see Sprouts section in this document), FDA REPRESENTATIVE SIGNATURE block, FDA REPRESENTATIVE(S) NAME AND TITLE (Print or Type) block, DATE ISSUED block, and any notation on the continuation sheet.

If the second box is checked, the reportable observation(s) will be noted in the appropriate place on the form. If the observation is not related to one of the citations on the form, the observation will be noted in #46 “Other Observations” section of the form.

Each observation includes three elements:

Observation: check the box for the specific section of the regulation that applies to the observation noted. If the Observation box is checked, the Description section will also be completed. If an observation relates to more than one section of the regulation, record the observation in the FDA 4056 section that is the most appropriate. The observation should not be listed more than once. Consider whether items discussed with management during previous inspections need to be added as observations to the current FDA 4056 if no corrective action has been taken and conditions have worsened or present a risk to the product.

Corrective action taken: the box is checked when a current observation is fully corrected before the close of the inspection. Do not check the box if you did not check the Observation box. Annotations accompanying a checked Corrective action taken box are “Reported Corrected, Not Verified” and “Corrected and Verified” (see Description below). It is best practice to verify the farm’s completed corrective actions as long as the verification does not unreasonably extend the duration of the inspection. Corrective actions that are not related to an observation recorded on the current FDA 4056 will not be annotated on the form. Document corrections to observations from prior inspections in notes and in the report (PFIR or inspection report summary). Do not check the Corrective action taken box if the observation is only partially corrected and/or if the farm has committed to corrective action but has not completed it by the close of the inspection.

Description: include enough detail in the description section for the farm and other readers to understand the specifics of the observation and the significance (see IOM 5.2.3, 5.2.3.1.4, and 5.2.3.2). Include a statement to indicate each observation’s rank in the format “This observation is ranked [rank number] of [total number of observations] in order of significance, with rank 1 being the most significant.” When there are multiple observations with distinct citations to include in one Description section, see Exhibit 5-17 for an example layout. For a handwritten FDA 4056, if you need additional room to write the description, end the Description section text with “…Continued below under the Continuation Sheet section…” The remainder of the text will be included on the continuation sheet. For eNSpect and PDF FDA 4056s, the Description section expands to accommodate all text entered. For eNSpect FDA 4056s, Description section contents will be laid out as described in this section when generated by the system.

If the farm has corrected the observation or has committed to correct it, the Description section should include only one of the following annotations:

1. Corrective Action: Reported Corrected, Not Verified.
2. Corrective Action: Corrected and Verified.
3. Corrective Action: Promised to Correct.

Additional details regarding corrective action are not to be included on the FDA 4056. Include the information in the report (PFIR or inspection report summary). Do not annotate the FDA 4056 with the farm's stated objections to an observation or to the form as a whole.

Sprouts

Use this section of the FDA 4056 for observations related to the Sprouts subpart of the Produce Safety Rule (21 CFR 112, Subpart M) when an inspection covers sprouts in addition to covering other types of produce subject to the PSR. Use the FDA 483 instead of the FDA 4056 for inspections that only cover sprouts. For all farms that do not engage in activities subject to Subpart M, check the box labeled "Check here if entity does not engage in growing, harvesting, packing, and/or holding of sprouts". Do not check the box if the farm engages in the listed activities. If sprouts activities occur but were not inspected, enter in the Continuation Sheet: "Sprouts (21 CFR Part 112, Subpart M) were not covered during this inspection."

Other Observations

Use section (46) of the FDA 4056 to document any observations that do not fall under one of the other sections (1 – 45) identified on the form. In Description on the form, add the relevant citation and short description, as well as fully explaining the observation per guidance in Description above.

FDA REPRESENTATIVE SIGNATURE

- eNSpect generated version: electronic signature of lead investigator.
- PDF version: electronic signature of lead investigator or state inspector.
- Paper version: signature in ink of each investigator and/or inspector.

NOTE: For FDA-4056 only. On the FDA 4056, the signature is captured on one page in the FDA Representative Signature block. Everyone present under FDA inspectional authority during the inspection should be listed in the Representative(s) Name and Title box.

The FDA 4056 should be completed and signed electronically in eNSpect prior to printing and issuance. In circumstances where eNSpect cannot be used to complete the FDA 4056, complete the fillable PDF form. Only the lead FDA representative is to electronically sign the PDF FDA 4056.

If electronic signature in eNSpect or the fillable PDF FDA 4056 is not possible, print the FDA 4056 and all FDA representatives present at the close-out of the inspection should sign in ink.

When it is not possible to complete an FDA 4056 using eNSpect, or the fillable PDF form, it is permissible to complete a hardcopy FDA 4056 in ink. Everyone present under FDA inspectional authority is to sign

the document in ink. A copy of the signed FDA 4056 must be obtained for inclusion in the PFIR, which is the equivalent of an EIR for produce farm inspections. (See IOM 5.5.10)

FDA REPRESENTATIVE(S) NAME AND TITLE - Name and title of all inspection team members (should match all members who signed the Form FDA 482(s), Notice of Inspection)

Date Issued – Date the inspection is completed and the form is issued.

Continuation Sheet

Use this section if needed to expand information from main sections of the form. Identify the section from which text is continued, e.g., "*DATES OF INSPECTION…" or "Continued from Observation area # [insert applicable number, 1-46] on page [insert number] …" followed by the continued text. Otherwise, follow specific instructions pertinent to the added text, such as for sprouts (see above) or for amendments (see IOM 5.2.3.1.6). If there is nothing additional to note, "N/A" or "Intentionally left blank" should be entered.

Additionally, all amended FDA 4056s must include in the Continuation Sheet section "AMENDMENT" followed by the amendment number. The first amended FDA 4056 for the inspection will have "AMENDMENT 1" printed in the Continuation Sheet section. Any additional amendments required for the same inspection will be identified with the next sequential number.

5-21 – Film Photography

General Considerations

If you are using a film-based camera (e.g., 35mm), follow applicable guidance in IOM section 5.6.7 regarding documentation of digital photographs in addition to the specific guidance below. Regardless of the technology used, you must create a trail, starting with the taking of the photo, confirming its original accuracy and establishing a record describing the chain of custody. To do this, you must make sure each photograph is described in your regulatory notes in sufficient detail to assure positive correlation of the photo with your inspection findings. One way you can do this is to photograph a card with your name, program division address and phone number as the first frame or picture on a roll of film. This will help identify the film and assist in tracking if it is lost or becomes separated from its identification envelope during processing or storage. Proper procedures will also allow the agency to provide evidence confirming the authenticity of the photographs in the event you are not able to testify personally.

Cameras

Film Prints Identification and Preparation

Identify each print used as an exhibit in the EIR on the margin with exhibit number, firm name, date taken or inclusive dates of inspection, and your initials. Do not place any identifying marks on the picture area of the print. Mount the photo(s) on letter size paper; a narrative description may be placed on the mounting paper next to the print if insufficient area is available in the photo margin. If borderless prints are created, place identification along the back bottom edge of the print and mount the print so the identification can be read without removing the print from the mounting paper.

All film prints mounted on paper and used as exhibits must be scanned utilizing appropriate hardware and labeled for submission in eNSpect. See SOP ORA-OO.004 Using eNSpect to Create, Store, and Preserve Electronic Records Associated with an Establishment Inspection Report. Store the original negatives according to the section below.

Film Negative Identification

Identify the edge of at least two negative strips, with the same information as for prints using a 3/16" strip of pressure sensitive tape. Place all negatives in an FDA-525 or similar envelope. Complete blocks 2, 3, 5, 7, and 12 and seal with an Official Seal, FDA-415a. If negatives are not part of a DOC Sample, enter firm name in the Sample Number block.

Do not scan the FDA 525 or envelopes containing the negatives and upload in eNSpect as exhibits. The actual photographs included and described in the EIR are the official exhibit and are maintained in the eNSpect system. The officially sealed negatives should be included with the unlabeled hard copy exhibits and attachments filed in accordance with applicable procedures. The following statement should be included section 5.11.4.3.16 - Additional Information, “The

officially sealed negatives of the photographs taken during the inspection are filed with the unlabeled exhibits and attachments."

Video cameras

Videotape Identification and Preparation

Unused videotapes should generally be used to capture the video and, for subsequent copies of the original recording. Handle and protect the original video record just as if it were a photograph (see IOM 5.6.7). If the video is planned to be used as an exhibit to an inspection, where possible employ technology to digitize the video in its entirety for identification and upload into eNSpect. Where this technology is unavailable, upload a document in place of the video in eNSpect explaining the circumstances and indicating the video is available in the firm's establishment file.

Identify the original video recording with a label with the firm name, date taken, and your initials. Seal the original copy of the video tape in an FDA-525 or similar envelope. If using a form FDA 525, complete blocks 2, 3, 5, 7, and 12. If you use a larger envelope, identify the envelope with your name, title, home program division, date, firm name, firm address (include zip code), and description of the contents of the envelope. Using either method, label the outside in large bold letters "STORE AWAY AND PROTECT FROM MAGNETIC FIELDS" and seal with an Official Seal, FDA-415a. Submit any officially sealed tapes with the unlabeled hardcopy exhibits in accordance with applicable procedures. The following statement should be included section 5.11.4.3.16 - Additional Information, "The officially sealed videotape(s).

5-22 – Pesticide Inspections/Investigations

Pesticide Inspections

The objective of a Pesticide Inspection is to determine the likelihood of excessive residues of significant pesticides in or on products in consumer channels, and to develop sources of information for uncovering improper use of pesticide chemicals.

Typically, many Pesticide inspections whether for use, misuse, drift, and similar pesticide applications are completed at the state level by agencies working with the Environmental Protection Agency (EPA) on the enforcement and investigation of pesticides covered under the "Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA)". Coordination with FDA State Liaisons and Emergency Response Coordinators is recommended.

This requires directing coverage to two major areas:

- Pesticide practices in the production and processing of many raw agricultural products and crops. Application of pesticide chemicals in establishments storing and processing raw agricultural products and crops.

Coverage of raw agricultural products will generally be on a growing-area basis.

Problem areas include:

1. Improper use of pesticides around animals and in raw agricultural crop/products - gross misuse of sprays and dips in animal husbandry may result in pesticide residues in foods, as misuse or misapplication of pesticides on raw agricultural crops/products may also result in pesticide residues in foods.
2. Use of contaminated animal feeds - waste and spent materials from processing operations may contain heavy concentrations of pesticide residues, which were present in the original commodity. See Compliance Policy Guide 575.100.
3. Past pesticide usage - past pesticide practices on growing fields. Past use of persistent pesticides may result in excessive residues in the current food crop. You may need to check on pesticide usage for several years prior to an incident to ensure you gather enough information. Some pesticides last for many years in the environment.

Current Practices

Cooperative Activities - important sources of information relative to evaluating the "Pesticide Environment" include:

1. Coordination of your inspection with your supervisor and the appropriate FDA state liaisons and or the divisional emergency management coordinators (ERC) is one of the starting point for this type of inspection/investigation. They will identify the appropriate state, local or regional agency responsible for pesticide use and applications within the jurisdiction, when available.
2. At the start of the growing season, spray schedules recommended for each crop by county agents, state experiment stations, large pesticide dealers, farmers cooperatives, et al should be obtained.
2. Visits to agricultural advisors may provide information relative to heavy infestation of insect pests and fungal infections on specific crops in specific areas.
3. Daily radio broadcasts in most agricultural areas may provide information on spray schedules, insect pests, harvesting and shipping locations, etc.
4. Field employees of fruit and vegetable canning and freezing plants usually recommend spray schedules, pesticides, and harvesting schedules for products produced by contract growers.
5. United States Weather Bureau Offices and their reports will provide data on weather conditions, which may affect insect growth and their development, size of fruit or leaf growth, and dissipation of pesticide chemicals.

6. USDA Market News Service daily price quotations, and weekly quotations in trade magazines provide information regarding harvesting schedules since market prices are indicators of how quickly a crop will be harvested in a given area. Growers who have the opportunity to obtain high prices may harvest their crops without regard to recommended pre-harvest intervals.
7. State Colleges of Agriculture seminars or short courses on food and vegetable production may alert you to significant departures from usual agricultural practices. Prior approval to attend such meetings should be secured from your supervisor.
8. Pesticide suppliers and distributors may provide information on spray practices, schedules, and the name and address of growers, etc.

NOTE: The U.S. Department of Agriculture has a Pesticide Data Program (PDP), which provides data on pesticide use and residue detection. This program helps form the basis for conducting realistic dietary risk assessments and evaluating pesticide tolerances. Coordination of this program is multi-departmental, involving USDA, EPA, and FDA, covered by a MOU (Federal Cooperative Agreements Manual). As a part of this program USDA collects data on agricultural chemical usage, and factors influencing chemical use, and collects pesticide residue data through cooperation with nine participating states. USDA provides this data to EPA, FDA, and the public. Several USDA publications are listed below as reference material.

Reference materials - the following reference materials provide background and data necessary or helpful in evaluating current practices. This material should be available at the program division office.

1. Pesticide Chemicals - Regulations under the Federal Food, Drug and Cosmetic Act on tolerances for pesticides in food administered by the Environmental Protection Agency (EPA).
2. EPA's Pesticide Regulations - Tolerances for Raw Agriculture Products. (See 40 CFR 180)
3. EPA's Rebuttable Presumption Against Registration (RPAR) List.
4. Pesticide Index. - By William J. Wiswesser. A publication containing information on trade names, composition and uses of commercial pesticide formulations.
5. The Daily Summary or Weekly Summary. News releases and reports from USDA.
6. USDA's Weekly Summary Shipments-Unloads.
7. Agricultural Economic Report No. 717 Pesticide and Fertilizer Use and Trends in U.S. Agriculture (May 1995)
8. Annual Pesticide Data Summary
9. Reports from USDA's Crop Reporting Board.
10. USDA's Pesticide Assessment Reports.

Growers

Preliminary investigation of growing areas at the start of the season will provide data necessary for program division work planning including production schedules, types and acreage of crops, pesticides used and the names and addresses of growers and shippers. The Produce Safety Network (PSN) can be of assistance in obtaining some of this information.

Growing Dates - The significant growing dates relative to pesticide usage are as follows:

1. Planting date,
2. Date of full bloom, and
3. Date of edible parts formation.

Harvest Dates - The dates of the anticipated harvest season will provide planning information relative to pre-harvest application and shipping.

Acreage - This will provide volume information for work planning.

PESTICIDE APPLICATION

Ascertain the actual pesticide application pattern for each crop. Look for objective evidence to document actual grower practice. Check the grower's supply of pesticide chemicals, look for used pesticide containers, visit his source of supply, etc. Check spraying and dusting practices. Establish if pesticide chemicals are used in such a manner that excessive residues might result.

The following information provides a basis for evaluating pesticide usage:

1. Pesticide Chemical Applied - List the common name if there is no doubt as to the chemical identity of the pesticide. Include labeling indications and instructions.
2. Method of Application - Describe the method of application i.e., ground rig, airplane, greenhouse aerosol, hand, etc.
3. Formulation - Describe the formulation i.e., wettable powder, emulsifiable concentrate, dust, granules, aerosol, etc. Express as pounds of active ingredient per gallon or percent wettable powder.
4. Number of Applications and Dates.
5. Rate of Last Application - Calculate the amount of active ingredient per acre.
6. Pre-Harvest Interval (PHI) - Calculate the number of days between the day of the last application of pesticide and the harvest date or anticipated harvest date. Compare to the PHI.
7. Visible residue on grower's crop.
8. Summary of Usage - Determine the USDA Summary Limitations and evaluate the responsible usage.

PESTICIDE MISUSE/DRIFT/SOIL CONTAMINATION

Pesticide residues, which exceed established tolerances, action levels, or "regulatory analytical limits", may be caused by pesticide misuse which can include:

1. Excessive application of a chemical on a permitted crop.
2. Failure to follow labeled time intervals between the last pesticide application and harvest.
3. Use of a non-approved pesticide on a crop.
4. Failure to wash a crop when pesticide labeling requires it (e.g., for certain EBDC's).

Other conditions, which may cause illegal residues, include spray drift and soil contamination.

Drift may be documented by determining which crops and pesticides have been grown/used in fields adjacent to those sampled. Determine direction of prevailing winds and wind condition on the day of spraying. Selective sampling will aid in determining if drift occurred. Compliance Samples collected to document pesticide drift should be Flagged as a Pesticide Sample and noted in the Remarks section of the CR as "Drift Sample - Maintain as Individual Subs".

Soil contamination by compounds, which are relatively stable in the environment, may cause systemic uptake of the compounds by growing crops. Follow-up investigations to violative samples may, in some limited cases, include soil samples as an attempt to determine the source of the contaminant. Do not routinely collect soil samples.

Packers and Shippers

Follow the same general procedure as in IOM 5.4.12.3. Observe and report the following:

1. Treatment Before Shipping - This may include stripping of leaves, washing, vacuum cooling, application of post-harvest preservative chemicals, use of cartons with mold-inhibiting chemicals, waxes, colors, fumigation, etc.
2. Identification of Growers' Lots - Determine procedure or methods used to maintain the identity of each grower's lot. Provide the code and key if any.
3. Labeling - Quote labeling or brand names.

4. Responsibility - Determine whether the packer or shipper knows what sprays have been used on the products shipped.

Pesticide Suppliers

Pesticide suppliers should be visited routinely during growing-area coverage. They may provide valuable information about pesticides being used on various crops in the growing area. Some suppliers may suggest spray schedules or advise growers about pesticide usage.

Determine what representations were made by the manufacturer of pesticide chemicals for which there is only a temporary tolerance or experimental permit. Get copies of any correspondence relating to sale and use of these products. Obtain names of growers to whom sales are made if such sale was not for use on acreage assigned under the experimental permit. Collect Official Samples of any crops treated with the pesticide.

Pesticide Applicators

Pesticide applicators may provide valuable information about pesticides being used on various crops in the growing area. Interview several pesticide applicators, particularly those using airborne equipment. Determine the pesticide chemicals, their formulation, and on what crops they are currently being applied. Determine who supplies the pesticides and how they are prepared to assure proper concentration. If state law requires the applicator to keep a record of each spray application, request permission to review such records. Determine what steps are taken to assure drift on adjoining crops does not result in violative residues. Where there is likelihood of drift, collect Selective Samples from adjoining fields.

Sample Collections

See IOM Sample Schedule Chart 3 - Pesticides.

5-23 – Standards of Identity for Food

The FD&C Act (Section 401 [21 U.S.C 341]) requires the Secretary of the Department of Health and Human Services to promulgate reasonable definitions and standards of identity (SOI) for food to promote honesty and fair dealing in the interest of consumers. When a SOI becomes effective, it establishes the common or usual name for the article, defines the article and fixes its standard of identity. It is then the official specification for the food. The food industry actively participates in the development of a SOI and supplies much of the data upon which the regulation is based. There are currently more 250 SOIs and these may be found in 21 CFR Chapter 1, Subchapter B, Parts 131-169. Additional information on FDA's standards of identity for food can be found here: Standards of Identity for Food | FDA.

The food standards (FS) inspection is made to obtain data for use, together with information from other sources in developing a food standard. Food standard inspections are also made to determine a firm's compliance with food standards regulations, when manufacturing a standardized food.

Conducting a food standards inspection

These inspection assignments usually originate from CFSAN. When an inspection is planned for the purpose of collecting data to support a proposed food standard regulation, the program division may elect to advise the firm, if CFSAN has not already done so. If the firm selected does not choose to cooperate, it may be necessary to visit additional plants to obtain the desired information. Selection of additional firms should be done in consultation with the CFSAN.

Some firms often contend their entire process and formulas are "trade secrets". Attempt to persuade management the term "trade secret" should only be used to cover the process and/or quantitative-qualitative formulation which is truly unique to the firm. In instances where the firm is reluctant to release any of the information requested, point out FDA will, within the limits of the Freedom of Information Act, make every effort to preserve the confidentiality of the composition, make-up, and production levels of the product using codes, which cannot be traced back to the firm. Include as much of the compositional and processing information as you can in the body of the report, without violating the firm's confidence.

FS establishment inspection reports

FS EIR's may be used as exhibits at public hearings and are subject to review by any interested party.

Three copies of the report are prepared. The original and one copy will be submitted to CFSAN, and one copy kept for the establishment file. Sign the original and duplicates of the first and last pages of each report sent to the Center.

Divide the report into three sections. To relate the sections of the report to each other and to any assignments, and to assure any parts of the reports made public will not be identified as to the name of the firm or individuals therein, each program division will set up a master list of numbers. One number will be assigned to each establishment covered, e.g., "BLT FS-3". For each FS inspection, place the assigned number next to the firm name on the EI record. All other pages of the report shall be identified only by this number, the name of the commodity, and date. Example: "EIR Frozen Fish Sticks 10-3-87 BLT

FS-3". This indicates a FS EI of frozen fish sticks conducted by Baltimore OHAFO Division 2E on 10-3-87 in a plant designated as #3.

Where a producer may be reluctant to release any of the information requested, point out the FDA will, within the limits of the FOIA, make every effort to preserve the confidentiality of the composition, make-up, and production levels of his product using codes, which cannot be traced back to the firm.

Body of the EIR

Prepare the body of the report following the narrative outline as for any other food EIR except for the restrictions below.

The body of the FS report should also contain information regarding the approximate annual value and volume as well as the percent of interstate business for each product covered. This is necessary because the coversheet, which contains this information, identifies the firm, and will not be made public. Processes and the listing of raw materials used by the firm, which are not restricted by the term "trade secret" should be included. Any opinions, recommendations, or other information obtained or offered by individuals interviewed should be reported. Any suggestions made by individuals interviewed regarding what should be placed in the Standards for the products covered should be included. All individuals interviewed, firm name, etc. should have an identifying code assigned.

The body of the report should not include names and titles of individuals, (including USDA, USDI, or other inspectors), trade secret information, labeling, trade names, formulas, sample numbers, firm name, or location of plant (other than by state or region), shipments, or other distribution information, legal status, or regulatory history. This information will be placed in the "Special Information" section of the report.

Special information section

This is a separate attachment to the EIR which lists the names and titles of individuals (including other government inspectors) and firms with a reference code for each. The EIR should refer only to "Mr. A.," "Mr. B.," "Firm X," "Firm Y", etc. Do not use the firm or individual's actual initials in the body of the report. Include all information excluded from the body of the report and mount all labels obtained during the EI Labels may be quoted in the body of the report, but do not identify the firm. List the "Special Information Sheet" in the FACTS endorsement section as an enclosure.

Supplemental Reports - If, because of an additional visit or visits to the same firm on the same project, it is necessary to prepare another EIR, flag the report with the same number as assigned to the original report. For example, mark the EI Record "BLT FS-3 Supplemental Report", and the remaining pages, "EIR Frozen Fish Sticks 10-25-87 BLT FS-3 Supplemental Report."

Violative inspections

When an inspection made in connection with the Food Standards project shows insanitary or other conditions which are not germane to the assignment or in the program division's opinion suggests regulatory action, an appropriate narrative of the violative conditions should be prepared as a regulatory addendum.

5-24 – RECONCILIATION EXAMINATIONS

Conduct reconciliation examinations only for cause or as directed by your assignment or supervisor.

Examinations are conducted on raw materials used in the manufacture of foods or cosmetics, or finished products received by the firm for further distribution. Preference should be given to products of foreign origin. Where possible, these examinations should be performed on products as they are received by the firm.

Consult the establishment file for any information on special conditions in the facility that may affect selection of personal protective equipment. Consult your supervisor for any recommendations on personal protective equipment. Have available all necessary personal protective equipment to conduct the activity.

As Part of an Import Field Examination and Entry Review - See IOM 6.3.1 and 6.4.4. For imported food and cosmetics, a reconciliation examination should be conducted:

1. Per Part A during all routine import field exams. You should only report time under the Counter Terrorism PAC at the direction of your supervisor or if there is a for cause assignment.
2. In instances where review of entry information raises suspicion (resulting in a detailed reconciliation exam per Part B.

A detailed reconciliation exam should be conducted when there are anomalies in entry declaration information. These may include new, unusual, or unfamiliar commodities, manufacturers, importers; suspicious trans-shipments; or credibility issues such as those between the product and declared country of origin.

If anomalies are found, entry documents should be requested and reviewed for discrepancies between the information declared through electronic filer submissions and that found in entry documents. Entry documents may include invoices, bills of lading, export certifications, and other relevant documents obtained from the importer, filer, or manufacturer/processor of the product. Fields in which discrepancies are found that may raise concern include country of origin, manufacturer, product description, product code, and quantity.

Avoid duplication of examination of the same foreign manufacturer unless a prior reconciliation examination disclosed an unexplained discrepancy.

Follow guidance below for domestic and import reconciliation exams.

RECONCILIATION EXAMINATION GUIDANCE PART A

Reconciliation examinations are performed to ensure that:

- The product is what it purports to be
- There are not unexplained differences in the quantity of product ordered, shipped, and received, and
- There are no signs of tampering or counterfeiting.

Before initiating the exam make a general assessment of the appearance of the lot. Look for packaging that: appears to have been opened and resealed; appears wet, stained, punctured, or powdered. Also, be alert to abnormal chemical odors. If any of these conditions are detected stop the exam and contact your

supervisor for guidance. If the lot appears normal proceed with the examination. To the extent possible the exam should be performed in a well-ventilated, well-lit area.

Determine, to the extent possible, whether:

- The actual goods in a lot are the same as those that are declared in the shipping documents.
- There is consistency in the manufacturer declared on the product labeling, bulk product packaging, and shipping documents; and
- There is no (unexplainable) inconsistency in actual quantity of goods in the lot, and the quantity ordered and declared in the shipping documents.

If no unexplained inconsistencies are detected, no further action is indicated.

If unexplainable inconsistencies are detected, document the occurrence, including photographs of the labeling and packaging, and an accurate count of the lot. Contact your supervisor, who should, in the case of imported products, contact the U.S. Customs and Border Protection for appropriate action. If the examination discloses evidence that inaccurate product identification data was submitted to the OASIS entry screening system, the program division should evaluate the need for follow-up with a compliance filer evaluation and consider providing the information to the U.S. Customs and Border Protection for appropriate action.

In addition, if unexplained inconsistencies are detected, follow part B of this guidance while conducting a detailed reconciliation exam.

RECONCILIATION EXAMINATION GUIDANCE PART B

Open the shipping packaging of a quantity of product approximating the square root of the number of shipping cartons/packages in the lot and examine the contents. Look for the following:

- Product identity on the package that does not match the identity declared on the shipping documents
- Mixed product sizes within a carton or within the lot;
- Product sizes that do not match the sizes declared on the shipping documents
- Differences in product configuration or package type (e.g. plastic containers mixed with glass jars or aluminum or steel cans)
- Easily apparent variations in weight
- Product labels that display crude, unprofessional, or inconsistent styles of print, color, or use of language
- Unusual placement of labels (e.g., off-center)
- Variations in lot coding ink color, appearance of embossing, or format (e.g., two line vs. three line, use of letters, numbers and symbols). unusually excessive use of a single code in a very large lot
- Differences between the actual can codes in the lot and those listed on the shipping documents
- The existence of a tamper-evident notice on the labeling when the packaging does not contain a tamper-evident feature
- Product that is beyond its expiration date
- Inconsistencies in expiration dates within a lot

If no unexplainable discrepancies are noted select at least 1 package at random from the entire shipment and examine their contents. For those products that the contents are visible through the package it is not necessary to open the package. For other products, open the package and examine and field destroy the contents. Look for the following:

- Differences between the product and that which is declared on the label
- Color differences in the product between containers of the same lot
- Style differences in the product between containers of the same lot or between the actual product and the label and document declaration (e.g., sliced vs. whole, colorless noodles vs. egg noodles)
- Readily detectable abnormal odors (e.g., strong decomposition, bitter almond, petroleum odor, garlic, chlorine, sulfur). Note: specific sensory examination is not expected.

Verification that the product is consistent with the product ordered may require that you obtain information from the owner of the goods, importer, filer, or custom house broker. Review of the following types of documentation may be necessary to accomplish the above instructions, to the extent that they are available: authentic label supplied by the owner of the goods, importer, filer, or custom house broker; purchase order; invoice; shipping records (bill of lading, weigh bill, manifest). Depending on the findings of the exam and record review, you may wish to request that the importer assist in an evaluation of the authenticity of the product, based on the importer's experience with the product.

Every effort should be made to document any discrepancies through use of photographs, and additional records that may be available from the filer, importer, owner, or customs house broker.

SPECIAL SAFETY PRECAUTIONS

See IOM Chapter S - Safety.

When performing an establishment inspection or reconciliation examination, follow these instructions:

1. If there are no signs of tampering or counterfeiting, use level I protection, which consists of: work gloves; coveralls; work boots; and in a dusty situation, a dust mask.
2. If there are signs of tampering or counterfeiting, use level II protection and consult your supervisor for any additional safety precautions needed. Level II protection consists of: work gloves worn over surgical gloves; full face respirator with appropriate cartridges; disposable coveralls; and work boots.

Consult with an Industrial Hygienist if you are unsure what protective equipment should be used during sampling.

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6.1 – Imports General

6.1.1 – Authority

Section 801 of the Food Drug and Cosmetics Act (FD&C) Act [21 U.S.C. 381] authorizes the FDA to examine foods, drugs, cosmetics, devices, and tobacco products offered for entry into the United States. Section 536 of the FD&C Act [21 U.S.C. 360mm] authorizes refusal of radiation-emitting products which fail to comply with the requirements of Section 534 (h) of the FD&C Act [21 U.S.C. 360kk (h)]. 19 CFR 151.4 of the U.S. Customs and Border Protection (CBP) regulations authorizes employees of the FDA to examine or take samples of entry goods released under immediate delivery.

The procedures outlined in this chapter cover imported goods subject to, but not limited to, the following acts/regulations:

1. Federal Food, Drug, and Cosmetic Act (FD&C)
2. Fair Packaging and Labeling Act (FPLA)
3. Nutrition Labeling and Education Act (NLEA)
4. Import Milk Act/ Filled Milk Act
5. Federal Caustic Poison Act
6. Bioterrorism Preparedness Act of 2002
7. Public Health Service Act, Part, Part F, Subpart 1, Biologic Products
8. Title 21 CFR Subpart E - Imports and Exports (1.83), etc.
9. Title 19 CFR Customs Duties (authority to sample delegated by CBP Regulations, etc.)
10. *Federal Cigarette Labeling and Advertising Act* and Comprehensive Smokeless Tobacco Health Education Act
11. Family Smoking Prevention and Tobacco Control Act

6.1.2 – Scope

The procedures in this section cover imported goods. Your personal safety during any import procedures outlined in this subchapter is important. For more information concerning personal safety, see IOM 5.3 and IOM Chapter S

6.1.3 – Division of Authority

The FDA determines if an article complies with the Acts it enforces. It also determines whether the article can be brought into compliance with the appropriate statute and authorizes reconditioning for that purpose.

Supervision over the reconditioning is exercised by either the FDA, or CBP, as mutually arranged. At ports in reasonable proximity to an FDA office, supervision is ordinarily exercised by the FDA. At remote ports, supervision may be exercised by CBP.

In the case of a refusal of admission action is by compliance, exportation and / or destruction of goods is carried out under the direction of CBP. However, the actual supervision of the destruction and / or exportation of violative goods may be conducted by FDA pursuant to a local FDA/CBP agreement.

6.1.4 – Entry Types

6.1.4.1 - Formal Entries

All articles offered for entry into the United States that are subject to the acts enforced by the FDA and possess a value greater than $2,500 are considered formal entries. These entries are subject to bond requirements, which include a condition for the redelivery of the goods, or any part of them, upon demand by CBP, at any time, and as prescribed for in the CBP regulations in effect on the date of entry. (section 801(b) of the FD&C Act [21 U.S.C. 381(b)], 19 CFR Part 113). The bond is filed with CBP which, in case of default, will take appropriate action for the collection of liquidated damages provided for in the bond after consultation with the FDA. (19 CFR Section 113.62and 21 CFR Section 1.97). Notification of the entry is generally accomplished by electronic submission

through the CBP Automated Commercial Environment (ACE). Non-electronic entries are submitted directly to the FDA. Electronic entries received by the FDA may be subject to manual review to determine if further action is needed, or if additional documentation is required. For entries requiring further review, the FDA will be provided the appropriate CBP entry documents (such as the CF 3461 / 3461ALT, commercial invoice, bill of lading and any other relevant documents to aid in making an admissibility decision), which will also document the extent of the interstate commerce. If an entry is not filed electronically, these documents will be submitted to the FDA at the time the CBP entry is made, in accordance with local port of entry operations.

6.1.4.2 - Informal Entries

Normally, informal entries with a value of less than $2,500) do not require a redelivery bond. All informal entries of articles subject to FDA jurisdiction and entered electronically, are forwarded to the FDA through the CBP/FDA ACE interface. In instances when the FDA takes action on an informal entry not filed electronically, agency personnel will record the informal entry in the FDA Import Systems as a manual entry (IOM 6.1.4.5). If agency action is indicated, the FDA will then request that a formal consumption entry be filed.

6.1.4.3 – Mail Entries

Mail entries consist of articles offered for entry by USPS international mail through International Mail Facilities (IMFs). They are often valued at less than $2,500 and are considered informal entries that do not require a bond or formal entry to be filed with CBP. When USPS receives international mail, CBP will screen the parcels and refer any FDA-regulated products of interest to the FDA. FDA divisions should arrange for coverage at their local IMF to receive these referrals. FDA personnel will review the referrals based on priority and determine whether the parcel should be sampled, released, or referred to compliance, the Office of Criminal Investigations (OCI), or a Partner Government Agency / Other Government Agency (PGA/OGA). Note that pharmaceutical items encountered through international mail may be subject to destruction. For further details, refer to the Procedures for FDA-Regulated Articles Shipped Through International Mail Facilities.

6.1.4.4 – Personal Baggage

CBP is responsible for examination of personal baggage at border-crossing offices, airports, and seaports. If CBP encounters an article subject to FDA regulations, they may refer it to the local FDA office for review.

During this review, if FDA personnel determine that the products referred are in violation of FDA regulations, they should refer the entry to compliance for applicable charges. FDA personnel may also need to determine if the products qualify as an exemption under personal importation. If it's found that a personal importation meets the criteria of a formal entry, FDA personnel should request thru CBP that a formal entry be filed. If no formal entry is filed, the referral should be processed in accordance with manual entry procedures (IOM 6.1.4.5). Since most personal importations are small in size and value, guidance has been developed for evaluating these importations. (See RPM Chapter 9-2"Coverage of Personal Importations".)

Entries with a value of $800 or less may fall under "Section 321."Generally, this form of entry applies to articles which pass free of duty and tax, and are imported by one person on a single business day (19 C.F.R. 101.1 . CBP and the FDA may conduct periodic "blitzes" on such entries to determine the volume and type of FDA-regulated goods being admitted under "Section 321." Note, however, that the use of the "Section 321" entry process should not apply to multiple shipments covered by a single order or contract that have been sent separately for the express purpose of securing free entry and avoiding compliance with pertinent laws or regulations.

6.1.4.5 – Manual Entries

Manual Entry is a term often used interchangeably with non-ABI entry and/or paper entry in the context of entries submitted to CBP and the FDA in a non-electronic manner outside of ACE.

Detailed instructions for creating a manual entry can be found in the Job Aid for the Entry Review Application.

When a manual entry is received, it may be necessary to enter the entry information into an FDA Import System. You should do this when the agency plans to conduct additional work on an entry (for instance, examination, sampling, detention, etc.). Note that information entered by the FDA is not transmitted to CBP as the FDA does not collect all the information CBP requires for a given entry. Once you have input relevant information into an FDA Imports Systems, (ER, SERIO, OASIS), the entry will be processed following usual procedures. Remember that for entries manually entered by FDA, there is no bond or monetary value attached.

In instances of manual entries not requiring further action, you should not need to create an electronic record. This includes entries directly released by the FDA after review of entry documentation.

Note: If the product being offered for manual entry is a human food or animal food/feed, prior notice filing is still required in advance of its arrival in the United States (IOM 6.1.5). For non-electronic entry filings, prior notice can be submitted through FDA's Prior Notice System Interface (PNSI).

As indicated in RPM 9-1, the FDA historically has and will continue to accept and process paper entries to determine admissibility for imported FDA-regulated products (regardless of value), if the paper entry submission process continues to be an acceptable entry submission process for CBP. And though the FDA accepts entry data submitted via non-ABI (paper/manual) means, electronically filed entries do take priority. CBP regulation, found at 19 CFR 141.61, cover the completion of entry and entry summary documentation.

***Note:** For detailed instructions on how to create a manual entry, please see the Job Aid for the Entry Review Application

6.1.4.6 – Import for Export (IFE) Entries

These are products imported under the provisions of section 801(d)(3) OF THE FD&C Act [21 U.S.C. 381 (d)(3)]. REFERENCES: Regulatory Procedures Manual Chapter 9-17, FD&C Act Section 801(d)(3) of the FD&C Act [21 U.S.C. 381 (d)(3)] allows the importation of certain violative FDA-regulated articles into the U.S. on a conditional basis ensuring that they are not for domestic distribution. Those articles include human and veterinary drugs (or their components); device components or accessories, or other devices requiring further processing for health-related purposes; and food additives, color additives, and dietary supplements including in bulk form. They must be explicitly intended for further processing or incorporation into other products and subsequent export. This section outlines procedures to help you facilitate the uniform review and admissibility process for IFE entries, and those that enable sufficient notification for domestic follow-up of IFE shipments.

The following documentation is required at the time of importation according to section 801(d)(3) of the Act [21 U.S.C. 381 (d)(3)] includes:

1. A statement that the article is intended to be further processed or incorporated into a drug, biologics product, device, food, food additive, color additive, or dietary supplement and will be exported under sections 801(e)or 802 of the FD&C Act [21 U.S.C. 381 (e) or 382] or section 351(h) of the Public Health Service Act (PHSA).
2. Information/documentation that identifies the manufacturer of the article, as well as each processor, packer, distributor, and/or other entity in the chain of possession from manufacturer to importer. (Attempt to gather the name and address of each entity in the chain of possession if such details not evident.)
3. Such certificates of analysis as necessary to identify the article, unless it is a device or falls under section 801 (d)(4) of the FD&C Act [21 U.S.C. 381 (d)(4)] - to include blood and blood components.

In addition, a good and sufficient bond must be executed providing for payment of liquidated damages in accordance with CBP requirements. Refer to RPM 9-17. However, note that some entry types may not be accompanied by a bond.

6.1.4.6.1 – IFE Entry Review

Import for Export entry procedures are as follows:

1. Divisions should ensure that all information required under section 801(d)(3) FD&C Act [21 U.S.C. 381 (d)(3)] is provided and that supporting documents are uploaded (if not already received from the broker or importer).
    a. Confirm that IFE or suspected IFE entry/lines are submitted with an intended use code (IUC) of "Import for Export" and with the IFE in the Affirmation of Compliance (A of C). If the entry/line lacks the IUC IFE and/or the IFE A of C, update the entry/line, record the reason for the update, save, and rescreen the entry/line. For entry/lines lacking complete supporting documents, request documents per IOM 6.2.3.1.
    b. If the required documents are not provided after they are requested, entry reviewers should request detention, indicating the products do not meet the regulatory requirements, are being offered for import using the IFE provisions, and are missing the required IFE documentation at the time of initial importation. Refer to RPM 9-17-3 for additional information.
    c. If all required documents are provided, including the IUC, and per conditions required by section 801(d)(3) FD&C Act 21 U.S.C. 381 (d)(3) , a "May Proceed" may be issued. NOTE: Ensure that all entry documentation has been uploaded to the entry/line prior to making an admissibility decision.
    2. If the entry/line was transmitted as an IFE, but review of the entry/line information or supporting documentation indicates that the articles are not intended to be further processed and exported per section 801(d)(3) of the Act 21 U.S.C. 381 (d)(3):
        - Update the entry/line with appropriate IUC and A of Cs, as appropriate.
        - Record the reason for update, save, and rescreen the entry/line.
        - Review the entry/line according to applicable requirements.

NOTE: If receiving a non-ABI entry declared as IFE, refer to the Entry Review Job Aid for specific instructions on creating a manual entry in ER.

6.1.5 - Prior Notice of Importation of Food and Animal Feed

The Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (also known as the Bioterrorism Act) requires that FDA receive prior notice of food, including animal feed, that is imported into the United States. Most of the information required by the final rule is provided to CBP by importers and brokers when foods arrive in the United States. The Bioterrorism Act requires that this information also be provided to FDA, prior to the arrival of an imported article of food into the country. Advance notice of import shipments allows the FDA, with the support of CBP, to target import inspections more effectively and better protect the nation's food supply against potential contamination from acts of bioterrorism and other public health emergencies. Prior notice can be submitted either through the Automated Broker Interface (ABI)/Automated Commercial Environment (ACE) or FDA's Prior Notice System Interface (PNSI).

6.1.5.1 – Prior Notice Inspection

Prior notice for food articles subject to the rule must be received and confirmed electronically by the FDA *no more than 15 calendar days* before the anticipated date of arrival for submission made through the PNSI, and *no more than 30 calendar days* before the anticipated date of arrival for submission made through ABI/ACE, and, dependent on the mode of transportation below, no fewer than:

- Two hours before arrival by land by road
- Four hours before arrival by air or by land by rail
- Eight hours before arrival by water

In addition, prior notice must be received and confirmed electronically by FDA before food is mailed by international mail. (The parcel must be accompanied by confirmation of FDA receipt of prior notice.)

6.1.5.2 – Products Requiring Prior Notice

Prior notice applies to food for humans and other animals that is imported or offered for import into the United States. For purposes of prior notice requirements, "food" is defined by section 201(f) of the Federal Food, Drug, and Cosmetic Act. as articles used for food or drink for man or other animals (including chewing gum) and articles used for components of any such articles.

Examples of "food" include:

- Dietary supplements and dietary ingredients.
- Infant formula.
- Beverages (including alcoholic beverages and bottled water).
- Fruits and vegetables.
- Seafood.
- Dairy products and eggs.
- Raw agricultural commodities for use as food or components of food.
- Canned and frozen foods.
- Bakery goods, snack foods, and candy (including chewing gum).
- Live food animals.
- Animal feeds and pet food.

6.1.5.3 – Products Excluded from Prior Notice

Foods that are excluded from the prior notice requirement include:

- Food carried by, or otherwise accompanying, an individual arriving in the United States for that individual's personal use (that is, for consumption by themselves, family, or friends, and not for sale or other distribution).
- Food that is exported without leaving the port of arrival until export.
- Meat products, poultry products, and egg products that are subject to the exclusive jurisdiction of the U.S. Department of Agriculture (USDA) under the Federal Meat Inspection Act (21 USC 601), (21 USC 601), the Poultry Products Inspection Act, or the Egg Products Inspection Act.;
- Food made by an individual in their personal residence and sent by that individual as a personal gift (that is., for non-business reasons) to an individual in the United States.
- Articles of food subject to Art. 27 (3)of the Vienna Convention on Diplomatic Relations (1961) i.e. shipped as baggage or cargo constituting the diplomatic bag.

6.1.5.4 – Prior Notice Submission

The prior notice must be submitted electronically and contain the following information, in accordance with 21 CFR 1.281:

1. Identification of the submitter, including name, telephone number, email address, and firm name and address.
2. Identification of the transmitter (if different from the submitter), including name, telephone number, email address, and firm name and address. If the business address of the individual transmitting the prior notice is a registered facility, then the facility's registration number, city, and country may be provided instead of the facility's full address.
3. Entry type and CBP entry identifier, if available.
4. The identification of the article of food, including complete FDA product code, the common or usual name or market name, the estimated quantity described from the largest container size to the smallest package, and the lot or code numbers or other identifier (if applicable).
5. If the food is no longer in its natural state (21 CFR 1.276(b)(10)), the name of the manufacturer and either (1) the registration number, city and country of the manufacturer or (2) both the full address of the manufacturer and the reason the registration number is not provided.

6. If the food is in its natural state, the name and growing location address of the grower, if known. If the identity of the grower is unknown, or the article has been consolidated from multiple unknown growers, the name and address of the firm that consolidated the articles of food from different growers or different growing locations can be provided.
7. The FDA country of production.
8. The identification of the shipper, express consignment operators, carriers, other private delivery service or senders if the food is mailed. This should include the name and full address of the shipper if the shipper is different from the manufacturer. If the address of the shipper is a registered facility, the submitter may submit the registration number of the shipper's registered facility city and country instead of the facility's full address.
9. The country from which the article of food was shipped. If the food was imported by international mail, the country from which the food was mailed.
10. The anticipated arrival information (port of arrival, date, and time). If the food is imported by international mail, the anticipated date of mailing. If the article of food is arriving by express consignment operator or carrier, and neither the submitter nor transmitter is the express consignment operator or carrier, and the prior notice is submitted via PNSI, the express consignment operator or carrier tracking number may be submitted in lieu of the anticipated arrival information. For post-refusal submissions, the actual date the article arrived is required.
11. The name and full address of the importer, owner, and ultimate consignee, except for food imported by international mail or transshipped through the United States. The name and address of the U.S. recipient should be provided for food arriving by international mail. If the business address of the importer, owner, or ultimate consignee is a registered facility, then the facility's registration number also may be provided in addition to the facility's full address.
12. The identification of the carrier and mode of transportation, except for food imported by international mail.
13. Planned shipment information as applicable by mode of transportation and when it exists. For food arriving by express consignment operator or carrier, when neither the submitter nor transmitter is the express consignment operator or carrier, the tracking number can be submitted in lieu of the Bill of Lading or Airway Bill number for prior notices submitted via PNSI.
14. The name of any country to which the article of food has been refused entry.

6.1.5.5 – Inadequate Prior Notice Submission

Food that is imported or offered for import with inadequate prior notice is subject to refusal and holding at the port or in a secure storage facility. The FDA provided guidance to its stakeholders and CBP staff on enforcing such prior notice requirements in its Compliance Policy Guide, Prior Notice of Imported Food Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002. This guidance, however, does not limit the FDA's ability to take actions that may be necessary, including conducting inspections for food safety and security concerns, or taking any other action under the FD&C Act. This policy will also not affect the ability of CBP to assess penalties under 19 U.S.C. 1595a(b) or to take enforcement action under any other authority.

6.1.5.6 – Prior Notice Process

The prior notice review process begins with automated electronic screening. If additional evaluation of the prior notice information is necessary, a manual review is performed by FDA headquarters staff at the Division of Food Defense Targeting (DFDT), which operates 24 hours a day, 7 days a week. The review process is designed to identify food products that may pose serious risks to public health so that appropriate action can be taken upon their arrival in the United States. Note that the review process is not impacted by the method of electronic submission and that results of the process are transmitted to CBP.

The DFDT may initiate an examination or other action by the FDA or CBP at the port of arrival or elsewhere, or in the case of rail shipments, at the closest appropriate examination site. The DFDT will advise the FDA field offices and/or CBP of the inspection requirements. The DFDT is also responsible for communication with submitters regarding the following: prior notice compliance, the initiation of a refusal or hold due to inadequate prior notice information or unregistered foreign manufacturers, responses to requests for review of refusals or holds, and completion of the prior notice process.

Food that meets prior notice requirements will be subject to further review by FDA staff for admissibility determination under section 801(a) of the FD&C Act. The FDA Import Systems screening will determine if further evaluation of the article of food is necessary (for instance, subject to the guidance in an import alert). If the FDA determines that refusal under section 801(a) of the FD&C Act is applicable, the appropriate procedures will be followed.

6.1.6 - Entry Processing

FDA division offices generally receive notification of all formal and informal entries subject to FDA's jurisdiction. Management for each port of entry determines coverage, hours of operation, and resource allocation for any office closures impacting normal working hours. In addition, FDA Import Systems allow for entries to be reviewed remotely by off-site personnel.

Entries submitted electronically to the FDA are screened against criteria established by FDA laws and regulations. Filers who submit entries via the ABI to Customs for cargo release are required to provide FDA-pertinent information on entries subject to its jurisdiction submitted through ACE. The means of receiving notification for non-ABI entries can be arranged through local Customs/FDA division agreements.

6.1.6.1 - U.S. Customs and Border Protection (CBP)

CBP's ACE uses guides established by each federal agency to identify which commodities are subject to their jurisdiction. These guides are known as Partner Government Agencies (PGA) flags. FDA flags include FD1, FD2, FD3, and FD4, which are defined accordingly:

- FD1: Entries covered by an FD1 flag may or may not be subject to FDA regulations. Electronic entries made by the filer may, based on information received from the importer regarding the intended use of the commodity, specify that the entry is not subject to FDA regulations, hence the resulting decision to "Disclaim" the entry. Otherwise, FDA required information must be submitted. The agency periodically performs reviews of "Disclaimed" entries is to help ensure the accuracy of declarations.
- FD2: Entries covered by an FD2 flag must include or reflect FDA-required information.
- FD3: Entries covered by an FD3 flag may be subject to prior notice under section 801 (m) of the FD&C Act and 21 CFR Part 1, subpart I, http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=1&showFR=1&subpartNode=21:1.0.1.1.1.7 21 CFR Part 1, subpart I(for instance, when the article has both food and non-food uses). The filer may, based on information received from the importer regarding the intended use of the commodity, specify the entry is not subject to prior notice and “Disclaim” the entry. If the product is an FDA-regulated product, but not a food, the entry can be disclaimed from prior notice by using the affirmation of compliance code “PND” in the entry.
- FD4: Entries covered by an FD4 flag may be “food” for which prior notice is required under section 801(m) of the FD&C Act and 21 CFR Part 1, subpart 1. Entries covered by FD4 flag must include prior notice required information.

Electronic entries for CBP review include all mandatory CBP entry-required information, (that is, entry number, entry date, importer identification, port of entry, vessel/voyage information, filer identification, Harmonized Tariff System (HTS) code for product description, information on foreign shipper, country of origin, etc.) Through the screening process in ACE, CBP determines if the article is subject to FDA examination (see OGA flag identifications

above). Note that CBP, the FDA, and 46 other PGAss have been working to modernize business processes through the implementation of the Automated Commercial Environment/International Trade Data System (ACE/ITDS). ACE/ITDS is a single-access point whereby industry can electronically submit all data required by various government agencies involved in international trade. (ACE replaced the Automated Commercial System (ACS) in 2016.)

6.1.6.2 – FDA

FDA's system enhancements include establishing Intended Use Codes (IUC) to assist entry reviewers in determining the end-use of the imported product. Commodities will fall in one of the three categories:

- IUC is required.
- IUC is optional.
- IUC is not applicable.

Affirmation of Compliance (or A of C) codes provide FDA reviewers with information concerning the imported article. They are also used by filers to affirm that the firm and/or product identified in an FDA line meet the requirements specific to the product being imported. A of C code requirements are dependent on the commodity being imported and can be impacted by the IUC. If you need to review the specifications and requirements for filing in ACE as per the final rule, refer to 81 FR 85854 Submission of Food and Drug Administration Import Data in the Automated Commercial Environment, and the FDA's Supplemental Guide for the Automated Commercial Environment/International Trade Data System (ACE/ITDS).
https://www.cbp.gov/sites/default/files/assets/documents/2023-May/FDASupplementalGuideVersion2.5.9.508c_3.pdf

FDA Import Systems will generate a "Notice of FDA Action," which will provide more specific information on the actions taken, broken down by each entry line (for example, "Samples Collected", "Detention," "Lines Released," or "Refusal of Admission"). As the status changes for a particular line, a new "Notice of FDA Action" will be issued to advise appropriate parties of the changes. For parcels not received through a USPS IMF, the use of one of the following designations: "Product Collected by FDA," "Detained," "Released," "Refused," or similar language on the "Notice of FDA Action," should be considered as satisfying the requirements of the law for "giving notice thereof to the owner or consignee." (See 21 USC 381(a).) See Exhibit 6-1 for an example of the "Notice of FDA Action".

Notices are designed to be electronically or physically distributed to the addressees. Those who hold an approved Import Trade Auxiliary Communication System (ITACS) account may opt to receive notices via email or as a download within ITACS. A copy of each notice is generated for the filer, importer of record, and consignee, and delivered to the party on the addressee line. (If the same firm acts in one or more of those functions, only one copy is produced for the firm.) Notices are official documents that provide notification of a change in the status of an FDA-regulated entry/line. The distribution of the notices is made by the FDA, not the filer, to ensure proper notification to the parties involved. The intention is for the FDA to distribute notices to the responsible parties without an intermediary.

6.1.7 – Voluntary Qualified Importer Program (VQIP) Entry Processing

The Voluntary Qualified Importer Program (VQIP) is a voluntary, fee-based program that provides expedited review and import entry of human and animal foods into the United States for participating importers who must meet eligibility criteria and pay a user fee that covers costs associated with the FDA's administration of the program.

The FDA works with CBP to expedite entry of VQIP foods into the United States. The agency sets screening in its Predictive Risk-based Evaluation for Dynamic Import Compliance Targeting (PREDICT) import screening system to recognize shipments of food that are the subject of an approved VQIP application. The system is designed to recognize the information and release the shipment immediately after the receipt of entry information, unless examination and/or sampling are necessary for public health reasons. The FDA limits its examination and/or sampling of VQIP food

entries to “for cause” situations for instance, when a food is or may be associated with a risk to the public health), to obtain statistically necessary risk-based microbiological samples, and to audit the effectiveness of VQIP.

6.1.8 – Photographs: Identification and Storage

Photographs are evidence documented during import field work and are a crucial element in case development. They should be clear (not fuzzy or pixelated, with labels legible) and capture evidence needed to support the appearance of a violation and the associated proposed charges. The photographs should capture, at a minimum, all sides of the product packaging (top, bottom, and sides, including blank sides); all labeling (particularly any package inserts and labeling that provides or reveals the intended use of the product, product value, directions for use, daily intake, and firm information); any available production (lot) codes and/or dates; an overall view of the lot(s) examined; and any adverse conditions observed.

Photographic evidence must be captured with a government-issued digital device and copied to your work computer’s hard drive to prepare it for labeling and uploading to permanent storage. Blurry or otherwise unusable photographs may be deleted once you confirm that you have captured all the necessary clear usable photographs. Briefly document in your regulatory notes that photographs were taken and uploaded to the FDA Import Systems.

Photographic evidence must be uploaded electronically to the entry/line via FDA Import Systems for all sample collections, Class 2 and Class 3 field/label exams, detention requests (when warranted), destructions, reconditioning, refusal verification discrepancies, and other situations as warranted. Digital photographs may be deleted from your work computer’s hard drive *after* you have uploaded them to an approved permanent storage media, such as through FDA Import Systems.

All photographic evidence (including photographs of labeling) must be identified with the following required information: entry/line number, collection/examination date, investigator’s initials, a brief description of the photo, and numbering that allows future reviewers to determine if any pages or photos are missing. (An example of an adequately identified photographic notation: 123-456789-1/11/1; 8/10/20; RS, information panel, right side, 1 of 4).

Photographs may be uploaded directly from a government-issued mobile device or computer file to an entry/line via FDA Import Systems. The system records the date, time, and investigator’s initials at the time of upload. The required information described above must be included within the file name and/or using the Document Remarks section specific to each photograph during the document upload process. However, there is no need to include the entry/line number when uploading from a mobile device or computer file as the photograph(s) will be directly associated to the entry/line. As such and using the example given above, the file name or Document Remarks section would be fulfilled by simply including the remarks: “information panel/right side, 1 of 4.”

Photographs may also be downloaded and combined into a single document (Word or PDF) for each entry/line, with the required information included within the document.

If photographic evidence is printed, it should be documented in your regulatory notes and the required information must be permanently affixed to the printed photos so that there is never any loss of association between the photographic evidence and the associated entry/line. This information must be recorded immediately above or below the photograph(s) (not directly on the photos) so that the integrity of the evidence is not compromised.

Note: If additional enforcement or legal actions, including, but not limited to, seizure, injunction, debarment, or prosecution are contemplated with respect to an import case, the procedures for preparing and maintaining digital photographs and video as evidence, as described in IOM 5.6.7 and IOM 5.7.4, must be followed.

6.2 – Entry Review

6.2.1 – General

Entry review (ER) consists of the review of any electronic data and/or hard-copy entry documentation received by the FDA for an FDA-regulated entry line, to determine if entry admissibility criteria for the commodity are met, and if additional actions--such as examination, sampling, or detention request--are applicable and/or necessary.

As an investigator, you may be assigned the role of an import entry reviewer. Entry reviewers use sound judgment based on their experience and training when performing entry review. All import entry reviewers receive both formal training and on-the-job training to ensure that they are familiar with admissibility requirements and can effectively use FDA databases. A combination of national import course participation and on-the-job training should result in the ability to conduct entry review independently with minimal supervision.

An entry reviewer is expected to possess the knowledge needed to perform the following tasks:

- Utilize the FDA Import Systems.
- Access and reference appropriate FDA databases.
- Reference initial admissibility job aids and other FDA work instructions to ensure accurate and consistent entry processing.
- Use the internet to access and review regulatory requirements not included in an FDA database (for example, to access the Interstate Certified Shellfish Shippers List).
- Make the appropriate initial admissibility entry decision (for instance, “May Proceed”, request field work, recommend detention) and provide remarks/justification as appropriate.
- Understand ORA Field Work Plan and Sample Collection Operation Planning Effort (SCOPE) obligations to assure that center-prioritized work is completed.
- Refer entries to OCI and PGAs when warranted.
- Refer entries to a supervisor and/or Compliance Branch (CB) when information is uncovered during ER that may require a national screening criteria recommendation by CB.

The entry reviewer takes one of three final entry review actions:

1. “May Proceed”
2. Detention Request (DER/DTR), or
3. Request Field Examination (FEX), Label Examination (LEX), and/or Sample Collection (SAM).

Entry review actions can be supported by:

1. Electronic and/or hard-copy entry documentation, including declarations of intended use.
2. Electronic systems screening of entry information.
3. Affirmations of Compliance (A of C), such as Registration and Listing.
4. Database Query.
5. Import Alerts (IA)/Import Bulletins (IB).
6. Past compliance history.
7. Compliance Program Guidance Manuals (CPGM).
8. Import Assignments, DIO Field Advisories and Notices, and SCOPE.
9. Intelligence from PGAs and OGAs.
10. Management directives.

NOTE:

ACE requires filers to submit certain data elements for FDA-regulated products. For specific ACE requirements, refer to the most current FDA Supplemental Guide. If inaccuracies are found with the transmitted manufacturer,

shipper, product code, or country data elements that could affect entry screening, you should correct the information, assign fault, save, and rescreen the entry/line.

- If information exists to support the appearance of a violation, or if compliance with the regulations cannot be confirmed (e.g., missing registration or listing approval), forward a Detention Request to the Compliance Branch.
- The reviewer may, at any time, assign or set up a work request for examination or sample collection (e.g., LEX, FEX, or SAM).

See Regulatory Procedure Manual (RPM) Chapter 9 and Initial Admissibility Job Aids on the Imports Program Commodity Specific Resources page on SharePoint for additional information concerning the review/processing of entries of specific types of commodities, including products subject to detention without physical examination.

Note, too, that entry review activities are reported as Import Investigation Time in FDA Import Systems.

6.2.2 – Initial Entry Review

Lines submitted electronically to the FDA are received with the initial work types of Quantity and Value (QAV) or No Quantity and Value (NQV). The quantity and value for each line are typically provided electronically for FDA review to aid in the admissibility process. Both are required to set up a work request. For non-ABI (paper) entries, follow the same decision-making criteria as electronic entry filing.

NOTE: If setting up work on a non-ABI entry, refer to the Job Aid for the Entry Review Application for specific instructions on creating a manual entry in ER.

Use the actual arrival date/time (for truck ports of entry) and submission date/time (for air, rail, and seaports of entry) when prioritizing entry review lines. In general:

- Lines with a QAV work type take priority over lines with an NQV work type.
- Lines with documents sent via Import Trade Auxiliary Communications System (ITACS) take priority over lines with documents sent via alternative means of transmission.

6.2.2.1 –Emergency and Perishable Shipments

Emergency or perishable shipments take priority over non-perishable shipments. An emergency shipment consists of one or more lines that require immediate review based on a demonstrated and urgent need or situation. Emergency entries are to be handled per import division discretion to control and prevent abuse by regulated industry and individuals.

Perishable products are articles not otherwise preserved in a manner to prevent the quality, safety and/or effectiveness of the article from being adversely affected if held for an extended period under normal shipping and storage conditions. Perishable products are raw and fresh products stored in ambient or refrigerated conditions. These products typically consist of raw/fresh seafood, raw/fresh produce (fruits and vegetables), and temperature and/or time-sensitive drugs, vaccinations, lab reagents, or biologics.

Device shipments may be released if the entry documents include documentation verifying approval by the Center for Devices and Radiological Health (CDRH). If you are unable to verify the authenticity of the approved document, please contact the center at cdrhimport@fda.hhs.gov.

6.2.2.2 – Reviewing Entry Data and Information

Electronically submitted entry lines that are not issued a “May Proceed” by the system are manually reviewed by entry reviewers.

Review of entry lines submitted electronically is conducted using the FDA Import Systems. It incorporates PREDICT, a screening tool that uses automated data mining, pattern discovery, and automated queries of FDA databases to

determine the potential risk of a shipment. It takes into consideration the inherent risk of certain commodities and information about the previous history of importers, manufacturers, and shippers. Those lines with the highest risk are flagged for additional review. FDA Import System recommendations should be reviewed and considered before taking any action. (For specific instructions on navigating through and using FDA Import Systems, refer to the Job Aid for the Entry Review Application.) .

When an entry reviewer issues a "May Proceed" for a line flagged for an IA that is indicated as Priority Review, they should record a remark in the Priority Review "Remarks" field that provides a clear justification as to why the line is not subject to detention without physical examination (DWPE). NOTE: The firm's intention to take a corrective action is not a sufficient reason to issue a "May Proceed" for the line. If the firm has taken corrective action, they should request to be removed from the IA; their request will need to be review by the appropriate FDA center and DIO.

The following, on the other hand, are some examples of acceptable remarks:

- "The product brand submitted for entry is not a brand name subject to DWPE."
- "Product is in powdered rather than liquid form."
- "Specific manufacturer and/or product is exempt from IA XX-XX."
- "Documentation shows imported item does not contain heparin."

The admissibility requirements that need to be verified when performing entry review for electronic and non-ABI (paper) entries are dependent upon the commodity being offered for import (in other words, whether they are foods, medical devices, drugs, radiological health products, cosmetics, biologics, and/or tobacco products). These commodity-specific requirements are outlined in the Initial Admissibility Job Aids, which are found on the Import Program Commodity-Specific Resources page and listed by center.

The following activities are performed by entry reviewers prior to making an initial entry admissibility decision:

- Reviewing the commodity-based PREDICT cumulative percentile rank and mashup in FDA Import Systems, which reveals the risk score. Request the most recent copy of the PREDICT Guide for Rules and Scoring.
- Reviewing all entry line flags in FDA Import Systems, including adhering to this further guidance:
  - If you observe an IA flag, determine if the firm and/or product combination is subject to DWPE.
  - If you suspect that the firm/product should have an IA flag, but it is not flagged, conduct follow-up investigative work to determine if the firm and/or product combination is subject to DWPE.
  - When a PREDICT rule does not fire or fires in error, report problems and provide feedback using the FDA Import Systems feedback functionality. For additional instructions on this functionality, refer to the Job Aid for the Entry Review Application.
- Performing firm/product searches on applicable center databases and reviewing entry documents when necessary.
- Requesting field work that aligns with the ORA Field Work Plan, SCOPE, obligations, and center assignments.
- Using applicable guidance and instructional documents to determine compliance with regulatory requirements.

Additionally, you should be familiar with the following resources when performing as an entry reviewer:

- Commodity-Specific Resources, which provide center-specific import information and include links to additional guidance documents and resources (for example, center contact information and case routing, initial admissibility resources, field and label examination work instructions and additional resources).
- FDA Affirmations of Compliance (A of C) for the Automated Commercial Environment, which provides definitions of required A of Cs for articles offered for entry.
- Compliance Program Guidance Manuals, which provide instructions to assist FDA personnel in evaluating compliance with the FD&C Act and other laws administered by the FDA.

- Internal documents, such as the ORA Field Work Plan, SCOPE, active import assignments, internal notices, advisories, bulletins, and Standard Operating Procedures (SOPs).
- RPM Chapter 9 "Import Operations and Actions."
- PREDICT Guide for Rules and Scoring.

6.2.2.2.1 – Manual "May Proceed"

If compliance with regulatory requirements can be confirmed using information transmitted electronically and/or information provided in entry documents, and there is no indication that a detention recommendation or request for field work is appropriate, the entry reviewer should issue a "May Proceed" for the entry line.

NOTE: No further manual verification of A of C data is needed if the line passes the automated database look-up.

The FDA will notify CBP and the filer (who is responsible for notifying the importer, or other designated parties). This automatic electronic notification is called a "May Proceed Notice." It indicates that the shipment may proceed without further FDA examination. The May Proceed action and subsequent electronic notification, may occur as a result of the initial FDA import systems screening, or after the division performs an "On-Screen-Review."

Note: An article allowed entry without FDA examination that is later found to be in violation of the law is still subject to FDA legal action. This is because the article was allowed admission by the agency without examination at the time of importation. (See section 304(d) of the FD&C Act [21 USC 334(d)])

6.2.2.2.2 – Rescinding a "May Proceed"

Rescinding a "May Proceed" should only occur for articles that are subject to a compliance action, or in other exceptional cases, and must be accomplished immediately. The action should not be used for routine or work plan examination or sampling purposes (See Section 6.3.11 for Rescinding an IB Release).

When an entry receives a "May Proceed", the conditional release period of the entry ends (Section 6.2.4) and does not re-open when the "May Proceed" is rescinded.

If you believe an entry line has inadvertently received a "May Proceed," or if additional information is received that warrants the line's further review for admissibility, you should take the following steps:

1. Obtain supervisory approval prior to rescinding the "May Proceed."
2. Notify the import filer immediately that the FDA "May Proceed" has been rescinded and that the line is pending an FDA Admissibility decision.
3. Generate an updated "Notice of FDA Action" and forward it to the filer, importer of record, and consignee within 24 hours of rescinding the "May Proceed."
4. Send a request to CBP, within 24 hours of rescinding the "May Proceed," to "Unset/Hold" the CBP Bond from liquidating in case the Compliance Branch needs to pursue a liquidated damages case against the bond for cargo that FDA has refused and which has not been redelivered for export or destruction.
5. ABI codes to indicate "PGA Decision Rescinded-Do Not Distribute Product" and "May Proceed Rescinded-Hold for Further Information From PGA" are sent to the filer.
6. If the shipment has been distributed, notify CBP and request that they issue a demand for redelivery. (See IOM 6.1.4.2 for information regarding informal entries.) CBP has 30 days to demand redelivery from the date the conditional release period ended (i.e., the "May Proceed" was issued.) Any delays compromise FDA's ability to request that CBP issue a Notice to Redeliver.
7. Record your process and communications with CBP in the Entry Remarks and/or Miscellaneous Info Received field in FDA systems to document follow-up when FDA issues a May Proceed inadvertently.

6.2.2.2.3 – Recommend Detention (DER/DTR)

The detention recommendation process is described in IOM section 6.2.5 – Detention Recommendations by Entry Reviewers.

6.2.2.2.4 – Request Examination and/or Sampling (LEX/FEX/SAM)

If you need to request field work as an entry reviewer, you should:

- Update transmitted data in line details if inaccuracies are found that would affect an admissibility decision or would result in inaccurate information being populated on a "Notice of FDA Action. Record reason for the update, save, and rescreen the data.
- Set the entry up for examination and/or sample collection by choosing the correct work type/Problem Area Flag (PAF) combination. Work should be set up in accordance with agency priorities, work plans, SCOPE, and assignments.
- Enter instructions in the "Instruction Text" field for the investigator to reference when work is set up for any reason other than routine surveillance. Instructions might be necessary and helpful, for example, when:
  - ORA assignments require specific remarks.
  - Specific exam instructions need to be followed during the examination (for instance, "further instructions, follow DOPG-Device-05 for Glucose Meters and Glucose Strips, Field Examinations.").
  - A specific discrepancy is found during the entry review process that needs to be evaluated during the examination and/or sampling.
  - There's a need to reference the results of previous violative examinations/samples (in these instances, include the previous entry/sample numbers for reference).
  - An Import Bulletin indicates it.
  - Special notes are applicable (for instance, in the event of any known safety precautions, or specifics about the product itself, etc.).

NOTES:

- Do not set up work routinely on a line that is confirmed to be subject to an Import Alert (IA). However, there may be special situations when a line subject to IA needs to be examined for a reason unrelated to the IA. In these situations, work may be set up under a PAF that is not related to the IA.
- The Job Aid for the Entry Review Application includes specific instructions on updating and re-screening electronic data, setting up work, and entering work instructions in the "Instruction Text" field.

6.2.2.2.5 – Notices

When the entry reviewer recommends detention or requests field work, the filer is notified through ABI (Automated Broker Interface) and the Notice of FDA Action generated by FDA Import systems. Notices of FDA Action are to be distributed as described in IOM 6.1.6.2. Additional information regarding issuance of notices can also be found in RPM Section 9-4-3

6.2.2.2.6 – Cancelled Entries

Entry reviewers should be able to identify CBP cancelled entries in FDA Import Systems. Entries that have been cancelled by CBP will display static text at the top of multiple screens that reads, "This Entry is Cancelled." The Entry Review Grab Bag (ERGB) will display a "Y" in the "Cncld" column, and the Current Entry Status field will display "ACS/ACE Entry Cancelled".

6.2.2.2.7 – Partner/Other Government Agency (OGA) Referral

The purpose of OGI (Other Government Agency – Investigations Branch) and OGC (Other Government Agency – Compliance Branch) work types is the ability to close a line without an admissibility decision being recorded by FDA. Selecting OGI/OGA from "Possible Actions" in FDA Import Systems allows Investigations Branch (IB) to close a line, with no further action after OGA referral from the OGA ERGB. Selecting OGC/OGA from "Possible

Actions" will route the line to Compliance Branch (CB) and allow CB to close the line, with no further action after OGA referral from the OGA Compliance Grab Bag.

Note: OGAs might be also referred to as PGAs (Partnering Government Agencies).

A situation in which IB may opt to use OGA referral to close a line, without an FDA admissibility decision, is when an entry has been refused, or seized, by another government agency (for instance, APHIS or CBP), precluding the FDA the opportunity to examine the entry and gain the adequate information needed to make an initial entry admissibility decision. In instances like these, the line(s) within the entry may be closed with no further FDA action, after the referral to an OGA has been recorded. Additionally, documentation showing evidence of the final disposition of the product should be obtained and uploaded to the entry/line prior to closure with OGA referral.

An Ad-Hoc OGA referral, found under the Action menu, allows field staff to record an OGA referral, but does *not* allow closure of the line with no further action after OGA referral. Ad-Hoc OGA Referrals differ from the use of OGI/OGC work types in that they are used strictly to provide information to the OGA without deferring FDA's responsibility to make an admissibility decision. If an Ad-Hoc OGA referral is recorded, the line will still need to be processed with an entry admissibility decision.

Regardless of whether or not the FDA had the opportunity to examine the goods, if the agency has adequate information to make an initial entry admissibility decision, the entry should still be processed according to established procedure. This includes "May Proceed" or a detention recommendation (DTR or DER). The OGA referral can still be recorded using an Ad-Hoc OGA Referral if needed.

If an entry has been acted on by an OGA and the entry has been cancelled by CBP, the entry will be automatically closed by the system if no work has been assigned. If work has been assigned, the field can send a request to close the cancelled entry to the ORA OISM DSS ISB Import Systems Problem Reports group.

If there is a need to refer a line to an OGA that is not found in the system, please contact the Division DIALs who will then work with DSS to have the OGA added.

6.2.3 – Entry Documentation

The admissibility of an article may depend on the submission of entry documentation. These may include: a Bill of Lading (BOL) or Airway Bill (AWB), invoices, purchase orders, certificates of analysis, copies of labeling, intended use statements, and/or other related documentation.

Note that CBP Forms 3461 and 7501 have been eliminated for electronic transmission of entries in ACE, so reviewers should not be holding up admissibility of lines to review these documents. However, they are still used for Non-ABI or paper entries.

6.2.3.1 – Request of Entry Documents (DRQ)

If during your initial review of an entry, you determine that additional information is necessary to make an admissibility decision, you should request documents via the "Documents Required" Entry Option (DRQ). You can do this, in the "Remarks" field of the "Issue Entry Option" page, by entering:

- The reason the documents were requested to assist in the future review of the entry or line.
  - **NOTE:** Do not, however, routinely request documents solely for the purpose of verifying the accuracy of submitted data.
- A summary of the data elements reviewed, and admissibility requirements needed for review.

This information will expedite review of the documents once they are received and will avoid a duplication of efforts. For example, the reviewer may also add information in the remarks field, such as:

"All affirmations of compliance reviewed (NDA, NDC or DLS) appear to be valid; requesting documents as per Assignment 123 to confirm product is an API. Set up work as indicated in the assignment."

Note, too, that the DRQ entry option sends an electronic message to the filer via the FDA-CBP Interface but does NOT generate a Notice of FDA Action.

6.2.3.2 – Receipt of Entry Documents

Entry documents may be submitted to the FDA in several ways, with differing levels of priority. Documents received via ITACS are given priority over documents received via other means. Documents can be submitted prior to or at the time of a DRQ.

If documents are not received, refer to Section 6.2.3.4, Failure to Submit Entry Documents and Follow-up Requests.

6.2.3.2.1 – Uploading documents received outside of ITACS

When work has been set up on an entry and documents have subsequently been received from the filer or importer outside of ITACS for instance, via email, mail, fax), upload the documents using FDA Import Systems. Instructions for uploading documents can be found in the Job Aid for the Entry Review Application. Examples of documents that should be uploaded by the entry reviewer include:

- Product labeling.
- Email correspondence that contains information that might affect admissibility.
- Entry documentation, such as invoices, packing slips, FDA forms, or CBP forms.

NOTE: Electronically viewed material, such as web pages, can also be uploaded via FDA Import Systems. Please ensure that for all records, the record retention policy is adhered to.

6.2.3.3 – Review of Entry Documents

When documents are received, you should review entries in chronological order (that is, by earliest submission date in FDA Import Systems and by email receipt date). Documents received via ITACS are given priority over documents received via other means.

If, after review of the entry documents, sufficient information exists to support the appearance of a violation, or if compliance with the regulations cannot be confirmed (e.g., missing Registration, Listing, Approval), forward a Detention Request to the Compliance Branch (See IOM 6.2.5).

If examination or sample collection is indicated, set up a work request (e.g., LEX, FEX, or SAM).
If the documents submitted do not provide sufficient information to make an entry admissibility decision, the reviewer may follow up by one of the following means:

- Direct communication (an email and/or phone call) with the filer or importer
- Entry Incomplete – Return, Deficient Entry (DEF) Entry Option
- Request Information (INF) Activity

In the follow-up communication, inform the importer/filer of the specific additional information needed, and that if such information is not provided, the FDA may take other action to continue the admissibility review.

Record direct communications with the filer or importer in the "Remarks" field of the Entry Details page, or via the "Log Miscellaneous information received" (MIB) function. Include the date, method of communication (email or phone), content or information requested, point of contact, and your name or initials, as the reviewer, in the remarks.

Please note that neither the DEF Entry Option nor the INF Activity sends an electronic message to the filer via the FDA-CBP interface; however, they do generate a Notice of FDA Action. For this reason, you should specify the

information you are requesting in the "Narrative" field of the DEF Entry Option and the "Information Requested" field of the INF Activity. In addition, if the INF Activity is used, it will display as a status in ITACS, advising the user to view the narrative for details via the Notice of FDA Action.

NOTE: Information entered in the "Remarks" field is for internal use only. Information entered in the "Narrative" field appears in the Notice of FDA action.

6.2.3.4 – Failure to Submit Entry Documents and Follow-up Requests

If entry documents are not received within three business days after requesting documents via the DRQ entry option (under 6.2.3.1), the system will automatically send an electronic message to the filer stating, 'Second and Final Request for Information' (DR2). This automated message does not generate a Notice of FDA Action. Documents received outside of ITACS must be uploaded into FDA Import Systems to prevent the DR2 message. In addition, as the reviewer, you can also send a follow-up request to the filer. You can do so by using any of the following options available:

- Direct communication (email or phone call) with the filer or importer
- Deficient Entry (DEF) Option
- Request Information (INF) Activity

In your follow-up request to the filer/importer, you should again indicate the specific additional information needed, and that if additional information is not received, the FDA will continue its admissibility review without the benefit of the additional information.

Record direct communications with the filer or importer in the "Remarks" field of the Entry Details page, or via the "MIB function." Include the date, method of communication (email or phone), content requested, and your name or initials as the reviewer.

If additional information is received after follow-up communication, proceed to making an entry decision unless additional follow-up is warranted.

If the requested information is not received, take appropriate action (for instance, set up field work or request detention). If detention is requested, refer to IOM 6.2.5.

6.2.4 – Entry Decision

Under the conditions of the entry bond, articles may receive a conditional release by CBP, pending a final admissibility decision by the FDA. This FDA entry decision must be made prior to the end of the conditional release period (within 30 calendar days after CBP has conditionally released the product), unless otherwise extended. If the agency does not take an action to extend the conditional release period, it will terminate upon the earliest occurrence of the following events:

- The date that the FDA issues a notice of refusal of admission.
- The date that the FDA issues a notice that the merchandise may proceed.
- At the end of the 30-day period following the date of release.

As indicated in 19 CFR 141.113, to extend the conditional release period, the FDA must issue a written or electronic notice (within 30 days of the conditional release of the merchandise), informing the bond principal (the importer of record) that the product will be examined, sampled, or has been detained. The DRQ, DTR, DER, DEF and INF functions do not extend the conditional release period.

6.2.5 - Detention Recommendations by Entry Reviewers

Importers introduce goods through multiple ports of entry and work with multiple import divisions. FDA personnel review these import entries utilizing data submitted by filers/brokers to make an initial admissibility decision. FDA-regulated products, which appear to be non-compliant and/or subject to detention without physical examination

based on an Import Alert or Import Bulletin, should be considered for field work or submission to the Compliance Branch (CB) with a detention recommendation. Since filers have interactions with multiple FDA import divisions, it is vital that entries be handled by a uniform procedure, regardless of the port of entry.

6.2.5.1 - Submission of Detention Recommendations to the Compliance Branch at the Entry Review Step

As an entry reviewer, you can recommend detention using one of two work types: DER or DTR.

- DER refers to a detention recommendation based on Detention without Physical Examination (DWPE) and is utilized when a product is subject to DWPE and is either listed on an Import Alert (IA), or meets the criteria found in Direct Reference Authority for DWPE (6.2.5.4.2.1, below).
- DTR refers to all other detention recommendations for products with the appearance of a violation, either because administrative requirements cannot be verified, or other evidence supports the appearance of a violation.

NOTE: If additional entry documentation is needed to support the detention recommendation, collect such documentation prior to submitting it. Include comments for all detention recommendations, articulating the reason why each line is being sent to the CB for review. Include photographs when warranted (See 6.1.8 PHOTOGRAPHS: IDENTIFCATION AND STORAGE for more details and instructions).

6.2.5.2 - General Procedures Pertaining to all Detention Recommendations (DER and DTR)

Entry reviewers should ensure detention recommendations are aligned with Center-specific requirements. To promote consistency across divisions, refer to the Center Specific Initial Admissibility Job Aids for instructions on commodity-specific requirements and center database use. Entry reviewers are also responsible for searching all applicable center databases prior to making a detention recommendation. Ensure that any research you conduct in the FDA database systems is documented in the remarks section of the detention recommendation.

Prior to submitting a detention recommendation, you should verify accuracy for all Line Details in the entry. If, at any time, data is found to be incorrect:

1. Correct the inaccuracies.
   NOTE: Quantity and Value are required to take a "Next Step" and for CB to take action.
2. Rescreen updated lines.
3. If data has been changed, click on "Save", then enter a brief description in the pop-up box, and assign fault to any errors as appropriate.

NOTE: Some firms or products may be subject to multiple import alerts, or compliance with multiple regulations may not be verifiable at the time of entry. In these situations, the entry reviewer should recommend detention for all applicable import alerts and/or problem area flags (PAFs).

6.2.5.2.1 - Entry Documents

Entry documents are not required for all detention recommendations made by an entry reviewer, as indicated below in sections6.2.5.3, 6.2.5.4, and 6.2.5.5. However, the CO does require entry documents for case review. If you need to make a detention recommendation, but do not have the entry documents, you can request them for CO use per these instructions:

1. If entry documents were not obtained prior to making the detention recommendation (DER or DTR), ensure that the "Entry Option" selected in the drop-down menu includes a document request, for instance, "Hold Designated, Others Go, Docs Required." This designation alerts the filer to submit needed entry documents to the FDA.
2. Entry documents received by IB outside of ITACS are to be uploaded via FDA Import Systems.
   a. Job Aid for the Entry Review Application JA-000038 contains instructions for uploading entry documents via FDA Import Systems.

b. OASIS Mail/Baggage Procedures contains instructions for attaching entry documents via OASIS.
c. System for Entry Review and Import Operations (SERIO) User Manual MAN-000091 contains instructions for uploading documents via SERIO.

6.2.5.3 - DER - Import Alert (IA)

A Detention without Exam Recommendation, or DER, is utilized in Entry Review for entries/lines that are subject to an Import Alert (IA).

Entry documents and additional evidence are not required prior to submission to the CB, if *all* of the following requirements are met:

- The elements in the electronic submission match the criteria found in the IA (for instance, Country of Origin ("C of O"), declared manufacturer, product description, etc.).
- The IA does not specify that entry documents must be submitted.
- No additional information is necessary to make an initial admissibility decision.
- No additional line information is required.

NOTE: You should request entry documents, and/or additional evidence, prior to a DER submission when the IA specifies that the shipment may be detained if it is not accompanied by certain additional entry documents and/or evidence. (Example: IA 28-02 for Indian Black Pepper states that Divisions may detain all shipments of black pepper from India not accompanied by a certificate, containing certain information, from the Indian EIC.)

When submitting a DER, please adhere to the following guidance:

1. Ensure that you follow the instructions for each applicable IA (more than one IA may apply to a line). Verify that electronic entry information matches the IA prior to submitting the DER to CB. This includes verifying the:
   a. C of O
   b. Firm Name and Address (for the manufacturer, shipper, consignee, or importer, as applicable to the import alert)
   c. Importer Description/Product Description (Some IAs are very general- ensure the specific product is subject to the IA)
2. Update and rescreen as appropriate.
3. Enter the following comments in the "Instruction Text" field located in the "Work Details" section of the "Work Request and Work Request Details" screen:
   a. Example: "Manufacturer/Product is subject to IA XX-XX" or "C of O/Product combination is subject to IA XX-XX"
   b. Also, if required by the IA, ensure that any research you've conducted in the FDA database systems is documented in the remarks section. Example: "Per IA XX-XX (Database Name) was reviewed and (Manuf/Supplier) was issued a W/L".
4. If it is suspected that an entry/line may be subject to an IA but cannot be confirmed from the electronic entry data, you should request and/or review entry documents. This may occur when a manufacturer name is listed on an IA, but the address differs from what was electronically transmitted.
   a. If the entry documents show that the electronic information submitted was incorrect, update and rescreen the entry/line. If the updated entry/line is subject to an IA, follow the DER procedures above.
   b. If review of the entry documents show that the entry/lines are not subject to the IA, as the reviewer, you can determine the appropriate next step (MPro, FEX/LEX, SAM, DTR).

6.2.5.4 - DTR

A Detention Recommendation (DTR) is used at the entry review step when, you, the reviewer cannot confirm that products being offered for import meet the FDA's admissibility criteria. Prior to recommending a DTR, you should plan to use the electronic submission, internal FDA databases, and any entry documentation submitted by the filer

to help make a determination. You may also assign a field/label exam or sample collection to aid your determination of admissibility.

6.2.5.4.1 - Similar to Import Alert

If the product appears to be similar to a product/manufacturer/C of O combination on IA, and additional information is needed to determine if the product is subject to IA, you should:

1. Request and review the entry documents.
2. Update and rescreen inaccurate data.
3. If the entry is indeed subject to IA, follow procedures for DER (See IOM Section 6.2.5.3).
4. If the product does not match the IA, determine the next step. This may include any of the following actions:
   a. "May Proceed"

      If the entry flagged for the IA, and is subsequently released:
      Provide feedback to the Import Compliance Systems Branch (ICSB) using ER if the line flagged incorrectly for an IA. (PREDICT Guide: Rules and Scoring). Include a comment as to why the product was not subject to the IA.
      For example: "Firm flagged for IA XX-XX, but product is not subject to IA (include reason why product is not subject to IA)."

   b. Request Field Work (SAM/FEX/LEX):

      Include pertinent instructions in the "Instruction Text" field located in the "Work Details" section of the "Work Request and Work Request Details" screen. Example: "Firm/product may be subject to IA XX-XX, collect pertinent evidence (labeling, photographs, entry documents, sample)".
      If a violation (different from the IA) has been determined, submit a DTR to CB. Include pertinent comments in the "Instruction Text" field located in the "Work Details" section of the "Work Request and Work Request Details" screen. Example: "No (Listing) found in (database searched) for (manuf/product)".

6.2.5.4.2 - Previous Violative Results (pending IA addition)

There are times as an entry reviewer that you may come across entries/lines that contain the same product and manufacturer as a previous entry/line that was found violative and is pending addition to Import Alert. Your next step will depend on the screening criteria, as well as whether or not ORA has direct reference authority.

NOTE: In these situations, a screening criteria may have been implemented by the CO to ensure reviewers are aware of the violative findings.

6.2.5.4.2.1 Direct Reference Authority for DWPE

When ORA has direct reference authority (DIO Advisory #1) *and* the electronic entry is an exact match to the previously found violative shipment, additional entry documents and/or evidence may not be necessary. **NOTE:** Do ensure any additional requirements included within your specific assignment are met.

When you encounter one of these shipments, and ORA has direct reference authority, you should:

1. Recommend Detention without physical examination (DER).
2. Include pertinent comments in the "Instruction Text" field located in the "Work Details" section of the "Work Request and Work Request Details" screen like previous violative findings, CMS/work activity number and/or entry number, Reference to the IA, any evidence collected. *Example: "Previous violative findings (issue found, CMS/work activity number and/or entry number) firm/product awaiting addition to IA XX-XX. Direct reference authority for (product) for addition to DWPE. No physical exam conducted."*

6.2.5.4.2.2 - No Direct Reference Authority for DWPE

When ORA does not have direct reference authority, the entry must stand on its own. There are many factors to consider in these types of situations, such as risk and pending cases. As such, discuss next steps with your supervisor and CB. Possible next steps could include the following:

- Request and/or review entry documents.
- Request Field Work (via SAM/FEX/LEX).

  Note any pertinent instructions in the "Instruction Text" field located in the "Work Details" section of the "Work Request and Work Request Details" screen. This may include previous findings, CMS/work activity number and/or entry number, instruction for field work.
  Example: "Previous violative findings (issue found and entry number) firm/product awaiting addition to IA XX-XX. Review labeling for ephedrine alkaloids."
- If a violation is determined for the current shipment, submit to CB under the applicable Problem Area Flag (PAF).

  "May Proceed" the entry if no violation is found with the current shipment.

6.2.5.5 - Registration/Listing/Approval

Some products may require registration, listing, and/or approval. The steps below describe how to recommend detention when compliance with these requirements cannot be verified.

Registration and Listing

1. When registration and/or listing is required, review the electronic submission. For those entries where compliance cannot be confirmed using the electronic data transmitted and internal FDA databases, request and review entry documentation.
2. Recommend detention (DTR) if the necessary registration or listing cannot be verified after reviewing the entry documents and the appropriate center database.
   NOTE: Failure to submit Affirmation of Compliance data or a look-up failure is not sufficient to recommend detention. Prior to recommending detention, you should make a reasonable effort to verify compliance with registration and listing requirements in the center databases using the manufacturer and product information provided.
   Include pertinent comments in the "Instruction Text" field located in the "Work Details" section of the "Work Request and Work Request Details" screen. This may include the database you reviewed, and any findings or evidence collected.
   Example: "No registration or listing found in (database) for manufacturing company (Provide specifics as to what does not match (name, street address, city))."
3. If additional information is not submitted in the electronic or paper entry and is required to make an initial admissibility decision (for instance, details regarding a drop ball test or can size), request that specific and necessary information from the filer.

Approval

1. If approval is required and it cannot be verified after reviewing the entry documents and searching the appropriate database, collecting additional product labeling is not required to recommend detention, unless specifically noted by additional guidance. If the entry reviewer is unable to determine if the product requires approval, collect the product labeling. Legible copies or photos of the labeling from the current shipment should accompany the detention recommendation.
   a. Reference the pertinent Initial Admissibility Job Aids for center requirements, for instance, intended use, end use, and annual reports (IOM Section 6.2.5.2).
   b. Include pertinent comments in the "Instruction Text" field located in the "Work Details" section of the "Work Request and Work Request Details" screen. Note such details as the database reviewed, findings, and any evidence collected.

Example: "No (approval e.g., NDA, ANDA, 510(k), PMA, etc.) found in (database) for manufacturing/product combination. Labeling, end use letter, and intended use included in submission."

6.3 - Field Examination

6.3.1 – General

A field examination is a physical inspection of products subject to FDA jurisdiction. Examinations may take place at the port of entry, warehouse, cold storage facility, or other designated examination site. Additional information about performing field examinations, specific to product and program area, may be addressed in the Compliance Program Guidance Manuals (CPGMs) and the Compliance Policy Guides (CPGs)

A field examination involves actual physical examination of the product to determine, for instance:

1. If the product and quantity present correspond to the product and quantity declared on shipping documents.
2. If there is any transit or storage damage.
3. If the product has been subjected to inadequate storage temperature conditions.
4. If there is any evident rodent, bird, or insect activity.
5. If there is lead present in any ceramic ware (via a Quick Color Test or QCT and/or Rapid Abrasion Test or RAT).
6. If any odors, uncharacteristic for the product or of spoilage, exist.
7. If any non-permitted food ingredients and/or color additives, are present in the product.
8. If there is general label compliance (via label examinations).

A label examination (LEX) is used when the investigations branch conducts a label review (LBL) of the physical product in the field to determine labeling compliance. This is significant as the remarks you enter and exam class you select may be used by compliance to make an admissibility decision for the product. A label exam should be consistently recorded as LEX. All other field examinations should be recorded as a FEX, along with the appropriate problem area flag (PAF)

When conducting a field examination, you should compare the documents provided by the filer/importer to those physically available during your inspection as well as to those electronically submitted. Record your observations in your regulatory notebook at the time of the field exam, including such information as:

- Date
- Entry number
- Name and address of the location where the exam is taking place
- Name and title of the persons providing information about the entry/lot being examined
- Information from the product labeling including the name of the product and any lot numbers or codes identified
- Number of units examined
- Documentation of any photos or labels collected
- Any abnormalities or discrepancies observed
- A record of the quantity of any product that was destroyed in the field as part of the field examination process, if any

Note: Additional instructions on taking regulatory notes can be found in IOM Subchapter 1A.1 REGULATORY NOTES.

A field examination, of course, does not have the same level of confidence as a laboratory sample analysis. Consequently, you should be prepared to apply more rigorous standards of acceptance in the field than those used for formal regulatory levels. For example, if the formal action guideline for whole insects is 10 per 100 gm in product X, you may sample product X when your field examination shows only one or two insects per 100 gm. A

decision to collect samples should be made in accordance with relevant CPs and any applicable assignments but is ultimately your discretion; sample collection based on field exam results should be based on findings significantly lower than specified by the formal guideline.

When the examination is classified as Class 2 or Class 3, you should take clear photographs of all products examined. (See 6.1.8 PHOTOGRAPHS: IDENTIFICATION AND STORAGE for more details and instructions.)

Additionally, see IOM 5.5.9.3 for suggestions on what to do if you're conducting a field examination and the firm responsible for the products invites individuals who are not directly employed by the firm to observe the examination. IOM 6.3.10 provides instructions on recording field/label examination results in FDA Import Systems.

6.3.2 - Field Examination Schedule

A field examination should include a physical examination of a minimum of five containers (cases, cans, bags, etc.) of a product--or as directed by Compliance Programs, specific product examination schedules (for example, LACF), or other guidance. All containers opened for exam should be identified with FDA, division abbreviation, the date of the examination, and the lead investigator's initials.

When you conduct any field examination, in addition to specific items discussed in the following sections, be alert to these possible discrepancies and situations too: "over-labeling," where a product name or identity may have been changed; a different manufacturer than the one transmitted or provided in the entry documents; a product without mandatory English labeling; changes in the expiration date or lot numbers; product quantity differences; product integrity issues; country of origin marking (under CBP authority 19 CFR 134), or similar questionable practices. If you encounter any of these situations, document your findings and discuss the appropriate action with your supervisor if needed.

6.3.3 - Field and Label Examinations – Foods and Cosmetics

6.3.3.1 - Food Safety

Microbiological - field examinations cannot be used for suspected microbiological contamination.
Filth and Foreign Objects - field examine only those product/container combinations in which you can physically view and examine the product, for instance, products which can be probed, products in see-through containers, etc.

Canned and Acidified Foods – See IOM Chapter 4 SAMPLE SCHEDULE CHART 1 ITEM 2.

Decomposition in Non-sealed Foods - This can include organoleptic examination for fish, seafood, frozen eggs, etc.

6.3.3.2 - Pesticides, Industrial Chemicals, Aflatoxins, & Toxic Elements

Field examinations cannot be performed for most pesticides, chemical contaminants, natural toxins, and metals, except for metals in dinnerware and the side-seam solders of cans.

NOTE: Divisions should use commercial versions of the Quick Color Test (QCT) and the Rapid Abrasion Test for lead, for instance, Lead Check Swabs, while conducting field examination of dinnerware and food cans to determine if follow-up sampling is required. The testing scheme for dinnerware can be found in CP 7304.019. Specific information regarding the techniques of testing dinnerware can be found in Lab Information Bulletin (LIB) 4127 on the Office of Regulatory Science (ORS) intranet site.

6.3.3.3 - Food and Color Additives

With regards to food and color additives, you should perform a visual examination of the container and a label review for the mandatory labeling requirements. Determine if a color additive is declared for a product to which coloring appears to have been added. Determine if a declared color additive is acceptable for use in the product.

The use of a color additive must conform with the requirements stated in the color additive's listing regulation. These requirements are outlined in the "Color Additive Status List" and the "Summary of Color Additives Listed for Use in the United States in Food, Drugs, Cosmetics, and Medical Devices." These lists provide the current status and use limitations of color additives permitted in food, drug, cosmetic, and medical device products.

Requirements for declaring color additives on food labels are provided in 21 CFR 101.22 (k). Color additives subject to certification may be declared by the names listed in 21 CFR parts 74 and 82 or by abbreviated names that omit "FD&C" and "No." The term "Lake" must be included in the names of color additive lakes. FD&C Yellow No. 5 is specifically required to be declared on food labels under 21 CFR 101.22 (k) and 21 CFR 74.705. Cochineal extract and carmine are specifically required to be declared on food labels under 21 CFR 101.22(k) and 21 CFR 73.100. Other color additives not subject to certification may be declared by the names listed in 21 CFR part 73 or in general terms such as "Artificial Color," "Artificial Color Added," or "Color Added."

Determine if a preservative declaration includes its purpose; for example, "Sodium Benzoate as a preservative."

6.3.3.4 – Nutrition Labeling and Food Allergen Labeling

The only valid field examination which can be performed for a nutritional or food allergen labeling related issues is a label examination for the mandatory labeling requirements. Refer to the "Industry Resources on the Changes to the Nutrition Facts Label" and Food Allergen Labeling and Consumer Protection Act of 2004 (FALCPA) requirements for guidance.

Note that there are requirements for voluntary gluten-free label claims. Such claims must meet the requirements in the gluten-free labeling of foods regulation (found at 21 CFR 101.91). This is an important public health issue for persons suffering from Celiac disease. For products that bear gluten-free claims, refer to "Gluten and Food Labeling" page for guidance.

Also see the "Food Labeling & Nutrition" website for the most up-to-date information regarding claims in labeling. Also, see CP 7321.005 to determine areas of emphasis for food labeling violations.

6.3.3.5 - Food Economics (On Consumer Size Containers only)

Field exam guidance as it relates to the following aspects:

Label Examination - Review labels for all aspects of the labeling requirements.

Net weight - See IOM 4.3.7.1

Food Standards - The only valid field examination which can be performed for Food Standards is a label examination for the mandatory labeling requirements of a particular Food Standard.

6.3.3.6 – Cosmetics

Valid cosmetic field examinations include a reconciliation examination for security purposes and/or a label examination for the mandatory labeling requirements. The most important labeling considerations are:

1. Ingredient Labeling (21 CFR 701.3).
2. Prohibited ingredients (21 CFR 700.11 through 700.27 and 21 CFR 250.250).
3. Non-permitted color additives (see Color Additives Status Lists).
4. Warning Statements (21 CFR 740.11, 740.12, 740.17, and 740.19).
5. Cautionary/Other Required Statements (for example, required caution statement and directions for patch test for coal-tar hair dyes - FD&C Act sec. 601(a); required caution statement for the color additive lead acetate - 21 CFR 73.2396; required label information for the color additive bismuth citrate – 21 CFR 73.2110; and required label information for the color additive henna – 21 CFR 73.2190).
6. Tamper-Resistant Packaging Requirements (21 CFR 700.25).
7. Other Labeling Requirements (21 CFR 701.10 through 701.13).

For further cosmetic-related questions, contact the Office of Cosmetics and Colors.

6.3.4 - Field and Label Examination – Drugs

A field examination involves actual physical examination of the product (minimum of five containers, or as directed by Compliance Programs). Please verify the following:

- Confirm that the product and quantity present correspond to the product and quantity declared on shipping documents.
- Examine the security and integrity of the container, including tamper-resistant packaging requirements.
- Examine product for any in-transit or storage damage, or inadequate storage temperature conditions.
- Examine for any over-labeling, where a product name or identity may have been changed.
- Examine if the manufacturer is the same as the one transmitted or provided in the entry documents.

A label exam involves an examination of the product label and all accompanying labeling. The drug products examined must comply with the general labeling requirements found in 21. CFR 201.1 – 201.328. Product labeling should bear all required information in English. If product labeling includes a language other than English, it should contain all required information in both languages. Exception: Labels in Spanish for distribution in the Commonwealth of Puerto Rico is authorized under 201.15 (c). For bulk drugs verify that product labeling complies with the requirement(s) found in 21 CFR 201.122. (Section 201.125 does not apply to bulk drugs but only to finished dosage prescription drug products.)

6.3.4.1 – Drug Listing and Establishment Registration

Bulk drugs and finished dosage forms should be evaluated for compliance with the drug listing and drug establishment registration requirements.

6.3.4.2 – Contamination

Drugs should be examined for container integrity, for example, cracked vials, ampoules, bottles, etc.

6.3.4.3 – Samples

Samples collected from lots where the drug substance or finished product has been subjected to actual or suspected contamination should be decided on a case-by-case basis.

6.3.4.4 - Special Instructions

Field examinations may be performed on drug lots to obtain information to determine the new drug status of a given shipment. Divisions should contact the CDER Office of Compliance, Office of Drug Security, Integrity and Response, Division of Imports Exports and Recalls, Import Export Compliance Branch for guidance.

6.3.5 - Field and Label Examinations – Devices

Field and label examination instructions issued by CDRH for specific devices are located on the Import Program intranet site under commodity-specific resources.

At a minimum, the label should include the name and place of business of the manufacturer, UDI, packer or distributor, and product identity. Be aware of mis-declared devices, (for example, TENS (transcutaneous electrical nerve stimulation) devices are often declared as therapeutic massagers but, in fact, should be declared as neurological therapeutic devices.) Products declared as destined for veterinary use only must include such a statement on the packaging and product.

CAUTION: If the sealed packaging, such as an outer crate, of a medical device indicates that the manufacturer's warranty will be violated should it be opened by someone other than a factory representative, DO NOT open the packaging. Consult with your supervisor regarding any further action. For additional information please contact cdrhimport@fda.hhs.gov.

It is a common industry practice to manufacture and/or assemble, package, and fully label a device as sterile at one establishment, and then ship such device in interstate commerce to another establishment or to a contract sterilizer for sterilization. During a field exam of non-sterile devices offered for entry that are labeled as sterile, which are destined for sterilization, per 21 CFR 801.150, each pallet, carton, or other designated unit must be conspicuously marked to show its non-sterile nature when it is introduced into and moving in interstate commerce, and while it is being held prior to sterilization.

The FDA will not support import action against the device as misbranded or adulterated when the non-sterile device is labeled sterile if the lot is marked appropriately as noted previously. 21 CFR 801.150 also requires a written agreement between the foreign firm and the importer of record. Specifically, there should be a written agreement in effect which: (i) Contains the names and post office addresses of the firms involved and is signed by the person authorizing such shipment and the operator or person in charge of the establishment receiving the devices for sterilization.(ii) Provides instructions for maintaining proper records or otherwise accounting for the number of units in each shipment to insure that the number of units shipped is the same as the number received and sterilized.(iii) Acknowledges that the device is nonsterile and is being shipped for further processing, and (iv) States in detail the sterilization process, the gaseous mixture or other media, the equipment, and the testing method or quality controls to be used by the contract sterilizer to assure that the device will be brought into full compliance with the Federal Food, Drug, and Cosmetic Act. This should be verified upon import.

6.3.6 – Field and Label Examinations – Biologics

With regards to biologics, you should review any applicable import alerts prior to conducting any field examinations of biological products subject to import alert.

In general, products regulated by Center for Biologics Evaluation and Research (CBER) do not warrant a field examination, because they are licensed under Section 351 of the PHS Act. In addition, lot release procedures pursuant to 21 CFR 610.2 apply to many products, such as vaccines.

If it is determined that a field examination is warranted for licensed or unlicensed CBER-regulated products, labeling for the product and its intended use should be examined.

Any questions should be sent to CBER Import Inquiry at CBERImportInquiry@fda.hhs.gov

6.3.7 - Label Examinations - Animal Products

Contact the CVM mailbox CVMImportRequests@fda.hhs.gov with questions on the importation of animal foods, drugs, devices, and other animal products. You should also be aware of any relevant import alerts, Compliance Policy Guides, or other guidance documents as they affect individual import situations. See the Commodity Specific Resources section in the Import Program intranet site for additional information or notifications on current import situations.

6.3.7.1 – Animal Drugs

Label examinations of animal drugs are visual examinations that are sometimes needed to determine product admissibility. A label examination may be necessary if:

- the product is an unapproved new animal drug, especially one for use in food animals;
- the product is sterile;
- the manufacturer is not registered with FDA or differs from the firm in the foreign drug manufacturer registration;
- the drug is not listed with CVM; or
- discrepancies between the information on the product label and the import documentation exist.

Bulk New Animal Drug substances and Active Pharmaceutical Ingredients (APIs) may be legally imported if the firm is registered with the FDA and it is destined to the holder of an approved New Animal Drug Application (NADA), Abbreviated New Animal Drug Application (ANADA), Index Listing or a Generic Investigational New Animal Drug

Number (JINAD) or Investigational New Animal Drug Number (INAD) exemption. For bulk drugs for use in compounding for animals, confirm the registration and listing status of the firm and product, and consult with the Center for the current status of the bulk drug substance presented for import.

Type A Medicated Articles are animal drugs and must meet the appropriate drug requirements listed above.

FDA personnel may allow veterinarians and animal owners to import unapproved drugs under the Personal Importation Policy (PIP). For more information, refer to the Regulatory Procedures Manual, section 9-2 Coverage of Personal Importations.

6.3.7.2 – Animal Devices

Devices intended for animals do not require 510(k), PMA, or any premarket approval. However, they are still subject to examination for adulteration and misbranding violations. When conducting your label exam, verify that labeling is not false, or misleading, and bears adequate instruction for use in each target animal group. When conducting your label exam, you should ensure that:

- Devices for animal use are clearly marked for animal use only.
- Prescription animal medical devices are labeled in the following manner: "Caution Federal law restricts this device to sale by or on the order of a licensed veterinarian."
- Non-prescription animal medical device labeling bears adequate directions for use by the lay user.

In addition to being regulated by CVM, animal devices that are radiation-emitting products are also regulated by CDRH. Import coverage for radiation-emitting products is provided for in CPGM 7386.007 Imported Electronic Product.

Note: Animal devices that include a drug component should be referred to CVMImportRequests@fda.hhs.gov.

6.3.7.3 - Animal Food and Feeds

Animal food and food components, including pet food, should be examined for conformance with all applicable and appropriate food labeling requirements listed in 21 CFR 501; be acceptable for animal food (for instance, not contain drug claims; be an approved food additive, generally recognized as safe (GRAS) for an intended use, or otherwise found acceptable as an animal food ingredient; and not contain hazardous levels of contaminants). For example, determine if a preservative declaration includes its function, such as "Sodium Propionate (preservative)."

A list of approved food additives for use in animal food is found in 21 CFR 573 and a partial list of GRAS substances for use in animal food is found in 21 CFR 582. Substances affirmed as GRAS for use in animal foods are listed under 21 CFR 584. Irradiation is considered a food additive and approvals for the use of irradiation for animal food are found in 21 CFR 579. Additionally, animal food GRAS substances that have been notified to the FDA can be found in the Animal Food GRAS Notices Inventory.

Ensure the use of a color additive conforms with the requirements stated in the color additive's listing regulation. For further questions, contact CVMImportRequests@fda.hhs.gov.

6.3.7.4 – Animal Grooming Aids

FDA does not regulate products intended solely to cleanse or beautify animals, commonly referred to as grooming aids. Cosmetic regulations outlined in the FD&C Act do not apply to products intended for animal use. Note, however, that products purporting to be animal grooming aids that are labeled as or otherwise intended for therapeutic purposes, may be considered animal drugs. This may occur when a grooming aid is labeled to contain an active drug ingredient, or to suggest or imply a therapeutic benefit. Refer to CPG Sec. 653.100 Animal Grooming Aids.

NOTE: Medicated shampoos are not animal grooming aids and are regulated by the FDA as animal drugs. Consult CVM before detaining these products.

6.3.7.5 – Animal Biological Products

Although animal biological products are "drugs" within the meaning of the FD&C Act, animal drugs produced and distributed in full conformance with the Virus, Serum, Toxin Act (VSTA) and its implementing regulations administered by the United States Department of Agriculture Animal Health Inspection Service (USDA-APHIS) are not subject to the animal drug approval requirements in section 512 of the FD&C Act. Under the regulations implementing the VSTA, 9 CFR part 101, animal biological products are defined, in part, as "all viruses, serums, toxins (excluding substances that are selectively toxic to microorganisms, e.g., antibiotics), or analogous products at any stage of production, shipment, distribution, or sale which are intended for use in the treatment of animals and which act primarily through the direct stimulation, supplementation, enhancement, or modulation of the immune system or immune response." (9CFR 101.2)

An MOU between APHIS and FDA (APHIS Agreement #04-9100-0859-MU, FDA Serial #225-05-7000) addresses jurisdictional issues concerning the regulation of certain animal products as biological products. Examples of products listed in the MOU as products generally regulated as animal biological products by USDA-APHIS include vaccines, viruses, bacterins, bacterial extracts, allergens, antiserums, antitoxins, toxoids, immunomodulators, immunoglobulins, and serum and plasma for passive transfer. Examples of products listed in the MOU as products generally regulated as animal drugs by FDA include antibiotics, antimicrobial peptides, anti-inflammatories, anthelmintic, antiprotozoal, competitive exclusion products, genetic constructs (non-vaccine), stem cell therapies, gene and somatic cell therapies, hormones, growth factors, growth promotants, whole blood, transfusions, and clotting products (except serum and plasma for passive immunity).

For questions regarding whether a product is regulated as a drug by the FDA, or an animal biological product by USDA-APHIS, contact CVMimportrequests@fda.hhs.gov.

6.3.8 - Field and Label Examinations -Radiological Health

Import coverage for radiation-emitting products is provided for in CPGM 7386.007, Imported Electronic Products.

When conducting fieldwork on radiation-emitting products, refer to the field and label examination work instructions issued by CDRH and located on the Import Program intranet site under commodity-specific resources. Additionally, field and label examinations for imported electronic products should include a review of the entry documents and FDA-2877, Declaration for Imported Electronic Products Subject to Radiation Control Standards, to determine if they are properly completed and accurate. This applies to each shipment of electronic products for which performance standards exist. Performance standards covering ionizing, microwave, and light-emitting radiation-emitting products are specified in 21 CFR 1020 through 1040.

6.3.9 - Field Examinations – Tobacco Products

Contact the Center for Tobacco Products (CTP) Office of Compliance and Enforcement, Division of Enforcement and Manufacturing, at CTP-ComplianceImports@fda.hhs.gov with general questions on the importation of tobacco products. Label examination instructions issued by CTP are located on the Import Program intranet site under commodity specific resources.

6.3.10 – Field/Label Examination Results

Examination results should be reported via FDA Import Systems for those lines that have been physically examined. Results should reflect the findings within the limitations of an examination for the specified problem area. An examination should not be reported on lines that have not been physically examined. If adverse findings are encountered, examination work type(s) should be added to the line, if needed, to record the adverse findings under the appropriate problem area.

Review the Line Details screen prior to completing the examination results. For example, make sure the product code matches the product, and that the manufacturer, country of origin, quantity, and value are correct. Add any lot codes, if applicable, and update the Location of Goods if needed. If data has been changed, enter pertinent remarks for the change, assign fault as appropriate, and rescreen the line to see if changes in the data result in changes to the flags and/or other screening hits.

Complete the examination results by navigating to Work Results:

The system will auto-fill the following fields: Entry/Doc/Line (Suffix), Lead Initials, Date Completed, Product Code, Product Description, Importer/Corrected Description, Requested By, Requested Of, PAF, PAC, and Reference.

However, you will need to enter data in the following fields, as described below.

6.3.10.1 – Date Completed

The Date Completed field will default to the current date. If necessary, update the Date Completed field to the date the examination was completed.

6.3.10.2 – Location of goods

Enter the location where the examination was or will be conducted, if availability and location of goods have not been entered, or if the exam location has changed. Include location name and address or resident post location. Note: if location and availability has been provided by the Broker through ITACS, changes to this field cannot be made.

6.3.10.3 – Remarks

Enter the type of examination performed, describe how the examination was performed, and note any samples collected or photos taken, or product and quantity destroyed in the field, as part of the examination process. If the examination was performed due to an assignment, import bulletin, or import alert, then enter pertinent information as instructed.

Example entries:

"Conducted food filth exam under CP03819A. Viewed outer cases under a black light. Opened 5 of 10 cases and viewed contents through transparent packaging. Collected a sample for micro analysis under CP03819C."

"Exam was conducted according to DOPG-XXXX-XX. Examined 200 units and found 6 devices with integrity issues. A sample was collected for integrity analysis and 7 photos documenting the exam were uploaded."

Note: Text entered in the Remarks Field does not appear on the Notice of FDA Action

6.3.10.4 – Summary

Enter the findings of the examination. Be as specific as possible in the allowed space. If the examination will be reported as Class 2, provide specific remarks detailing why Class 2 was chosen.

Example entries:

"All cartons are accounted for. No macro filth observed during examination. Exam Class 2 as this line to be held for analysis of line 1 of 4."

"Observations include no ingredients statement, no serving size, and incomplete nutrition info. Label submitted to CB for review."

Note: Text entered in the Summary Field does not appear on the Notice of FDA Action.

6.3.10.5 – Exam Class

Select the appropriate Exam Class:

Class 1 – No Adverse Findings within Problem Area: No adverse findings were noted within the limitations of the examination for the specified problem area. The entry line may be IB Released, sampled for a different problem area, referred to Compliance Branch for a different problem area or have additional work types added to it as appropriate. Additional action should not be taken within the specified problem area that was deemed Class 1

Class 2 – Other Findings: Class 2 is intended to be used only for those situations that do not meet the definitions of Class 1 or Class 3. Some examples of when to use Class 2 include the following (this list is not intended to be all-inclusive):

1. Potential adverse findings were observed. Observations lead to the collection of a sample or referral to compliance branch in the specified problem area for final admissibility determination.
2. The product appears to be in violation, within the limitations of a field examination for the specified problem area; however, investigations branch is using discretionary authority to release the product. If this option is used, describe in detail in the Summary field the reason(s) why this violative product is being released, such as, "This product meets the criteria for release under the Personal Importation Policy (PIP) as stated in the Regulatory Procedures Manual (RPM)." Note: The exemption for releasing a personal importation with a class 2 field exam findings only applies to the mail environment.
3. No adverse findings were observed, within the limitations of an examination for the specified problem area; however, the line is sampled within the same problem area due to the firm/product having a violative history in that problem area, or as directed by an assignment, import bulletin or other guidance.
4. No adverse findings were noted, within the limitations of an examination for the specified problem area; however, the line is being held and referred to compliance branch pending sample analysis of another line. (Note: it is inappropriate to record a field examination if no physical examination occurred. The "Same Action As" function allows for the holding of lines where no examination occurred pending the analytical results of another sampled line.)

Class 3 – Adverse Findings within Problem Area: The product appears to be in violation within the limitations of an examination for the specified problem area. Further action must be taken under the specified problem area, i.e., sampled or referred to the compliance branch for final admissibility determination.

NOTE: If a FEX/LEX is conducted and the examination identifies a violation, you should record the findings as a Class 3 FEX/LEX and submit to compliance as a DTR with the appropriate PAF. For example, if there are labeling claims that may warrant marketing clearance and/or approval, record the findings as a Class 3 LEX and submit to Compliance as a DTR/AAP.

Be sure to click "OK" to save the examination results.

6.3.10.6 – Record Time

Select the correct PAC from the drop-down menu. Enter your time. If more than one person worked on the examination, click on the "Add" button. A box will come up, and you can then select the person's name from the drop-down menu and select the correct PAC from the drop-down menu. Enter that person's time. Repeat for each person who worked on the examination. Click "OK." Note: Time is entered in decimal format in tenths of an hour (6-minute increments).

6.3.10.7 – Next Steps

Once the work has been submitted, and if no other work was set up on the line, you will be prompted to Next Steps.

If the exam was classified as Class 1, you will have the option to IB Release or Add Work.

If no other work needs to be added to the line, the line will be released by selecting IB Release and entering Remarks, including an appropriate summary of remarks entered in the Exam Results. If product was destroyed in the field as part of the field examination process, record what was destroyed in the Remarks field. Note: Text entered in the Remarks field does not appear on the Notice of FDA Action.

If work needs to be added to the line, select Add Work. The system will take you to the Work Request and Work Request Details page to add work as appropriate.

If the exam was classified as Class 2, you will have the option to IB Release, Refer to CB, or Add Work.

If the exam was classified as Class 2 with no adverse findings, but the line is to be held pending sample analysis of another line, follow Division procedures for notifying Compliance Branch. If the exam was class 2 with adverse findings, but IB is using discretionary authority to IB Release the line, remarks should include a detailed description of why the product was released when adverse findings were found.

If the exam was classified as Class 3, you will have the option to Refer to CB or Add Work.

If no other work needs to be added to the line, the line will be referred to CB by selecting Refer to CB and entering Remarks, including an appropriate summary of remarks entered in the Exam Results.

6.3.11 – Rescinding an IB Release

Rescinding an IB Release should only occur for articles that are subject to a compliance action, or in other exceptional cases, and must be accomplished immediately. This action should not be used for routine or work plan examination or sampling purposes (See Section 6.2.2.2.2 for Rescinding a May Proceed).

Note that when an entry receives an IB Release, the conditional release period of the entry ends (Section 6.3.4) and does not re-open when IB Release is rescinded.

If an entry line inadvertently receives an IB Release or additional information is received that warrants further review for admissibility, you should:

- Obtain supervisory approval prior to rescinding the IB Release.
- Notify the import filer immediately that the FDA IB release has been rescinded and the line is pending an FDA Admissibility decision.
- Generate an updated Notice of FDA Action and forward it to the filer, importer of record, and consignee within 24 hours of rescinding the IB Release.
- Send a request to CBP, within 24 hours of rescinding the IB Release, to Unset/Hold the CBP Bond from liquidating in case Compliance Branch needs to pursue a liquidated damages case against the bond for cargo that the FDA has refused and not redelivered for export or destruction.
- Send to the filer ABI codes to indicate “PGA Decision Rescinded-Do Not Distribute Product” and “Release Rescinded-Hold for Further Information From PGA”.
- If the shipment has been distributed, notify CBP and request that they issue a demand for redelivery. (See IOM 6.1.4.2 for information regarding informal entries.) CBP has 30 days to demand redelivery from the date the conditional release period ended (i.e., the “IB Release” was issued.) Any delays compromise FDA’s ability to request CBP issue a Notice to Redeliver.
- Record this process and communication with CBPI in the Entry Remarks and/or Miscellaneous Info Received field to document FDA follow-up when FDA issues an IB Release inadvertently.

6.4 - Import Sample Collection

6.4.1 – General

In general, the difference between official domestic and import samples is that import samples do not require official seals or collection of a 702(b), reserve portion (See Chapter 4 for sampling instructions and guidelines.) There are instances when the collection of a reserve portion and an official seal is warranted, for instance, when enforcement action (a seizure, injunction, prosecution) is contemplated. Some sample sizes are provided in the Sample Schedule Section (See Chapter 4). When using the sample sizes furnished elsewhere in this manual, do not collect the duplicate portion of the sample unless directed by your division. In addition, when preparing to collect import samples, you should always be aware of your personal safety. (Refer to IOM 5.3.)

Import sub samples should be identified in accordance with IOM 4.7.2.1. If an Entry number is used for subsample identification ensure the collection report is completed as soon as possible and notify the sample custodian of the sample number. The collection report should clearly indicate how the sub samples are identified.

Collect, prepare, handle, and ship import samples in a manner which ensures the samples' integrity. It is important that samples are packaged properly and labeled completely and legibly on the outside of the immediate sample container before delivery to the laboratory. This allows the sample custodian to properly store the samples and expedite delivery to the appropriate laboratory branch.

Attaching a Form FDA 525, Sample Package Identification, is not required; however, if a Form FDA 525 is not used, the outside of the immediate sample package should be identified with the following information:

- Sample number, if available at time of shipment.
- Entry/Line number, if sample number not available at the time of shipment or sample delivery.
- PAC/PAF (include all if multiple PAC/PAFs going to the same lab) See IOM 6.4.8, Sample Collection Reports.
- Date of collection.
- Storage Condition (for instance, ambient, frozen, or refrigerated).
- Lead CSO's initials.
- The number of bags/cartons in the sample if more than one, and the sub numbers in each container, (for instance, bag/box 1 of 3, subs 1-10, etc.)

Note: If an FDA 525 is used, affix it to the outside of the sample container. Do not affix it on the outside of the shipping container.

Including a copy of the collection report (CR) is not required unless specifically requested by a lab.

You should also take clear photographs of all samples collected. (See 6.1.8 PHOTOGRAPHS: IDENTIFICATION AND STORAGE for more details and instructions.)

The FDA does not pay for import samples at the time of collection. The importer should be advised they may bill the responsible division. Also, the FDA will not pay for violative import samples, per 21 CFR Part 1.91, (see IOM 6.4.2.5).

When collecting an import additional sample (ADS), the original import collection report (CR) or sample number should be referenced in the remarks section of the CR. An ADS should always be recorded on the same entry/line as the original sample.

Import Samples are compliance samples, except for those collected for pesticide analysis. (See IOM Sample Schedule Chart 3 (Chapter 4) for guidance.)

6.4.2 – General Import Sampling Policies

6.4.2.1 - Ports Covered by FDA

For electronic entry submissions, if the filer receives a message indicating FDA review, the filer will provide appropriate entry information to the FDA office having jurisdiction over the port of entry. The filer can also submit the entry documents electronically to the FDA via the Import Trade Auxiliary Communications System (ITACS).For those entries submitted by paper, all appropriate entry documents should be included with the package sent to the local FDA office.

After evaluating the entry, if FDA decides to collect a sample, the appropriate individuals/firms will be provided with a Notice for Sampling and advised:

1. If the entry is to be held intact for FDA examination or sampling;
2. Only those items designated for examination or sampling items need be held; etc.

6.4.2.2 – Sampling for Ports with no FDA personnel present

For those ports where the FDA does not generally have staff located under its normal operating schedule, the responsible FDA division office will coordinate coverage with the responsible CBP Port manager to assure FDA notification. If the FDA decides to examine or sample articles being entered through such a port, then CBP, the importer, and broker will be notified.

Generally, for these entries, examination and/or sampling can take place at the point of destination. Under certain conditions, however, FDA may ask CBP to collect a sample at the point of entry for forwarding to the FDA servicing laboratory. Appropriate information on the entry, sample requirement, and requirements for holding the entry will be provided to the CBP officials and importer by the responsible division.

6.4.2.3 – Notification of Exam/Sampling Requested

If an examination or sample is requested, the FDA must notify CBP, the broker or filer, importer, or other designated parties. Notification, either through the electronic entry system or other form of notification (Notice of FDA Action), will indicate there is a hold on the entry identifies the specific product(s) to be sampled, etc.

6.4.2.4 - "Notice of FDA Action - Samples Collected"

After a sample has been collected by FDA, a "Notice of FDA Action - Samples Collected" is issued to the importer of record, consignee, and filer. If CBP collects the sample for FDA, depending on local FDA/CBP agreement, the division will enter the entry information into FDA Import systems and issue the Notice of FDA Action.

For those entries where specific lines (items) of an entry are not sampled, examined, or are pending further review, the Notice of FDA Action will indicate which lines (items) have been issued a "May Proceed." (See RPM Chapter 9, subchapter 9-21"Notice of Sampling" for detailed guidance.)

6.4.2.5 - Payment for Samples

The FDA will pay for all physical samples collected by FDA and found to be in compliance (See 21 CFR 1.91). In addition, the agency will pay for physical samples collected by FDA as an audit of private laboratory analytical results submitted to FDA when the FDA audit sample is found to be in compliance. (NOTE: The agency does not pay for samples found to be non-compliant (violative) or for samples taken in connection with the supervision of a reconditioning.) (See IOM 4.2.8.2 for guidance on sample costs.)

Billing for reimbursement should be made to the FDA division office in whose territory the shipment was offered for import. FDA will not pay for a sample if the article is initially found to be in violation, even though it is subsequently released. Refer to IOM 4.2.8 for payment for samples.

Samples taken in connection with the supervision of a reconditioning are not paid for by FDA.

6.4.3 - Procedure When Products Cannot Be Sampled Or Examined

If the entry is still under the control of the import division, yet the sample collection cannot be completed, the division may annotate the notice to the filer and importer that no product was collected and return the entry to the filer designating the entry "May Proceed." If the designated product was part of a multi-line entry where other products were collected, the notice issued for the other items sampled will be appropriately updated with the release of the product not sampled.

When a notice is issued for the collection or examination of a product in the FDA Import Systems, and neither operation is accomplished, the filer will be advised through a revised Notice indicating the article is given a "May Proceed" status. The system will print a status of "May Proceed" in the Line Summary, and also print a detail section "Lines Which May Proceed."

In FDA Import Systems, the following are definitions used to describe "May Proceed" or "Release" actions:

May Proceed: "Product may proceed without FDA examination. FDA has made no determination the product complies with all provisions of the Food, Drug, and Cosmetic Act, or other related acts. This message does not preclude action should the products later be found violative." (No compliance decision has been made.)

Release: "The product is released after FDA examination. This message does not constitute assurance the product complies with all provisions of the Food, Drug and Cosmetic Act, or other related Acts, and does not preclude action should the product later be found violative." (A compliance decision has been made.)

Divisions will follow the appropriate guidance under each of the above procedures, according to their import operations.

6.4.4 – Pre-Sampling Procedures

Review the submitted entry (electronic or hard copy documentation) to ensure that the location of the product(s) is known and the lots are available for FDA examination/ sampling before initiating action. The general description of the shipment in the entry documentation submitted to the FDA should match the description of the product(s) in the invoice from the broker.

6.4.5 – Sampling Techniques

Follow guidance furnished in IOM Subchapter 4.3 - Collection Technique.

6.4.6 - Sample Collection Reports

For every sample collected, a corresponding electronic collection report must be completed in FDA Import Systems (See IOM Exhibit 6-4.) (Also see IOM 1.1 English language requirement.)

Review the Line Details prior to completing the collection report. (See below for detailed steps.) You are responsible for making sure all fields in the Line Details screen are complete and correct. For example, make sure the product code matches the product, and that the manufacturer, country of origin, quantity, and value are correct. Add any lot codes if applicable and update the Location of Goods if needed. If the data has been changed, enter pertinent remarks for the change, assign fault as appropriate, and rescreen the line to see if changes in the data result in changes to the flags and/or other screening hits.

NOTE**:** If you start a collection report and need to exit at any time to make a correction in the Line Details, you will lose the original collection report and a new sample number will be assigned when you return to the Collection Report screen.

To review the Line Details:

1. Access the Line Details screen by double clicking the work type field, (for example, “SAM”). This will open the Entry/Line Summary screen. Click the “Line Details” button.
2. Review all data and verify that it is complete and correct. For example, make sure the product code matches actual product, and that the manufacturer, country of origin, quantity, and value are correct. Add any lot codes, if applicable, and update the Line Availability information if needed. If there is a “build button” on the line you need to correct, you must use the build function to make corrections. All fields that are white or highlighted in purple can be updated.
3. If data has been changed, click the “Save” button, then enter a brief description in the pop-up box of corrections made. Assign fault to any errors as appropriate.
4. After any changes are saved, click on “Rescreen” in the Application Tool bar to see if changing the data caused the line to hit on any other criteria or alerts.

Complete the collection report by navigating to Work Results.

If the line was sampled for more than one PAF, and analysis will be performed at the same laboratory, only one collection report should be generated, unless otherwise directed. Select all PAFs going to the same laboratory before navigating to work results.

NOTE: Collect a separate set of subs for each PAF, unless otherwise directed by the laboratory or assignment. MIC/MET samples cannot be split or shared between labs.

If the sample will be split and sent to more than one laboratory, complete a separate collection report for each laboratory. The system autofills the following fields for you: Entry/Doc/Line (Suffix), Lead initials, Date Collected, Product Code, Product Code Description, Importer Corrected Description, Requested By, Requested Of, Location of Goods, and the Sample Number, Total Quantity, PAF, PAC, and Reference. The Date Collected, and Location of Goods can be corrected on this screen if needed.

However, you will need to enter data in the fields below.

6.4.6.1 - Date Collected

The Date Collected should reflect the date the sample was collected, not the date the sample was recorded. Only one date can be entered. If the sample collection was accomplished over several days, use the last date of collection. This date should also be used to identify the physical sample.

6.4.6.2 – Episode

An "episode" is defined as a violative pesticide (or other chemical contaminant) finding along with all samples collected in follow-up to that finding. All samples must be associated with one responsible firm (grower, pesticide applicator, etc.) and one specific time period (for instance, growing season). For example, if samples of cantaloupes from Mexico revealed violative residues, then any destination point samples or subsequent compliance samples from the same shipper or grower would, along with the original sample, be considered an episode. For this, you would enter the episode number. (See IOM 4.6.2.27.8.)

6.4.6.3 - Submitted To

Divisions are instructed to submit samples utilizing the Lab Servicing Table (LST) Dashboard located on the intranet on the ORS Sample Distribution site. The LST Dashboard is an interactive tool showing respective sample capacities by PAF and servicing lab. The LST Dashboard can be used to identify all servicing labs with current available capacity for a selected PAF. Special notes or instructions are also included on the LST Dashboard, which may include directions pertaining to diversions and/or suspensions.

The Lab Servicing Table (LST) will continue to be updated as a reference. The LST Dashboard is a supplement to the LST.

When completing a sample collection, the Lab Selection screen will include a "Lab Reference" button that links to the LST Dashboard. After referring to the LST Dashboard to identify a lab with available capacity, select the appropriate servicing lab via the listed laboratory values.

6.4.6.4 - Quantity Collected

Enter the number of sampled units you collected.

6.4.6.5 – Units

Select the appropriate units from the pull-down menu. The Calculated Cost will automatically populate based on the Value submitted in the Line Details, along with Quantity Collected, and Units selected.

6.4.6.6 – DescText

Enter a description of the sample, which includes the following details:

1. Number of subs collected.
2. Weight/volume of each sub.
3. Brief product description.
4. Type of container the subs were collected in.
5. Lot sampled.

Describe how you collected the sample:

Specify any special sampling techniques; if the sample was collected randomly, aseptically, selectively, etc.; and the number of master cases that were collected from.

For example: *"Sample consists of 12 subs /16 oz. (1lb) each of IQF Cod Fillets collected at random from lot B129A1. Sample was collected aseptically from 12 master cases and packed in 12 whirl-pak bags."*

Note that any text you enter in this field will be printed on the "Notice of FDA Action." This field also transfers to the "Sample Description" field in FACTS.

6.4.6.7 - Hand Ship

Enter the method of shipping and describe how sample integrity is maintained, including the sample chain of custody. This should reflect all of the following:

1. How the sample was held and stored until shipment.
2. How the sample was prepared for shipping.
3. The method of shipment

For example: "Transported from firm in a closed cooler with gel packs, sample was then transferred to freezer #1 in the locked sample room until shipped via UPS to PRL- NW in a cooler with Gel packs."

NOTE: This field only transfers to the "Lab Receipt of Samples" screen in FACTS and may not be easily seen by laboratory personnel. **As such, please enter any special handling instructions in the Remarks field.**

6.4.6.8 – Remarks

Enter any additional information that is pertinent to the sample collection, such as:

1. Special handling instructions or storage condition requirements as necessary.
2. When applicable, any guidance documents that were consulted to complete the collection, such as Compliance Program Guidance Manuals, and assignment or field examination guidance documents.
3. Additional information that your Division, Laboratory, Compliance Program, Assignment, or Import Alert/Bulletin requires.
4. Any specific analysis instructions needed (for instance, any specific pathogen or mycotoxin screen needed).
5. Any controls or photos collected.

Examples: “Store frozen. Master case code: PRODUCTION DATE 1319. Open and closed controls submitted with the sample. Analyze for milk protein per IB XX-BXX”

“Store Ambient. Sample collected per DOPG-XXXX-XXXX. Examined 200 units from lot 1234 for defects and identified 6 with pitting. Analyze for device integrity”

Notes: This field transfers to the “Collection Remarks” field in FACTS.

Be sure to review the entire screen before clicking “OK.” The sample will be transferred immediately in FACTS to the respective laboratory once the OK button is clicked (unless your supervisor has set up a supervisory review of your work).

6.4.6.9 - Record Time Screen

Enter your time in the Record Time screen. If more than one person has worked on the sample, click “Add”. A box will pop-up. You may then select the other person(s) from the drop-down list, select the PAC, and enter their time. Note: Time is entered in decimal format in tenths of an hour (6-minute increments).
Examples:
6 min = 0.1
12 min = 0.2
18 min = 0.3
24 min = 0.4
30 min = 0.5

6.4.7 – Updating a Sample Collection Report

FDA Import Systems will allow users to make corrections to a collection report up until the laboratory has set the sample to “In Progress” in FACTS. Note that a collection report may only be corrected once. To update a collection report, select Sample Query from the Query drop down menu and search by sample number or entry number. Select the applicable sample number and click Update Collection Report. The updatable fields will become enabled for modification. These include: Quantity Collected, Units, Desc Text, Handling/Shipping, and Remarks. Once all necessary changes have been made, enter a reason for the update and click submit. At this point, the View Update will become enabled. If a change was made to the Quantity Collected, Units, or Desc Text, a new Notice of FDA Action must be generated. * It is important to generate and send the Notice as it notifies the parties that changes were made to the collection data.

*NOTE: If a change was made to Hand/Ship or Remarks fields ONLY, then no new Notice is needed.

6.4.8 – Additional Samples (ADS)

An additional sample (referred to as "ADS" in FDA Import Systems) is a physical sample collected from a previously sampled lot of either a domestic or imported product. Additional import samples will have a different sample number from the original sample number. Generally, an additional sample is used to complete an initially designated analysis, or to allow the lab to perform additional analyses. Situations where an additional sample may be appropriate:

- When you need to convert a sample from surveillance to compliance for the same PAF.
- When sample is damaged in route, in cases where a new sample and sample number is needed (for instance, Lab Class 5).
- When a new sample collection under the same PAF/PAC is needed as FDA Import Systems do not allow for a new sample collection on those situations.

The additional sample must be collected from the same entry line as originally sampled. In the collection report, reference the original sample number in Remarks section of Collection Report to explain the link to the original sample (for instance, why the additional sample was collected). The additional sample may be pulled from the same product boxes/containers, or from previously unopened ones, depending on the situation.

6.4.9- Special Domestic Import Samples (SDI)

The SDI sample work type should only be used when directed by a special sampling assignment, for certain perishable products collected for metal (MET) analysis or for products collected for nutritional analysis (NIS). It should not be used when collecting samples for multiple PAFs, or if the product appears to be violative or has a history of being violative.

If a product is identified for collection as an SDI under a special sampling assignment, or other directive, follow the instructions outlined in the assignment or directive.

SDI samples should be recorded per IOM 6.4.6 – Sample Collection Reports. Additionally, SDI samples require the following:

- A description of the product label as per IOM 4.5.9 - Product Label in the “Remarks” section.
    - Include brand names and size of lot if not already recorded in the “Line Details” screen.
- An official seal (Form FDA 415a) on the sample container(s).
    - Follow instructions in IOM 4.7.4.
- Collector’s ID on the seal per IOM 4.6.2.12 Collector’s ID on Seal.
    - Include collectors ID on the seal in the “Remarks” section.

Note: This information is required so that the FDA can utilize its domestic authority if the sample analysis results are violative.

After sample collection time is recorded, the user will be prompted to “Add Work” or “IB Release.” The collector should select “IB Release” after any necessary work is completed. After the “SDI” sample work type has been recorded, additional work that would hold the line cannot be added. Once the line is released, the user should generate the Notice of FDA Action (NOA). The NOA will contain a section labeled “SAMPLES COLLECTED AND RELEASED” with additional language pertaining to the release of those lines. When the SDI line is released, the line will be closed. If all lines in the entry have been closed, the entry will be closed.

The import compliance branch will be notified of and responsible for any necessary follow up (such as submitting a screening criteria request and/or coordinating with the appropriate domestic division and program for follow-up actions) on SDI samples found to be violative.

6.5 - Import Procedures After Examination / Sampling

6.5.1 - Procedure When No Violation Is Found

If the shipment is found in compliance after examination, the importer of record, consignee (where applicable), filer, and CBP are notified with a Notice of Release. The shipment may be admitted. (See RPM Chapter 9-7 “Release Notices" for detailed guidance).

6.5.2 - Procedure When Violation Is Found

6.5.2.1 - "Notice of FDA Action - Detained"

If examination of the sample or other evidence indicates the article appears to be in violation and detention is the course of action chosen by the Division, the filer, owner, and consignee (where applicable) are advised of such action by "Notice of FDA Action - Detained." The Notice will specify the nature of the violation charged and designate a site for the owner or consignee (or authorized representative) to appear at a hearing. These hearings are informal meetings with the Division, designed to provide the respondents an opportunity to present evidence supporting admissibility of the article. Ordinarily, the respondents are allowed 10 working days to appear. However, if for some compelling reason the Division determines ten (10) working days are insufficient, this time period may be extended. On the FDA Import System generated "Notice of FDA Action," this date is identified under the caption "Respond By." (See RPM Chapter 9, subchapter 9-10 “Response (Hearing) to Notice of FDA Action – Detained.)

6.5.2.2 - Response to "Notice of FDA Action - Detained"

Response to the "Notice of FDA Action - Detained" may be made personally by representative, or by mail. The importer may present evidence supporting the admissibility of the article, request refusal of admission, propose an effective manner of reconditioning or other method to remove the product from the authority of the FD&C Act.

6.5.2.3 - Request for Authorization to Relabel or Recondition Non-Compliant Articles

The FDA may authorize relabeling or other remedial action upon the timely submission of an "Application for Authorization to Relabel or To Recondition Non-Compliant Articles," (Form FDA 766 - See Exhibit 6-2). This form is also available in fillable formats online here.

Application may also be made by letter and the execution of a good and sufficient bond by the owner or consignee (See section 801(b) of the FD&C Act [21 U.S.C. 381(b)]). The redelivery bond on file with the Port Director of CBP for the particular importation applies to any relabeling or other action authorized; a new bond will not have to be filed.

After review of the application, FDA will notify the importer of its approval or disapproval. If approved the original application will be returned outlining the conditions to be fulfilled and the time limit within which to fulfill them will be noted. Notification to other parties will be made where appropriate. A copy will be retained in the division files. (RPM Chapter 9, subchapter 9-10 "Response (Hearing) to Notice of FDA Action - Detained", and subchapter 9-12, "Reconditioning" for detailed guidance).

6.5.2.4 - Inspection after Approved Reconditioning Has Been Completed

After the relabeling or reconditioning operation has been completed, the applicant will submit the "Importer's Certificate" (page 2 of Form FDA 766, Exhibit 6-2) or advise the division that reconditioning is complete. At this point, the FDA may conduct a follow-up inspection and/or sampling to determine compliance with the terms of the approved reconditioning application, or it may accept the statement from the importer with no further follow-up. The follow-up inspection and/or sampling may be made by FDA or CBP, depending on agreements between the division and local CBP. Photographs should also be taken as warranted (See 6.1.8 PHOTOGRAPHS: IDENTIFICATION AND STORAGE for more information and instructions). The "Report of Investigator/Inspector" (section 4, page 2 of Form FDA 766, Exhibit 6-2), or other appropriately completed summary of reconditioning, should be forwarded to the appropriate FDA office.

6.5.2.5 - Procedure When Conditions of the Approved Reconditioning Application Have Been Fulfilled

If the conditions of the approved reconditioning application have been fulfilled, the division will notify the owner or consignee by Notice of Release. This notice is usually identified as "Released after Reconditioning." A copy is also sent to the filer. Where there is a non-admissible portion (or rejects), they must be destroyed or re-exported under FDA or CBP supervision. A Notice of Refusal of Admission should also be issued for the rejected portion. Additionally, the FDA may include in its approval of the reconditioning a provision for the non-admissible portions (rejects) of the reconditioning to be destroyed and not exported.

6.5.2.6 - Procedure when Conditions of the Approved Reconditioning Application Have Not Been Fulfilled

If the initial attempt at reconditioning is unsuccessful, a second attempt should not be considered unless a revised method of reconditioning shows a reasonable assurance of success.

If the conditions of the approved reconditioning application have not been fulfilled, a "Notice of Refusal of Admission" is issued to the importer, consignee (where applicable) to the filer, with a copy also sent to CBP.

6.5.2.7 - Procedure after Hearing – Release Notice

If, after presentation of testimony, the division determines the article should be released, the importer of record and consignee are issued a notice of release. The Notice will declare that the detained goods may be admitted. The Notice will also be identified "LINES RELEASED AFTER DETENTION" and, where appropriate, explain the reason for the change of action. A copy of the Notice is sent to all parties receiving the Notice of Sampling/Notice of Detention. (See RPM Chapter 9, subchapter 9-7 "Release Notices" for detailed guidance.)

6.5.2.8 - Procedure after Hearing - Refusal of Admission

When the importer requests the Division issue a “Notice of FDA Action - Refusal of Admission,” or the Division decides the shipment still appears to be in violation, the importer, owner, and consignee where applicable, are issued a "Notice of FDA Action - Refusal of Admission." On this Notice, the charge(s) is stated exactly as shown on the original (or amended) “Notice of FDA Action - Detained”. A copy of the Notice is also sent to CBP. (See RPM Chapter 9, subchapter 9-11 "Notice of FDA Action - Refusal of Admission" for detailed guidance.)

The “Notice of FDA Action - Refusal of Admission” provides for the exportation or destruction of the shipment, under CBP supervision, within 90 days of the date of the notice, or within such additional time as specified by CBP Regulation. The Notice will also contain language regarding the requirement for redelivery and contain all the above required information concerning the product and associated charge(s). The FDA file remains open until the division receives notification indicating that the goods were either destroyed or exported.

Following issuance of the “Notice of FDA Action - Refusal of Admission,” the entry refusal is communicated with CBP for the issuance of the CBP form 4647 Notice to Mark and/or Redeliver (CBP form 4647), per Work Instruction WI-000618. In certain situations, CBP may follow up to ask for the hard copy notice of refusal. CBP then issues the CBP form 4647 (Demand for Redelivery) for the entry and notifies the appropriate FDA Division Mailbox. Divisions should follow local port post-refusal processes after receipt of the CBP form 4647 email, including uploading a copy of the CBP form 4647 to the entry/line. If it is discovered that the CBP form 4647 has not been issued for a refused entry, please check with the Compliance Officer and notify CBP CTAC (CTAC@cbp.dhs.gov).

Keep in mind that, throughout this process, the FDA is responsible for the protection of the U.S. public regarding foods, drugs, cosmetics, tobacco products, etc., until the violative article is either destroyed or exported.

6.5.2.9 - Payment of Costs of Supervision of Relabeling and/or Other Action

After completion of the authorized relabeling or other action, the FDA will submit a detailed statement of expenses incurred, including travel, per diem or subsistence, and supervisory charges on a Form FDA 790 (See IOM Exhibit 6-3, Charges for Supervision). This is completed by FDA employees regarding the supervision of the authorized relabeling or other action to CBP–Revenue Division. The expenses shall be computed based upon the following:

- Supervising officer’s time
- Analyst's time
- Per diem allowance
- Travel other than by auto (actual cost of such travel)
- Travel by auto (mileage, toll fees, etc.)
- Administrative support

Future enhancements to FDA’s import system may result in electronic processing of the supervisory charges submitted to CBP, in which case the Form FDA 790 will no longer be used. (See RPM Chapter 9, subchapter 9-13 "Supervisory Charges" for detailed guidance.)

CBP, upon receipt of the charges for supervision, will send a notice for payment to the identified importer of record. The expenses shall include charges for supervision of destruction of the article or rejects. The remittance

by the owner or consignee shall be to CBP. Payment of supervisory charges should not be accepted by any FDA division offices.

6.5.2.10 – Exportation and Destruction of Goods Refused Admission -

Exportation and destruction of refused goods are done under CBP supervision. However, if after a reasonable time, the FDA has not received notification of exportation or destruction, the Division should investigate the status of disposition. Divisions should also consider, under certain conditions, verifying that the refused goods have, in fact, been held intact pending exportation or destruction, or that a re-export actually occurred. During these activities, plan to take photographs of destructions witnessed and any discrepancies noted as warranted (See 6.1.8 PHOTOGRAPHS: IDENTIFICATION AND STORAGE). Note, too, that guidance on refusals to be verified may change, based on the reason for detention and other factors, and that each Division involved in performing Import Operations has been assigned a set number of import exams of refused entries as part of ORA's workplan.

6.5.2.11 – Bond Action

Under the provisions of the FD&C Act (Section 801(b) of the FD&C Act [21 U.S.C. 381(b)]) and CBP regulations (19 CFR 113.62), a bond is required for all conditionally released articles offered for importation. This bond provides relief to the government on the default of the conditions of the bond and the payment of liquidated damages in the amount specified in the CBP Notice Of Assessment Or Liquidated Damages for failure to redeliver such goods.

Bond actions are taken when an entry is distributed prior to FDA release and cannot be redelivered, or when an article has been detained and refused, and the article is not destroyed or exported in accordance with the requirements of the law.

If the division has evidence that the entry, or any portion of an entry subject to FDA jurisdiction, was disposed of in violation of the terms of the appropriate Act, or its regulations, or of the terms of the bond, (see 19 CFR Section 113.62 (l)(1)) it should immediately contact the appropriate Customs office.

The division, upon receiving evidence that the refused article was not exported or destroyed, should immediately investigate the matter. (See Section 6.5 of the IOM, Import Investigations.) The division should also send a detailed statement showing the importer's liability under the redelivery bond or other applicable customs bond to the responsible CBP office. If the facts warrant, *and* the article was under detention, *and* the Notice of Refusal of Admission has not been issued, immediately issue a Notice of Refusal to the owner or consignee, with a copy to CBP.

Upon the receipt of an application for relief (appeal for Mitigation or Cancellation of Assessed Liquidated Damages), CBP may agree to mitigate the damages assessed. However, in cases involving FDA goods, CBP does not usually mitigate unless the FDA is in full agreement with the action [see 21 CFR section 1.97 (b)]. (See RPM Chapter 9, subchapter 9-14 "Bond Actions" for detailed guidance.)

6.6 - Import Investigations

6.6.1 – Import Investigations General

Import operations normally focus on entry review, field examinations, and sample collections. However, investigations are also an essential tool in uncovering and developing evidence documenting violations such as entry misdeclaration, product substitutions, and "port shopping." Invaluable sources of information that may prove relevant to such violations include: Import Alerts, assignments from headquarters or other Programs / Divisions, interagency cooperation, and local intelligence.

When documenting these situations, your supervisor will request a memo of investigation be sent to the compliance branch. Follow your division procedures, and IOM Subchapter 8.1.9., for preparation of memorandums.

When examining, sampling, or following up on refused imported products, you may use an affidavit to document the facts surrounding the situation. (Refer to IOM 4.4.5 and Exhibit 6-5 for guidance on preparation of an affidavit.)

6.6.2 - Investigations Involving the Importation Process

During the importation process, FDA personnel often encounter attempts to bypass proper FDA record review, inspection and/or sampling, as well as the willful attempt to import goods known to violate the Act. In addition to such actions as detention, refusal, and placement onto an Import Alert, the FDA also performs investigations and forwards the evidence collected to support a recommendation for CBP sanction under Title 19, which includes authorities for administrative seizures, civil money penalties, revocation of conditional release privileges, and bond actions (including liquidated damages, increases to bond amount, requirement of single-transaction bond).

6.6.3 - Reporting Investigations Involving the Importation Process

An investigational memo with supervisory endorsement should be generated for all instances described under IOM 6.6.4, Import Violation Patterns. The memo should normally be provided to supervisory staff for endorsement within ten business days of the last investigational activity and endorsed by supervisory staff within five business days. Memos that are endorsed for regulatory consideration should then be forwarded to Compliance uploading them into FDA Imports Systems for further follow-up. If no memo is generated, then the importer and/or broker should be advised, and that advisement should be documented in accordance with division policy.

6.6.4 - Import Violation Patterns

The below investigational points should be covered to promote a thorough investigation. Note than any given situation may overlap into more than one pattern. While not an exhaustive list, the following four patterns may be encountered:

1. Failure to hold (See IOM 6.6.4.1 – 6.6.4.3)
2. Substitution (See IOM 6.6.4.4)
3. Importer misdeclaration (See IOM 6.6.4.5)
4. Filer misdeclaration (See IOM 6.6.4.6)

6.6.4.1 - Failure to Hold

Failure to hold means that the goods have been distributed by the importer/consignee without an FDA release from import status. *Please note that this is defined as distribution without a release, not merely moving the goods outside of the port area. FDA personnel may encounter this situation at various points in the importation process, including initial exam/inspection, sample collection, audit sample collection, reconciliation examination after a health hazard finding, verification of a reconditioning, and refusal verification. The following steps should be taken on all Failure to Hold cases:

1. Collect entry documentation (CBP form 3461 or 7501, invoice, packing list, bill of lading).
2. Determine distribution, by collecting and analyzing pertinent distribution records.
3. Determine who authorized the distribution. (Note: There may be more than one responsible party.)
4. Determine if the importer was aware of the health hazard associated with the product.
5. Obtain the authorizing person’s explanation as to why the goods were distributed. (Items (1), (2), (3), (4), and (5) should be covered in one or more affidavits.)
6. Perform a data search via ORADSS or other means to determine the importer’s history and discuss relevant findings with supervisory and compliance staff.
7. Coordinate with CBP the issuance of a Demand for Redelivery (form 4647) if one has not already issued per a refusal. Form 4647 can be issued for the purposes of examination/sampling, not merely because of an FDA refusal. In such circumstances, the deadline for redelivery is 30 days, instead of the 90 days post-refusal.
8. Determine the importer’s bond type and amount.

6.6.4.2 - Failure to Hold – Health Hazards

Distribution of goods where there is direct evidence of a significant health hazard, such as an FDA finding of *Salmonella* contamination in a ready-to-eat food entry, should be regarded as a concern of the highest priority. In addition to the eight common steps listed above, the following additional step should be taken:

- Consult with supervisory staff, compliance staff, and the division's Recall and Emergency Coordinator as needed to address retrieval from and/or notification to the consignees, as well as consideration for any public warning.

6.6.4.3 - Failure to Hold - Health Hazards – Detention Without Physical Examination (DWPE)

Distribution of goods where there is evidence of a significant health hazard that only meets the appearance of a violation evidentiary standard (the standard under the 801(a), admissibility process) --such as an entry of a ready-to-eat food detained without physical examination (DWPE) due to a history of *Salmonella* contamination--should still be regarded as a concern of high priority. In addition to the eight common elements listed above under Section 6.5.4.1, the following additional steps should be taken:

- Consult with supervisory staff and compliance staff as needed to determine if the FDA should collect samples for analysis.
- Consult with supervisory staff, compliance staff, and the district's Recall and Emergency Coordinator, as needed, to address retrieval from and/or notification to the consignees, as well as consideration for any public warning.

6.6.4.4 – Substitution

Substitution is an attempt by the importer or importer's agent to present goods to the FDA as corresponding to a particular entry when they are, in fact, not the goods from that entry. FDA personnel may encounter this situation at various points in the importation process, including initial exam/inspection, sample collection, audit sample collection, reconciliation examination after a health hazard finding, verification of a reconditioning, and redelivery examination. Substitution may occur as an attempt to hide distribution without FDA release (Failure to Hold). The investigation may reveal negligence, gross negligence, or fraud. The following steps should be taken when evidence of substitution is encountered:

1. Confirm that the goods are being presented to the FDA as corresponding to a particular entry. In some situations, you may only be able to show associated entry documents to the importer or importer's agent and request confirmation that the goods presented correspond to that entry. Confirmation can be accomplished by performing the following steps:
   a. Collect all available evidence supporting that the presented goods were substituted. This may include labeling, lot codes, and the condition of the goods themselves. Photos are invaluable in these instances. Examine the entire shipment as this would minimize the possibility of the importer successfully claiming at a later time that the portion not examined was in fact not substituted.
   b. Collect all available evidence to show any attempt to conceal the substitution. For example, in a partially substituted entry, the substituted goods are in the center, bottom position on a pallet; or placement of the substituted goods is in the front position of the trailer.
2. Determine the importer's, or importer's agent's, explanation for the discrepancies. Collect this in an affidavit, along with a description of the declared/actual goods and the substituted goods.
3. Until it is determined otherwise, consider all substitution cases to involve distribution of the actual goods without FDA release. (See IOM 6.5.4.1, FAILURE TO HOLD.)

6.6.4.5 - Importer Misdeclaration

Importer misdeclaration refers to the importer's provision of incorrect and/or incomplete information to the FDA and CBP, usually via the filer. When FDA personnel encounter this situation, it is usually during the initial examination or sampling of the entry. It may be the case that the investigation reveals negligence, gross negligence, or fraud. The following are examples of this kind of activity:

- The importer provides information to the filer that does NOT include a product that is present in the entry, and as a result, that product is not included in the declaration (undeclared goods).
- The importer provides the filer information that a product is manufactured by firm X, when it is, in fact, manufactured by firm Y. As a result, the filer declares the product as manufactured by firm X (misdeclared goods).

6.6.4.6 - Filer Misdeclaration

Although this section is oriented to filer interventions, it must always be recognized that the filer is the agent of the importer, and the importer is ultimately responsible. Filer misdeclaration refers to the importer's provision of correct information to the filer who then files an erroneous entry to CBP. The following are examples of this activity:

- The filer omits a product properly listed on the entry invoice from the declaration (undeclared goods).
- The importer provides the filer information that a product is manufactured by firm X, but the filer declares it as manufactured by firm Y (mis-declared goods).
- The importer provides an invoice to the filer that lists product X, but the filer declares product Y. When FDA personnel encounter this situation, it is usually during the initial examination or sampling of the entry (mis-declared goods).
- The filer selects a food Process Identification Code (PIC) for packaged food (which should only be selected when no other PIC applies, per the instructions of the FDA's Product Code Builder on the Web) when the broker does not have sufficient information to determine if any other PIC applies (misdeclared goods).

6.6.4.6.1 - Repeated Filer Misdeclaration

In the event a filer continues to mis-declare a product to CBP or the FDA, and/or continues to introduce or present to CBP or FDA any erroneous types of documentation which may violate the FD&C Act, the following steps should be taken:

1. Document what information was available to the filer to file the entry. Collect any relevant records not already obtained.
2. Document the undeclared or mis-declared products through the collection of labeling and/or photos.
3. Obtain the filer's explanation for the discrepancies in an affidavit along with (1).
4. It may be necessary, in some fact patterns, to also collect an affidavit from the importer. For example, if a filer declares a cosmetic product code for fluoridated toothpaste because the importer failed to provide the filer information about whether the toothpaste did or did not contain fluoride, it may be necessary to collect that information via an affidavit from the importer.
5. Conduct a Filer Evaluation to examine records and determine the extent of the problem. The FDA should gather enough evidence to support a possible broker penalty, with the following to be considered:
    a. If the filer has no history of filing erroneous entries to FDA, divisions should consider further training and or placing the filer back to phase 1 filing status and withhold a request to assess a broker penalty against the filer.
    b. If the filer has a history of filing erroneous entries to FDA, and the filer continues to disregard FDA's attempts to provide guidance, train, and document guidance provided of filing entries

through the Automated Broker Interface (ABI), the FDA should contact (CBP) to request that a broker penalty be assessed against the filer.

6.7 - Filer Evaluations

6.7.1 – General

The FDA makes admissibility decisions based on the electronic entry data transmitted by the filers. The admissibility process is reliant upon data provided by parties outside of the FDA, most notably, the entry filers transmitting import entry information to the FDA on behalf of importers. As such, the FDA is dependent on entry filers to submit the most accurate data to make sound, risk-based admissibility decisions.

Towards this end, the FDA also conducts periodic filer evaluations to monitor the accuracy of this transmitted entry data. Filer evaluations are conducted based on the physical location within an import division and may include entry lines transmitted by filers that are physically located within a different import division. (Follow SOP-000217 "Import Filer Evaluation" when conducting import filer evaluations. and the Filer Evaluation Program Resources.) The FDA's Filer Evaluation website also contains helpful regarding the Filer Evaluation Program.

6.8 – Foreign Supplier Verification Programs (FSVP)

6.8.1 - FSVP Inspections

FSVP inspections are conducted to ensure that imported food is produced using processes and procedures that provide at least the same level of public health protection as food produced in the United States. The FSVP website contains resources for legal, regulatory, guidance, and policy issues for the FSVP regulation.

The FSVP Resources website also contains an all-in-one resource for investigators who are conducting FSVP Inspections.

Refer to the FSVP Implementation Work Instructions in conjunction with this subchapter when conducting an FSVP Inspection.

Additionally, refer to Compliance Program 7303.878 Foreign Supplier Verification Programs Inspections for more information on FSVP.

6.8.1.1 - Pre-Inspection Activities

Prior to conducting an FSVP inspection, you'll want to contact the FSVP importer by email, using the FSVP Pre-Inspectional Contact Email Template. If the FSVP Importer does not provide their telephone number in response to the email, or does not respond to the email, you should call the importer. During this pre-inspection communication you should:

1. Identify yourself and inform the importer that the FDA will be conducting an FSVP inspection.
2. Verify the firm or person identified at entry is the "importer," as defined in 21 CFR 1.500, and that the imported food is subject to the FSVP regulation.
3. Verify the importer's contact information (their name, email address, phone number, and physical address).
4. Determine if the importer of the food is a manufacturer/processor or re-packer, and if they should be inspected under any other specific human or animal programs, such as the Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Human Foods Regulation (Preventive Controls for Human Foods Rule) or Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Animal Foods Regulation (Preventive Controls for Animal Food Rule).

5. If the importer is a produce importer, determine whether the importer is also a grower, and as such should be inspected under the Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption (Produce Safety Rule).
6. Verify the FSVP records are available on-site. If the records are off-site, advise the importer that they will need to retrieve the records.
7. Determine if any FSVP records need to be translated. If translation is required, the importer may be given a reasonable time-period to acquire the translated versions of the document.

6.8.1.2 - Preparation and References

Steps to take before undertaking an inspection:

1. Using FDA Import Systems, review the firm's FSVP inspectional history (including active consumer complaints), the compliance history of the products, and the foreign supplier associated with the products targeted for FSVP review. Ensure the highest risk products are covered.
2. Using FDA Import Systems, prepare a list of the foods imported by the importer and the foreign supplier for each food.
3. Conduct the preliminary assessment of potential hazards to determine the known, or reasonably foreseeable hazards, that should be addressed in the importer's hazard analysis, if applicable.
4. Still using FDA Import Systems, determine if the FSVP Importer may be a Very Small Importer (VSI) as defined by 21 CFR 1.512(b)(1)(i)(B) .https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=1.512 If you determine that the importer may be a VSI, confirm with the importer during the inspection that this is the case and if, as a VSI, they choose to follow the VSI Modified Requirements. Document this VSI status discussion, including the importer's response, in the Tabular EIR (T-EIR).
5. Review and become familiar with the appropriate parts of the FSVP regulation found at 21 CFR Part 1, subpart L.
6. Ensure that you have received all necessary training that may be required. Consult your supervisor with any questions.

6.8.1.3 - Inspectional Authority

Authority to review records required of FSVP importers falls under the statutory provisions of section 805 of the FD&C Act, 21 CFR 1.510(b)(1), 21 CFR 1.510(b)(3), 21 CFR 1.512(b)(5)(ii)(A), and/or 21 CFR 1.512(b)(5)(ii)(C).

You can also consult IOM subchapter 2.2 for broader information on inspectional authority.

6.8.1.4 - FSVP Inspectional Activities

At the start of the inspection, locate the person who is most responsible on site. Introduce yourself by name, title, and organization. Show your credentials (for on-site inspections only), explain the purpose of the inspection, and issue a properly signed and completed original of the Form FDA 482d, Request for FSVP Records (the division office address should be the pre-alignment district office associated with the importer's geographical location).

If this is an initial inspection, provide FSVP education materials. Briefly explain the fact sheets and refer the importer to additional documents that can be found on the FDA.gov FSVP website.

(See also IOM subchapter 5.1.4.2.1 for general information on issuing the Notice of Inspection.)
If this is a remote inspection, refer to the FSVP Implementation Work Instructions for conducting Remote Inspectional Activities.

6.8.1.4.1 – Conducting the FSVP Records Review

Review the importer's required FSVP records for the products and foreign suppliers as assigned, or as needed, to ensure appropriate coverage of the firm's FSVP programs. When following up on an inspection during which an FDA 483a was issued, review the FSVP records for the observations documented on the FDA 483a during

the previous inspection. You'll also want to determine, of course, if the importer corrected the observations that were identified during the previous inspection and what those corrective actions were. Also, verify that it was those specific actions that corrected the observations.

For each FSVP product reviewed during the inspection, review documentation that the importer meets the definition of "importer," per 21 CFR 1.500.

Review the list of the imported foods you prepared in IOM Subchapter 6.7.1.2 with the importer, and then document which foods do not have an FSVP plan. If the importer is required to comply with the requirements in section 1.504, request to review the importer's hazard analysis. It is important to determine if the importer has identified any known or reasonably foreseeable hazards for each food. Compare your preliminary assessment of potential hazards to the importer's hazard analysis. If there are discrepancies, discuss with the importer to determine their reasoning behind the discrepancy. After reviewing the importer's hazard analysis, request to review the necessary records. Document the results of your preliminary assessment of potential hazards comparison to the importer's hazard analysis in the T-EIR.

If the importer states that they do not have an FSVP, determine whether the importer maintains records that satisfy the FSVP requirements. Importers may not be aware of the specific requirements of the FSVP regulation, but upon further questioning, may be able to provide documents that fulfill FSVP requirements. Encourage the importer to take corrective actions for any observations identified during the inspection.

If the records review indicates there may be a public health concern relating to a food or foreign supplier (for instance, evidence that the food is adulterated or misbranded, or that there are significant deficiencies at the foreign supplier), determine if the importer took the appropriate corrective actions and also documented the corrective actions taken. For example, if an importer's sampling and testing records indicate that a sample was positive for *Salmonella,* determine if the importer took appropriate corrective actions (for example, importer did not import the food, imported food was recalled, importer worked with the foreign supplier to address the problem, importer discontinued use of the foreign supplier). In addition, document and collect available information relating to the food and foreign supplier; document FSVP observations on the Form FDA 483a, when applicable; and report the findings to your supervisor.

Document all discussions with the importer as it relates to FSVP and the records review in the T-EIR.

6.8.2 - FSVP Observations

The FDA 483a, FSVP Observations is intended to assist firms inspected in complying with the laws and regulations enforced by the FDA. The FDA 483a is the agency's primary means of notifying, in writing, an inspected establishment's top management of significant objectionable conditions relating to violations of the FD&C Act observed during an inspection. The issuance of written inspectional observations is mandated by law and by ORA policy.

6.8.2.1 - Preparation of Form FDA 483a

The FDA 483a should only be issued at the conclusion of the inspection. Use care, during the inspection, to not show or reveal to the firm's management any draft, unsigned copy of the FDA 483a, or electronic copy of the FDA 483a on your computer screen. You should issue only a signed FDA 483a at the closeout discussion with management.

The FDA 483a should adhere to the following general principles:

- Observations that are listed should be significant and correlate to regulated products being inspected.
- Observations of questionable significance should not be listed on the FDA 483a. Discuss these observations with the firm's management immediately? so that they understand how uncorrected problems could become a violation. Detail this discussion in the T-EIR.

The FDA 483a should have the following characteristics:

- Each observation should be clear and specific.

- Each observation should be significant and ranked in order of significance.
- All copies of the FDA-483a should be legible.

If an observation made during a prior inspection has not been corrected, or is a recurring observation, it is appropriate to note this on the FDA 483a and document it in the T-EIR. Corrective actions are not listed on the FDA 483a but are reported in the T-EIR.

The products and foreign supplier inspected must be identified on the FDA 483a, when documenting an observation for the importer's lack of an FSVP.

Collect documentation to support observations. Do not copy records that do not support observations, unless otherwise directed. Contact your supervisor if you are unsure of the evidence required to support an observation.

Generate the FDA 483a in eNSpect. To generate the FDA 483a, complete the FSMA and FSVP Inspection Protocol (IP) for each FSVP product that is reviewed.

At the close of the inspection, provide the importer with a copy of the FDA 483a and discuss each observation with them. Also discuss any non-significant observations not documented on the FDA 483a. Encourage the importer to make voluntarily corrective actions.

During the closeout discussion with the FSVP importer, inform the importer that they should respond to the FDA 483a *within 15 business days* after the end-date of the inspection and that their response may impact FDA's determination of the need for follow-up action. Provide information to the importer on where to send their response according to their division's procedures (That should be the address of the Division office associated with the importer's geographical location, which is listed on the FDA 483a or FDA 483a response e-mail address associated with the applicable division). Hard copies of inspections records should be stored at the pre-alignment district office associated with the importer's geographical location.

6.8.2.1.1 - Individual Headings

Enter data in the individual FDA483 headings as advised here:

District Office Address and Phone Number – Legibly print the district office address where the firm is physically located, regardless of investigator's division or duty station. Include the district office commercial telephone number and area code.

For example, if a firm is located in Salt Lake City, UT, then the district office would be Denver District Office. See Appendix E for boundary maps.

Name and Title of Individual to Whom Report Is Issued – Enter the legal first name, middle initial, and last name, along with full title, of the person to whom the form is being issued.

Firm Name - Enter the full, legal name of the firm, including any abbreviations, quotation marks, dashes, commas, etc.

Street Address-Enter Street address of the firm (However, not a P.O. Box unless P.O. Box is part of the address such as on a Rural Route).

City, State and ZIP Code - Enter the firm's city, state, and ZIP code.

E-Mail Address – Enter the email address for the FSVP contact at the firm.

Date(s) of Review of your FSVP Records - Enter actual or inclusive date(s) of inspection.

FEI Number - If the FDA Establishment Identifier is on the assignment, enter it here. If not readily available, leave blank.

Employee(s) signature and Employee(s) name and title – List here the names of everyone who participated in the inspection with the issuance of an FDA 482d even *if* they are not available to sign the FDA 483a. Each member of an inspection team should sign the FDA 483a; however, absence of a team member at the conclusion of an inspection need not prevent issuance of the FDA 483a. (See IOM 5.2.8.) If you use an eNSpect-

generated FDA 483a, ensure you have a copy for the program division files; an unsigned photocopy or printed duplicate is unacceptable. See IOM 5.5.10.3.

6.8.2.1.2 - Signature Policy

Everyone present at issuance signs the first and last pages of the FDA 483a and initials each intervening page in the signature block. The lead CSO's signature will appear on all pages of the FDA 483a, and the remaining team members' signature will appear on the last page.
(See IOM 5.5.10.5 for more information on Reports of Observations.)

6.8.3 - FSVP Reporting

Following an inspection, you are required to prepare a report of your findings. Reporting includes the data and summary entered using eNSpect, a Tabular Establishment Inspection Report (T-EIR), attachments, and exhibits. Your (T-EIR) should be prepared to accurately and concisely communicate the findings of your inspection and be adequate for its intended use.

6.8.3.1– Establishment Inspection Report (EIR)

Based on the observations documented on the FDA 483a and other information captured on the IP in eNSpect, you will use the FSVP Tabular Establishment Inspection Report (T-EIR) application in the eNSpect system to generate the T-EIR. The requirement to answer IP Question 1.5.1. replaces the requirement to complete the PRA "Memorandum to File." Document the reason for selecting the importer for inspection in the EIR. Write the EIR according to this subsection and IOM subchapter 5.7.

6.8.3.1.1 - FSVP Records Review

Document the review of the importer's required FSVP records in the T-EIR. Identify the product and foreign supplier covered by each FSVP. Report the results of the comparison of your preliminary assessment of potential hazards to the importer's hazard analysis, if conducted, and any resulting discussion you had with the importer. This information must be documented with sufficient detail to demonstrate the firm's compliance with FSVP, or lack thereof.

For each product covered during the inspection, verify that the importer meets the definition of "importer" and document in the EIR as follows:

- If the importer was the owner or consignee when the food was offered for entry into the United States, attach a copy of a purchase order or some other documentary proof.
- If the importer was the U. S. agent or representative when the food was offered for entry into the United States, attach a copy of the written agreement to serve as the FSVP importer.
- If the importer does not meet the definition of importer, explain this determination in the TEIR and obtain information on the actual importer.

Document all corrective actions taken by the importer to correct the observations that were identified during the previous inspection. Describe what corrective actions were taken and whether those specific actions corrected the observations. Document any immediate corrective actions that the importer took during the inspection and any corrective actions promised for completion in the future, including when (date) they expect to complete the corrective action. In addition, document any corrective actions taken during the inspection in the corrective action reporting system (CARS) within eNSpect.

6.9 – Glossary of Import Terms

Note common import language and their meanings below. (Refer to the "Regulatory Procedures Manual | FDA Glossary" for a more complete listing of import terms.)

6.9.1 – American/ US Goods Returned (AGR or USGR)

Goods produced in the U.S. which are exported, and then returned to the United States. They are considered imports. (See Sec. 801(d)(1)of the FD&C Act [21 U.S.C. 381]).

6.9.2 – Additional Sample

A physical sample collected from a previously sampled lot of either a domestic or imported product. Generally, an additional sample is used to complete an initially designated analysis, or to allow the lab to perform additional analyses. Additional import samples will have a different sample number from the original sample. Additional domestic (or domestic import) samples may also have another sample number, but they must be flagged as an "ADD" Sample, with the original sample number referenced in the "Related Sample" block on the Collection Record.

6.9.3 – Affidavit

An affidavit is a written document for which the signer swears before an authorized official (FDA) that the statements in the document are true. The signer is referred to as the affiant and has knowledge of material facts relating to the movement or condition of the goods. FDA affidavits are used when collecting samples, establishing interstate commerce, for consumer complaints, and to document information from informants.

6.9.4 – Affirmation of Compliance (A of C)

Data elements transmitted to FDA electronically that affirm a product meets a specific FDA regulation. This value is provided to help expedite the FDA's review of product compliance in making an admissibility decision at time of entry. Some affirmations require a qualifier, which are numeric or alpha-numeric values representing a specific firm, product, certification, registration, application, or other value often on file with the FDA.

6.9.5 – Air Waybill

A type of bill of lading that serves as a receipt of goods by an airline and as a contract of carriage between the shipper and the carrier. It will include terms and conditions, description of goods, and charges. Unlike a bill of lading, an AWB is non-negotiable, and does not specify which flight the shipment will be sent on or when it will arrive.

6.9.6 – Audit Sample

A sample collected to verify analytical results provided by a certificate of analysis, or private laboratory analysis that purports to show a product complies with the FD&C Act and/or regulations. This sample type will usually be used with an import sample. At least one FDA audit sample should be included as evidence when processing removal of a product, shipper, or country from DWPE. (See IOM 4.1.4.12)

6.9.7 – Automated Broker Interface (ABI)

A component of CBP's Automated Commercial System (ACS) that tracks, controls, and processes all goods imported into the United States. It is a voluntary program available to brokers, importers, carriers, port authorities, and independent service centers and allows qualified participants to electronically file required9import data with Customs. ACS is being replaced by CBP's Automated Commercial Environment (ACE), which will track, control, and process all imported and exported goods.

6.9.8 – Automated Commercial Environment (ACE) (ACE Supplemental Guide)

The Automated Commercial Environment, or ACE, is a centralized system for all transactions related to imports and exports. Filers electronically submit all information related to an inbound shipment using this system, and the government processes the transaction systematically and sends status updates.

6.9.9 – Bill of Lading (BOL)

The written order from a shipper to a carrier to move goods from one place to another. When available, this is the best source of shipping dates, origin, and name of shipper.

6.9.10 – Break-Bulk Cargo

Cargo transported in individual units, such as bags or cartons, which are not containerized.

6.9.11 – Bond Action

Action taken by Customs resulting in forfeiture of all, or a portion of, an entry bond when an importer fails to redeliver merchandise covered by such a bond.

6.9.12 – Consumption Entry (CE)

" Entered for Consumption" means that an entry summary for consumption has been filed with CBP in proper form, with estimated duties attached. The duty can be submitted electronically at the same time as the entry is transmitted, or on a 15-day schedule when approved by CBP. A consumption entry is a type of entry used when goods are imported for use in the United States and going directly into U.S. commerce without any time or use restrictions placed on them. "For use in the United States" means for commercial, business, or personal purposes.

6.9.13 – Conditional Release

Entry/Immediate Delivery must be filed within 15 calendar days of arrival of goods in the United States. Goods may be released for immediate delivery if they are arriving by land from Canada or Mexico. Products may be released for immediate delivery pending entry process completion. Even though CBP has allowed the immediate delivery, any FDA-regulated products are conditionally released until the FDA makes an admissibility decision. The conditional release period ends when the FDA "May Proceeds" the entry or issues a refusal. The goods may be moved but CBP can request redelivery within 30 days.

6.9.14 – Container Freight Station (CFS)

Another location authorized to receive goods under U.S. Customs Bond for the purpose of breaking bulk and redelivery of cargo. Containerized cargo can be moved from the place of unlading to a designated container station or may be received directly at the container station from a bonded carrier after transportation in-bond, before the filing of an entry of goods.

6.9.15 – Customs Bonded Warehouse (CBW)

One of several classes of CBP Warehouses authorized to receive goods that have not been entered into U.S. commerce. Goods are entered into a Customs Bonded Warehouse (CBW) by a "formal entry" or "warehouse entry" requiring complete documentation for the entry, and payment of a fee, but not payment of duty and taxes. Goods in the warehouse can be held for up to five years. After five years, the goods must be entered, exported, or destroyed. Goods in a CBW can be manipulated, but except in certain smelting operations, cannot be manufactured into something else. If the CBW is located in the United States, the goods are in interstate commerce and subject to the FD&C Act. (See CPG Sec. 110.600 FDA Authority Over Products of Foreign Origin Located in Foreign Trade Zones, Bonded Warehouses or on Bonded Carriers.)

6.9.16 – Data Universal Number System (DUNS)

A unique nine-digit business identification number provided by the company Dun & Bradstreet (D&B). Upon request, D&B will assign a DUNS number for each physical location of a business.

6.9.17 – Date Collected

The date an import sample is collected.

6.9.18 – Date of Arrival

The date a carrier transporting imported cargo arrives in the United States.

6.9.19 – Date of Availability

The date imported cargo is available/accessible for examination by the FDA. Note that goods may not be available for examination as soon as they arrive in the United States, due to the way the items have been shipped/stored.

6.9.20 – Detention Recommendation (DTR)

Used when review of the entry information cannot confirm that products being offered for import meet FDA's admissibility criteria. Examples include products in which the required registration, scheduled process filing, 510(k), or pre-market approval (PMA) cannot be verified at the entry review step.

6.9.21 – Detention

A temporary administrative action taken by the FDA against articles offered for entry which are not or appear not to be in-compliance with the laws the FDA administers. Detained articles can be released if brought into compliance, or are refused entry or seized, if not brought into compliance.

6.9.22 - Detention Without Physical Examination (DWPE)

An action directed against specific products manufactured or shipped by specific foreign firms. "Import Alerts" list products that may be detained without physical examination due to their violative history or potential.

6.9.23 - Detention and Hearing Process

The opportunity for an importer or designee to present evidence, or testimony, to overcome the appearance of a violation and to give the FDA confidence that the product is in compliance. This information is provided to the FDA compliance officer listed on the Notice of Detention and Hearing. The evidence must be provided during the hearing period. The format for providing this evidence may vary from a series of email or telephone conversations to a more formal meeting.

6.9.24 - Domestic Import (DI) Sample

A sample of an imported article collected after it has been released from import status. (See IOM 4.1.4.2.5.)

6.9.25 – Entry

Delivery, or offer for delivery, of merchandise into the Customs Territory of the United States from an outside point.

6.9.26 – Entry Admissibility File

The file, in hard copy and/or electronic (whichever is appropriate) maintained by the Division that contains relevant documentation to support the Division's admissibility decision.

6.9.27 - Entry Documents (Entry Package)

Information submitted to CBP to determine the goods quantity, its contents, and the parties of interest. Actual documentation for an individual entry can vary greatly, but it generally consists of an invoice, purchase order, AWB and/or BOL. Entry documents can be submitted electronically to the FDA, preferably through the Import Trade Auxiliary Communications System (ITACS) or via paper submission.

6.9.28 – Entry Line Item

Each portion of an entry that is listed as a separate item in an entry. An importer may identify merchandise in an entry in multiple portions; however, an item in the entry having a different tariff description must be listed separately. (See IOM 6.7.27)

6.9.29 – Establishment

A place of business or residence, including all equipment essential to such business or residence, identified, and defined accordingly as the following:

- Grower: Raises livestock, raw agricultural products, or aquaculture products for sale, via farms, feedlots, dairy farms, and botanical farms/operations).
- Manufacturer: The site-specific location where the product is manufactured, produced, or grown.
- Packer/repacker: Packs a product, or products, into different containers without making any change in the form of the product. Includes packers of raw agricultural products and medical gas repackers.
- Producer: A person who grows, mines, harvests, fishes, traps, hunts, manufactures, processes, or assembles a product.
- Salvage Operation: An establishment dealing primarily in the reconditioning and resale of damaged goods.
- Shipper: Firm or individual responsible for introducing merchandise into interstate commerce by way of transport who does not act as a manufacturer, repacker, or distributor.
- Warehouse: A private or public facility for the storage of consumer products, including products reshipped from the producer or grower to the manufacturer or other customer.

6.9.30 – Failure to Hold

Failure to hold means that the goods have been distributed by the importer/consignee without an FDA release from import status. Such goods are usually subject to CBP's redelivery provisions. (See IOM 6.7.31 – REDELIVERY BOND.)

6.9.31 – FDA Import Systems

System for Entry Review and Imports Operations (SERIO) – SERIO is a 24/7/365 mission-critical system that supports the FDA's surveillance and regulatory enforcement of import products into the nation. It provides a web browser interface, as well as back-end services to process business logic. SERIO is also available as a mobile application that can be installed on an FDA iOS device. This mobile application will securely communicate with the same back-end services that are available for the web browser interface.

Operational & Administrative System for Import Support (OASIS) – OASIS is a 24/7/365 mission-critical system that supports the FDA's surveillance and regulatory enforcement of import products into the nation.

6.9.32 – Field Examination, or FEX

A comprehensive physical examination to perform surveillance activities to determine admissibility, including activities performed as part of required reconciliation exam. FEX examples: can-by-can exams, bag-by-bag exams for filth, and/or organoleptic examinations for decomposition to determine if a sample collection is indicated.

6.9.33 – Filer

A CBP term used to identify the individual or firm responsible for filing an entry. Also known as a Customs House Broker.

6.9.34 – Filer Evaluation

To determine the quality and accuracy of data that filers are submitting, the agency conducts periodic filer audits. This evaluation informs both the filer and the FDA about the overall performance of the filer.

6.9.35 – Filer Misdeclaration

Refers to the importer's provision of correct information to the filer, who then files an erroneous entry to the FDA and CBP. (IOM 6.6.4.6)

6.9.36 – Food Safety Modernization Act (FSMA)

The FDA Food Safety Modernization Act (Pub. L. 111-353) enables the agency to better protect public health by strengthening the food safety system. It enables FDA to focus more on preventing food safety problems rather than relying primarily on reacting to problems after they occur. The law also provides the FDA with new enforcement authorities designed to achieve higher rates of compliance with prevention and risk-based food safety standards, and to

better respond to and contain problems when they do occur. The law also provides the FDA with important new tools to hold imported foods to the same standards as domestic foods and directs the FDA to build an integrated national food safety system in partnership with federal, state, local, tribal, and territorial authorities.

6.9.37 – Foreign Supplier Verification Program (FSVP)

A program that importers covered by the rule must have in place to verify that their foreign suppliers are producing food in a manner that provides the same level of public health protection as U.S. safety standards--including the use of preventive controls or produce safety regulations as appropriate--and to ensure that the supplier's food is not adulterated and is not misbranded with respect to allergen labeling.

6.9.38 – Formal Entry

The entry type required for shipments valued over $2500, or for shipments containing specific commodities designated by CBP. Formal entry is usually a three-step process in which:

1. "Entry" gains the release of the goods from CBP control,
2. "Entry Summary" includes determination of the classification and collection of the duty/taxes owed.
3. "Liquidation" finalizes the entry process and CBP changes to classification and monies owed.

6.9.39 – Foreign Trade Zones, or FTZ

Zones established under the Foreign Trade Zones Act. Goods properly admitted into an FTZ are considered outside the territory of the United States for the purposes of duty and taxes. Several classes of goods are present in an FTZ at any one time. Some of these classes provide duty advantages when the goods are eventually entered into U.S. commerce. Other classes of goods are prohibited by law from entering the commerce and must be exported or destroyed. There is no time limit on how long goods can remain in an FTZ without entry or export. Note that if the FTZ is located in the United States, the goods are in interstate commerce and subject to the FD&C Act. (See CPG Sec. 110.200 Export of FDA Regulated Products from U.S. Foreign Trade Zones)

6.9.40 – FSVP and/or HACCP Importer

The importer who, for a specific food, is subject to the importer requirements in FDA's FSVP regulation (21 CFR part 1, subpart L), or the requirements applicable to importers in the juice or seafood HACCP regulations (21 CFR 120.14 and 123.12, respectively). Under both the FSVP and the HACCP importer regulations, the importer is the U.S. owner or consignee at the time of entry into the United States or the U.S. agent or representative of the foreign owner or consignee at the time of entry into the United States (21 CFR 1.500 (FSVP)); (21 CFR 120.3(h) (juice HACCP)); and (21 CFR 123.3(g) (seafood HACCP)). An FSVP or HACCP importer must be physically located in the United States. When the FSVP or HACCP importer for a food is a U.S. agent or representative for the foreign owner or consignee, the U.S. agent or representative is responsible for meeting the FSVP or HACCP requirements with respect to that food.

6.9.41 – Immediate Delivery (ID)/ Conditional Release

Entry/Immediate Delivery (CF 3461) must be filed within 15 calendar days of arrival of goods in the United States. Goods may be released for immediate delivery if they are arriving by land from Canada and Mexico. Products may be released for immediate delivery pending entry process completion. Even though CBP has allowed the immediate delivery, any FDA-regulated products will be conditionally released until the agency makes an admissibility decision. The conditional release period ends when FDA "May Proceeds" the entry or issues a refusal.

6.9.42 – Import Alerts

Guidance documents concerning significant re-occurring, new, or unusual problems affecting import coverage. They can be found online here.
https://www.fda.gov/ForIndustry/ImportProgram/ActionsEnforcement/ImportAlerts/default.htm

6.9.43 – Importer of Record

The party in whose name the entry is made. Note that, for example, a Customs House Broker might make an entry and become the "importer of record" by using their importer ID and bond on behalf of their client, the true "importer" of the goods. For FDA purposes, the "importer of record" is the person or company filing the redelivery bond under Sections 802(b)and 536(b) of the FD&C Act [21 U.S.C. 382(b) and 360mm(b)].

6.9.44 – Import Refusal

FDA's final decision that a detained shipment is in violation of FDA laws and regulations. A refused shipment must either be destroyed or exported under the supervision of CBP and the FDA within 90 days of the date of the Notice of FDA Action (Refusal Notice).

6.9.45 – Import Sections

Import Sections 536, 801 and 802 are those sections of the FD&C Act containing the Import/Export Provisions.

6.9.46 – Import Status

The standing, or status, of an article in the import database system that has not yet been released.

6.9.47 – Importer Misdeclaration

Refers to the importer's providing incorrect and/or incomplete information to the FDA and CBP, usually via the filer. This misdeclaration may include incorrect product codes and/or product descriptions; incorrect/incomplete manufacturer/shipper name/address; and/or incorrect quantity and value. It may occur as an attempt to avoid FDA and/or CBP actions/regulations, such as DWPE, sampling, duties, etc.

6.9.48 – Informal Entry

A simplified import entry procedure accepted at the option of CBP for any shipment not exceeding a specified value. Informal entries are filed with complete paperwork and any duties and taxes are paid at the time of filing. The entry liquidates at time of filing.

6.9.49 – Immediate Transportation (IT)

An entry document filed with CBP by the importer that allows the immediate transport of goods without a determination of admissibility, from the port of unloading under CBP bond. In general, the importer must file a consumption entry within six months of the date of importation or export the goods. The FDA typically examines these goods at an inland port of entry.

6.9.50 – Import Trade Auxiliary Communication System (ITACS)

A system that provides the import trade community with four functions: the ability to check the status of FDA-regulated entries and lines, the ability to submit entry documentation electronically, the ability to electronically submit the location of goods availability for those lines targeted for FDA exam, and the ability to check the estimated laboratory analysis completion dates for lines which have been sampled. ITACS account management functionality enables the electronic distribution of Notices of FDA Action via email and as downloads from within ITACS.

6.9.51 – Label Examination

Surveillance activities in the field to determine admissibility of a product based on a label/labeling examination performed on the physical product.

6.9.52 - Line (Line Item)

A line is each portion of an entry which is listed as a separate item on an entry document. An importer may identify goods in an entry in as many portions as they choose, except for items in the entry having a different tariff description and rate, which must be listed separately.

6.9.53 – Lot

A lot is an entry, group of entries, or a portion of an entry of goods that can clearly be defined as appropriate for FDA sampling and examination purposes.

6.9.54 – Mail Entry

Merchandise offered for entry through the U.S. mail. In instances where the value of the merchandise is less than $2,500, an entry document is generally not required to be filed with CBP. Mail entries are often informal entries and do not generally require a bond to be filed with CBP. Industry guidance can be found here: https://www.fda.gov/forindustry/importprogram/importbasics/ucm432659.htm

6.9.55 – Marks

Words or symbols, usually including the country of origin, that marked on cartons, bags, and other containers of imported goods for identification purposes. Marks are a CBP requirement.

6.9.56 – May Proceed

The release performed after identifying and determining the line/entry meets certain admissibility requirements. This means the product can be distributed into U.S. commerce. However, a release does not preclude future FDA action if a problem is found later.

6.9.57 – Notice of FDA Action

Gives notice to the owner, operator, or agent- n-charge of an imported product, providing more specific information on the actions taken by the agency, broken down by each entry line (including, "sample collected," "intended for sampling," "detained," "released," or "refused"). The notice provides notification of the right to a hearing on the detention of a product which appears violative to the FDA, or for the administrative destruction of a drug. The notice identifies the charges for which the product appears violative.

6.9.58 – Personal Baggage Entry

Entry of merchandise by personal baggage.

6.9.59 – Personal Import Policy (PIP)

Instructions to FDA staff for handling personal-use quantities of FDA-regulated imported products encountered in personal baggage and mail shipments, to best protect consumers with a reasonable expenditure of resources.

6.9.60 – Port (Point) of Entry

The CBP location where the Consumption Entry is made. This may or may not be at the Port of Unloading (the point of physical entry into the United States).

6.9.61 – Predictive Risk- based Evaluation for Dynamic Import Compliance Targeting (PREDICT)

A risk-based analytics tool that the FDA uses to electronically screen all regulated shipments imported or offered for import into the United States.

6.9.62 – Prior Notice

In the case of an article of food that is being imported or offered for import into the United States, a notice provided to the FDA prior to entry in the United States, with information about the article, manufacturer, shipper, grower, the country of origin, and anticipated port of entry. Prior notice must be submitted to the FDA electronically, via either the CBP Automated Commercial Environment (ACE) or the FDA Prior Notice System Interface (FDA PNSI). (Prior Notice of Imported Food Guidance for Industry)

6.9.63 – Private Laboratory

Independent laboratories providing analytical services to importers, customshouse brokers, and others.

6.9.64 – Product Code

An FDA product code describing a specific product and containing a combination of five to seven numbers and letters. The product code submitted with each FDA line item should match the actual product name and/or invoice description of the product.

6.9.65 – Reconditioning

When a product is detained because it violates FDA laws and regulations, the importer of record may submit an application to the agency requesting permission to re-label or recondition the product in an attempt to bring it into compliance.

6.9.66 – Redelivery Bond (AKA Entry Bond) -

A bond posted by the importer of record with CBP. For FDA-regulated products, this is currently in the amount of three times the value of the imported product, to insure redelivery of the product for examination, reconditioning, export, or destruction.

6.9.67 – Re-export

A term used to identify goods shipped out of the United States after being offered for entry. This is not the same as an export of U.S. manufactured goods and is not covered by the restrictions in Section 801(e) of the FD&C Act.

6.9.68 – Relabeling -

The process of modifying labeling in order to come into compliance with FDA regulations. Relabeling is considered a form of reconditioning.

6.9.69 – Release with Comment -

An FDA compliance action releasing goods into interstate commerce advising the importer of violations with the FD&C Act that are not a health risk to the public. It also advises that future entries which continue to violate the Act may be refused.

6.9.70 – Sample/Product Collection (SAM)

SAM is a physical collection of product in the field with a subsequent analysis submitted to an FDA servicing laboratory, or a documentary sample where the sample evaluation is based upon the documents accompanying the product.

6.9.71 – Section 321 (De Minimis)

The process by which cargo can be imported by one person on one day, as cited in 19 CFR 10.151. The value of the imported cargo may be free of duties and taxes when valued at 800 U.S. dollars or less.

6.9.72 - Stripping (Of Containers)

The removal of articles from a transportation container for examination or sampling.

6.9.73 – Substitution

An attempt by the importer/consignee to present goods to the FDA as corresponding to a particular entry when they are in fact not the goods from that entry. May occur as an attempt to hide distribution without an FDA release and avoid CBP bond actions. (See IOM 6.7.15, FAILURE TO HOLD.)

6.9.74 – Supervisory Charges

Supervisory charges are the charges associated with FDA supervision of the reconditioning and examination of articles

after detention. (See 21 CFR 1.99).

6.9.75 – Testimony

An individual's statement given in writing (such as an affidavit or a declaration) or by appearance under oath at a proceeding. The statement might be in response to a deposition or interrogation. Testimony is covered by 21 CFR 20.1. Testimony may also be information a firm submits to overcome the appearance of the violation, or to otherwise support the release of their product. Testimony should be provided to the contact listed on the FDA Notice of Action, which is usually a compliance officer. It can be provided in person, or via email, telephone, fax, hard copy.

6.9.76 – VQIP Quality Assurance Program (QAP)

A compilation of the written policies and procedures used to ensure adequate control over the safety and security of the foods being imported by the VQIP importer. Any format can be used to organize the QAP to include all foods and all of the written policies and procedures under VQIP.

6.9.77 – Warehouse Entry (WE)

An entry document filed with CBP by the importer which allows the goods to go immediately into a bonded warehouse.

6-9.78 – Relabler

Relabeler - Changes the content of the labeling from that supplied from the original manufacturer for distribution under the establishment's own name.

6-1 Notice of FDA Action

EXAMPLE

United States Food and Drug Administration

Division of Southeast Imports

Notice of FDA Action

Entry Number: F21-6048076-0

Notice Number: 1
April 14, 2023

Importer:
Fan Marino Inc 14807 Nw
46nd Ave
Baltimore, FL 55054-0000

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Port of Entry:	5201, Miami, FL
Carrier:	LAMINA GRANDE LTD;
Date Received:	April 14, 2023
Arrival Date:	April 16, 2023
Filer of Record	Big Filer Company., Miramar, FL 44122-1907
Consignee:	Transfer Recive, Davie, FL 66172-0000

HOLD DESIGNATED

Documents Required and Notify FDA of Availability

Summary of Current Status of Individual Lines

Line ACS/ACE/FDA	Product Description	Quantity	Current Status
11/1	FRESH SNOWPEAS	1600 CT	Pending FDA Review 04-14-2023
11/2	FRESH SUGAR PEAS	1640 CT	Pending FDA Review 04-14-2023

* = Status change since the previous notice. Read carefully the sections which follow for important information regarding these lines.

@ = Consignee ID

FDA will not request redelivery for examination or sampling, if the products not released by FDA are moved, following Customs conditional release to a location within the local metropolitan area or to a location approved by the FDA.

All products in this entry not listed above may proceed without FDA examination. This notice does not constitute assurance the products involved comply with provisions of the Food, Drug, and Cosmetic Act or other related acts, and does not preclude action should the products later be found violative.

Please provide documentation concerning all products in this entry to the FDA. Include the Customs Entry document (e.g. CF-3461 or CF-7501), bill of lading/airway bill, and commercial invoice for these products, annotated to show the Customs/FDA line numbers sent electronically.

Notice of FDA Action
Entry Number: F21-6048076-0

Notice Number 1
Page: 2

Also, advise FDA upon actual availability, and include location and location identifiers, where applicable, for all lines in this entry.

FDA's Import Trade Auxiliary Communication System (ITACS) is the preferred method for submission of entry documents and availability information. This submission will automatically link the documents and availability information to the entry in FDA's admissibility system and will facilitate FDA's processing of entries. ITACS may be accessed at https://itacs.fda.gov.

Jose Galan, Investigator
U.S. Food and Drug Administration
1800 Eller Drive, Suite 200
Fort Lauderdale, FL 33316

(954) 782-7816
(954) 782-3384 (FAX)
JOSE.GALAN@FDA.HHS.GOV

Notice Prepared For: The Division Director, U.S. Food and Drug Administration
Notice Prepared By: FOX

This example of a Notice of FDA Action is a model and should not be considered all inclusive. The format and wording in the actual Notice of FDA Action issued by FDA from their Import Systems may appear different.

EXAMPLE

United States Food and Drug Administration

Division of Southeast Imports

Notice of FDA Action

Entry Number: F21-6048076-0

Notice Number: 2
April 18, 2023

Importer:
Fan Marino Inc 14807 Nw
46nd Ave
Baltimore, FL 55054-0000

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Port of Entry:	5201, Miami, FL
Carrier:	LAMINA GRANDE LTD;
Date Received:	April 14, 2023
Arrival Date:	April 16, 2023
Filer of Record	Big Filer Company., Miramar, FL 44122-1907 Transfer Recive,
Consignee:	Davie, FL 66172-0000

HOLD DESIGNATED

Documents Required and Notify FDA of Availability

Summary of Current Status of Individual Lines

Line	ACS/ACE/FDA	Product Description	Quantity	Current Status
*	11/1	FRESH SNOWPEAS	1600 CT	Product Collected by FDA 04-18-2023
*	11/2	FRESH SUGAR PEAS	1640 CT	Product Collected by FDA 04-18-2023

* = Status change since the previous notice. Read carefully the sections which follow for important information regarding these lines.

@ = Consignee ID

FDA will not request redelivery for examination or sampling, if the products not released by FDA are moved, following Customs conditional release to a location within the local metropolitan area or to a location approved by the FDA.

All products in this entry not listed above may proceed without FDA examination. This notice does not constitute assurance the products involved comply with provisions of the Food, Drug, and Cosmetic Act or other related acts, and does not preclude action should the products later be found violative.

Please provide documentation concerning all products in this entry to the FDA. Include the Customs Entry document (e.g. CF-3461 or CF-7501), bill of lading/airway bill, and commercial invoice for these products, annotated to show the Customs/FDA line numbers sent electronically.

Notice of FDA Action
Entry Number: F21-6048076-0

Notice Number 2
Page: 2

Also, advise FDA upon actual availability, and include location and location identifiers, where applicable, for all lines in this entry.

FDA's Import Trade Auxiliary Communication System (ITACS) is the preferred method for submission of entry documents and availability information. This submission will automatically link the documents and availability information to the entry in FDA's admissibility system and will facilitate FDA's processing of entries. ITACS may be accessed at https://itacs.fda.gov.

Jose Galan, Investigator
U.S. Food and Drug Administration
1800 Eller Drive, Suite 200
Fort Lauderdale, FL 33316

(954) 782-7816
(954) 782-3384 (FAX)
JOSE.GALAN@FDA.HHS.GOV

SAMPLES COLLECTED

Line ACS/ACE/FDA	Product Description	Est. Cost
11/1	FRESH SNOWPEAS	$1.22
Sample :	1 KG - Collected 1 approx 2.2 lb sub of Fresh Snowpeas from 1 carton s/a/r from a total lot of 1600 Cartons.	
11/2	FRESH SUGAR PEAS	$1.44
Sample :	1 KG - Collected 1 approx 2.2 lb sub of Fresh Sugar Peas from 1 carton s/a/r from a total lot of 1640 Cartons.	

Notice Prepared For: The Division Director, U.S. Food and Drug Administration
Notice Prepared By: FOX

This example of a Notice of FDA Action is a model and should not be considered all inclusive. The format and wording in the actual Notice of FDA Action issued by FDA from their Import Systems may appear different.

EXAMPLE

United States Food and Drug Administration

Division of Southeast Imports

Notice of FDA Action

Entry Number: F21-6048076-0

Notice Number: 3
April 27, 2023

Importer:
Fan Marino Inc 14807 Nw
46nd Ave
Baltimore, FL 55054-0000

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Port of Entry:	5201, Miami, FL
Carrier:	LAMINA GRANDE LTD;
Date Received:	April 14, 2023
Arrival Date:	April 16, 2023
Filer of Record	Big Filer Company., Miramar, FL 44122-1907 Transfer Recive,
Consignee:	Davie, FL 66172-0000

HOLD DESIGNATED

Documents Required and Notify FDA of Availability

Summary of Current Status of Individual Lines

Line	ACS/ACE/FDA	Product Description	Quantity	Current Status
*	11/1	FRESH SNOWPEAS	1600 CT	Detained 04-26-2023
*	11/2	FRESH SUGAR PEAS	1640 CT	Released 04-26-2023

* = Status change since the previous notice. Read carefully the sections which follow for important information regarding these lines.

@ = Consignee ID

FDA will not request redelivery for examination or sampling, if the products not released by FDA are moved, following Customs conditional release to a location within the local metropolitan area or to a location approved by the FDA.

All products in this entry not listed above may proceed without FDA examination. This notice does not constitute assurance the products involved comply with provisions of the Food, Drug, and Cosmetic Act or other related acts, and does not preclude action should the products later be found violative.

Please provide documentation concerning all products in this entry to the FDA. Include the Customs Entry document (e.g. CF-3461 or CF-7501), bill of lading/airway bill, and commercial invoice for these products, annotated to show the Customs/FDA line numbers sent electronically.

Also, advise FDA upon actual availability, and include location and location identifiers, where applicable, for all lines in this entry.

Notice of FDA Action
Entry Number: F21-6048076-0

Notice Number 3
Page: 2

FDA's Import Trade Auxiliary Communication System (ITACS) is the preferred method for submission of entry documents and availability information. This submission will automatically link the documents and availability information to the entry in FDA's admissibility system and will facilitate FDA's processing of entries. ITACS may be accessed at https://itacs.fda.gov.

DETENTION

The following products are subject to refusal pursuant to the Federal Food Drug and Cosmetic Act (FD&CA), Public Health Service Act (PHSA),or other related acts in that they appear to be adulterated, misbranded or otherwise in violation as indicated below:

Line ACS/ACE/FDA	Product Description	Respond By
11/1	FRESH SNOWPEAS	May 16, 2023

FD&CA Section 402(a)(2)(B), 801(a)(3); ADULTERATION
The article is subject to refusal of admission pursuant to Section 801(a)(3) in that it appears to bear or contain a pesticide chemical residue, which causes the article to be adulterated within the meaning of section 402(a)(2)(B) of the FD&C Act. Bears or contains: Sample was found positive to tebuconazole.

Please direct your response to:

Chago Martinez, Compliance Officer U.S.
Food and Drug Administration
15100 NW 67 Ave, Suite 400
Miami, FL 33014

(305) 444-1248

CHAGO.MARTINEZ@FDA.HHS.GOV

You have the right to provide oral or written testimony, to the Food & Drug Administration, regarding the admissibility of the article(s) or the manner in which the article(s) can be brought into compliance. This testimony must be provided to FDA on or before the dates shown above.

LINES RELEASED

Line ACS/ACE/FDA	Product Description
11/2	FRESH SUGAR PEAS

Chago Martinez, Compliance Officer U.S.
Food and Drug Administration
15100 NW 67 Ave, Suite 400
Miami, FL 33014

(305) 444-1248

CHAGO.MARTINEZ@FDA.HHS.GOV

These products are released. This notice does not constitute assurance that the product released complies with all provisions of the Food, Drug, and Cosmetic Act, or other related Acts, and does not preclude action should the product later be found violative.

Notice Prepared For: The Division Director, U.S. Food and Drug Administration
Notice Prepared By: SFF

This example of a Notice of FDA Action is a model and should not be considered all inclusive. The format and wording in the actual Notice of FDA Action issued by FDA from their Import Systems may appear different.

EXAMPLE

United States Food and Drug Administration

Division of Southeast Imports

Notice of FDA Action

Entry Number: F21-6048076-0

Notice Number: 4
May 18, 2023

Importer:
Fan Marino Inc 14807 Nw
46nd Ave
Baltimore, FL 55054-0000

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Port of Entry:	5201, Miami, FL
Carrier:	LAMINA GRANDE LTD;
Date Received:	April 14, 2023
Arrival Date:	April 16, 2023
Filer of Record	Big Filer Company., Miramar, FL 44122-1907 Transfer Recive,
Consignee:	Davie, FL 66172-0000

HOLD DESIGNATED

Documents Required and Notify FDA of Availability

Summary of Current Status of Individual Lines

Line	ACS/ACE/FDA	Product Description	Quantity	Current Status
*	11/1	FRESH SNOWPEAS	1600 CT	Refuse 05-17-2023
	11/2	FRESH SUGAR PEAS	1640 CT	Released 04-26-2023

* = Status change since the previous notice. Read carefully the sections which follow for important information regarding these lines.

@ = Consignee ID

FDA will not request redelivery for examination or sampling, if the products not released by FDA are moved, following Customs conditional release to a location within the local metropolitan area or to a location approved by the FDA.

All products in this entry not listed above may proceed without FDA examination. This notice does not constitute assurance the products involved comply with provisions of the Food, Drug, and Cosmetic Act or other related acts, and does not preclude action should the products later be found violative.

Please provide documentation concerning all products in this entry to the FDA. Include the Customs Entry document (e.g. CF-3461 or CF-7501), bill of lading/airway bill, and commercial invoice for these products, annotated to show the Customs/FDA line numbers sent electronically.

Also, advise FDA upon actual availability, and include location and location identifiers, where applicable, for all lines in this entry.

Notice of FDA Action Notice Number: 4
Entry Number: F21-6048076-0 Page: 2

FDA's Import Trade Auxiliary Communication System (ITACS) is the preferred method for submission of entry documents and availability information. This submission will automatically link the documents and availability information to the entry in FDA's admissibility system and will facilitate FDA's processing of entries. ITACS may be accessed at https://itacs.fda.gov.

REFUSAL OF ADMISSION

REDELIVERY WITH FDA VERIFICATION REQUESTED

Examination of the following products have been made and you have been afforded an opportunity to respond to a notice of detention. Because it appears that the products are not in compliance, you are hereby notified that they are refused admission.

Line ACS/ACE/FDA	Product Description
11/1	FRESH SNOWPEAS

Refused : 7,199 KG

FD&CA Section 402(a)(2)(B), 801(a)(3); ADULTERATION
The article is subject to refusal of admission pursuant to Section 801(a)(3) in that it appears to bear or contain a pesticide chemical residue, which causes the article to be adulterated within the meaning of section 402(a)(2)(B) of the FD&C Act. Bears or contains: Analytical results support the original analysis finding of 0.044 ppm tebuconazole in subject sample (LOQ: 0.010 ppm). There is no tolerance for tebuconazole in snowpeas as per 40 CFR 180.474

Additional residue detected ? violative:
0.103 Carbendazim: no tolerance for carbendazim in snowpeas as per 40CFR180.371

For the District Director of Customs:

Chago Martinez, Compliance Officer U.S.
Food and Drug Administration
15100 NW 67 Ave, Suite 400
Miami, FL 33014

(305) 816-1458

CHAGO.MARTINEZ@FDA.HHS.GOV

A request has been made to Customs to order redelivery for all the above product(s), in accordance with 19 CFR 141.113, which were conditionally released to you under terms of the entry bond. Failure to redeliver into Customs custody will result in a claim for liquidated damages under the provisions of the entry bond.

These products must be exported or destroyed under Customs supervision within 90 days from the date of this notice, or within such additional time as the Division Director of Custom specifies. Failure to do so may result in destruction of the products. Distribution of the products may result in their seizure and/or injunction or criminal prosecution of persons responsible for their distribution.

You are required to have FDA verify the identification, exportation, or destruction of the above products. Contact the individual listed above to arrange for the required verification.

After completion of the exportation or destruction forward the original of the signed CF-7512 or CF3499, along with any other documents required by Customs, and a copy of this notice to:

U.S. Customs and Border Protection
8731 NW 47th Street
Room 777, Team 300

Notice of FDA Action
Entry Number: F21-6048076-0

Notice Number: 4
Page: 3

Miami, FL 33122

In addition forward copies of the signed CF-7512 or CF-3499, and any other records which document export or destruction, to the individual listed above.

Notice Prepared For: The Division Director, U.S. Food and Drug Administration
Notice Prepared By: BBB

This example of a Notice of FDA Action is a model and should not be considered all inclusive. The format and wording in the actual Notice of FDA Action issued by FDA from their Import Systems may appear different.

6-2 FORM FDA 766 – Application for Authorization to Relabel or Recondition Non-Compliant Articles

APPLICATION FOR AUTHORIZATION TO RELABEL OR RECONDITION NON-COMPLIANT ARTICLES

FORM APPROVED: OMB No. 0910-0046
EXPIRATION DATE: 8/31/2026

Public reporting burden time for this collection of information is estimated to average .25 hour per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to the address to the right:

Department of Health and Human Services Food and Drug Administration Office of Chief Information Officer Paperwork Reduction Act (PRA) Staff *PRAStaff@fda.hhs.gov*

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

Please do NOT send your completed form to the above PRA Staff email address.

SECTION 1 Instructions for completing the FORM FDA-766 are found on pages 3 and 4.

1. TO: Director of _____ Division, Food and Drug Administration

2. APPLICATION DATE

3. ENTRY NO. AND LINE NO.

Application is hereby made for authorization to bring the article(s) below into compliance with the Federal Food, Drug, and Cosmetic Act and other related Act(s).

4. PRODUCT

5. QUANTITY

6. QUANTITY TO BE RECONDITIONED

7. PRODUCTION CODES

8. Redelivery bond has been posted by the applicant. The article(s) will be kept apart from all other article(s) and will be available for inspection at all reasonable times. The operations, if authorized, will be carried out at:

and will require about _____ days to complete. A detailed description of the method by which the article(s) will be brought into compliance is given in the space below:

We will pay all supervisory costs in accordance with current regulations.

9. APPLICANT AND FIRM NAME

10. ADDRESS OF FIRM

11. APPLICANT'S SIGNATURE

SECTION 2 - FDA ACTION ON APPLICATION

12. TO: *(Name and Address)*

13. DATE

14. Your application has been: ☐ Denied because: ☐ Approved with the following conditions:

Time limit within which to complete authorized operations: _____

When the authorized operations are completed, fill in the importer's certificate on the reverse side and return this notice to this office.

15. SIGNATURE OF DIVISION DIRECTOR

16. DIVISION

17. DATE

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SECTION 3 - IMPORTER'S CERTIFICATE

18. Location where reconditioning operation occurred	19. DATE

20a. I certify that the work to be performed under the authorization has been completed and the article(s) are now ready for inspection at: _____

20b. Contact Information: _____

21. The rejected portion is ready for the approved disposition under FDA or CBP supervision and is held at:

22. APPLICANT AND FIRM NAME	23. APPLICANT'S SIGNATURE

SECTION 4 - REPORT OF INVESTIGATOR / INSPECTOR

TO PORT DIRECTOR OR DIVISION DIRECTOR	24. DATE *(MM/DD/YYYY)*

25. I have examined the within-described article(s) and find them to be the identical article(s) described herein, and that they have been:

_____ on: _____, 20___,

as authorized, except:

SECTION 5 - DATA ON RECONDITIONED ARTICLE(S)

26. Acceptable Portion:

27. Rejections:

28. Loss (if any):

29. Did importer recondition entire shipment?

30. Time and cost of supervision:

31. INSPECTING OFFICER NAME	32. DATE *(MM/DD/YYYY)*

33. INSPECTING OFFICER SIGNATURE

6-3 Form FDA 790 Charges for Supervision

CHARGES FOR SUPERVISION

☐ Federal Food, Drug, and Cosmetic Act, Section 801 (b) and (c)
☐ 21 CFR 1005.24

TO: *(Insert Address)*	FROM: *(Insert Address)* DHHS
PORT DIRECTOR OF CUSTOMS	FOOD AND DRUG ADMINISTRATION

PRODUCT	FDA SAMPLE NO.
CARRIER	CBP ENTRY NO.
IMPORTER OF RECORD	ENTRY DATE
CONSIGNEE	

The following is a list of charges incurred by this Agency for supervision of operations performed in accordance with the above-designated Act or Regulation. You are requested to collect payment, including any expenses incurred by your Department, for deposit into Treasury Miscellaneous Receipts.
Under Section 801(c), default of payment shall constitute a lien against any future importation made by the owner or consignee.

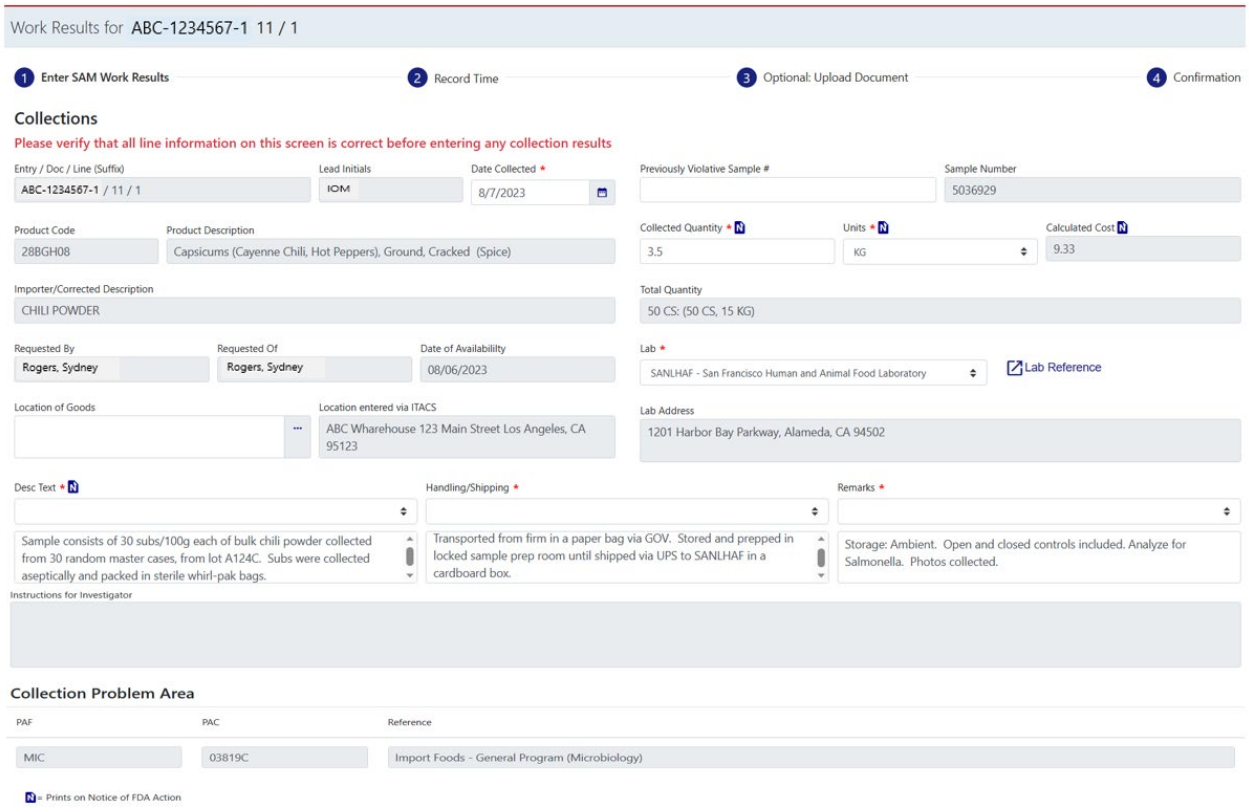
TYPE OF CHARGES	UNIT			CHARGE PER UNIT	TOTAL CHARGE
	HOURS	DAYS	MILES		
INVESTIGATORS TIME					
ANALYSTS TIME					
PER DIEM, PAID PER GOVERNMENT TRAVEL REGULATIONS					
AUTOMOBILE USE					
OTHER TRANSPORTATION EXPENSES *(Itemize)*					
MISCELLANEOUS EXPENSES *(Itemize)*					
GRAND TOTAL					

REMARKS

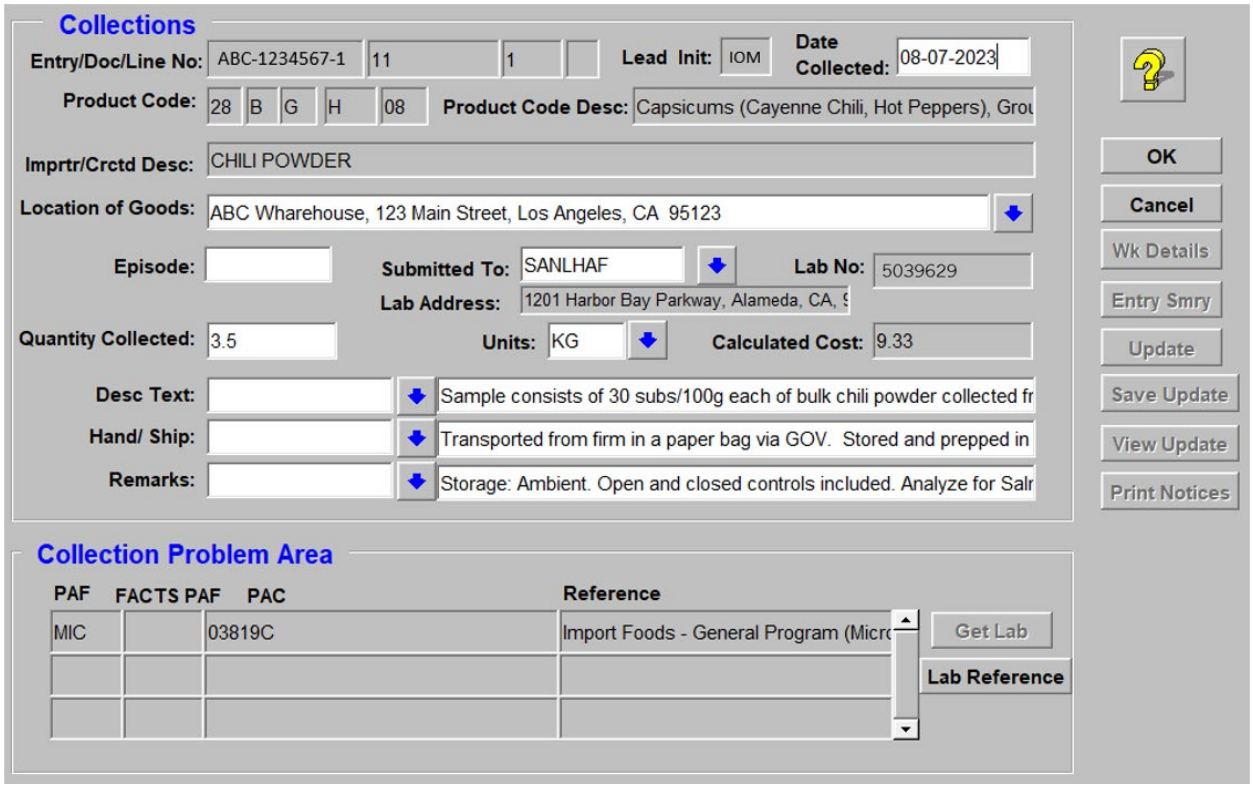
FORM FDA 790 (8/13) PREVIOUS EDITION MAY BE USED UNTIL SUPPLY IS EXHAUSTED. PSC Publishing Services (301) 443-6740 EF

6-4 Sample Collection in FDA Import Systems Screen Shot

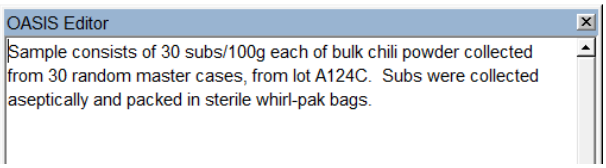
SERIO



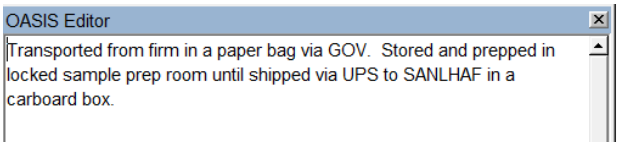
OASIS



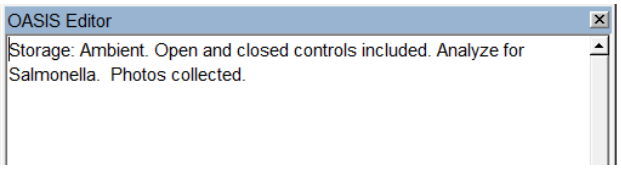
Desc Text:



Hand/Ship:



Remarks:



6-5 FORM FDA 463a AFFIDAVIT

AFFIDAVIT

SAMPLE NO.

STATE OF: Texas

COUNTY OF: Hunt

Before me, Sydney H. Rogers, an employee of the Department of Health and Human Services, Food and Drug Administration, designated by the Secretary, under authority of the Act of January 31, 1925, 43 Statutes at Large 803; Reorganization Plan No. IV, Secs. 12-15, effective June 30, 1940; Reorganization Plan No. 1 of 1953, Secs. 1-9, effective April 11, 1953; and P.L. 96-88, Sec. 509, 93 Statutes at Large 965 (20 U.S.C. 3508) effective May 4, 1980; to administer or take oaths, affirmations, and affidavits, personally appeared Felicia M. Rodriguez in the county and state aforesaid, who, being duly sworn, deposes and says:

I am the Import Manager for ABC Foods Warehouse, 234 Industry Avenue, Commerce, TX, where I have worked for about 3 years, and as such have knowledge of products imported, held, processed and/or shipped by my firm.

On 1/06/14, we received a shipment consisting of five 200 kg burlap bags of dried Ancho Peppers, manufactured by Del Campo, Extension Del Mina #4, Guadalajara, Mexico, covered by entry BAD-1234565-7.

On 1/08/14, my firm repacked this shipment of peppers into 25 kg burlap bags for distribution to restaurants and other customers.

On 1/13/14, Investigator Rogers visited my firm and showed me copies of documents including Customs form 3461 marked with the entry number of Entry BAD-1234565-7, Bill of Lading #2345RRR678, dated 1/03/14 and invoice 45678, dated 1/02/14. I am familiar with these documents and they cover the shipment of peppers my firm received.

Part of the repackaged peppers from Entry BAD-123456-7 were sold and distributed by my firm on 1/08/14. Three 25 kg burlap bags were shipped to John's Pepper House, 3456 First Avenue, Dallas, Texas; and two 25 kg bags were shipped to Casa De Juanita, 5678 Mulberry Drive, Fort Worth, Texas. I have identified and provided copies of the shipping documents that cover this distribution to Investigator Rogers. These documents are invoice 999888, dated 1/08/14 and UPS B/L 787878000009, dated 1/10/04 which covers the shipment to John's Pepper House and invoice 757575, 1/08/14 and UPS B/L 2323232323, 1/10/14 which covers the shipment to Casa De Juanita. The rest of the repackaged peppers remain at my firm.

I received the Customs and Border Protection release for this entry on 1/06/14 and I believed I could ship the product. I was informed by Investigator Rogers I was not supposed to ship the product until I received the FDA release. I will keep the remainder of the shipment intact.

I read this statement and agree it is true.

AFFIANT'S SIGNATURE AND TITLE: Felicia M. Rodriguez, Import Manager

FIRM'S NAME AND ADDRESS *(Include ZIP Code)*: ABC Foods Warehouse, 234 Industry Avenue, Commerce, TX 75428

Subscribed and sworn to before me at ABC Foods Warehouse, 234 Industry Avenue, Commerce, TX 75428 *(City and State)*,

this 13th **day of** January, **20** 14.

Sydney H. Rogers *(Employee's Signature)*

Employee of the Department of Health and Human Services designated under Act of January 31, 1925, Reorganization Plan IV effective June 30, 1940; Reorganization Plan No. 1 of 1953, effective April 11, 1953; and P.L. 96-88, effective May 4, 1980.

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SUBCHAPTER 7.1 - RECALLS

7.1.1 - DEFINITIONS

7.1.1.1 - Recall

A recall is a firm's removal or correction of a marketed product that the FDA considers to be in violation of the laws it administers and against which it would initiate legal action (e.g., seizure). Market withdrawals and stock recoveries are not considered recalls. See the FDA's recall policy outlined in 21 CFR 7.1/7.59- Enforcement Policy - General Provisions, Recalls (Including Product Corrections) - Guidance on Policy, Procedures and Industry Responsibilities.

7.1.1.2 - Recall Classification

Recall Classification is the numerical designation, i.e., I, II, or III, assigned by the FDA to a particular product recall to indicate the relative degree of health hazard presented by the product being recalled.

7.1.1.2.1 - CLASS I RECALL

Class I Recall is a situation in which there is a reasonable probability that the use of, or exposure to, a violative product will cause serious adverse health consequences or death.

7.1.1.2.2 - CLASS II RECALL

Class II Recall is a situation in which use of, or exposure to, a violative product may cause temporary or medically reversible adverse health consequences or where the probability of serious adverse health consequences is remote.

7.1.1.2.3 - CLASS III RECALL

Class III Recall is a situation in which use of, or exposure to, a violative product is not likely to cause adverse health consequences.

7.1.1.3 - Recall Type

Recall type is a designation based on whether the recall is Voluntary, FDA Requested (at the request of the Commissioner or his/her designee), or ordered under section 518(e) of the FD & C Act [21 U.S.C 360h (e)].

7.1.1.4 - Recall Strategy

Recall strategy is a planned specific course of action to be taken in conducting a specific recall, which addresses the

depth of recall, need for public warnings, and extent of effectiveness checks for the recall.

7.1.1.5 - Depth of Recall

Depending on the product's degree of hazard and extent of distribution, the recall strategy will specify the level in the distribution chain to which the recall is to extend, i.e., wholesaler, retailer, user/consumer, which is known as the depth of recall.

7.1.1.6 - Recall Number

The recall number is assigned by the responsible Center, for each recalled product it classifies. This number comprises a letter designating the responsible Center (see letter Codes below), a 3- or 4- digit sequential number indicating the number of recalls classified by that Center during the fiscal year, and a 4-digit number indicating the fiscal year the recall was classified. For example: F-100-2011 identifies the 100th recall classified by the Center for Food Safety and Applied Nutrition (CFSAN) in FY-2011. The following letters are used to identify the Centers.

Letter	Center/Office
F	Foods and Cosmetics - (CFSAN)
D	Drugs - (CDER)
Z	Medical Devices & Radiological Health – (CDRH)
V	Veterinary Medicine and animal food/feed - (CVM)
B	Biologics - (CBER)
N	Medical Devices (Voluntary Safety Alerts and Notifications)
T	Tobacco Products – (CTP)

7.1.1.7 - Medical Device Notification Order

A medical device notification order is an order issued by FDA requiring notification under section 518(a) of the FD&C Act [21 U.S.C. 360h (a)]. The directive issues when FDA determines a device in commercial distribution, and intended for human use, presents an unreasonable risk of substantial harm to the public health. The notification is necessary to eliminate such risk when a more practicable means is not available under the provisions of the Act.

7.1.1.8 - Medical Device Notification

A medical device notification is a communication issued by the manufacturer, distributor, or other responsible person in compliance with a Notification Order. It notifies health professionals, and other appropriate persons, of an unreasonable risk of substantial harm to the public health presented by a device in commercial distribution.

NOTE: Medical Device Notifications are to be handled by the divisions as recalls. They will go through the stages of alert, recommendation, classification, field notification, firm notification letter, firm effectiveness checks and status reports, FDA audit checks and termination recommendations.

7.1.1.9 - Medical Device Safety Alert

A medical device safety alert is a notification to device users that, under certain circumstances, use of or exposure to the device may pose a risk of harm (the exposure mentioned in this definition excludes electronic product radiation exposure - see 21 CFR Subchapter J). CDRH will only consider a notification to be a safety alert if the device is not violative. The notification alerts users of the associated risk and steps to be taken to reduce or eliminate the risk. Safety alerts will be entered in RES and processed accordingly.

7.1.1.10 Sub-Recall

A sub-recall is an action taken by a recalling firm's account to notify own-accounts/consignees of the recall where no changes were made to the recalled product.

If the recalling firm's account changes the recalled product (e.g. used the product as a component of a new product, re-labeled the product to obscure the original product name and/or lot code, repackaged the product, etc.) the account will have created a new product which could warrant a new recall instead of a sub-recall.

7.1.1.11 Consignee

A consignee is anyone who received, purchased, or used the product being recalled.

7.1.1.12 Account

The account is the location where the audit check is being done.

7.1.1.13 Division Recall Coordinator

Each Division has at least one Division Recall Coordinator who enters and monitors recalls. A list of Division Recall Coordinators and their contact information is at https://www.fda.gov/Safety/Recalls/IndustryGuidance/ucm129334.htm

7.1.1.14 Market Withdrawal

A market withdrawal is a firm's removal or correction of a distributed product for a minor violation that would not be subject to legal action by the FDA or that involves no violation (e.g., normal stock rotation practices, routine equipment adjustments, repairs, theft, etc.).

7.1.1.15 – Notification, Non-distribution, and Recall of Controlled Substances for Human or Animal Use Order

A controlled substance notification order is an order issued by FDA requiring non-distribution and the mandatory recall of controlled substances under section 569D of the Act [21 U.S.C. 360bbb-8d], as amended by section 3012 of the Substance Use-Disorder Prevention That Promotes Opioid Recovery and Treatment for Patients and Communities Act (SUPPORT ACT). Refer to Chapter 7 of the REGULATOY PROCEDURES MANUAL , 7-5-3 FDA Mandated Controlled and Ordered Recalls and Attachment K.

SUBCHAPTER 7.2 - RECALL NOTIFICATION / INSPECTION

7.2.1 - RECALL SCENARIOS ENCOUNTERED DURING INSPECTIONS

The Division Recall Coordinator (DRC) or designee sends a recall alert within one working day of receiving necessary information to the appropriate Center Recall Unit (CRU) and OSPOP/DE/ROB (Office of Strategic Planning and Operational Policy Division of Enforcement Recall Operations Branch) through the Recall Enterprise System (RES) with basic information regarding the recall. See RPM Chapter 7-10, Attachment A for a list of information for the recall alert.

A recommendation for recall classification is submitted through RES by the DRC or designee within five working days after the recalling firm has provided the information (10 days if the recall has already been completed). See RPM Chapter 7-10, Attachment B for a list of information for the recall recommendation.

Due to the potential public health impact of recalls, when you find a recall during your inspection it is imperative to submit any information obtained to your DRC as soon as possible. The Division should not wait for writing, typing and submission of the EIR or memorandum when sharing recall documents with the DRC or submitting the recall alert or recommendation.

If the firm has decided to initiate a recall during an inspection or investigation, you should prioritize the removal of potentially hazardous product. Coordinate with your DRC and SCSO to ensure the following tasks are completed:

1. Provide firm management with your DRC's contact information and request that management obtain their FDA Division's review of recall correspondence and any press releases before they are issued to prevent misunderstandings between the firm, its customers, and the FDA. An updated list of contact information for FDA's DRCs can be found at https://www.fda.gov/safety/industry-guidance-recalls/ora-recall-coordinators;
2. At the firm's request, provide guidance in preparing recall communications and obtain complete copies including the text of phone conversations to submit to your DRC. See Chapter 7 of the RPM, Industry Guidance for Recalls, and IOM Exhibit 7-1 for an example of recall communications;
3. Obtain a complete distribution list of all shipments of the lot(s) involved, including foreign distribution;
4. Obtain copies of all labels and labeling associated with the recalled product(s) and any documentation of what led to the recall;
5. Advise the firm on how the returned products should be handled. Sometimes FDA will witness or otherwise verify the reconditioning or destruction of the products returned under the recall;
6. Obtain an Official Sample of the recalled product when necessary (See IOM 7.2.7);
7. Obtain as much information in the RPM Chapter 7, Attachment B as time allows; and
8. Take any other steps necessary in your judgment, or that your Division requires.

7.2.1.1 – Firm Has Used Recalled Product to Manufacture New Product

If you are conducting an inspection or investigation at a firm who has received recalled product and used it in the production of a new product, or has relabeled recalled product, it may warrant the initiation of a new recall. Collect documentation on how the recalled product was manipulated, including finished product labels, to provide to your DRC immediately. If there is question about the potential hazard or violation of the new product, discuss the situation with your DRC and SCSO prior to discussing the initiation of a new recall with the firm.

7.2.1.1.1 – Potential New Food Recalls

For potential new food recalls, the following are some areas to be covered:

1. Incoming ingredient quality control procedures;
2. Quality control over ingredients at the time of use, and the products in which the ingredients are used;
3. A detailed description of the methods used in preparation and packaging of the processed product;
4. How the finished product is stored and shipped;
5. Labeling of product, and any cooking instructions for consumer or purchaser;
6. Quality control testing of the finished product. Detail any test(s) performed by firm; and
7. For products produced in USDA plants, determine if the USDA was notified of the suspect incoming ingredient? Did USDA determine what testing was done by the firm?

7.2.1.2 – Learning of Completed Recalls During Your Inspection

If you are conducting an inspection and learn that a recall has occurred, obtain the following from the firm to provide to your DRC:

1. Complete copies of recall communications including the text of phone conversations;
2. Complete distribution list of all shipments of the recalled lot(s), including foreign distribution;
3. Specimens or copies of all labels and labeling associated with the recalled product(s); and
4. Take any other steps necessary in your judgment, or that your division requires.

This information should be shared immediately. Do not wait until the submission of the EIR to notify the DRC that a recall has taken place.

7.2.2 – ROOT CAUSE INSPECTIONS

If FDA learns of a potentially violative product that may cause or has caused a class I or significant class II recall, an inspection may be assigned to determine the root cause(s) of the problem(s). Deficiencies in the firm's corrective and preventive action should be documented as violations subject to possible regulatory action.

An important objective of the inspection is to identify the root cause for the recall and assure the firm has implemented effective corrective actions to eliminate its recurrence. In some cases, firm management will have conducted its own analysis and reached conclusions about the problem and its root cause. It is important to verify that the firm's conclusions and judgments, about the root cause of the problem that led to the recall, are discriminating enough to identify the true cause(s) and steps taken are sufficient in depth and scope. Without identifying the true root cause, it will be difficult for the firm to implement an effective corrective action.

Determine if the firm conducted a failure analysis using quality tools such as cause-and-effect diagrams (i.e., fishbone diagram or Ishikawa diagram), fault tree analysis (FTA), or failure mode and effects analysis (FMEA). Determine if the following variables were considered; 1) the length of time since the product had been manufactured and sold; 2) complaints or returns for the same or similar problems; 3) reworking of the product prior to release or distribution that may have been due to the same or similar problems; and 4) process or personnel changes which occurred about the time the problem appeared.

In addition to verifying the identification of the root cause:

1. Issue a Notice of Inspection (FDA 482);
2. Discuss the suspected problem with management and review the firm's complaint file;
3. Investigate all areas, control points and/or circumstances which may have a bearing on the product's deficiency;
4. Fully develop individual responsibility for the problem;
5. Review batch records, processing logs and/or other types of records for violative lots and associated lots;
6. Review and obtain copies of the firm's quality control/analytical data; and
7. Determine any actions the firm has taken, is taking, or has planned to take to prevent similar occurrences. If corrective action is not underway, determine the firm's timetable for achieving correction.

7.2.2.1 - State Monitored Recalls

The FDA is not ordinarily involved in classifying and auditing Interstate Milk Shippers (IMS) and Interstate Shellfish Shippers (ISS) product recalls where such actions have been, or are being, handled expeditiously and appropriately by the State(s). However, the FDA Division office in which the recalling firm is located must be assured that all States involved in an IMS or ISS plant's recall are participating in ensuring removal of the product from commerce and that, when appropriate, the States issue warnings to protect the public health.

In the event that the FDA determines that the States are unable to effect the recall actions necessary, it will classify, publish, and audit the recall; it will issue a public warning when indicated.

7.2.3 - MEDICAL DEVICE RECALLS

Medical device recalls may result from manufacturing defects, labeling deficiencies, failure to meet premarketing requirements [PMA, 510(k)], packaging defects or other nonconformance problems. How firms identify the causes of medical device recalls and corrective action activities is essential to the analysis of medical device failures and the determination of the effectiveness of the medical device GMP program. It is also useful in evaluating the medical device program, and for directing attention to problem areas during inspections. 21 CFR Part 806.1 requires device manufacturers and importers to report certain actions concerning device corrections and removals. They must also maintain records of all corrections and removals regardless of whether such corrections and removals are required to be reported to FDA. (See 21 CFR Part 806.20). Failure to report as required by 21 CFR 806.10 and failure to maintain records as required by 21 CFR 806.20 are violations and should be listed on the FDA483, Inspectional Observations. You should collect documentation that will enable CDRH to evaluate the firm's compliance with 21 CFR Part 806.

Each device manufacturer or importer must submit a written report to FDA of any correction or removal of a device initiated by such manufacturer or importer, if one was initiated:

1. To reduce a risk to health posed by the device; or
2. To remedy a violation of the Act caused by the device which may present a risk to health, unless the information has been provided according to 21 CFR 806.10 (f), or the correction or removal action is exempt

from the reporting requirements under 21 CFR 806.10(b).

Manufacturers of radiation-emitting electronic products which are also medical devices are subject to both the EPRC and Medical Device authorities of the FD&C Act. Manufacturers are required to perform corrective actions on their electronic products when a radiation safety problem exists involving a defect or a failure to comply with a mandatory performance standard. The corrective action is required to be a repair, replacement, or refund of such product at no cost to the consignee.

Collection of complaint, PMA and 510(k) related information is necessary to determine compliance with the GMP requirements. During recall follow-up inspections, answers should be obtained to the questions below, in addition to routine recall information. For firms where it has been established a manufacturing defect led to the recall, conduct a complete GMP evaluation of the manufacturing operations. Report such inspections into FACTS as "qualifying" GMP inspections.

7.2.3.1 - Problem Identification

1. How did the firm identify the nonconformance which led to the recall (e.g., complaint, in-house data, etc.)?
2. If the recall was due to a device defect, did the firm conduct a documented failure analysis of the device, using such techniques as fault tree or failure mode analyses? If so, report whether these results were provided for review.
   a. Did the firm determine the failure mechanism (e.g., shorted component, incomplete weld, etc.)?
   b. If not, how did firm determine the cause of the nonconformance?
   c. If not, what rationale does the firm have for not conducting a failure analysis?
3. Did the firm determine at what phase of the device life cycle the nonconformance occurred (i.e., design, manufacturing, storage, use, etc.) and the actual cause of the nonconformance (i.e., software design error, process out of specifications, employee error, user misuse, etc.)? What evidence does the firm have to support the determination?
4. Did the firm determine if the nonconformance resulted in an injury or death?
5. If a component, at least partly, caused the defect, determine if the same component was used in other devices manufactured by the firm. If so, has the firm conducted an analysis to assure the defect in the component will not have a deleterious effect on the operation of the other device(s)?
6. If a component was responsible for the device defect, what other device manufacturers use the same component (and especially the same lot number of the component)? Has the manufacturer of the recalled device notified the component manufacturer? Has the component manufacturer contacted its other customers about the problem?
7. Why was the component defective? Did the manufacturer of the component change the specifications without notifying the finished device manufacturer? Did the component fail to meet its release specifications?
   NOTE: A visit to the component manufacturer may be needed to adequately answer questions 5, 6 and 7. Before doing so, confirm with CDRH and your supervisor that the matter is egregious enough to warrant this "next step."
8. Did the finished device manufacturer have an incoming component/raw material sampling and testing procedure? If not, why not?
9. If the manufacturer recalled the device because the labeling was inaccurate, or the wrong labeling was applied to the device (label mix-up), determine the following:
   a. What quality system procedures should have been established to prevent the problem?
   b. If the label or instructions for use were inaccurate, was the inaccuracy introduced in the design stage, or was it due to a printing problem?
10. If the device has been on the market for a year or more, and the manufacturer claims the problem is the result of design:
    a. Determine why the problem was not detected earlier. How many reports concerning the problem did the firm receive before deciding a recall was necessary? Does the firm have a procedure established for determining if a recall is necessary, and if so, did it follow the procedure? Obtain a copy of the procedure.
    b. If the firm doesn't provide rational answers to the above questions, determine if they explored other possible causes for the problem.
    c. Was the design feature that caused the problem included in the design of the device that was the subject of a premarket submission?
    d. If the design feature that caused the problem is part of the original design, did the manufacturer recall all products manufactured since the device was introduced to the market? If not, why not?
    e. If the problem was introduced via a design change, did the manufacturer follow established design change or change control procedures? If yes, are the procedures adequate? Was the nature of the problem such that it should have been anticipated, and the design verification/ validation study fashioned to detect the problem?
    f. Has the manufacturer recalled all products distributed since the design change was introduced? If not, why not?

7.2.3.2 - Corrective Action

1. Describe the corrective action taken to correct the immediate problem, e.g., redesign, modify SOP, process validation, etc.
2. Did the firm qualify/validate the corrective action?
3. Did the firm establish responsibility to assure that the corrective action would be implemented and satisfactorily completed?

4. What action did the firm take to prevent recurrence of the nonconformance, e.g., training, increased process monitoring, etc.?
5. Was the nonconformance information provided to those responsible for the areas in which the nonconformance occurred?
6. Did the firm determine if the nonconformance extended to other devices?
7. Did the firm determine if changes were needed in procedures and, if so, did it validate and implement the changes?
8. Has the manufacturer taken appropriate corrective action?

7.2.3.3 - Complaint and Medical Device Reporting (MDR) Reporting

Determine if adequate complaint investigations were performed as required by 21 CFR 820.198 (b). Also, determine if the investigation verified the complaint was a failure of the device to meet any or all of its specifications.

For complaints related to the recall, the firm should have made a determination whether the events are MDR reportable. Any event associated with a death or serious injury must be reported under MDR. Malfunctions likely to cause or contribute to a death or a serious injury are also reportable under MDR. Document the firm's explanations for the events they believe are nonreportable. Failure to submit required MDR reports are violations and should be listed on the FDA-483 at the completion of the inspection.

Provide adequate documentation with the EIR to cross-reference complaints with associated MDRs.

Device Information - Obtain the 510(k) or PMA number for each device under recall as well as UDI information. If there is no 510(k) or PMA, determine if the device is a pre-enactment device (i.e., in commercial distribution prior to May 26, 1976). If multiple devices are being recalled, obtain this information for each device model or catalog number under recall.

7.2.4 - DRUG RECALLS

7.2.4.1 - Recalls of Human Drug Products

If the recalled product is covered by a New Drug Application (NDA) or Abbreviated New Drug Application (ANDA), determine if the defective product involves the type of problems shown under CFR 314.81 (b)(1)(i) and (ii). Also note whether or not the firm reported the problem to the FDA Division office that is responsible for the firm within 3 working days of its receipt of the information, as required by that section.

7.2.4.2 - Recalls of Veterinary Drug Products

Veterinary Drug Products recalls are classified by, and health hazard evaluations are obtained through, CVM's Division of Drug Compliance. To inquire about specific veterinary drug product recalls or to obtain information on how to proceed, email CVM Recalls at CVMRecalls@fda.hhs.gov .

7.2.5 - HUMAN CELLS, TISSUES, AND CELLULAR AND TISSUE BASED PRODUCTS (HCT/Ps) FOR IMPLANTATION, TRANSPLANTATION, INFUSION, OR TRANSFER

The FDA may consider an order of retention, recall, destruction, or cessation of manufacturing when any of the conditions specified in 21 CFR 1271.440 (a)(1) to (3) exist. The conditions include an agency finding that:

1. The HCT/P is infected or contaminated so as to be a source of dangerous infection to humans; or
2. An establishment is in violation of the regulations in this part and, therefore does not provide adequate protections against the risks of communicable disease transmission.

In addition to the conditions noted above, the agency may issue an order of cessation of manufacturing until compliance with the regulations has been achieved, as stated in 21 CFR 1271.440 (a)(3), when the FDA determines there are reasonable grounds to believe there is a danger to health. An order to cease manufacturing would be issued where violations create an urgent situation involving a communicable disease, because an establishment is in violation of the regulations in Part 1271 and, therefore, does not provide adequate protections against the risks of communicable disease transmission. An order to cease manufacturing is a remedial action taken to put important protections in place to prevent communicable disease transmission.

NOTE: FDA will not issue an order for the destruction of reproductive HCT/Ps, nor will FDA carry out such destruction itself (21 CFR 1271.440 (f)).

7.2.6 – TOBACCO PRODUCT RECALLS

When you become aware of, or obtain information about, a possible tobacco product recall, contact the Center for Tobacco, Office of Compliance and Enforcement, Division of Enforcement and Manufacturing. See CTP's intranet site for contact information.
http://inside.fda.gov:9003/CTP/ucm249908.htm

7.2.7 - SAMPLE COLLECTION

Collection of samples for regulatory consideration is at the discretion of Division management. Consult your supervisor and/or compliance branch for guidance. If a sample is indicated, only collect documentary samples for electronic products or medical devices, unless otherwise instructed.

If, after consulting with the Centers and Division Management it is determined that an official sample should be collected, ship an appropriate sample as

directed by the Center and your Division. Keep the Center informed on the status of the shipment.

SUBCHAPTER 7.3 - MONITORING RECALLS

7.3.1 - INSPECTIONS TO MONITOR RECALL PROGRESS

It may be necessary to inspect the firm between the recall initiation and the termination of a recall for several reasons including: to monitor the recall's progress, verify product disposition, or conduct a reconciliation of the distribution records for the recall. An inspection may also be assigned by your division if the Division Recall Coordinator requires assistance collecting necessary information from a firm, and the recall is potentially class I or significant class II. These visits are limited inspections on an as-needed basis. Issue an FDA-482Notice of Inspection and collect needed information. During these inspections, remind recalling firms to submit periodic status reports to FDA. See 21 CFR 7.53.

7.3.2 - FDA RECALL AUDIT CHECKS

NOTE: Do not conduct recall audit checks at DOD and VA facilities, as the FDA has a Memorandum of Understanding with them, and they have their own procedures for recalls.

7.3.2.1 - Definition

A recall audit check is a personal visit, telephone call, letter, or a combination thereof, to an account of a recalling firm, or a user or consumer in the chain of distribution. It is conducted to verify consignees at the recall depth specified by the strategy have received notification about the recall and have taken appropriate action.

7.3.2.2 - Level of Audit Checks

Conduct the number of audit checks requested in your assignment. If you are unable to do so, contact your supervisor for further instruction.

7.3.2.3 - Conducting a Recall Audit Check

The purpose of a recall audit check is to confirm the account received the recall notification from the notifying firm and followed all instructions included in the notification. The notifying firm may be the recalling firm, or a downstream account that received the recalled product and is conducting a sub-recall (such as a distributor). Notifications sometimes come in through other means, for example an automated notification system sent to hospitals. These other means are not considered to be an official notification of the recall, as the recalling firm, or a downstream account, did not directly contact the consignee.

Prior to conducting a recall audit check, review the recall audit check assignment given to you. Your assignment will contain the necessary details of the recall, recall strategy, and a list of accounts to be audited (Please Note: The assignment may list specific accounts to be audited or may provide a list of accounts to choose from). Conduct the audit check by the due date provided in the assignment. Pay particular attention to the type of product recalled, the labeling of the product, and the recall notification attached to the assignment which the recalling firm sent to their accounts. Take note of the depth of the recall listed in the assignment (i.e., wholesale, retail, consumer level). Your responsibility is to verify the account received the same recall information, they followed the instructions in the recall notification, and that the recall has been carried out to the appropriate depth listed in the assignment. The assignment will include how checks will be conducted, i.e., visit, phone calls, email, etc. as well as detailed instructions specific to the recall. Do not conduct recall audit checks by visit at consumer homes unless specifically directed in your assignment. If the assignment is for email audit checks, please use the email audit check template provided in the assignment.

During your review of the assignment, try to gain an understanding of the list of accounts, and whether those listed actually received or may have received the recalled lot. This information affects the endorsement for the audit check. If the list is specific to the recalled product lot, the account should have received it. If the list is not so specific, or the account you are auditing does not know or remember if they received the recalled lot, the account should still follow the instructions in the recall notification and initiate a sub-recall of the product, if needed. This information affects the endorsement of the recall (see section 7.3.2.6 Endorsing the Recall Audit Check). It is appropriate to challenge the account if the distribution list is included with the assignment includes them as a consignee for the specific recalled lot, and they say they never received the product.

When initiating a recall audit check, attempt to make contact with an individual at the account who has knowledge of the receipt of recall notifications and the disposition of recalled products. In hospitals, this responsibility may be held within the Risk Management or Safety departments. PLEASE NOTE: In the case of an audit check at the consumer level, attempt to verify you are speaking with the individual who was indicated as having received the product before disclosing the name of the recalled product and verifying they received notification of the recall.

If the account did not have any knowledge of the recall prior to your recall audit check, inform them of the recall, provide them with a copy of the press release (if available) and recall notification letter, encourage them to follow the recall instructions, and document that you did so. DO NOT give the account a copy of your recall assignment.

If your audit check discloses the account did not follow the recall instructions (for example, recalled product being held for sale, or a requested sub-recall has not been initiated), encourage the account to follow the recalling firm's instructions. If the account chooses not to follow the recall instructions, document the title/responsibility of the

individual at the account who chose not to follow the recall instructions and reason.

When you conduct an audit check by visit, it is important to examine the storage sites where the recalled product is stored and check the shelf stock to ensure all recalled product has been identified, removed from areas of use, and properly quarantined or destroyed/corrected. This is especially important in Class I recalls.

For some recalls, the strategy may be a correction instead of a removal. Recall audit check assignments for field corrections may instruct you to verify that either the field correction has been completed, or to assess whether the recalling firm issued the initial instructions to discontinue and/or modify the use of the product, and the account followed those instructions. Detail the status of the correction in the remarks section of your form FDA 3177.

If you encounter a refusal to permit entry or provide information during a recall audit check, document the name and title of the individual who refused, and the reason why they refused the audit check. Contact your supervisor for additional instruction.

FDA has a contract with a third party to conduct recall audit checks on behalf of the FDA. Any questions you or the firm may have regarding the third-party contract should be directed to OSPOP/DE/ROB at orarecalloe@fda.hhs.gov. There are also other entities conducting audits (e.g., state investigators conducting audits as part of their state duties or on behalf of the FDA, private firms who conduct audits on the behalf of a recalling firm)
If during your audit check you find that the consignee used the FDA regulated product to manufacture USDA-regulated product, distributed product to a USDA facility, or the product was used in or procured for one of the USDA nutrition programs (i.e., National School Lunch Program), complete the recall audit check. Provide the information to your Division Recall Coordinator, who will forward it to OSPOP/DE/ROB, who will share it with the USDA. If during your audit check you find that the consignee is a DoD supplier and/or used the FDA regulated product to manufacture DoD products, complete the recall audit check. Provide the information to the FDA Liaison to DoD as per IOM section 3.2.3 – DEPARTMENT OF DEFENSE (DoD), 3.2.3.6.1 – DoD/FDA Liaisons; the FDA Liaison will forward it to the DoD Liaison and appropriate ORA/OSPOP/DE/ROB contact.

During your audit check, verify that the consignee has conducted a sub-recall to the level specified in the assignment. If the consignee is unsure if he or she handled the recalled product, then collect the distribution list. Inform the consignee that a sub-recall may be necessary. If an account has not conducted a sub-recall, follow the procedures outlined in "Exhibit 7-3, #7."

Conduct sub-recall audit checks to the level specified in the assignment. Sub-recall audit checks may be made by telephone for accounts in another division, in lieu of creating a separate recall audit check assignment for that division to conduct the sub-recall audit checks.

7.3.2.4 - Audit Check Reporting

The results of your audit check should be reported on a form FDA 3177, "Recall Audit Check Report" form. See IOM Exhibit 7-3. It is preferred that Divisions complete the form FDA 3177 electronically. Divisions have the option of completing the form FDA 3177 electronically or as a hard copy. Directions for completing the form FDA 3177 can be found in Exhibit 7-3. Conducting the Recall Audit Check. The form FDA 3177 will be routed through your supervisor to the recall coordinator at the division monitoring the recall, who will store the official signed form in the recall file.

Identified exhibits should be submitted with your FDA 3177. Identify each page or file with the following information:

- RES Event number (as listed in your assignment)
- Direct account name or sub-account name, whichever is applicable
- Investigator's initials and date of the audit check
- Exhibit and page numbers

FACTS allows you to enter the amount of time spent conducting your audit check. When you complete a recall audit check, you should report your time using the "Miscellaneous Operations Accomplishment Hours" screen using the code OP 17.

Submit one OP 17 per RES event. In the Assignees Accomplishment Hours block of the Miscellaneous Operations screen, enter the FEI of the recalling firm and for the "#Ops" enter the number of separate audit checks conducted.

7.3.2.5 - Ineffective Recalls

An audit check is considered ineffective if one of the following conditions were found:

A. The account did not receive formal notification from the notifying firm. Note: in instances where the account was not formally notified but still took action based on information learned about the recall from a source other than the notifying firm, the audit check is still ineffective.

B. The account did not follow the instructions provided by the notifying firm. If the account is not sure if they received the recalled lot(s), they should still follow the instructions in the notification.

C. The account distributed the recalled product, but did not conduct a sub-recall, if applicable.

D. The account received the type of product under recall, cannot determine whether they received the specific recalled lots, and did not conduct a sub recall. The account should still conduct a sub recall if there is any possibility that they received the recalled lot(s).

7.3.2.6 Endorsing the Recall Audit Check

Recall audit checks should be endorsed by the Supervisory Investigator based on the information collected during the audit check.

The audit check should be endorsed based on conditions found when the audit check was conducted and not based on the account's actions to correct ineffectiveness. Choose the endorsement that is best described by one of the scenarios below.

An audit check should be endorsed "Effective" if the account was notified of the recall by the appropriate notifying firm and followed, or is in the process of following, the instructions in the recall notification. Please note: If you selected "No" for question 5a or 6a on the 3177, you cannot endorse the 3177 as "Effective". If both 5a and 6a on the 3177 are "Yes", the 3177 should be endorsed as "Effective"

The following are examples of ineffective recall audit checks:

A. "Ineffective – Notifying Firm"

- The account did not receive formal notification from the notifying firm. Note: in instances where the account was not formally notified but still took action based on information learned about the recall from a source other than the notifying firm, the audit check is still ineffective.

B. "Ineffective – Consignee"

- The account did not follow the instructions provided by the notifying firm. If the account is not sure if they received the recalled lot(s), they should still follow the instructions in the notification.
- The account distributed the recalled product, but did not conduct a sub-recall, if applicable.
- The account received the type of product under recall, cannot determine whether they received the specific recalled lots, and did not conduct a sub recall. The account should still conduct a sub recall if there is any possibility that they received the recalled lot(s).

Your Division's Recall Coordinator can assist you if you need help evaluating if an account must conduct a sub-recall. In some instances, (e.g., field corrections) the effectiveness of the recall audit check may be determined by the assignment and discussion with the recall coordinator.
If the account assigned for a recall audit check is out of business, endorse the audit check as "Out of Business".

Endorse as "Other" on very rare occasions, such as if the account cannot remember whether or not they received the recall notification and does not carry the recalled product.

7.3.3 - RECALL TERMINATED/RECALL COMPLETED

7.3.3.1 - Definitions

Recall Terminated - A recall will be terminated when the FDA determines that all reasonable efforts have been made to remove or correct the violative product in accordance with the recall strategy, and when it is reasonable to assume that the product subject to the recall has been removed and proper disposition or correction has been made commensurate with the degree of hazard of the recalled product. Written notification that a recall is terminated will be issued by the appropriate Division office to the recalling firm.

Recall Completed - For monitoring purposes, the FDA classifies a recall action "Completed" when all outstanding product, which could reasonably be expected is recovered, impounded, or corrected.

7.3.3.2 - Closeout Inspection

Some recalls may require a limited inspection at the recalling firm as a final monitoring step to verify the recall has been completed. A memorandum or limited EIR should be prepared. See RPM Chapter 7, Attachments B1, "Recommendation for Recall Classification and Termination" and Attachment C, "Recall Termination or Recommendation for Termination" for the format. Portions of this format (i.e., Section II and certain items in Section III) will be completed by your supervisor, Recall Coordinator, or compliance officer, depending upon your Division's policy.

During the closeout inspection, you should witness destruction or reconditioning of the recalled product, when possible, when unable to do so, obtain written documentation from the firm and/or any state or local government agencies that may have witnessed or otherwise verified product disposition. The disposal of large amounts of contaminated or hazardous items may require the firm to file an Environmental Impact Statement (EIS), or pre-disposal processing to render the goods harmless. Do not agree to witness destruction without resolution of these issues. Obtain a "Letter of Voluntary Destruction" from the firm whenever you witness this operation. See IOM 2.6.4.1.

SUBCHAPTER 7.4 - SPECIAL RECALL SITUATIONS

7.4.1 - General

There are several special recall situations which may require you to deviate from the normal recall procedures. Seek your supervisor's or R&E Coordinator's guidance on these. Examples include:

1. Products in the possession of U.S. Defense Installations;
2. NDA and ANDA withdrawals;

3. National Academy of Science (NAS)/Nuclear Regulatory Commission (NRC) (DESI) recalls of drugs judged ineffective; and
4. Recalls involving jurisdiction of more than one Federal Agency (e.g., FDA/EPA, FDA/Consumer Product Safety Commission (CPSC), etc.).

7-1 RECALL COMMUNICATIONS EXAMPLE

MODEL DRUG RECALL LETTER

[Company Letterhead]

(in red print) URGENT: DRUG RECALL – Nonsterile injectable

[Date]
[Contact name or Department]
[Firm Name]
[Address]

Dear [wholesaler, retailer, consumer]:

This is to inform you of a product recall involving: [Brand Name (generic) dosage form, strength, description and size of packaging, NDC or UPC codes, lot numbers]

See enclosed product label for ease in identifying the product at the [wholesale/ retail/ user level].

This recall has been initiated due to [describe problem and how it was discovered]. [Use/Consumption] of this product may [describe any potential health hazard].

This product was shipped between [range of distribution dates] or This product was shipped to you on [date]. [If possible, provide consignee with shipping dates and quantities shipped.]

Immediately examine your inventory and quarantine product subject to recall. [If this is a retail or user level recall, include the following] In addition, if you may have further distributed this product, please identify your customers and notify them at once of this product recall. Your notification to your customers may be enhanced by including a copy of this recall notification letter [or Enclosed is a letter you should use in notifying your customers should you choose to create a separate letter.]

[Your notification must include instructions on what customers should do with the recalled product.]

You will be reimbursed by check or credit memo for the returned goods and postage.

Please return the enclosed card immediately providing the requested information. If you have any questions, call [name] at [phone number] [days of week] between [start time] am to [end time] pm [state time zone].

This recall is being made with the knowledge of the U.S. Food and Drug Administration. The FDA has classified this recall as class _____ (if classified).

We appreciate your assistance.

John Doe
President

PLEASE FILL OUT AND RETURN

We do not have any stock of List 1234, Cyanocobalamin

Injection Lot No. 4321 on hand

We have requested our accounts to return their stocks of this merchandise to us.

We are returning _____ bottles of List 1234, Lot No. 4321

Name _____

Address _____

First Class
Permit No. 2

BUSINESS REPLY MAIL

No Postage Stamp Necessary if mailed in U.S.A.

Postage will be paid by:

JOHN DOE LABORATORIES
Somewhere, U.S.A. 12345-0909

Henry Doe

JOHN DOE LABORATORIES

FIRST CLASS MAIL

A. B. C. Pharmacy
Anywhere U. S. A.

(red print) URGENT DRUG RECALL

7-2 FORM FDA 3177 RECALL AUDIT CHECK REPORT

1. RECALL INFORMATION

a. RES NUMBER	b. RECALLING FIRM	c. RECALLED CODE(S)	d. PRODUCT(S)

2. PROGRAM DATA *(FDA Users Only)*

a. MONITORING DIVISION	b. FEI NUMBER OF RECALLING FIRM

c. PAC CODE

3. AUDIT ACCOUNTS

a. DIRECT	b. SUB-ACCOUNT (SECONDARY) *(Leave blank if none.)*
PHONE NO.:	PHONE NO.:

c. SUB-ACCOUNT (TERTIARY) *(Leave blank if none.)* — PHONE NO.

4. CONSIGNEE DATA

Contacted by: ☐ Phone ☐ Visit ☐ Other

a. NAME OF PERSON CONTACTED & TITLE

b. TYPE CONSIGNEE

☐ Distributor ☐ Consumer ☐ Pharmacy
☐ Retailer ☐ Physician ☐ Restaurant
☐ Processor ☐ Hospital ☐ School
☐ Other: _____

c. DOES (DID) THE CONSIGNEE RECEIVE RECALLED PRODUCT?

☐ Yes ☐ No

5. NOTIFICATION DATA

a. FORMAL RECALL NOTICE RECEIVED? *(If answer is other than "Yes", explain in remarks and skip to item 6c.)*

☐ Yes ☐ No ☐ Cannot be determined

b. RECALL NOTIFICATION RECEIVED FROM

☐ Recalling Firm ☐ Other *(Specify below)*
☐ Direct Account
☐ Sub-Account

c. DATE NOTIFICATION RECEIVED *(mm/dd/yyyy)*

d. TYPE OF NOTICE RECEIVED *(e.g., letter, phone)*

6. ACTION AND STATUS DATA

a. DID CONSIGNEE FOLLOW THE RECALL INSTRUCTIONS? *(If "No", discuss in "Remarks" action taken as a result of audit check.)* ☐ Yes ☐ No

b. AMOUNT OF RECALLED PRODUCT ON HAND AT TIME OF NOTIFICATION

c. CURRENT STATUS OF RECALLED ITEMS

☐ Returned ☐ None on Hand
☐ Corrected ☐ Was Still Held for Sale/Use*
☐ Destroyed ☐ Held for Return/Correction*
* = Ensure Proper Quarantine/Action

d. DATE AND METHOD OF DISPOSITION

7. SUB-RECALL NEEDED? *Did consignee distribute to any other accounts? (If "Yes", collect information and/or provide details in "Remarks" or Memo.)* ☐ Yes ☐ No

8. AMOUNT OF RECALLED PRODUCT NOW ON HAND

9. INJURIES/COMPLAINTS

a. IS CONSIGNEE AWARE OF ANY INJURIES, ILLNESS, OR COMPLAINTS?

☐ Injury ☐ Complaint
☐ Illness ☐ None

If answer is other than "None", collect relevant information, document findings, and route per division procedures.

10. REMARKS *(Include action taken if product was still available for sale or use.)*

CHECK		FDA ENDORSEMENT
Signature		Signature
Printed Name and Title		Printed Name and Title
Date of Audit Check *(mm/dd/yyyy)*	FDA Division	Date of Endorsement *(mm/dd/yyyy)*

☐ **Effective** ☐ **Out of Business**

☐ **Ineffective** *(Indicate level)*
☐ *Notifying Firm*
☐ *Consignee*

If "No" is checked for 6a and/or 6a, "Effective" cannot be selected as an Endorsement.

☐ **Other** *(Specify)*: _____

FORM FDA 3177 (08/19) RECALL AUDIT CHECK REPORT Page 1 of 1

PSC Publishing Services (301) 443-6740 EF

7-3 Instructions for Completing the FDA 3177 Recall Audit Check Report

Completing the FDA 3177 Recall Audit Check Report Form

Note: Obtain as much information as possible in order to successfully complete the FDA 3177 Recall Audit Check Report Form as follows:

1. RECALL INFORMATION

a. RES NUMBER – Enter the Recall Enterprise System (RES) number as listed in your assignment.

b. RECALLING FIRM – Provide the name and address of the firm listed in your assignment as the recalling firm.

c. RECALLED CODE(S) – Provide the UDI, lot, batch, or serial number indicated as the recalled product in your assignment. If there are more numbers than can fit in the space, state that there are numerous lots under recall and refer to the assignment.

d. PRODUCT(S) – Provide the name of the recalled product as indicated in your assignment. If numerous products are involved, use a generic term (such as ice cream, dried fruit, etc.).

2. PROGRAM DATA – Complete as per division policy.

a. MONITORING DIVISION – Enter the monitoring division as listed in your assignment. The monitoring division is often the division where the recalling firm is located, and is responsible for evaluating the effectiveness of the entire recall.

b. FEI NUMBER OF RECALLING FIRM – FEI number of the recalling firm as listed in your assignment.

c. PAC CODE – PAC code given in your assignment.

d. HOURS – has been removed from the 3177, but operational hours should still be entered into FACTS as instructed in IOM section 7.3.2.4.

3. AUDIT ACCOUNTS

Do not add any text to the sub-account or tertiary account fields (3a and 3b) if you are not reporting audit check information for these downstream accounts. Adding text (such as N/A) to these fields impacts how RES reads the form.

a. DIRECT – The name, address, and telephone number of the account that was listed in your assignment as receiving the product directly from the recalling establishment. This may or may not be the same account at which you are conducting your audit check.

b. SUB-ACCOUNT (SECONDARY) – If the Direct account indicates the recalled product(s) were further

distributed, complete this section for each sub-account audited as well as the DIRECT account section with the name, address, and telephone number of the applicable establishments.

c. SUB-ACCOUNT (TERTIARY) – If the Secondary account indicates the recalled product(s) were further

distributed, complete this section for each sub-account audited, the SUB-ACCOUNT (SECONDARY) section, and the DIRECT account section with the name, address, and telephone number of the applicable accounts.

4. CONSIGNEE DATA

Contacted by: The method used to conduct the audit check (check the appropriate box).

a. NAME OF PERSON CONTACTED & TITLE – The name and title of the person at the account being audited who provided the most information during the audit check.

b. TYPE CONSIGNEE – The type of establishment at which you are conducting your audit check (check the appropriate box – if none, check "Other" and describe the type of establishment).

c. DOES/DIDTHE CONSIGNEE RECEIVE THE RECALLED PRODUCT? – If the account at which you are

conducting the audit check never received the recalled product, indicate "No". If the account received or may have received the recalled product, indicate "Yes". This includes if the company is unsure they received the recalled lot.

5. NOTIFICATION DATA

a. FORMAL RECALL NOTICE RECEIVED? – Indicate if the account received formal notification of the recall (check the appropriate box). Formal notification may be received from the recalling firm, direct account or the secondary/tertiary firm. If notification is received informally e.g. press release, subscription service, or social media, indicate "No" and explain in Remarks how the account received notification. If there is some reason why you cannot determine if a notification was received (for example, it may have been discarded) indicate "Cannot be determined" and explain in Remarks.

b. RECALL NOTIFICATION RECEIVED FROM – The firm that formally notified the account at which you

are conducting your audit check (check the appropriate box).

c. DATE NOTIFICATION RECEIVED – Date the account received the formal notification.

d. TYPE OF NOTICE RECEIVED – How the formal notification was received (letter, phone, e-mail, automated messaging system, etc.).

6. ACTION AND STATUS DATA

a. DID CONSIGNEE FOLLOW THE RECALL INSTRUCTIONS? – If the account followed or is following all of the recall instructions prior to your audit check, indicate "Yes". If the account did not follow or has not begun to follow the recall instructions prior to your audit check, indicate "No". Explain what was/was not done in Remarks, and if the account took action as a result of your audit check.

b. AMOUNT OF RECALLED PRODUCT ON HAND AT TIME OF NOTIFICATION – The amount of recalled product the account had at the time they received formal notification from the notifying firm.

c. CURRENT STATUS OF RECALLED ITEMS – Indicate the status of the recalled items at the account at the time of your audit check (check the appropriate box). If the recalled product is still being held for sale/use, or was being held for return/correction, ensure that the account properly quarantined the product (if applicable) and followed the recall instructions. In the case of a medical device recall with instructions that permit the device to remain in use awaiting correction or servicing of the device, mark "was still held for sale/use". Include details of the product status in the Remarks

d. DATE AND METHOD OF DISPOSITION – Indicate the date and method the recalled product was destroyed/returned/corrected.

7. SUB-RECALL NEEDED? – If during the course of an audit check, you find the recalled product has been further distributed, and your audit check for the recall has not reached the depth indicated in your assignment, a sub-recall may be needed. For example, if your assignment indicates the recall depth is at the retail level, and you are auditing a wholesaler, the wholesaler should conduct a sub-recall to reach the retail level.

In the case of a sub-recall, collect distribution of the recalled product, the sub-recall notification, and any other pertinent information to attach to your form FDA 3177. Carry out the recall audit check to the depth indicated in the assignment. Determine if the consignee followed the instructions and conducted a sub-recall. If they did not, then inquire with the consignee about their willingness to continue the recall to the depth specified in the recall strategy and gather as much distribution information as possible. Indicate "Yes" in this section and add as much detail as possible in Remarks.

In some cases, if the consignee has re-labeled, repackaged, or remanufactured the recalled product, a new recall may be needed instead of a sub-recall. However, a new recall may not be needed, if the consignee has manipulated the recalled product in a way that corrects the initial reason for the recall (e.g. if the consignee re-labels the product so the labeling issue is no longer a concern, or if the consignee heat treats the product adequately to eliminate the hazard causing the original recall).

If you determine a new recall is needed, or are unsure, collect all relevant information, including labeling to be evaluated with the assistance of your division's Recall Coordinator (refer to section 7.3.2.4 for labeling instructions of attachments).

Indicate "No" in this section if the product has not been further distributed and your evaluation finds that a sub-recall is not necessary.

8. AMOUNT OF RECALLED PRODUCT NOW ON HAND – The amount of recalled product still at the account during your audit check.

9. INJURIES/COMPLAINTS

a. IS CONSIGNEE AWARE OF ANY INJURIES, ILLNESS, OR COMPLAINTS? – Ask the consignee if they have firsthand knowledge of any injuries, illness, or complaints pertaining to the recalled product. Collect relevant information and route per division procedures.

10. REMARKS – Use this section to provide details that could not be addressed in the previous sections, or to give additional information. If you need additional space for remarks or other information, attach a written document to the 3177 and reference the attachment in the remarks section.

CHECK – Place a handwritten or electronic signature, followed by your name and title printed or typed, the date your audit check completed, and your division.

ENDORSEMENT – Follow section 7.3.2.6 Endorsing the Audit Check. Please note: If you selected "No" for question 5a or 6a on the 3177, you cannot endorse the 3177 as "Effective".

If changes need to be made after the document has been signed, the signer needs to clear the electronic signatures by right clicking on the signature and pressing "clear signature". Then the form can be modified and re-signed.

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8.1 - Investigations and Inspections

8.1.1 – Background – What is an investigation?

An *investigation* is an information-gathering activity conducted for several reasons and this definition applies across ORA programs. The purpose of an investigation is to determine and document facts concerning an issue to inform the agency in making sound decisions. Used informally, *investigation* can apply to a very general activity. It may refer to a response to a more formal request for specific information. Information obtained during an investigation may lead to other operations such as sample collections or inspections.

This chapter contains specific information on many types of investigations, and each section provides guidance on how to conduct those investigations, special reporting requirements, and where additional assistance can be obtained. Recall work, a special type of investigation, is covered in Chapter 7. Reporting an investigation is covered in Section 8.1.9 of this chapter.

8.1.2 - Investigations, Inspections, and Form 482? – When do you issue an FDA 482?

Investigations generally do not require an FDA 482, but there will be times when you need to issue an FDA 482, such as when you are at a manufacturing site or doing work like an *inspection* (e.g., collecting records at a manufacturer or shipper to document *interstate commerce*). Consult with your supervisor to determine the proper course of action for these situations. Investigations may be performed at a location not subject to FDA inspection.

8.1.3 - External Requests for Investigative Information – What if someone asks you about an investigation?

Investigations will naturally lead to interest from outside groups. Consumers, industry, press, and other external stakeholders may want information about your investigations. Do not reveal any information about an investigation to anyone outside of the agency without express permission. Direct any requests for information to the FDA's How to Make a FOIA Request webpage (https://www.fda.gov/regulatory-information/freedom-information/how-make-foia-request). Refer all media inquiries to the ORA Press Office at ORAPress@fda.hhs.gov (see IOM 1.7).

In the case of complaints where a sample has been collected from the complainant they may be informed of FDA's findings when an examination is made of the sample. When you collect a sample from a complainant, and they ask for analytical results, they may be told that the FDA will advise them of the general nature of the findings. Enter the complainant's contact information (name, address, phone number and email) into the Collection Remarks section of the Collection Report. Be sure to consult with your supervisor prior to collecting samples from a complainant. See IOM 4.4.3.3 and IOM 4.6.2.9. The Firm's Home District Compliance Branch will notify the Complainant of the Sample results.

8.1.4 - Office of Criminal Investigations – Who is OCI?

8.1.4.1 - OCI Responsibilities

ORA's Office of Criminal Investigations (OCI) has the primary responsibility for all criminal investigations conducted by the FDA, including suspected tampering incidents and suspected counterfeit products. Similarly, OCI has primary responsibility — and is the primary point of contact for — all law enforcement and intelligence matters.

8.1.4.2 - Reports of Criminal Activity

All reports of suspected or confirmed criminal activity, including suspected tampering or counterfeiting incidents, must be reported to the appropriate OCI field office or resident office without delay. Additionally, all threats or perceived threats against FDA-regulated products are to be referred immediately to the local OCI field office or to OCI headquarters. In those instances where OCI does not, or cannot initiate a criminal investigation in a timely manner, the division offices will consult with OCI to determine the proper follow-up.

8.1.4.3 - Liaison with Law Enforcement / Intelligence Community

OCI is the FDA's liaison with the law enforcement community for criminal investigations and related matters. In addition, OCI serves as the primary point of contact between the FDA and the intelligence community on all matters of mutual interest. OCI participates in numerous law enforcement and intelligence task forces both nationally and internationally including as a full-time representative at Interpol.

All contacts regarding requests or questions received from federal, state, or local law enforcement agencies or intelligence agencies are to be referred without delay to the local OCI field office. Similarly, law enforcement contacts to FDA headquarters or centers should be referred to OCI headquarters.

When FDA personnel receive information or requests from law enforcement or other agencies, they should obtain the caller's name, organization, and the details of the request. The caller should then be referred to the appropriate OCI component. After referring the caller to OCI, contact the affected OCI unit to provide the caller's information. This will prepare OCI of the expected contact. FDA personnel should not respond to inquiries concerning criminal investigations, including questions seeking confirmation of whether FDA is or is not conducting a criminal investigation.

8.1.5 - Types of Investigations – What situations lead to investigations?

You may conduct a variety of investigations in your career. Some types of investigations include, but are not limited to complaint investigations, disaster investigations, health fraud investigations, and product tampering investigations. When conducting any investigation, keep an open mind. Each investigation will be unique.

8.1.5.1 - Defective Products

A defective product is one that fails to do what it is expected to do. For example, a diabetes medication that fails to adequately control blood sugar levels that is prescribed for that reason. A defective product will typically result in a recall where the product may be destroyed or reconditioned.

Investigations into defective products could be initiated as a result of consumer or industry complaints that may indicate the need for follow up with the consumer or industry representative, which would be conducted as an investigation. Investigations are initiated in order to determine facts surrounding a claim related to the status or disposition of a subject FDA-regulated product. Subsequent findings would determine necessary follow-up and/or FDA action (e.g., inspection, sampling, product recall).

8.1.5.2 - Injury, Illness, Death

Escalation must occur when there is indication of a life-threatening injury/illness or adverse reaction or death. Follow up may vary depending on the situation. You may be asked to conduct investigations at complainants' residences or at firms to investigate any potential causes for the adverse reaction. Inspections at firms may also be warranted. These investigations could be assigned by Office of Emergency Operations (OEO), the Coordinated Outbreak Response and Evaluation (CORE) Network, or other agency components.

You may need to collect medical records or in some cases autopsy reports during these investigations. (See *Section 8.1.6.2* of this Chapter for guidance on obtaining medical records.)

When discussing complaints with a firm representative, do not provide any identifying information of the complainant, for example, name, phone number, or city or state of residence. Reports of adverse reactions may be received from consumers or health care professionals through voluntary reporting such as MedWatch. Reports may be received from state or federal partners.

NOTE: Follow any program specific guidance related to investigation preparation, collection of these records, etc.

8.1.5.3 - Criminal Investigations

During your work, you may encounter situations that involve criminal or fraudulent activity as defined under Title 18 USC and Title 21 USC. Criminal activity noted by FDA consumer safety officers (CSO) is typically cases of individuals and/or firms making false statements or providing false documents during the course of an inspection or other official activity. There are other violations of Title 18 and criminal violations of Title 21 USC that you may encounter.

Fraud is a separate criminal act from false statements and involves a false representation of a matter of fact whether by words or by conduct, including concealment of information, intended to deceive another for advantage.

In all cases of criminal activity including fraud, OCI is the primary investigative office for FDA. Gather as much initial information as possible and notify your supervisor. You may be asked to assist OCI in its investigation. If so, follow their directions and do not discuss the investigation with anyone outside of the investigation.

8.1.5.4 - Surveillance

During your inspectional, investigational, and other activities, be alert to anything which may be new or unusual or interesting from FDA's viewpoint such as:

- New firms.
- New products.
- New production and distribution practices.
- New equipment and industrial processes.
- Seasonal practices.
- Industry trends.
- Recent or on-going construction and plans for future expansion.
- Proposed products.
- New ideas the firm is contemplating.
- New products in the development stage.
- Activities about a firm's competitor.
- Plans for consolidation, mergers, diversification, etc.

If this information relates to a firm you are not currently inspecting, report the information using a Memo of Investigation and route through your supervisor appropriately. If the information relates to a firm being inspected report in the Establishment Inspection Report (EIR). (See *Section 8.1.9* for details on reporting your investigation.)

8.1.5.5 - Washouts

A “washout” is defined as an operation where you are unable to complete an assigned inspection. When you encounter a washout, you should determine the reason you are unable to conduct the inspection. For example, a firm that operates seasonally may be available for inspection later in the year. If a firm has moved, attempt to find the forwarding address of the firm. If the firm remains in the local area, do not treat it as a washout but conduct the inspection at the new location. Each washout should be investigated so that you are able to explain why you could not conduct the inspection. (See *Section 8.1.9* for details on reporting your investigation.)

8.1.5.6 - For Cause/Fact-Finding/Information Gathering

A for cause, fact-finding, or information gathering investigation is generally received by the division from an outside source like a center, ORA headquarters, or another division. It will generally be a request to obtain specific information from a firm or other source. One example could be obtaining interstate documentation from a shipper of a product to support a regulatory action, such as a seizure in another division.

8.1.5.7 - Complaints

A complaint is a notification that a product may be in violation of the laws and regulations administered by FDA . A complaint may be related to the following areas:

- Economic problems/misbranding (i.e., labeling).
  - Short weight.
  - Deceptive or misleading packaging and labeling.
  - Fraudulent products.
- Filth, decomposition, foreign objects, microbial or chemical contamination
  - Animal/plant/insect material.
  - Off appearance, off odor, or off taste.
  - Glass, metal, plastic, or other foreign objects.
  - Bacteria, yeasts, molds, or fungi.
  - Pesticides, industrial, or other chemicals.
- Defective products
  - Sub potency or super potency.
  - Particulate matter.
  - Failure to operate as intended.
- Adverse reactions
  - Allergic reactions.
  - Expected reactions.
  - Birth defects and problem pregnancies.
  - Death.
- Tampering

Complaints are received from various sources, including consumers, other government agencies, Congress on behalf of their constituents, trade associations, etc. *SOP-000544 – Consumer Complaint Procedure* describes the receipt and processing of consumer complaints in detail.
The FDA Office of Emergency Management/Office of Emergency Operations (OEM/OEO), 1 (866) 300-4374 and Emergency.Operations@fda.hhs.gov, must be notified immediately of all death, life-threatening injury/illness, and suspected tampering complaints. OEM/OEO must also be notified of all complaints regarding infant formula/baby food. Advise OEM/OEO of the status of all such follow-up investigations.

As unique situations arise, OEM may provide guidance concerning the type of follow-up to be made.

Note: Link to SOP-000544 is available to FDA employees on the FDA intranet. The link is: http://qmis.fda.gov:80/mc/main/index.cfm?event=showFile&ID=NE3SFDMGIZHCVHQIGE&static=false&mcuid=ANONYMOUS&mcsid=MOPVZCL2FFHJBIFCQG. Users who need a copy of the SOP outside FDA should use the Freedom of Information Process described in Section 8.1.3 to get a copy of the SOP.

8.1.5.7.1 - Types of Complaints

8.1.5.7.1.1 - Injury/Illness Complaints

A complaint indicating a life-threatening injury/illness, hospitalization, or death requires immediate reaction. It may require immediate investigation.

There are additional considerations with life-threatening and non-life-threatening injury/illness complaints. The prior medical history of the complainant may provide indications regarding allergies, drug side effects or drug-food/drug-drug interactions which may be responsible for the illness or injury. Medical verification should be sought in these situations.

8.1.5.7.1.2 - Non-Injury/Illness Complaints

Generally, these do not require immediate follow-up at the consumer level. Follow-up may include examining the parent lot, referral state, or local agency, or deferral until the next regularly scheduled inspection. Examples include mold in beverages, obvious filth, or insects in canned goods, etc. It may be possible that adequate investigation would be contacting the dealer, advising them of the nature of the complaint and requesting notification of any action taken. Non-injury/illness complaints do not need to be reported to the OEO unless product tampering is suspected, or the product is a baby food or infant formula.

8.1.5.7.2 - Sources of Complaints – Who provides us with complaints?

Complaints come from many sources. Regardless of the source, all complainants should receive a prompt and courteous response.

8.1.5.7.2.1 - Consumer

Consumers contacting field offices with complaints of injury, illness, or product defects should receive a prompt, courteous response, and assurance that their complaints will receive appropriate consideration. (See *SOP-000544 – Consumer Complaint Procedure*.)

8.1.5.7.2.2 - Industry

Industry complaints should be treated in the same manner as consumer complaints.

8.1.5.7.2.3 - Confidential Source

A Confidential Source is an individual who provides non-public information about an FDA-regulated entity/product, alleging potential violation(s) of federal law, or an illicit or unsafe product or activity, and who requests anonymity.

Note: The term “Confidential Informant” is used only by OCI in relation to criminal investigations. ORA Complaint Coordinators and Investigators use the term “Confidential Source” during the course of their work. It is important to avoid the disclosure of a confidential source to a firm. The investigator conducting the investigation or inspection should not disclose the complainant’s information or report the information in the EIR. The complaint itself should be treated in the same manner as consumer complaints.

To maintain confidentiality, a memorandum regarding confidential information should be submitted as a separate operation, linked to the original report or submitted as an attachment to the EIR. There may be times when the report may be discussed in the EIR but, it will not disclose the source of the information. Discuss with your supervisor before including information obtained from a confidential source in the EIR.

8.1.5.7.2.4 - Whistleblower

A whistleblower is an individual who discloses information regarding an FDA-regulated entity/product that the individual acquired during their current or former employment, alleging potential violation(s) of federal law, or an illicit or unsafe product or activity. The complaint itself should be treated in the same manner as consumer complaints. It is important in these types of complaints that the identity of the whistleblower is not disclosed. The investigator should follow the same protocol as dictated in the Confidential Source section above by not disclosing the complainant's information or reporting the information obtained from the whistleblower in the EIR or any format where the complainants' information could possibly be released under the Freedom of Information Act.

8.1.5.7.2.5 – Anonymous Complainant

An Anonymous Complainant is an individual, usually a consumer or someone on behalf of consumer, who contacts FDA with concerns and provides information that a product in commercial distribution may be in violation of the laws and regulations administered by FDA and requests anonymity.

8.1.5.8 - Disaster/Emergency Response – How do we protect the consumer during a disaster or emergency?

The objective of FDA investigations in the aftermath of disasters is to determine whether or not foods, drugs including biologics, cosmetics, and devices affected by the catastrophe are safe for human and animal use; and if not, to effectively have them removed from commerce.
In disaster operations, FDA may assist state, local, and other federal agencies in removing contaminated or unfit merchandise from the market.

State and local officials usually assume direct responsibility for facilities and products under their jurisdiction, as their laws and regulations can be immediately invoked; however, FDA assistance is sometimes requested. Based on the size and scale of the disaster, FDA may receive an official request for assistance through FEMA, FDA/state Rapid Response Teams, or ad hoc through traditional state contacts.

If contacted by emergency response personnel for follow-up assignments, please work with your supervisor to engage district Emergency Response Coordinator (ERC) for further coordination.

8.1.5.8.1 - Preparedness



Disaster preparedness is the first step to ensure personal safety and response efficiency. Measures taken to prepare for and reduce the effects of disasters both personally and professionally are crucial before an incident occurs.

It is recommended as a preparedness measure that you familiarize yourself with your local Continuity of Operations Plan (COOP). COOP is the initiative that ensures that federal government departments and agencies can continue operation of their essential functions under a broad range of circumstances including all-hazard emergencies, natural, man-made, and technological threats, and national security emergencies. Today's threat environment makes COOP planning even more critical. Your local COOP will alert you to likely disasters for your geographic area.

Preparedness Resources:

FDA's Emergency Operations Plan (http://inside.fda.gov:9003/PolicyProcedures/SOPsbyProgram/EmergencyResponse/ucm381277.htm)

FEMA Preparedness (www.Ready.gov)

8.1.5.8.2 - Safety



ORA considers the safety of staff to be of the utmost importance.
In a disaster or pending disaster the personal protection of yourself and your family is your primary concern. Provide for your own safety as you perform your assigned FDA duties in a disaster area. Inoculations and protective clothing should be considered.
See Chapter S-Safety. Particularly S.8.1 - General Preventive and Protective Measures, https://fda.sharepoint.com/sites/insideFDA-EmployeeResources/SitePages/Occupational-Health-Services.aspx, S.17.2 -Immunizations, and S.9- PPE.

Disasters produce dangerous situations (e.g., high water, escaping gases, fallen electrical lines, damaged buildings, falling rubble, etc.), so care and extra safety precautions must be observed.

A Personal Safety Plan may be developed when dealing with disaster situations.

Be aware of hazards you may encounter while traveling in an affected zone such as power outages, damaged or impassable roads, and a lack of available supplies in the area.
Personal Protective Equipment (PPE) should be considered where appropriate. For example, appropriately fit-tested respirators such as N95 masks should be worn where there is a risk of inhaling pathogens. Each situation requires a careful evaluation and determination of effective PPE. Your supporting industrial hygienist should be consulted for guidance.

Safety Resources:

- DFI Field Alert #16 (http://inside.fda.gov:9003/downloads/policyprocedures/guidanceregulations/fieldinvestigations/ucm010162.doc)

- ORA Safety Contacts (http://inside.fda.gov:9003/ORA/Offices/OORS/Safety/default.htm)
- ORA Radiation and Laser Safety Resources (http://inside.fda.gov:9003/ora/offices/oors/safety/ucm655438.htm)

8.1.5.8.3 - Response



CAUTION: Although procedures in this subchapter do not cover disasters resulting from a radiological event (presence or release of radioactive materials), it is possible you may discover products suspected of contamination by radioactive materials in the disaster area. If you suspect the presence of radioactive materials, take no action on the materials yourself, but have the area cordoned off at once. Notify the command official (official in charge) and immediately contact your IMT or supervisor, as applicable, to alert the radiological health representative and the state radiation control agency. Follow their instructions.

8.1.5.8.3.1 - Use of Incident Command System (ICS)

During some disasters, FDA may implement an Incident Command System (ICS) for response. ICS is a standardized approach to managing incidents at the on-scene level. It is the combination of procedures, personnel, facilities, equipment, and communications operating within a common organizational structure. ICS is scalable and flexible and can be used for small, as well as large and complex, incidents and planned events.

As a CSO, you will typically be assigned under the Operations Section of the Incident Management Team (IMT). All operations you conduct, and your reporting structure will be provided by the IMT and shared via an Incident Action Plan (IAP). An IAP contains the incident objectives, the overall strategy for managing an incident, personal safety guidance, a comprehensive listing of the tactics, resources, and support needed to accomplish the objectives. (Note: Some CSOs with ICS position specific training may serve in a leadership role on the IMT.)

While serving on an IMT, your reporting will be to your team leader and not to your supervisor. The IMT will provide specific guidance for reporting. Your activities will be reported through the IMT and not through normal channels. Reporting may vary depending on the incident and its objectives. You will not be following reporting guidance later in this chapter.

8.1.5.8.3.2 - Management of Disasters without ICS

Specific investigation assignments should come from your supervisor and reporting will be through the normal means, unless directed otherwise.
Response Resources:

- Disaster Response Flow Diagram (DRFD) package (Exhibit 8-9)
- Incident Management Handbook (IMH) (http://inside.fda.gov:9003/downloads/policyprocedures/sopsbyprogram/emergencyresponse/ucm391230.pdf)

- Emergency Operations Plan (EOP) (http://inside.fda.gov:9003/downloads/PolicyProcedures/SOPsbyProgram/EmergencyResponse/UCM228297.pdf)
- Homeland Security Presidential Directive 5 (https://www.dhs.gov/publication/homeland-security-presidential-directive-5)

8.1.5.8.4 - Disaster Types

The types of natural and man-made disasters that affect FDA operations are:

8.1.5.8.4.1 - Floods

All flood water, regardless of its source, must be considered a polluting medium because of overflowing sewers, outhouses, decomposing livestock, street run-off water, etc.

Depending on the extent of the flood, first determine the locations of the major stocks of regulated products. Food and drugs will normally receive first priority. As stocks of goods are located, rapidly survey the extent of damage, then concentrate on affected materials. Use your camera extensively. Examine the walls of buildings, storage areas, and the top and sides of stacked or tiered goods for flood water residue, debris, and a well-defined high-water mark. Finished products, ingredients, and containers stacked above this line are still of concern because other problems probably exist (e.g., vermin defilement, failure of refrigeration, thawing of frozen items, etc.).

Any suspect material should be embargoed by local officials or held pending final disposition. Management is usually cooperative and willing to do things it may not normally do to get back to normal operations as quickly as possible. Cooperate with management but avoid hasty decisions.

Many products are quickly rendered unsuitable for human consumption by flood water. Items such as bread, cakes, cookies, candies, bulk flour, sugar, bulk liquids, and similar items not in jars or hermetically sealed containers can often be immediately hauled to disposable areas and destroyed.

Determine areas which have lost power. In facilities such as frozen food firms, and frozen or refrigerated warehouses, check the sites for length of down-power and condition of the products. If power is restored in time to avoid thawing, or prevent spoilage of refrigerated items, and products were not inundated, or otherwise affected, there is no need for further examination.

Even though flood waters may not have inundated the firm, the situation may have caused sewer and waste lines to backflush into basements and immediately drain out again. Debris or sewage particles along walls and on low floor surfaces or presence of sewage odors are evidence of backflushing.

Grain, cottonseed, soybeans, dried bean products, peanuts, and similar products may become flood damaged in terminal elevators, on farms, and in flat storage facilities. In

addition to flood water contamination, molding products may develop mycotoxin contamination. Examine susceptible products and facilities for damage, inundation, and mold.

Rodent activity may increase in flooded areas as the vermin seek food and shelter. Be alert to rodent defilement on products.

As lots of products are checked, embargoed, or released and the immediate situation returns to normal, firms will want to start operating. Prior to beginning operations, examine equipment and processing facilities for pollution and its aftermath. Plant operation must not be permitted unless proper cleanup and sanitizing is performed.

8.1.5.8.4.2 - Earthquakes



Extreme care must be exercised when working in earthquake areas. Do not enter severely damaged buildings.

Most damage from an earthquake comes from the aftershocks, falling debris, and resulting fires and flooding. Items under FDA jurisdiction are most likely to suffer physical damage, spoilage from lack of refrigeration, and/or fire and flood damage.

8.1.5.8.4.3 - Hurricanes and Tornadoes

Investigate following the guidance in *Flooding* Section above. In addition, examine products for evidence of physical damage caused by flying objects and crushing by debris. Physical damage to product containers may be extensive. Broken or leaking containers of materials such as chemicals, oils, fertilizers, etc., may have contaminated FDA-regulated products. See the *Chemical Spills, Hazardous Waste Sites, Wrecks* section below on chemical contamination from various sources.

8.1.5.8.4.4 - Chemical Spills, Hazardous Waste Sites, Wrecks

Chemical spills occurring on land or water can pose a serious threat to the environment and contaminate FDA-regulated products both directly and indirectly. See IOM 3.2.11 for information.

In wrecks, the physical impact usually causes most damage. Toxic items in the same load may rupture and add to the contamination. In train wrecks, other railcars loaded with chemicals, oils, or other contaminating materials may rupture and contaminate food and drug products in otherwise undamaged cars. Removal of the wreckage may cause further physical damage or chemical contamination. Exposure to weather may also adversely affect the products.

Do not overlook the possibility that runoff of toxic chemicals from wrecked and ruptured cars may contaminate adjacent or nearby streams supplying water to downstream firms under FDA jurisdiction.

Hazardous waste sites also pose a hazard to the immediate environment and other locations off-site, if runoff contaminates nearby surface waters or, if leachate, contaminates ground water supplies.

8.1.5.8.4.5 - Fires, Explosions, Riots

FDA operations following these disasters are usually localized and do not normally involve many personnel or extended resources.

Examine products for exposure to excessive heat, physical damage from flying objects, falling debris, and lack of refrigeration in down-power areas. Examine for water damage from firefighting activities and handle these as a flooding situation. Be alert for possible pollution from using non-potable water in firefighting.

Firefighting often involves use of chemicals. Examine products for residues from possible toxic fire extinguishing materials and question fire authorities regarding this issue.

In addition, chemical contamination in fire disasters can also be present from other sources, including:

1. Stored chemicals rupturing from heat or from impact of falling debris.
2. Spraying or leaking chemicals (liquid, powder, dust, granules) as damaged containers are being removed or salvaged from the fire area.
3. Tracking of chemical material from contaminated areas to other areas by fire crews or others.
4. Burning or melting plastic containers, insulation, and other building materials.
5. Leaking fuels, storage batteries, anti-freeze, etc., from burning, damaged or overheated equipment.
6. Chemicals from melting or vaporizing electrical insulation and, in particular, cooling chemicals from leaking or exploding electrical transformers. Large commercial transformers are often directly involved in the fire area and may leak or explode from the heat, spreading toxic liquid chemicals (some transformer oils contain con-centrations of PCB) over a large area, even contaminating products in non-fire areas.

8.1.5.8.5 - Bioterrorism

The field was issued guidance from 2001 which includes the following:
If a bioterrorism act is suspected, FDA staff should not collect or accept samples from any local, state, or law enforcement agency as such actions will be coordinated by OCI and the FBI, as appropriate. If an FDA-regulated product is suspected in a tampering, please call OEM/OEO immediately. In the FBI/OCI determines the product is not suspect, OEM/OEO will issue further guidance to the division office.

Office of Emergency Operations / Office of Emergency Management (OEM/OEO) emergency operations 24-hour phone number is 1 (866) 300-4374. The e-mail is emergency.operations@fda.hhs.gov.

For additional information see Guidance to the Field on Bioterrorism (10/17/2001) (http://inside.fda.gov:9003/downloads/policyprocedures/guidanceregulations/fieldinvestigations/ucm023333.doc). *(Note: This link is only available on the FDA Intranet site and cannot be accessed by individuals outside the FDA network. Requests can be made through the FOI process described in Section 8.1.3)*

8.1.5.8.6 - Embargoes

See IOM 3.3.1 and IOM 2.7.1.

FDA does not have embargo authority, but does have administrative detention authority as specified in:

- The Federal Meat Inspection Act (https://www.fsis.usda.gov/policy/food-safety-acts/federal-meat-inspection-act)
- The Poultry Products Inspection Act (https://www.fsis.usda.gov/policy/food-safety-acts/poultry-products-inspection-act)
- The Egg Products Inspection Act (https://www.fsis.usda.gov/policy/food-safety-acts/egg-products-inspection-act
- Certain parts of the FD&C Act, namely Section 304(g) [21 U.S.C. 334(g)](g) [21 U.S.C. 334(g)] for medical devices, drugs, and tobacco and Section 304(h) [21 U.S.C. 334(h)] for human and animal food

States and local jurisdictions have embargo authority over FDA-regulated products. Embargoes are an effective tool for keeping adulterated and misbranded products from the consumer market. State and local embargoes can be employed immediately requiring the merchandise be held, destroyed, or reconditioned without time consuming delays. Some state and local embargo powers are limited to the length of time the product can be embargoed and a minimal quantity or value. In these cases, the use of federal administrative detention, injunction, and seizure action should still be considered. Your division will determine if embargoes are warranted and work with state or local authorities to obtain them.

8.1.5.8.7 - Field Operations

On-site inspectional and investigational activities will normally be conducted with other FDA personnel and state or local counterparts.

An assessment must first be made of the disaster area to determine the extent of damage, and the amounts and kinds of merchandise involved. This may be done by contacting local Emergency Operation Centers on current conditions, and from firm and mapping details of the impacted area provided by the OEO Geographic Information System (GIS). If an IMT is activated the Planning Section and Safety Officer will perform this assessment.

Whether operating within an IMT or not, once personnel are mobilized and assignments are issued, operational procedures will be similar, regardless of the type of disaster. Normally, you will search, identify, and investigate foods, drugs, devices, and cosmetics for actual or possible contamination and taking the necessary steps to preclude their use until they are released, reconditioned, or destroyed.



CAUTION: Although procedures in this subchapter do not cover disasters resulting from a radiological event (presence or release of radioactive materials), it is possible you may discover products suspected of contamination by radioactive materials in the disaster area. If you suspect the presence of radioactive materials, take no action on the materials yourself, but have the area cordoned off at once. Notify the command official (official in charge) and immediately contact your IMT or supervisor, as applicable, to alert the radiological health representative and the state radiation control agency. Follow their instructions.

When in doubt as to the condition of any materials affected, request holds or embargoes pending final outcome of further examinations. See *Section 8.1.5.8.6.*

8.1.5.8.8 - Field Examination and Samples

Field examinations are an effective tool for determining adulteration or misbranding during disaster investigations. Judge the extent of field examination and sample collections necessary, based on the nature and magnitude of the disaster.

In major catastrophes, large numbers of samples may not be necessary because of obvious visible contamination and the emergency disposition powers invoked by state and local officials. In minor local disasters, such as fires, riots, train wrecks, truck accidents, or shipwrecks, lots may be held pending outcome of examinations and extensive sampling may be required.

Field examinations should focus on obvious adulteration, such as physical damage to products or containers, or damage to labeling.

Examine bulk containers and their contents, including underground storage tanks. Examine material in rail cars, truck trailers, and storage silos. Be especially alert for rail car and trailer movement. These may quickly disappear, as clean-up crews arrive.

8.1.5.8.9 - Product Disposition

Lots under embargo, or voluntarily held pending examination or analysis, must be secured until the examination or analysis is completed, and a release decision is made. If the material can be released, it is returned to the owner.

Depending on the circumstances and the magnitude of the disaster, segregation, destruction, or reconditioning of affected goods may be accomplished in the immediate area or the materials may be moved to distant locations for further manipulation.
FDA normally opposes movement of affected goods since control of the lots is difficult. However, in cases of widespread disasters, reconditioning centers established in non-disaster areas may be the most efficient way to handle the problem.

8.1.5.8.9.1 - Segregation

The segregation process often creates a multitude of problems, especially when insurance claims agents and salvage firms become involved. You are not to segregate materials yourself. This is the responsibility of the owner or his agent. You should advise them what constitutes releasable conditions. After segregation, you may be instructed to advise them about product release based on your examination and/or laboratory results.

8.1.5.8.9.2 - Destruction

It is not your responsibility to say how condemned products are to be destroyed. This is a concern of the owner and the state or local health agencies that condemned the products. FDA may be asked to aid in or recommend destruction methods. The most common destruction method is crushing and dumping in a land fill in approved areas. See IOM 2.6.1. Destruction methods usually are worked out with state or local officials. The final decision in major operations may be required of the command officials or higher headquarters, especially if the environmental impact is significant.
Control products to be destroyed and protect them from pilfering at destruction sites.

8.1.5.8.9.3 - Reconditioning

Affected products may often be reconditioned depending on the condition of the product, its container, type of product, intended use, and extent and type of contamination.

Any reconditioning must be closely supervised, with proper safeguards for product accountability. Control must be maintained over the complete operation, with proper disposition of the rejected portion and the reconditioning of the acceptable portion performed to the satisfaction of all health officials.

Certain food products which cannot be salvaged for human or animal use might be of use in non-food or non-feed industries. However, these must be denatured to render them unfit for food or feed use. Firms must account for the amounts of product denatured, to whom it was sold, and the final use of the product. Examination of the product at its final destination and/or a spot check may be required to assure it is utilized in non-food or non-feed products. Reconditioning plans should be reviewed by the division's Compliance Branch in consultation with the appropriate center or by the IMT if ICS is being used for the incident.

It is your responsibility to assure the firm is following the reconditioning plan and that no product is diverted from the plan.

8.1.5.8.9.4 - Relabeling

Relabeling may be the only reconditioning required if damage is solely to the label and all the following conditions are met:

- The new label contains all mandatory information, is not misleading in any way, and conforms with the FD&C Act in all other aspects.
- Label codes are carried over to the new label.
- The product is not contaminated; and

- The container has its original integrity.

8.1.5.9 - Counterfeiting and Tampering

8.1.5.9.1 - Reporting Contacts

All reports of counterfeiting, tampering, or tampering threats must be immediately reported to the Office of Criminal Investigations (OCI) headquarters office, Special Agent in Charge-Headquarters Operations (SAIC-HQS OPS) at 240-276-9500 and the Office of Emergency Management (OEM)/Office of Emergency Operations (OEO) at 1 (866) 300-4374 (24 hours); or through CMS following SOP-000544.

If the complaint or report involves a United States Department of Agriculture (USDA) regulated product, the district office should report it directly to the USDA and notify OCI, SAIC-HQS OPS, and OEM/OEO immediately. Notification of OCI may be done online at OCI's *Report Suspect Criminal Activity* website: (https://www.accessdata.fda.gov/scripts/email/oc/oci/contact.cfm). OEM/OEO can be notified by e-mail at emergency.operations@fda.hhs.gov and by phone 24 hours a day at 1 (866) 300-4374.

Do not conduct any investigation into these reports unless you have been directed to do so by management following their meeting with OCI.

8.1.5.9.2 - OEM / OEO Responsibility

OEO/OEM is the focal point for communications; especially in those counterfeiting/tampering cases where regional/national coverage is necessary. Alert OEM immediately to all suspected or confirmed counterfeiting/tampering incidents, whether or not there is an injury/illness involved, especially if media attention will be initiated by any source.

8.1.5.9.3 - Coordination with Other Government Agencies

The Federal Bureau of Investigations (FBI) and the USDA share enforcement of the Federal Anti-Tampering Act (FATA) with FDA as described below:

1. FBI Responsibility - The FBI has concurrent jurisdiction under the FATA over products regulated by FDA. The FDA understands the FBI's primary interest in the FATA matters will be to investigate; particularly, those cases which involve a serious threat to human life or a death. SAIC-HQS OPS or the local OCI field office will coordinate all referrals to the FBI in accordance with agency policy.
2. USDA Responsibility - The USDA will investigate and interact with the FBI on counterfeiting/tampering of products regulated by USDA. If a counterfeiting/tampering complaint or report is made to an FDA district office and involves a USDA-regulated product, the district office should report it directly to the USDA and notify OCI, SAIC-HQS OPS, and OEM/OEO immediately. Notification of OCI may be done online at OCI's *Report Suspect Criminal Activity* website: (https://www.accessdata.fda.gov/scripts/email/oc/oci/contact.cfm).

Isolated incidents of counterfeiting/tampering not investigated by OCI and not meeting the criteria for FBI or USDA follow-up, may be referred to the appropriate state or local

investigative agencies, as outlined in section 8.1.5.9.4. The appropriate center should be consulted in these cases. Assistance should be provided to cooperating officials as necessary or where requested.

8.1.5.9.4 - Authority & Responsibility

FDA is authorized to investigate reported counterfeiting/tampering of FDA-regulated consumer products under the FATA, Title 18, USC, Section 1365 and Title 18, USC, Section 2320. See IOM Exhibit 8-1. In most cases, the authority for such investigations is also found in the FD&C Act.

OCI has the primary responsibility for all criminal investigations of counterfeiting/tampering/threat incidents of FDA regulated products. Given that responsibility, OCI field offices will coordinate responses to counterfeiting/tampering reports with the district offices they deem appropriate, to ensure initial investigative steps are taken in a timely and efficient manner.



In those incidents where OCI does not, or cannot, initiate a criminal investigation, they will inform the division of their decision and the division will determine the proper follow-up, which could include further investigation by the division or referral to local or state authorities. The division will keep OCI informed of their follow-up activities and any relevant changes in its status. Prior to initiation of any tampering investigation, you and your supervisor should evaluate the situation from a personal safety perspective. You and your division management may also need to determine if a situational plan is warranted. Refer to IOM 5.2 - Personal Safety, and IOM 5.3.1.1 Situational Plan, for more information.

8.1.5.9.5 - Release of Information

During any investigation related to counterfeiting or tampering, no information should be released without management approval. If there are inquiries about the investigation, contact your supervisor.

8.1.5.9.6 - Investigation

The purpose of these investigations is to determine if counterfeiting/tampering has occurred; the seriousness of the problem; the quantity of affected products on the market; the source of the counterfeiting/tampering; and quick removal from consumers or commerce of any contaminated product. OCI will seek to identify and initiate criminal prosecution of those persons responsible for criminal activity associated with counterfeiting/tampering/threat incidents.

FDA will investigate reports of counterfeiting/tampering associated with FDA-regulated products. Priority will be given to reports of death, illness, injury, or a potential health hazard. Adhere to existing procedures and instructions as outlined in the IOM and RPM when conducting counterfeiting/tampering investigations, inspections, sample collections, special investigations, and related activities including interviews, record examination, direct observation, affidavits, etc.

8.1.5.9.7 - General Procedures

Counterfeiting/Tampering incidents historically have occurred in unpredictable forms and products. Standard operating procedures (SOPS), in most cases, will suffice for these investigations. As events take place, specific instructions for some investigations may be provided by OCI headquarters and/or your division office. Expeditious resolution is important, especially when a health hazard may be involved.

Attempt to answer the following questions as rapidly as possible:

- Has counterfeiting/tampering occurred, or can the condition of the product be explained by other means?
- Is death, injury, or illness associated with the report and, if so, does it appear to be caused by the product counterfeiting/tampering?
- Does the incident appear to be isolated or wide-spread?
- Is it likely other, similarly affected FDA-regulated products remain in distribution, and if so, what is the extent and magnitude of distribution?
- If the incident involves more than a single container, could counterfeiting/tampering have occurred at the production facility or in the distribution chain rather than at retail?
- Can specific persons or points in the distribution chain be identified as possibly causing the problem?

Be sure to coordinate your efforts with OCI SAIC/IOD HQS OPS and OEM/OEO.
In many counterfeiting cases, ORA investigators and OCI agents conduct joint inspections/investigations at the distributors. It is the purpose of the ORA investigators to document receipt and distribution of counterfeit products and to discuss voluntary recall of those products. OCI agents will at the same time conduct their investigation into the knowledge and source of the counterfeit products. It is not your purpose to accompany the OCI agent during his/her investigation.

8.1.5.9.8 - Sampling

8.1.5.9.8.1 - Tampering Cases

Whenever a sample is collected for suspected tampering, you must collect an authentic sample of the same product. It should be from the same lot and code, if at all possible. The sample size for the authentic portion is at least six in-tact units. Follow normal sampling techniques; however, recognize that there may be forensic evidence available such as fingerprints and hair that can be lost if the sample is not handled properly.

The Forensic Chemistry Center should be contacted prior to sampling. They can give specific directions regarding sampling in each situation, especially related to the preservation of forensic evidence like fingerprints.



Samples should be packed to avoid movement of the product container within the bag. Individual dosage units from previously opened containers can be protected by removing them from their container utilizing spoons or forceps. Secure them in separate containers so they do not rub or smear possible evidence. Further guidance can be found in the FBI "HANDBOOK OF FORENSIC SERVICES" (https://www.fbi.gov/file-repository/handbook-of-forensic-services-pdf.pdf/view). As a precaution, rubber gloves may be worn inside of cotton gloves as protection against toxic or caustic substances.

Ship samples with extreme care to ensure their integrity. Thoroughly describe your sample and its characteristics on the collection report (C/R) to facilitate analysis. Include any descriptive terms used by individuals associated with the complaint. If special instructions to preserve fingerprints or for further handling are indicated, they should be noted on the C/R. If speed is imperative, consider hand delivery to the lab.

8.1.5.9.8.2 - Counterfeiting Cases

If sampling is indicated during an investigation of counterfeiting, follow the directions from OCI or the Forensic Chemistry Center regarding collection, packaging, and shipment of the sample. Authentic samples should only be collected when requested by OCI in consultation with FCC.

8.1.5.9.9 - Complainants

Some complaints about “foreign objects” may be tampering complaints. The complainant may state they found something in a product. You should be aware that any complaint investigation of foreign objects may become a tampering investigation.

Consumers are likely unaware of the provisions of the Federal Anti-Tampering Act (FATA). A general discussion of the FATA, its provisions for investigation, filing of false reports, and counterfeiting/tampering can be useful and informative to those individuals. Consumers are often unaware that merely filing a false report is a serious crime and once aware may rescind previous statements. In general, this would close an investigation, but you should discuss this with your supervisor.

Prior to concluding your interview of the complainant, obtain a signed affidavit attesting to the circumstances of the complaint, as directed by IOM 4.4.5. Include a statement in the affidavit similar to the following, "I have been informed of the provisions of the Federal Anti-Tampering Act and also that the providing of false information to the federal government is illegal." It is permissible to pre-type this statement at the bottom of an affidavit, FDA 463a, and photocopy it before use if you have a large number of counterfeiting/tampering complaints to investigate.

8.1.5.9.10 - Continuance of Investigation

Some investigations may continue after the interview and sample collection from the consumer. If you are directed to continue the investigation at the retail, distribution, or manufacturing

sites, obtain specific guidance from your management or OCI before proceeding. You may be conducting an inspection at a firm simultaneously with an OCI investigation. You should not disclose to the firm officials anything about an OCI investigation.

8.1.5.9.11 - Refusals

All refusals encountered during counterfeiting/tampering investigations should be documented using existing procedures. Refusals of requests should be documented in detail. Assure the firm is aware of the non-routine nature of the request. If a search warrant or other court order is necessary, OCI will lead or direct this part of the investigation. Report all refusals to the local OCI field office.

8.1.6 - General Investigative Techniques – What do I do during an investigation?

8.1.6.1 - Interviews

An interview is a one-on-one structured conversation to obtain accurate, reliable information. To gain the most facts and information, be prepared and conduct the interview methodically with a set purpose.

8.1.6.1.1 - Preparation

Interviews may be conducted in various agreed upon meeting places. Choose a non-threating place for the interview, such as a conference room or private office free from distractions or interruptions. Silence your phone to avoid incoming calls. If possible, conduct the interview away from the person's normal area of business. If interviewing a consumer at their home, try to interview them in an area of their home that has the least distractions. If possible, conduct the interview sitting directly across from the interviewee.

Begin by researching your topic. Set a specific purpose and objectives for what you want to learn during the interview.

8.1.6.1.2 - The Interview

- Set the tone. In most cases, you may tell the interviewee what they can expect. Start out with generic or easy-to-answer questions to establish a baseline and to put the subject at ease.
- Avoid asking leading questions. Ask open-ended questions that encourage the interviewee to talk and provide a full answer rather than a "yes" or "no" (e.g., Tell me about…, How did you…, Why was this…, etc.) Avoid combining more than one idea into the same question. Frame the question to generate an answer one fact at a time. Avoid questions that are accusatory or that trigger a defensive response. 'Yes' and 'no' questions may be used at the end of the interview to affirm facts.
- Keep an open mind.
- Do not express your opinions, thoughts, and your own conclusions about the situation or what the interviewee says. You are trying to learn information and facts from the interviewee so avoid being too familiar with the topic in your responses. Set aside any potential biases while conducting the interview.

- Take detailed notes or have another CSO present to take notes. This is extremely helpful since you are focused on the objectivity of the interview. If taking notes makes the interviewee uncomfortable or hinders the interview, you may take notes immediately after the interview and identify the time between the interview and your notetaking and explain the circumstances for not taking contemporaneous notes during the interview. Only use quotes ("…") if you are certain they are exact. It is a good practice to read a quote back to the interviewee to confirm its accuracy.
- Pay attention to the subject's verbal and non-verbal communication.
- Ask for clarification and more detail if responses are not clear to you during the interview. Repeat answers back to the subject to ensure you heard the information correctly. Ask if documents exist and to support any part of the interviewee's story. Collect any available relevant documents.
- Follow-up questions may help establish additional facts. If your questions are avoided or the answers seem evasive, try rephrasing the question and ask it again. You may also change topics and return to an issue later.
- Allow the interviewee enough time to answer your questions and avoid interrupting them. Sometimes silence can be a tool to prompt further explanation or reaction. Before concluding the interview, ask the subject if there is anything else they would like to provide or discuss. Ensure that the interviewee has your contact information in case they recall any more material information later.
- Interviews and discussions with complainants where tampering is suspected or alleged, should include a discussion of the Federal Anti-Tampering Act (Exhibit 8-14). This discussion needs to be documented in the investigation report/memo. See IOM 4.4.3.3

8.1.6.1.3 - Safety



Developing a Situational Safety Plan may also be required. Refer to IOM 5.2
In preparation for any consumer complaint interviews, you should take your personal safety into consideration. Refer to IOM 5.3.1.1 for more information.

8.1.6.1.4 - Basic Information to Obtain

Obtain an accurate and complete description of the product, e.g., brand name, product name, flavor, or variety, how packaged, storage conditions required (i.e., refrigerated or shelf stable) etc. Refer to *Consumer Complaint Procedure (SOP-000544)* Section 6.1.4.

It is important to accurately determine the sequence of events leading up to the complaint.

You cannot rely on consumers responding to follow-up calls or providing additional information later.

8.1.6.2 - Medical Records

In investigating complaints where the complainant was seen by a health professional, contact the health professional concerning the nature of the alleged illness/injury, and the relationship to the product. You may occasionally find the complainant has not mentioned the product to the health professional as a potential cause of the illness or injury. Use judgment as to the usefulness of

collecting medical records. Examples of medical records to collect include: Admission History and Physical; Emergency Room/Clinic Record of the event if patient not admitted; Discharge Summary; Autopsy Report; and Death Certificate. See also IOM 5.6.11.4.

If collection of medical records is necessary, use the letter template found in Exhibit 8-2. It may be necessary to use multiple letters if medical records are at different locations. If you encounter resistance from the medical professionals in providing records, you may refer them to 45 CFR 164.512(b) which explains the exemptions allowing FDA access to the medical records.

FDA is exempt from the HIPAA Privacy Rule as a public health authority. If a situation arises in which information sharing is impeded by the belief that FDA lacks authority to receive this information, you may share the language below during disease outbreak investigations or consumer complaint follow-up. References are provided for further information.

"The Health Insurance Portability and Accountability Act (HIPAA), Standards for Privacy of Individually Identifiable Health Information; Final Rule (Privacy Rule) permits disclosure of privacy information without a written patient authorization for specific public health purposes. Specifically, the Privacy Rule permits covered entities to disclose this type of information to 'a public health authority that is authorized by law to collect or receive such information for the purpose of preventing or controlling disease, injury, or disability, including…the conduct of…public health investigations'[1]. Per the Privacy Rule, 'public health authority means an agency or authority of the United States…including the employees or agents of such public agency…that is responsible for public health matters as part of its official mandate'[2]. FDA, as a public health authority responsible for ensuring the public health and safety with regards to FDA-regulated products, meets this definition. Our authority to receive information related to FDA-regulated products comes from the Federal Food, Drug and Cosmetic Act (FD&C Act), the Public Health Service Act, and regulations issued under those authorities.

"The Privacy Rule permits covered entities to disclose protected health information (including personal privacy information) directly to the FDA for certain public health activities and purposes, provided that the disclosure is limited to the minimum amount necessary. During FDA follow-up to reports of illnesses potentially associated with FDA-regulated products, access to personal privacy information including names and contact information is necessary in order to ensure timely follow-up and, potentially, removal of implicated products from commerce. FDA is also responsible for safeguarding personal privacy information released to us according to the Freedom of Information Act and the Privacy Act[3] and our information disclosure regulations[4], and is obligated to comply with

[1] 45 CFR 164.512, from the Privacy Rule, available at https://www.law.cornell.edu/cfr/text/45/164.512

[2] 45 CFR 164.501, also from the Privacy Rule, available at https://www.law.cornell.edu/cfr/text/45/164.501

[3] 5 USC 552, 5 USC 552a, from The Privacy Act of 1974 5 USC 552a (as amended), available at https://www.law.cornell.edu/uscode/text/5/552 and https://www.law.cornell.edu/uscode/text/5/552a

[4] 21 CFR Parts 20 and 21, from FDA information disclosure regulations 21 CFR Parts 20 and 21, available at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=20

all applicable protections, procedures, and legal requirements against the unauthorized disclosure of this information.

"Consequently, personal privacy information including case names and contact information should be shared by state and local health departments with FDA authorities during an investigation of potentially adulterated FDA-regulated products, including illness outbreaks potentially associated with FDA-regulated foods. Prompt information sharing speeds the agency's investigation and can prevent additional illnesses and/or deaths due to an adulterated FDA-regulated product."

If the investigation is related to an outbreak/illness and the Office of Emergency Operations or Coordinated Outbreak Response and Evaluation is coordinating the incident and a medical officer has been assigned to the investigation it is preferred that the CSO, with supervisory concurrence communicates with the medical officer about the documents to collect prior to the collection. In the absence of a medical officer being assigned or available, the CSO in collaboration with the supervisor, should collect medical records most relevant to the incident. Once collected, the Office of Emergency Operations or CORE if involved, or the supervisor in consultation with their management should identify a medical officer to review the records.

The records containing personal identifiable information (PII) and medical information need to be protected. All medical information sent to the medical officer electronically needs to be encrypted. Hardcopy records shipped to the medical officer need to include shipment tracking information and request signature upon receipt. The medical records should be addressed to the attention of the specific medical officer who will be conducting the review.

Any hard copy medical records in the possession of the CSO after sending to the medical officer or returned by the medical officer, should be placed in a sealed envelope, identified to contain PII and medical information and filed with the investigation memo.

When collecting medical records from a Department of Defense (DoD) medical facility, identify yourself to the commanding officer of the facility or representative and request authorization to examine and copy records. Please note that DoD Directive 6040.2, Release of Information from Medical Records authorizing release of medical information to government agencies, has been rescinded by DoD; if the representative of the facility requests a letter authorizing release, use the same letter as above.

If the hospital does not accept the FDA letter for Authorization for Medical Records Disclosure, obtain and complete the one the facility provides.

Collect all medical records pertinent to the investigation. See IOM 5.6.5.

References are available at: https://www.law.cornell.edu/cfr/text/45/164.512 and https://www.cdc.gov/mmwr/preview/mmwrhtml/m2e411a3.htm.

8.1.6.3 - Sample Collection

Chapter 4 covers general sample collection methods and authority. In general, collection of samples during an investigation will be directed by the assignment or in discussion with your supervisor. Opened containers of product are rarely sampled.

Prior to initiating sample collection, you may consider contacting the home division of the manufacturing plant. They may be aware of an existing issue related to the product and problem. Samples should be collected immediately, while they are available.

When a consumer portion is collected, intact containers of products of the same lot should be collected from the retail and wholesale levels if available. When collecting samples at retail or wholesale, ask if the firm is aware of any other complaints concerning the product. Refer to IOM 4.3.4.1 for additional information concerning collection of consumer portions. Maintain the confidentiality of the complainant. If the distributor inquires about holding or recalling the product, refer them to your supervisor.

8.1.6.4 - Internet Investigations

The internet can provide useful information when conducting many types of investigations, including obtaining basic background information. Often you can use your government issued computer or cell phone for basic firm information (e.g., hours of operation, key personnel, location, directions, etc.). In these cases, you are using the internet as a tool to assist as you determine where and how to collect information and conduct your investigation.

When conducting specific internet investigations and documenting evidence online, refer to Introduction to Internet Investigations

(https://fda.sharepoint.com/sites/insideFDA-ORA-Office-of-Partnerships-and-Operational-Policy/SitePages/Health-Fraud-Branch.aspx)

Note: This website is on the FDA Intranet and not accessible outside of the FDA Network.

8.1.7 - Locations for Investigations – Where could you conduct an investigation?

Some examples of locations for investigations include:

- Retail establishments.
- A consumer's residence.
- Other government agencies.
- Location agreed upon with a complainant.
- Hospitals/physicians' offices.
- Online.

Depending on the circumstances involved, an investigation can be performed at almost any location.

8.1.8 - Internal and External Organizations Involved - Who else will I encounter during an investigation? Why are they involved?

The agency works cooperatively with many outside organizations, primarily other federal government agencies and state, local, tribal, and territorial (SLTT) authorities. Internally, you may work with individuals from ORA headquarters, OCI, other programmatic divisions or center employees. Some of these organizations become involved due to contractual obligation, statutory obligation, request for expertise, or memorandum of understanding (MOU). Chapter 3 of the IOM provides information about major organizations that FDA interacts with, both federal and state.

8.1.8.1 - Interagency Referral

One of FDA's functions is to assist SLTT and other federal agencies in conducting investigations, collecting samples, and conducting plant inspections. If you find information during the course of an investigation that may be relevant to another federal agency, a referral request can be made by filling out an online form https:/www.accessdata.fda.gov/scripts/IRF/.

Primary regulatory authority may belong to FDA or another agency. It is important to be aware of which organization has primary regulatory authority during an investigation.

For Grade A Milk products, raw molluscan shellfish, and retail food operations, within ORA, the Office of State Cooperative Programs (OSCP) has lead responsibility. For these cooperative programs, the state has primary authority for investigations. FDA often accompanies and assists states during investigations through the Office of State Cooperative Programs. If your investigation involves Grade A Milk or Milk Products, raw molluscan shellfish, or retail food operations, contact the Office of State Cooperative Programs before investigating.

8.1.8.2 - Intra-agency/Cross-Program

Outside of ORA, you may be involved other components of FDA. FDA staff work closely with one another to ensure the safety, efficacy, and security of FDA-regulated products. FDA functions are organized into the following:

- The Office of Foods and Veterinary Medicine (OFVM) provides oversight of FDA's food and feed programs as well as leads the implementation of the FDA Food Safety Modernization Act of 2011 (FSMA). OFVM includes the Center for Veterinary Medicine (CVM) and the Center for Food Safety and Applied Nutrition (CFSAN) which includes the Coordinated Outbreak Response and Evaluation (CORE) Network.
- The Office of Medical Products and Tobacco (OMPT) provides high-level coordination and leadership across the centers for drugs, biologics, medical devices, and tobacco products. This office also oversees special medical programs.
- The Office of Global Operations (OGO) is focused on globalization and import safety of food and drug production and supply. OGO provides direction and support to ORA and the Office of International Programs (OIP).

8.1.9 - General Investigation Reporting - How do I report my investigation? How do I get credit for the time I spent on it?

Reporting an investigation is almost always done using a memorandum (see Exhibit 8-3) and captured as an operation in eNSpect (explained in more detail below). The format of the investigation memo is not as defined in sections as an establishment inspection report (EIR). As a general guideline you can first summarize why or give the reason for the investigation, what was covered, and briefly state the findings. After this, you can go into detail about how you conducted the investigation and what you found. Reporting the course of your investigation and your findings chronologically works in most situations. For long narratives, using headings will make it easier for the reader to follow your reporting. Some types of investigations have forms that need to be completed in addition to the narrative within the memo. For example, FDA Form 3623, the Farm Investigation Questionnaire (FIQ), must be completed for all farm investigations.

For import specific investigations see IOM 6.6.3.

8.1.9.1 - Entering investigation operations in eNSpect

eNSpect is used to capture information about the assignment, the establishment, and the investigation. Investigation operations are reported in eNSpect as either a Domestic Investigation (OP13) or Foreign Investigation (OP15). General information on how to complete these operations in eNSpect field client are provided below. (For complete instructions, refer to the eNSpect Resources Site for the current eNSpect User Guide and eNSpect training.) The "Investigation" tab in eNSpect includes the "Details," "Time & Coverage," and "Endorsement" pages.

The "Endorsement" page has three sections: Endorsement, Attachments, and Supervisor Feedback. Attachments, such as the investigation memo, are uploaded to support your findings under the "Attachments" section of the endorsement page. All three sub-sections must be completed, and each has a maximum of 4000 characters per text box. The narrative entered in these sub-sections will depend on several factors (e.g., program/division, type of investigation, assignment). If the character limit prevents you from describing all relevant facts, an investigation memo should be prepared and uploaded under the "Attachments" section. If the space is adequate to report your investigation, you may not need to prepare a memo. For example, reporting OEI improvement activities and firms determined to be out of business (OOB) are two situations where a memo usually is not necessary. However, this can also depend on your program and/or division procedures. Programs of divisions may require a memo for all investigations. Consult with your supervisor if you are unsure whether a memo is required for the investigation.

Your supervisor or other designated individual will review and endorse the investigation report (OP13 or OP15) in eNSpect. An inspection (OP11 and OP12) can be converted to an investigation (OP15 and OP13, respectively) in eNSpect when you were unable to complete the inspection (often referred to as a "washout"). Obtain supervisory concurrence before converting an inspection to an investigation due to a washout. For example, your supervisor may want you to hold onto an inspection assignment and inspect a seasonal firm later in the year rather than converting the inspection to an investigation as a washout.

Reasons to convert an inspection to a washout include the following: Out of Business (OOB); Not Official Establishment Inventory (NOE); Inactive (INA); Seasonal (SEA); Operational but not an FDA obligation (OPR); Pre-Production (PRE-PROD), and Firm does not meet assignment criteria (OPR). The information reported in your investigation, especially the reason for the investigation, may be helpful to future investigators. If the investigation finds further action is recommended, do not convert the associated inspection assignment to a "washout" in eNSpect. Report the operation using an ad-hoc eNSpect investigation (OP13 or OP15). Do not return the associated inspection operation (OP12 or OP11) to FACTS for conversion to an investigation. An example of a further action would be a request for Import Alert because of an inspection refusal in a foreign country.

8.1.9.2 - Investigation memo: format, content, endorsement, and routing

Exhibit 8-3 demonstrates the general format of a memorandum of investigation (investigation memo), which includes the originating division/office; responsible firm; FDA Establishment Inventory (FEI); to/from; date; and subject. When writing an investigation memo, consider the following:

- Document all pertinent information (e.g., who, what, when, where, why). At a minimum, the investigation memo should contain the following information: the reason for the investigation; background and history, if any; findings; and recommendations.
- Provide details of how you conducted the investigation and describe pertinent data, references, attachments, etc.
- Headings may be used if it contributes to presenting your report in a clear, logical, and concise manner.
- Routing for the memorandum should be included. Consult with your supervisor if unsure of the correct routing information to include.

8.1.9.3 - Reporting complaints/follow-ups

Refer to *SOP-000544, Consumer Complaint Procedure*, in the Quality Management Information System (QMiS) for detailed instructions on intake, tirage, escalation, dispositioning, and follow-up of consumer complaints of FDA-regulated products received by and/or submitted to ORA personnel.

If you conduct an inspection to follow-up on a complaint, any findings related to the complaint should be documented in the Establishment Inspection Report or in one of the following ways for an OP13/OP15, if not involving confidential sources, whistleblowers, etc.,
If you conduct an inspection as above, but it involves a confidential source or whistleblower, follow directions for reporting provided in Consumer Complaint section related to Confidential Sources or Whistleblower.

Information contained in the investigation memo or sub-sections of the "Endorsement" section of eNSpect, should at a minimum include a general discussion of the complaints that were covered and the complaint number(s). The complaint numbers should be recorded in the endorsement of the OP13/OP15. All FDA complaints requiring coverage during an inspection or investigation will populate in the eNSpect assignment based on the FEI. The consumer complaints tab in eNSpect must be completed for complaint coverage and suggested follow-up disposition when FDA complaints are listed.

Investigations (OP13 or OP15) covering complaints must only contain one FEI and have the investigation basis of consumer complaint.

The time spent on the consumer complaint follow-up should be reported in the eNSpect assignment (OP13 or OP15) under the appropriate complaint Program/Assignment Code (PAC) for any complaints covered during the investigation. Refer to the PAC Master List for the appropriate PAC.

If a sample is collected during a domestic consumer complaint follow-up investigation, the sample number is linked to the OP13 in eNSpect by entering the sample number under the "Details" page in eNSpect. In addition, an OP31 (Sample Collection) with a collection report containing all relevant information will be completed. If the primary response to the complaint is collection of a sample and no further investigation, no assignment (OP13 or Op12) is generally created for completion in eNSpect. In this case all relevant documents would be included with the OP31 collection report.

8.1.9.4 - Reporting information obtained from a confidential source

During an investigation, inspection, or other operation, you may acquire information from a confidential source. See IOM 5.4 for information on how to interview confidential source and document information obtained from them. Information received from a confidential source during an investigation should be captured in an investigation memo as an attachment to the OP13/OP15. See IOM 5.4 for suggestions on how to protect the identity of the confidential source when writing your investigation memo. Information contained within an OP13/OP15 is outside the scope of FMD-145 (Release of the Establishment Inspection Report (EIR) and should be reviewed by FOIA personnel for appropriate action before release.

If during an inspection you interview a confidential source or whistleblower, do not include any identifiable information in the EIR and prepare a separate memo of investigation to cover this part of the inspection. Enter as an OP 13 or OP 15. See 5.4.

8.1.9.5 - Reporting investigations conducted during disaster response

There is no prescribed format for narrative reporting of disaster operations. Consult with your supervisor as to your division's preference. If operations were conducted as an investigation, you will likely write an investigation memo to document the activities. The memo should briefly describe the onset of the disaster, its magnitude, and your activities. Include cooperation with officials, planning operations, and the logical sequence of your activities.

Your memo must contain exhibits consisting of photographs, diagrams, records, references to samples, and any other items necessary for proper presentation of the operation. Refer to RPM Chapter 8 "Emergency Procedures," for guidance on reporting natural disasters and civil disorders. List amounts of materials or products destroyed and the method of destruction. Prepare charts and lists as necessary to provide documentation of all affected lots destroyed, reconditioned, or released. Include kinds and amounts of materials segregated, released, reconditioned, and destroyed and method of reconditioning and/or destruction.

In situations where an ICS structure has been implemented, operations are reported through the IMT and use of ICS forms, situation reports, after-action reports, or other documents as appropriate to the operation. The IMT will direct you on reporting your time spent working on the operation. If a sample of an FDA-regulated product is collected as part of the disaster response under ICS, an OP31 (Sample Collection) with a collection report containing all relevant information will usually be completed. In this case, your time spent conducting the sample collection would be reported in FACTS as part of the OP31 and using the PAC appropriate for the assignment.

8.2 - Human and Animal Food Investigations

8.2.1 - Coordination

The initial step in coordination of a human and animal food investigation is notification of the potential incident. Notification to FDA may be received from SLTT officials via the district ERC or divisional staff; consumer complaints or adverse event reporting portals; or from federal entities such as the Centers for Disease Control and Prevention (CDC) alerting the FDA of illness clusters. Regardless of the source, once a potential incident is identified, the district ERC (DERC) is the primary point of contact (POC) for coordination of the response at the field level. (See Communications SOP for ERCs)

If agency-level central coordination is needed, CORE or CVM will most often provide management of the incident based on whether human or animal foods are suspected. However, there are instances when food incidents may be coordinated by OEM or a CFSAN office based on the specific commodity and scope of incident. *(See Exhibit 4 for the "Table Depicting Incident Coordination Body by Type of Incident.)*

8.2.2 - Foodborne Illness Outbreak Investigations

8.2.2.1 - Cooperation with Other Agencies

One of FDA's functions is to assist SLTT and other federal agencies in conducting investigations, collecting samples, and conducting firm inspections if warranted.

In addition to state and local health departments, the following federal agencies may also become involved in investigating foodborne disease outbreaks:

- Centers for Disease Control and Prevention (CDC)
- U.S. Department of Agriculture (USDA)
- Environmental Protection Agency (EPA)

CDC becomes involved in foodborne outbreaks when people in more than one state are sick with the same germ from contaminated food. Their role involves coordinating the epidemiologic investigation, including identifying illnesses. CDC works directly with CORE to provide epidemiological information to help identify a possible food vehicle and focus the scope of FDA's investigation. During an outbreak, CORE and CDC coordinate with internal and external partners (including international governments) to help determine the outbreak source and prevent future illness.

USDA is responsible for investigating outbreaks involving meat and poultry products under their jurisdiction. Whenever a complaint is received involving any meat-containing product, including such items as soups, combination infant foods, frozen dinners, etc., evaluate the need to contact

USDA. Most products containing red meat or poultry are regulated by USDA. The exceptions include:

- products containing meat from game animals, such as venison, rabbits, etc.
- meat-flavored instant noodles
- "pork and beans" (which contains only a small amount of pork fat and is regulated by FDA)
- Closed face sandwiches

USDA-regulated products display on their labels a round "shield" with the USDA Establishment Number. Alternatively, the establishment number may be identified in the lot number. Red meat products under USDA jurisdiction will often contain the abbreviation "EST" followed by a one to four-digit number; poultry products under USDA jurisdiction will contain the letter "P" followed by a number.

IOM 3.2.1 and 3.2.4.3 provide information for reporting suspected outbreaks to USDA and CDC. In addition, FDA and CDC have an agreement that FDA will be immediately advised whenever CDC ships botulism antitoxin anywhere in the United States or its possessions.
Whenever a water source is suspected as a likely origin of the agent of an illness outbreak, the EPA should be notified. For example, when investigating a foodborne outbreak on a vessel passenger conveyance, you may find the water used in food preparation to be from a land-based source or from an on-board water treatment plant. Both of these sources would fall under EPA jurisdiction. See IOM 3.2.11.

When two or more people get the same illness from the same contaminated food or drink, the event is called a foodborne illness outbreak. For more information related to foodborne illnesses, please refer to https://www.fda.gov/food/recalls-outbreaks-emergencies/outbreaks-foodborne-illness

8.2.2.2 - Outbreaks on Foreign Flag Vessels

If a suspect outbreak involving a foreign flag vessel or a U.S. flag vessel with an international itinerary comes to your attention, report it to your supervisor and the district ERC immediately. The district ERC will provide the information to OEM/OEO. The CDC assumes primary jurisdiction for foreign flag (non-U.S. registry) and U.S. flag vessels with international itineraries entering the U.S. and traveling in U.S. waters. See IOM 3.2.4.3.

8.2.2.3 - Outbreaks Involving Interstate Conveyances

Reports of illness attributed to travel on an interstate conveyance (plane, bus, train, or vessel) are a shared responsibility of FDA, CDC, USDA, EPA, and potentially others. When a report of illness is received, notify the district ERC in your division/district. The ERC will contact the CORE Signals Team at CORESignalsTeam@fda.hhs.gov. Please include the CFSAN Office of Food Safety Interstate Travel on any email correspondence (Joseph.morin@fda.hhs.gov). In addition, you are encouraged to share the report with state and local public health officials. The following activities are to be coordinated with local/state public health officials: Interviews with the ill passenger(s), family members (well and ill), caregivers, and/or health professional (as appropriate) should be sufficiently probative to hypothesize if the food, water, or an environmental transmission is related to the

illness. Transmission of illnesses, particularly viral diseases, by ill employees and contaminated environmental surfaces can result in illness carryover between successive trips and should be considered. Factors such as symptoms, time of onset of symptoms, food history for the 72 hours prior to onset of the first symptom, any clinical laboratory results, and other potential exposures should be documented. The carrier should also be contacted to determine if other reports of illness have been received (passengers and employees). Obtain any illness logs from the carrier. The information developed should be evaluated to determine if further follow-up is necessary. On those carriers where a reservation system is used, obtain the names and phone numbers of passengers, and a passenger manifest, if available. If a reservation system is used, then a passenger manifest should also be available. A manifest will provide passenger seating, which will help identify additional cases based on proximity or in the event of an etiological agent like Norovirus, the passengers who occupy the seat on the next flight could also be at risk of infection. It may be necessary for the state/local health authorities, CDC or FDA to contact other passengers to determine if they became ill.

If additional cases are uncovered during these contacts, immediately notify the appropriate ERC in your division who will then contact the CORE Signals Team at CORESignalsTeam@fda.hhs.gov and the state and local public health authorities in all of the affected states. FDA will work cooperatively with these authorities and request their assistance in conducting an epidemiological investigation and collecting patient specimens. Note: If at any time the local/state public health officials are unable to assist with an investigation, have the district ERC notify CORE Signals Team at CORESignalsTeam@fda.hhs.gov who will contact the CDC and request assistance with the epidemiological investigation.

8.2.2.4 - Outbreak Management

CORE coordinates FDA's efforts to prevent, detect, investigate, respond to, evaluate, and apply lessons learned from foodborne outbreaks and public health incidents. Along with ORA, CFSAN subject matter experts (SME), and others in FDA, CORE manages the strategy and implementation of outbreak response activities and evaluates environmental, epidemiologic, and laboratory data to inform assignments and direction of outbreak investigations related to foods, cosmetics, and dietary supplements. ORA's primary role in the outbreak investigation is to perform activities related to tracing food from source to destination; food and environmental sample collection and analysis; and facility investigations.

If you become aware of a foodborne outbreak, contact the appropriate district ERC immediately who will then contact the CORE Signals Team at CORESignalsTeam@fda.hhs.gov.

8.2.2.5 - Conducting Foodborne Illness Follow-up

A priority for all foodborne illness investigations is to establish the basis for implementing control measures to stop transmission and prevent additional illnesses.

CDC is the federal agency with primary responsibility for investigating large, multi-state foodborne illness outbreaks. FDA plays a role in outbreak response generally by collecting samples, obtaining traceback information, and conducting food establishment inspections. CDC guidance for

investigating foodborne illness is available at Investigating Outbreaks (https://www.cdc.gov/foodsafety/outbreaks/investigating-outbreaks/index.html). SLTT generally conducts small, local foodborne illness outbreaks using generally the same process. In FDA, CORE guides investigations into the cause of foodborne illness outbreaks after notification from CDC that an outbreak is ongoing.

A resource for conducting epidemiological investigations is the *Council to Improve Foodborne Outbreak Response* (CIPHOR). Its website (https://cifor.us/) has many resources available to aid during an epidemiological investigation.

If you receive a report of a foodborne illness or an outbreak provide details to your district ERC and determine the extent of investigation you need to conduct. If you are required to respond to a foodborne illness outbreak use the following as guidance.

8.2.2.5.1 - Preparation

Divisions should maintain enough supplies of equipment used for sampling during a foodborne illness investigation. Assure all sterile supplies are within expiry. It is important that swabbing materials be monitored and utilized in a first in, first out manner to prevent the expiry of supplies.

8.2.2.5.2 - Interviews

Reports of foodborne illness can come from many sources, such as:

- Laboratories
- Hospital-based laboratories
- Clinical laboratories
- National or regional commercial referral laboratories
- Local or state health department laboratories
- CDC laboratories
- Health care institutions
- Hospitals (e.g., hospitalized patients reported by infection control practitioners)
- Emergency departments
- Long-term–care facilities or nursing homes
- Physicians
- Schools and childcare centers
- Food establishments (e.g., restaurants)
- State health departments

Regardless of the source of the report, the diagnosis must be verified by a thorough case history and, if possible, by examination of appropriate food samples and clinical specimens.

8.2.2.5.2.1 - Conducting Interviews

Normally, conducting foodborne illness interviews is not a role CSOs will perform since food history/symptoms are typically gathered by CDC and/or SLTT partners. Follow the guidelines upon contacting the affected person in the General Interview section (Section 8.1.6.1) of this chapter and the following:

- Identify yourself and explain the purpose of the visit or call.
- Ensure confidentiality.
- Conduct interviews in a private location.
- Be non-judgmental.
- Show empathy and attempt to build rapport with the interviewee.
- Exhibit genuine concern for persons affected and be sincere and respectful when requesting personal and confidential information.
- Set your level of communication based on the person being interviewed.
- Be tactful. People are sometimes sensitive to questions about age, gender, special dietary habits, ethnic group, excreta disposal, and housing conditions. Phrase questions thoughtfully.
- While keeping the interview as conversational and as natural as possible, communicate a sense of urgency and emphasize the positive contribution already made by the interviewee toward the control and prevention of foodborne illness.
- Use open-ended questions.
- Phrase your questions so the interviewee(s) will describe their illness and the foods and events which they feel are associated.
- Accurately record what interviewees say.
- Gently redirect, as needed.
- Probe if answers are vague, particularly about time of symptom onset.
- Asking references may help their memory, for example, “What did you do prior to eating lunch?”
- Work with epidemiology staff to provide language interpretation, if needed.
- Thank interviewee at closing and explain how the information will be used.

8.2.2.5.2.2 - Information to Gather

Targeted, effective and pertinent information gathering is critical in a foodborne illness outbreak investigation. Per the CDC: Health officials use three types of data to generate hypotheses about the likely source of an outbreak: epidemiologic, traceback, and food and environmental testing. Investigators begin by trying to pinpoint how the pathogen spread. They review details such as:

- The specific pathogen causing illness
- Where sick people live
- How old they are, their sex, and race/ethnicity
- Did they have contact with a sick person

When a contaminated food is suspected, investigators must consider many different foods that may be causing the illness. Interviews help to establish a list of foods people ate before getting sick and collect information on other exposures such as restaurants where the ill person ate and stores where they bought food. This list is used to help investigators determine what food or ingredients the sick individuals may have in common.

Consult with management, ERCs, CFSAN, SMEs, state liaisons, state partners, FDA, CORE, and others involved in the outbreak, as necessary, to determine what information is needed from the interviewee(s). Interview topics can include:

- Interviewee information
- Clinical information
- A standard list of food items
- Each meal a person ate before becoming ill and all meals and snacks eaten seventy-two hours before onset of illness. The food, even the meal, which precipitated the illness, might not be obvious and the type of illness will sometimes provide clues:
  - If the first and predominant symptoms are nausea and vomiting, concentrate questions on foods eaten recently.
  - If the first and predominant symptoms are diarrhea and abdominal cramps, foods eaten six to twenty hours before onset of illness are suspect.
  - If diarrhea, chills, and fever predominate, foods eaten twelve to seventy-two hours before onset of illness are suspect.
  - More unusual illnesses often present different clinical patterns. For instance, some illnesses such as Typhoid Fever and Hepatitis A, have incubation periods greater than 72 hours.
- Food allergies, special diets, vitamins, and supplements
- Sources of food at home/outside of the home
- Animal contact and pets
- Specific food categories
- Food shopping habits
- Travel
- Restaurant dining
- Attendance at events where food was served

Although some may not have been ill, use this detailed interview approach with each individual identified in the initial complaint or alert, until there is sufficient information to determine the scope and source of the foodborne illness outbreak.

8.2.2.5.3 - Medical Records

Physicians' and hospitals' records can be useful in verifying reported signs, symptoms and other clinical data and can sometimes rule out the possibility of foodborne illness. See General Section on Medical Records (Section 8.1.6.2).

8.2.2.5.4 - Sampling Procedures



CAUTION: Never taste any of the food products. Handle all samples with caution to prevent accidental exposure to and/or ingestion of even minute amounts of the contaminated or suspect product.

8.2.2.5.4.1 - Sample Collection

During investigations of foodborne illnesses, cooperate with other public health officials in collecting samples of items that may be associated with the outbreak.

Use interview information and a menu or data from an attack-rate table to determine which of the foods from the implicated meal are most suspect and collect samples of the suspect foods. Check storage areas for items that may have been overlooked. Check garbage for discarded foods or containers. Suspect foods often are discarded by an operator if he thinks someone may have become ill as a result of eating in his establishment. Because one of the primary tasks of the investigator is to prevent further illness, take appropriate action to prevent distribution or serving of any suspect food. If no foods remain from the suspect meal or lot, try to collect samples of items prepared in a similar manner, but subsequently to the suspect lot. Collect ingredients or raw items used in the suspect food. Determine supplier, distribution, and code information on ingredients and packaged foods to aid any investigation of the same lot in distribution channels.

Collect samples aseptically. If foods are to be examined for organophosphate pesticides or heavy metals, do not use plastic containers. Use glass jars with foil-lined lids because substances from the plastic can leach into the food and interfere with analysis.

The following are examples of articles normally collected:

- Remaining portions of all suspect foods.
- Parent stocks of suspect foods.
- Insecticides, rodenticides, or other poisons which may be involved.
- Suspect food containers such as cans, bottles, etc.
- Utensils or materials used in the preparation and storage of the suspect food.
- Table scrapings and food residues from equipment such as slicing machines, cutting boards, etc.

NOTE: Clinical specimens such as vomitus, stools, swabs of nasal and throat passages, or open sores or lesions of food workers are collected by local, state, or CDC health officials or private physicians. Do not collect these samples.

8.2.2.5.4.2 - Sample Size

In general, follow the IOM SAMPLE SCHEDULE in Charts 1, 2, and 3 (IOM, Chapter 4). Where only small amounts of items remain, such as partial meals/leftovers, empty containers with adhering particles, etc., collect all or as much as possible by scraping from utensils, equipment, or containers. It may also be necessary to collect the empty containers.

8.2.2.5.4.3 - Sample Handling

Record the temperature of the room, refrigerator, or warmer in which the food was stored, and the temperature of the food that remains after a sample is collected.
Inform the laboratory of the type and number of samples. Discuss methods to preserve and transport samples, time of arrival, and the person who will receive the shipment.
Follow guidance in Chapter 4 for collecting, handling, and shipping samples. See IOM 4.7.5.6.

If the suspect food is a commercial product, examine the original package or container for coding information to identify the place and time of processing. Your division may notify all

agencies responsible for regulating the products alleged or suspected to have caused the illness. Collect additional packages bearing the same code number for analyses for microorganisms, toxins, seam defects, vacuum, leaks, or other conditions. Be as specific as possible in requesting the type of analysis.

8.2.2.5.5 - Establishment Investigation

After a foodborne illness outbreak is reported and an investigation is initiated, the initial impact of the incident can create confusion at the facility and could result in conflicting information if too many entities become involved.

The responsibility for investigating foodborne illness outbreaks rests on a core team of people who each contribute different knowledge and skills. For FDA-initiated investigations/inspections, one FDA investigator should be designated as the inspection team leader. The team leader will set and enforce priorities, coordinate all activities associated with the investigation, serve as the point of contact about the investigation, communicate with other organizations involved in the investigation and communicate the recommended course of action determined by team to ORA management. A supervisor and/or ERC should be the coordinator for overall division activities and the division contact for headquarters personnel. All communications from FDA field or other offices to the firm's management should be channeled through the supervisor/ERC. The lead investigator should be responsible for all phases of the physical inspection of the facilities and briefing the supervisor about team progress. See IOM 5.4.

Upon arrival at the establishment where the suspect food was processed or prepared, identify yourself to the person in charge and state the purpose of your visit. Emphasize the purpose of the investigation is to determine what contributed to the outbreak, so preventive measures can be taken. Attempt to create a spirit of cooperation. Consider the position, feelings, and concerns of the manager and facility staff; defensive reactions are common.

Many factors could have contributed to contamination before foods came under the control of the manager. Assure the manager that these possibilities will be investigated. Inform the manager of the activities proposed and benefits gained for educating their workers.

When investigating the root cause of the contamination obtain the following documents: inspection reports (state and/or federal), detailed epidemiological data and traceback investigation reports to try to pinpoint locations of interest, environmental monitoring records, verification records of the identity, safety, strength, purity, efficacy, and accuracy of raw materials and packing materials used, and any analysis of resource availability, (e.g., documenting sufficient manpower and prescribed raw materials, packaging materials utilized, substitutions made, etc.), and historical data on weather events, e.g., flooding, for foods produced in the open outdoor environment.

Perform the following activities:

1). conduct personnel interviews to determine their qualifications, knowledge, experience, and training;

2). review related logbooks, records, processes, laboratory data;

3). document observations made with photos and videos whenever possible;

4). visit the facilities or farms, where causes of the event occurred (where possible).

5) Describe the processes, equipment, and facilities.

6) Evaluate the following: the suitability of equipment, facilities, and utility systems; the calibration and preventative maintenance of the equipment and instruments used; the adequacy and the implementation of the relevant standard operating procedures (SOP) utilized by the food business operator; and the Good Manufacturing Practices (GMPs), preventive controls and food safety standards, as applicable, utilized in the area where the product concerned was produced, processed, packed and/or held.

Include all relevant information in the investigation memo or EIR as appropriate.

Review of distribution records and examination of warehouse stock are two important aspects of a foodborne illness follow-up inspection. Field examination should include an inventory by code of all stock on hand. When conducting field examinations, follow instructions in IOM Sample Schedule Chart 2 (IOM, Chapter 4).

8.2.2.5.5.1- Food Handlers Interviews

If a food is already suspect, interview separately all persons who were directly involved in processing, preparing, or storing of the food and others who could have observed preparation and storage. Ask questions in a sequence that discloses the flow of food from the time it was received until it was served or distributed. Especially inquire about foods that were prepared several hours or days before being served with the suspect meal and about foods that have specific temperature requirements. Ask similar questions, suitably modified, of the managers or workers who were involved in producing, transporting, processing, preparing, or storing food at other levels of the food chain, as well as individuals who prepared the food at home.

Food workers who fear criticism or punitive action because of their possible role in the outbreak do not always accurately describe the food handling as it actually happened. Their descriptions should be plausible, account for possible sources of contamination, and indicate possibilities of survival and potential for growth of pathogens. If the description does not contain all the information desired, rephrase the questions and continue the inquiry. Seek confirmation of one person's story by talking to others who have knowledge of the food operation, or by watching the food preparation or processing practices. Be alert for inconsistencies among the accounts, as told by different individuals.

8.2.2.5.6 - Possible Contamination Source

It is important to understand the pathogen and the factors that contribute to the contamination that resulted in the foodborne illness. Some pathogens, such as Norovirus, are associated with

human fecal contamination, while other pathogens, may be more commonly associated with a particular food source (e.g., raw meat and E. coli O157:H7).

CDC has identified the most common causes of foodborne illness:

- Food from unsafe source.
- Poor personal hygiene.
- Improper food holding temperatures.
- Improper cooking temperatures.
- Contaminated equipment of cross-contamination of raw with ready-to-eat foods

You may want to familiarize yourself with Factors that Contribute to Outbreaks of Foodborne Illness (https://www.cdc.gov/nceh/ehs/nears/factors-contribute-to-outbreaks.htm) before beginning a foodborne illness investigation.

Exhibit 8-5 (https://cifor.us/uploads/resources/CIFOR-OUE-Agent-List_FINAL.pdf) provides details about possible food associations with different illness symptoms, latency and factors that contribute to outbreaks. Although the table lists possible clinical specimens to collect, you should not collect clinical samples. A SLTT health department may be able to assist and collect those samples for analysis at a state laboratory.

8.2.2.5.7 – Conducting Traceback Investigations

Traceback investigations are important epidemiological tools that are used to determine the source of food implicated in foodborne outbreaks. Traceback investigations may prevent further sale and distribution of contaminated food. Commonly, SLTT agencies conduct the initial epidemiological investigation of foodborne outbreaks and identify suspect product(s) requiring tracebacks.

CORE issues traceback assignments to the appropriate division(s) and coordinate inter-division assignments for traceback investigations. The assignment will generally provide all the guidance needed to conduct the traceback investigation.

Other resources available include:

- the FDA *Guide to Traceback of Fresh Fruits and Vegetables Implicated in Foodborne Outbreaks*, dated April, 2001
- the Office of Training Education and Development (OTED) training: *ER220: Traceback Investigations*.

8.2.2.6 - Reporting

8.2.2.6.1 - Reporting Epidemiological Investigations

Follow the reporting guidance in this chapter to report epidemiological investigations. Promptly submit a complete narrative of the investigation, including references to exhibits, samples, medical records, and laboratory reports. There is no prescribed reporting format, but it should be in a logical order. With the inclusion of investigative memos in eNSpect EIR, eNSpect can be utilized to prepare these memos. See the eNSpect EIR Quick Reference Guide for detailed information. See also IOM 8.10.

Submit copies of any written reports and documents for all injury or illness complaints involving all CFSAN products (see section 8.2 and 8.4.5) using encrypted email, secure fax transmission, or mailing.
If using mail, use this address:

Food and Drug Administration
CFSAN/OSAS
CAERS Staff (HFS-700)
5001 Campus Drive
College Park, MD 20740
Attn: CAERS Monitor

Illness/injury complaints involving special nutritional products (refer to IOM 8.2.3.2) must be accompanied by a CMS Complaint with Adverse Event Section completed when forwarded to CFSAN.

If additional follow-up on any complaint involving a CFSAN product is necessary, the Division of Field Program Planning and Evaluation (HFS-635) will issue an assignment.

8.2.2.6.2 - Reporting Food Adverse Events

Prompt reporting is essential. You may save the lives of others with prompt reporting. If consumers contact you to report adverse events including injury, illness, or death related to a human or animal food, dietary supplement, or cosmetic, they should be directed to report through the following online reporting systems. If they do not want to report through those systems, you may report for them.

8.2.2.6.2.1 - Food and Cosmetics

Details on reporting adverse events related to human food can be found at the CFSAN Adverse Event Reporting System (CAERS) website (https://www.fda.gov/food/compliance-enforcement-food/cfsan-adverse-event-reporting-system-caers).

8.2.2.6.2.2 - Dietary Supplements

Details on reporting adverse events related to dietary supplements can be found at the How to Report a Problem with Dietary Supplements website (https://www.fda.gov/food/dietary-supplements/how-report-problem-dietary-supplements).

8.2.2.6.2.3 - Cosmetics

Details on reporting adverse events can be found at the How to Report a Cosmetic Related Complaint website (https://www.fda.gov/cosmetics/cosmetics-compliance-enforcement/how-report-cosmetic-related-complaint).

8.2.2.6.2.4 - Veterinary Products

Details on reporting adverse events and complaints for animal food and animal medical products can be found at the CVM Report a Problem website (https://www.fda.gov/animal-veterinary/safety-health/report-problem).

8.2.2.6.2.5 - Reports of Criminal Activity

If a consumer calls to report criminal activity, they should be directed to the Report Suspected Criminal Activity website (https://www.accessdata.fda.gov/scripts/email/oc/oci/contact.cfm).

8.2.3 - Injury, Illness, Death

Injury, illness, product defect, and adverse reaction complaints should receive a prompt, courteous response, and assurance their complaints will receive appropriate consideration. Complaint Escalation must be done when there is an indication of a life threatening injury or adverse reaction, per SOP-000544.

When you are investigating injuries or adverse reactions, do not make comments or enter discussions with firms as to the involvement of particular products, unless specifically instructed to do so. Many adverse reactions come to FDA from consumers or health care professionals through the voluntary reporting branch of the MedWatch system. Complainant name, address, and contact information should always be kept confidential, unless express permission is given by the complainant to share it.

Whenever the press has been informed about a complaint, follow instructions found in Section 1.6.1. When the responsible firm invites the news media to observe the inspectional process, follow instructions found in Section 5.1.4.3.

NOTE: CFSAN Adverse Events Reporting System (CAERS) Staff, HFS-845, 240-402-2405, Fax: 301-436-2452, or email CAERS@fda.hhs.gov, can assist with questions pertaining to field follow-up related to foods, seafood, food additives, dietary supplements, infant formulas, and medical foods. CAERS personnel can assist in obtaining guidance from CFSAN's experts.

8.2.3.1 - Procedures

When investigating all injuries and adverse reactions the consumer complaint coordinator will follow *SOP-00045 Consumer Complaint Procedure*.

Once it is determined by program management that follow-up is deemed necessary, an assignment will be created and assigned to a CSO, who will then fill out the Follow-up Consumer Compliant Report in FACTS.

The following should be addressed and confirmed during a follow up investigation with the complainant.

- Details on the product involved, including brand name, product labeling, and any codes including lot, expiry, and/or use by codes.
- The source of the product. Where did the consumer obtain it?
- Details of how the product was used, including frequency, in what amounts, any known previous adverse reactions or pre-existing allergies and whether anyone else used the product in the household.
- If appropriate, determine if label directions were followed.
- Copies of all labeling/inserts.
- Any research the complainant may have conducted or relied upon and collect copies or internet web addresses.
- Complete description of the incident (sequence of events) and the nature of the injury or adverse reaction, including date, time, location, and symptoms or description of injury.
  - Any hospital or physician's records available and identify pre-existing conditions which may have a bearing on the injury or adverse reaction.
  - Photographs of the victim's injuries, if significant. See Section on Medical Records.
- List names of other persons involved, such as beauty salon operators, medical personnel, lawyers, insurance agents. Obtain their views on the injury or adverse reaction. The views of an attending physician are important because they may vary markedly from those of the patient.
- Determine if the consumer reported the adverse reaction to the manufacturer and the manufacturer's response.
- Any other consumer complaints, injuries or alleged adverse reactions reported to the manufacturer concerning the product.
- If necessary, obtain distribution information of the implicated lot(s) from the manufacturer.

8.2.3.2 - Specific Product Reporting (Food, Dietary Supplement, and Cosmetic – Injury or Reaction)

8.2.3.2.1 - Dietary Supplements

It is extremely important that FDA conducts appropriate investigations and follow-up on adverse events attributed to dietary supplement products. DSHEA removed dietary supplement and ingredients from food additive regulations and therefore it is the agency's burden to prove them unsafe. An important source of information concerning potentially unsafe dietary supplements and ingredients is consumer complaints.

Injuries or other adverse reactions may be associated with the use of products which:

- Vary from the declared potency or concentration.
- Contain deleterious substances accidentally included in manufacturing.
- Have changed composition or become contaminated after shipment.
- Are mislabeled as to identity warnings or instructions for use.
- Have not been used according to label instructions or the directions of the manufacturer or prescriber.
- Are dangerous when used according to directions.

When investigating adverse events attributed to dietary supplements, direct attention to, and document:

- Details on the product involved, including lot codes and expiration dates.
- Source of the supplement. Where did the consumer obtain it?
- Details on the consumer's use of the product including frequency, dose used, concomitant treatments, and whether administered by the user or someone else.
- Details on the directions of use provided with the product or otherwise (on the web or from a practitioner). Obtain copies of labeling and any additional information concerning use of the product by the consumer.
- Nature of the injury. Include any hospital or physician's records available and identify pre-existing conditions which may have a bearing on the injury. Obtain photographs of the victim's injuries, if significant. See IOM 8.1.6.2 for the procedures used to obtain medical records.
- Names of other persons involved, such as medical personnel, lawyers, insurance agents, etc. Obtain their views on the injury. The views of the attending physician are important because they may vary markedly from those of the patient.
- Complete description of the incident (sequence of events) and the nature of the injury or adverse reaction, including date, time, location and symptoms or description of injury.
- Any hospital or physician's records available and identify pre-existing conditions which may have a bearing on the injury or adverse reaction.

Photographs of the victim's injuries, if significant. See Section on Medical Records

8.2.3.2.2 - Cosmetics

For clarification of the distinction between cosmetics and drugs, refer to the document, "*Is it a cosmetic, a drug or both? (or is it soap?)"* located at https://www.fda.gov/cosmetics/cosmetics-laws-regulations/it-cosmetic-drug-or-both-or-it-soap

If you are unsure about a products status, you may contact the Office of Cosmetics and Colors at (240) 402-1130.

8.2.3.2.2.1 - Causes

Injuries or adverse reactions may arise from cosmetics which:

- Are inherently dangerous or which may prove harmful or injurious to a consumer.
- Cause primary irritation of skin, eye, or mucous membranes (including the lungs and urinary tract) or which may be due to an individual sensitization reaction or allergic response, or due to ingestion.
- Have undergone formulation changes or been chemically or microbiologically contaminated while in the possession of the manufacturer, dealer, distributor, or end user.
- Are misbranded because they contain unlisted ingredients, lack instructions for safe use for certain high-risk products (e.g., depilatories, hair dyes), or lack any required warning statements.

- Have been misused.

8.2.3.2.3 - Investigation Requirements for Serious Adverse Events of CFSAN Regulated Products

If the suspect product is a cosmetic, interview the injured person and/or the reporter of the event and complete the FACTS Consumer Complaint Cosmetic Report. If the suspect product is not a cosmetic, interview the injured person and/or the reporter of the event and complete the FACTS Adverse Event Questionnaire.

If the suspect product is an infant formula or baby food, immediately inform OEM/OEO at 866-300-4374 or Emergency.Operations@fda.hhs.gov and investigate on a high-priority basis due to the continued sensitivity to these incidents. This will include follow-up with the doctor or hospital, sample collection, and analysis of appropriate product. Refer complaints involving baby food regulated by USDA for appropriate follow-up. See IOM 8.1.8.1 and 3.2.1.2.

Obtain Medical Records as described in Section 8.1.6.2.

If the adverse event is a death, the following medical records should be considered for collection:

- Admission history and physical or emergency room/clinic record of the event if the patient was not admitted
- Discharge Summary
- Autopsy Report
- Death Certificate

If you believe a suspect product should be sampled, discuss with your supervisor.

For all events, a memo of investigation will be completed. Send a complete copy, including copies of all labels and labeling, Medical Records Letter [IOM Exhibit 8-4] and medical records collected to the CAERS Staff.

8.2.3.2.4- Undeclared Allergen/Allergic Reactions

Suspected undeclared allergen complaints should receive high priority. Undeclared allergens in food products often result in recalls.

The following should be addressed and confirmed during a follow-up investigation with the complainant:

- List all the complainant's food allergies.
- List all foods consumed within approximately an hour prior to reaction.
- Amount of suspect food consumed.
- Time of on-set.
- Specific symptoms experienced and the order they occurred.
- Medical or other treatment received.
- The ingredient statement from product packaging.

- Any label statement related to a "may contain" statement and record the statement.

Inspectional follow up at the manufacturing plant may be warranted to determine if suspect allergen is added to the product; or if the possibility of cross-contact exists.

8.2.3.3 - Veterinary Products-Complaints/Adverse Reactions

If you become aware of human illnesses associated with CVM-regulated products, contact the appropriate ERC in your division and/or regional office immediately who will then contact the CORE Signals Team at CORESignalsTeam@fda.hhs.gov.

Investigations of complaints of animal food, both medicated and non-medicated, should be investigated like other complaints. Discuss any investigation with your supervisor. The CVM Office of Compliance can be consulted concerning appropriate follow-up and sample collection related to complaints.

8.2.3.4 - Sample Collection

When directed to collect a sample, collect the product which appears to have caused the injury and an official sample from both the same and other lot codes, if available. Check with your supervisor if you have any doubt as to the appropriateness of collecting a sample related to an investigation. See IOM 4.7.5.4.1 for routing of injury and complaint samples to the laboratory.

8.2.3.4.1 - Cosmetic Samples

Many cosmetic products such as permanent hair dyes, home permanents, deodorants, hair straighteners, etc. are known to cause adverse reactions. Samples of these products should not be collected except in cases of alleged severe or unusual injury (e.g., multiple complaints). In cases of obvious allergic type reactions, samples should not be collected. For example, most cosmetic products which get into the eye will cause temporary eye irritation and, in such cases, a sample generally should not be collected.

8.2.3.4.2 - Microbiological Contamination

Collect samples associated with consumer complaints in which microbiological contamination is suspected.

8.2.3.4.3 - Allergen Samples

Collect a sample if the allergen is visible (i.e., nuts,) is not declared on the label, and if deemed necessary by division management. In all other cases, collect a sample only after consultation with OEM/OEO (e.g., national consumer complaint coordinator) and CFSAN. See IOM Sample Schedule Chart 13 for guidance on sample size. Note: the sample size may be modified depending on product availability.

8.2.4 - Special Events

Special Events (SEs) are organized, pre-planned mass gatherings of national or international importance that usually garner significant media coverage and are typically attended by dignitaries or public

personalities. The venues for these events are predominantly large retail food establishments such as stadiums, arenas, convention centers, and hotels which contain retail food establishments that are under the jurisdiction of state and local agencies. SLTTs, United States Secret Service (USSS), or the event organizer may request FDA assistance.

See Special Event Planning Guidance (SEPG).

NSSEs are a select group of SEs that are designated by the Secretary of the U.S. Department of Homeland Security (DHS) to be of significant importance and may be a potential target for terrorists due to the event's visibility or political connection(s). The types of SEs/NSSEs supported by FDA include Presidential inaugurations, major national political conventions, North Atlantic Treaty Organization (NATO) and other summits of geopolitical significance, Olympic Games held in the U.S., and some major sporting events. You may be requested to investigate food suppliers to the SE to verify compliance with regulations. This investigation, referred to as a Supply Chain Integrity Check (SCIC), may be performed onsite or through an online record review.

8.2.5 - Farm Investigations

A farm investigation of a raw agricultural commodity (RAC) may be conducted in response to traceback information obtained during a foodborne illness outbreak investigation that implicates one or more farms, ranches, packing houses, or other such operations as being involved in handling the outbreak suspect RAC. Generally, CORE would request a domestic farm investigation through the district ERC for the responsible ORA Human and Animal Food (HAF) program division office. HAF program division offices may also initiate or be assigned by CFSAN or ORA/OHAFO to perform a farm investigation as needed to protect public health. The goals of a farm investigation are to gather information, to identify potential environmental sources of the outbreak agent, to identify routes of contamination from potential outbreak agent sources to the implicated RAC, to observe and document potential contributing factors to the outbreak such as practices, procedures, or conditions that may facilitate proliferation, spread, growth, survival, or contamination by the outbreak agent, and to support regulatory action, if appropriate.

8.2.5.1 - Approach

A team approach is utilized for a farm investigation (see IOM 5.2.8 Team Investigations). A lead CSO should be identified from the Produce Safety Network (PSN) or the responsible HAF division office that has attended both the FD226 Produce Inspections for Regulators Course, and the FD326 Produce and Sprout Investigations for Regulators Course. A minimum of three team members should participate and ideally all members should have produce farm training and/or produce farm inspection experience. The appropriate state regulatory agency having jurisdiction over produce farms should be notified and invited to participate. Additional SMEs may be added to provide needed expertise such as wildlife, soils, agricultural water, or epidemiology. CORE, CFSAN Produce Safety Staff, and/or ORA HQ may assist with identifying appropriate SMEs and providing technical guidance during the investigation.

The implicated grower should be notified in advance of the investigation as he/she or a representative of the grower will need to be present to provide information to assist the

investigation. Generally, an FDA 482 will be issued to the grower or packing house, if different. If the investigation expands to fields not owned by the grower, a new 482 must be issued to those growers. Please see IOM 5.2.8 Team Investigations for additional information.
CORE has implemented formalized outbreak incident operation processes. The CORE operation guides are available through the inside.FDA.gov website.

8.2.5.2 - Sampling

A variety of environmental samples may be collected during a farm investigation, including environmental swabs and water from both the field and the packing house, and soil and wildlife scat samples from the growing environment. Do not collect human fecal matter unless specifically assigned or pre-approved to do so. In general, FDA laboratories are not prepared to receive human feces.

Instructions for collecting soil and water samples on farm investigations are found in IOM Ch. 4, in the Salmonella Sample Schedule Chart 1, and are also covered in FD326 (Produce and Sprout Investigations for Regulators Training Course). Additional sampling guidance can be found in SOP-001052 (ORA Field Bulletin #30 – Food Program Area – Instructions for Environmental Sampling), and ORA Outbreak Response Field Guide #1 covering E. coli, Listeria, and Salmonella inspections and investigations at sprout operations. Specific sample collection instructions or methods may also be included in the CORE farm investigation assignment.

All environmental samples are investigational. Use the product code builder to identify the proper code for the type of environmental sample collected, including swabs, soil, water, and animal scat. Do not use the product code of the implicated produce for environmental samples. Produce samples collected from the field or prior to packing (i.e., not finished product) are labeled as investigational. Product that has completed processing on the packing line are labeled official product samples.

8.2.5.3 - Form 3623 Farm Investigation Questionnaire

FDA Form 3623, the Farm Investigation Questionnaire (FIQ), must be completed for all farm investigations, as covered in FD3263. Some portions may not be applicable, such as the use of biosolids. These questions may be marked as N/A. However, questions for practices that may be used but are not currently in use should be completed by use of interview techniques with the grower to the extent possible. The FIQ should be completed on-site to ensure all information is collected and submitted to CORE and/or the CFSAN Produce Safety Staff if requested and included in the Investigation Memo or EIR as an attachment. To avoid duplication, the FIQ may be used to provide information under the “Manufacturing Processes” section by either reference or cutting and pasting into that section. A short summary and flow diagram(s) describing the steps from planting through harvesting and/or packing should be included along with this.

8.2.5.4 - Reporting

Domestic outbreak work assignments will be designated in FACTS as either an operation 12 inspection (OP12) or an operation 13 investigation (OP13). Foreign outbreak work assignments will be designated in FACTS as either an operation 11 inspection an operation 15 investigation.

For FACTS operation 11 or 12 farm inspections see Chapter 5 for reporting; however, if an outbreak is ongoing and the information is needed immediately, it may be necessary to prepare a separate memo to submit to CORE prior to completing the EIR.

For FACTS operation 13 or 15 investigations, follow reporting guidance in this chapter.

8.2.6 - Infant Formula and Baby Food

There is a continued sensitivity to all reported incidents involving infant formula and baby food. All complaints involving either infant formula or baby food are to be immediately escalated following SOP-000544. Appropriate follow-up with the consumer, potential inspection of the manufacturer, and follow-up with the doctor or hospital if appropriate should be done. Samples can be collected as part of the follow-up. Complaints involving baby food regulated by USDA should be referred to USDA for appropriate follow-up. See IOM 3.2.1.2. There are two exceptions for collecting samples as part of the follow-up to infant formula/baby food complaints. Do not collect samples unless directed for:

- Complaints involving outdated product in the marketplace with no associated injury or illness only require investigation to ensure all outdated product has been removed from the identified retail and/or wholesale source.
- Complaints involving an illness associated with normal appearing product when the follow-up investigation discloses that the event does not appear to be product related or was an allergic response to a properly labeled product per a physician's diagnosis. When complaints involving food products intended for infants are received, NOT-000210 should be reviewed to verify if it meets criteria in the memo.

8.2.7 - Tampering Involving Alcoholic Beverages

All tampering complaints involving alcoholic beverages should be entered as a consumer complaint in CMS. OEM/OEO and OCI should be notified immediately following SOP-000544. OEM/OEO can be notified by e-mail at emergency.operations@fda.hhs.gov and by phone 24 hours a day at 1 (866) 300-4374.

For all other complaints involving alcoholic beverages, please see IOM 3.2.8.1 for guidance.

8.3- Drug Investigations

8.3.1 - Investigations Coordination

The following procedures should be followed for investigating suspected adverse drug reactions, including drug-induced birth defects:

- If you are interviewing the consumer, conduct the normal complaint investigation and gather all pertinent information regarding the product, patient, adverse event, etc. If the consumer received medical treatment, obtain a medical records release (Exhibit 8-2). Reporting of drug adverse experiences is voluntary and you should encourage and assist complainants and health care providers to complete the MedWatch form (FDA 3500) (see Exhibit 8-10) and submit to MedWatch. Report your findings in the FACTS Consumer Complaint follow-up screens and in a memo of investigation.

- If you are investigating an adverse reaction at the manufacturer, conduct your investigation to determine whether the adverse event was caused by a drug quality defect. Determine if the manufacturer was aware of the complaint, has investigated, and per IOM 5.14.4 Adverse Event Reporting has submitted the reportable event to FDA. For additional information regarding DQRS (MedWatch Reports) and NDA FARS (New Drug Application Field Alert Report) see the applicable compliance program in the Compliance Program Guidance Manual (CPGM). Determine if the manufacturer is aware of any similar reported events. Collect current labeling of the product to determine whether this was an expected or unexpected adverse event. Your findings will be reported through the FACTS Consumer Complaint follow-up screens and a memo of investigation or EIR.
- You may also be directed to conduct investigations at other establishments, such as pharmacies, doctors' offices, or distributors. Conduct your normal complaint investigation determining each party's role and involvement. If individuals interviewed are not required to report adverse drug reactions, encourage and assist them to complete and submit the FDA 3500 form to MedWatch.

In all cases of suspect drug-induced adverse reactions, the center will review the information on the FDA 3500 form and will issue assignments to the field if additional information is needed.

8.3.2 - Illness/Injury

Drug injuries or reactions, either human or veterinary, result from the use of products which may:

- Vary markedly from declared potency.
- Contain deleterious substances.
- Be mislabeled as to identity, warnings, or instructions.
- Have been mistaken for other drugs despite proper labeling.
- Have changed composition or become contaminated after shipment.
- Be dangerous when used according to directions.
- Have not been used in accordance with label directions or directions from the prescriber.
- Have been improperly administered or administered without the necessary precautions.
- Have been contaminated with objectionable microorganisms, soaps, or cleaning solutions.
- Have been misidentified.
- Be labeled as sterile drugs but are found to be non-sterile.
- Have adverse effects that were not identified prior to marketing.

8.3.2.1 - Reporting

8.3.2.1.1 - Reporting Forms – Drugs

Submit drug complaints and injuries to:

MedWatch
The FDA Medical Products Reporting Program (HFD-410)
Food and Drug Administration
5600 Fishers Lane
Rockville, MD 20857
Fax Number: 301-827-7241

8.3.2.1.2 - Reporting Forms – Veterinary Products

Submit veterinary injuries or adverse reaction reports to:

Food and Drug Administration
Center for Veterinary Medicine
Division of Surveillance (HFV-210)
7500 Standish Place
Rockville, MD 20857

In addition, follow specific reporting instructions as indicated per an assignment.

8.3.3 - Complaints

The FDA Office of Emergency Management/Office of Emergency Operations (OEM/OEO) HFA-615, 301-796-8240 must be notified immediately of all life-threatening injury/illness, death, and suspected tampering complaints. This may be accomplished by adding the OEO team name to the CMS ORA Consumer Complaint Initial Disposition Decision, per SOP-000544.

- Injury/illness complaints
  - Any illness/injury related to infants should be considered high priority. These complaints are to be thoroughly investigated.
- Complaints and adverse reactions associated with veterinary products including animal drugs, medicated feeds, and medical devices for animals are handled through the FDA CVM Division of Veterinary Product Safety (HFV - 240). Veterinarians, animal owners, and drug manufacturers may report problems to their local FDA district offices or directly to CVM. The division should advise the complainant to complete an FDA 1932a, "Veterinary Drug Adverse Experience, Lack of Effectiveness or Product Defect Report" for drug adverse events associated with unapproved animal and approved human drugs and veterinary devices. For approved animal drugs, the complainant should be instructed to call the manufacturer directly to report the event. Detailed instructions and options for different case scenarios are available at https://www.fda.gov/AnimalVeterinary/SafetyHealth/ReportaProblem/default.htm.

For 3-day Field Alert Reports (FAR), drug sponsors now have the option to electronically submit 3-Day field alert reports (FARs) directly to CVM. CVM will receive the electronic 3-Day FAR from the sponsors and will automatically generate and email a .pdf of the FAR with associated attachments to the appropriate district office. Some sponsors may still send the 3-day FAR through the traditional route to the district office. The district office should email the form and any other attachments to CVM. The drug manufacturer should notify and submit the FAR to their respective district office within three days. The district offices will ask for additional information if necessary and submit the 3-day FAR to the Division of Veterinary Product Safety.

Complaints and adverse reactions associated with animal feeds including pet food products are handled through the Division of Compliance (HFV-230) at CVM. Veterinarians, animal owners, and firms may report pet food problems to consumer complaint coordinators at their FDA district office or OEM/OEO; the district will complete a CMS Consumer Complaint Report and follow SOP-000544 for escalation. Pet food reports may also be made directly to CVM using FDA's Safety Reporting Portal. Instructions for stakeholders to report problems associated with pet food products are available at

https://www.fda.gov/AnimalVeterinary/SafetyHealth/ReportaProblem/default.htm. If you become aware of human illnesses associated with CVM-regulated products, contact the appropriate ERC in your division and/or regional office immediately who will then contact the CORE Signals Team at CORESignalsTeam@fda.hhs.gov.

8.4 - Device Investigations

8.4.1 - Injury/Illness

When investigating incidents implicating medical devices, you must first confirm whether the device was a contributing factor. An appropriate follow-up, such as an inspection at the manufacturer may be necessary. The cause of medical device injuries may originate with the manufacturer, operator, user, or from other factors including, but not limited to, the transportation or installation of the device. Additionally, an illness may occur as a result of device specifications not being met, such as a device labeled as sterile not meeting sterility requirements.

Obtain the following information for medical devices:

1. A complete description of the incident (sequence of events) and the injury/illness, including:
   a. UDI, Type, model, serial number and manufacturer of the device, and copies of any labeling for the specific device(s) involved including instructions for use or operations manual(s).
   b. Details of the alleged incident, including: number of people involved; symptoms, onset time, duration, and outcome; date and time of occurrence; reports of other investigating agencies and their conclusions, (e.g., fire marshal or OSHA reports); similar incidents which may have resulted in injury/illness; and all operational SOPs, written or unwritten.
2. Copies of medical records and/or laboratory records. Use an FDA 461, Authorization for Medical Records Disclosure, IOM Exhibit 8-2, signed by the patient or other authorized person, when obtaining these records.
3. Official cause of death, death certificate, and/or autopsy report, if indicated.
4. Determine if the device malfunctioned, and the cause.
5. The condition of the device at the time of use. Review its maintenance history, including responsibility for maintenance (past and present), special service calls, repairs, whether component warning or safety systems were functional, maintenance records, changes or corrections accomplished just prior to or immediately after the incident, and who performed the activity. An interview with biomedical engineering department personnel may be indicated.
6. Who has access to the device? Determine if individuals using the device are familiar with its operation.
7. The results of any examination or inspection of the device by the hospital or other party to determine the cause of the incident.
8. Whether there are other devices of the same model number or lot number on the premises.

8.4.1.1 - Types of device injuries or illnesses include:

8.4.1.1.1 - Mechanical, Electrical, or Electromechanical Devices

Injuries caused by mechanical, electrical, or electromechanical devices may result from devices that:

- Do not conform to specifications due to mistreatment (e.g., damage in transit), or failure to comply with good manufacturing practices.
- Malfunction due to incorrect installation.
- Have not been used in accordance with labeled instructions.
- Have been used/installed with incompatible accessories or parts which are not compatible.
- Have been used under conditions which interfere with their ability to function (e.g., electromagnetic interference (EMI), fluid seepage into electrical circuits, etc.).
- Have been damaged during use, or random failures.
- Have not been adequately designed for intended use (unstable, poor structural integrity, electrical leakage, reusable but unable to thoroughly clean, etc.).
- Do not contain adequate directions or warnings.
- Are intended to be sterile but are non-sterile.
- Fail or deteriorate for any reason.

8.4.1.1.2 - Devices for Implant

Causes of injuries which may result from implanted devices include those listed in IOM 8.4.1.1.1. An injury or illness may also result because the materials used in the implant are not biocompatible, thereby causing an adverse tissue reaction and/or deterioration of the implant. It is important to obtain information relating to a medical professional's interpretation of the relations.

8.4.1.1.3 - In-Vitro Diagnostic Devices

In Vitro Diagnostics (IVD) are instruments that can include, gas chromatographs and automated blood analyzers, and much of the information under IOM 8.4.1.1.1 is applicable.

Injuries to patients from IVD products may be considered indirect because they are due to complications resulting from misdiagnosis or delays in patient treatment due to incorrect test results. Examples of IVD failures include false positives, false negatives, and erratic results. Poor performance or failure may be due to poor manufacturing practices or user error.

Manufacturing problems include:

- Process errors and mix-ups (varying fill in kit components, improper ingredient addition, etc.).
- Labeling does not contain adequate directions or warnings or contains incorrect information.
- Labeling mix-ups.
- Contamination making the product unusable or causing misdiagnosis.

- User error due to poor directions for use, operator's manual, or inadequacies in labeling requirements.
- Use of unclean, not maintained, or improperly calibrated equipment.
- Improper storage or use of reagents.

For In Vitro Diagnostic devices determine:

1. How the results of the test are used; screening, therapeutic drug monitoring, epidemiological information, monitoring the course of a disease, etc.
2. The role in overall determination of patient clinical care.

8.4.2 - Confidential Sources

FDA may receive external complaints that request their identity to be kept confidential or anonymous. In this case, the complainant's information should not be disclosed in the investigation memorandum or EIR. The complaint should be assessed to determine if it is a non-injury/illness complaint, life-threatening injury/illness complaint, non-life-threatening injury/illness complaint, or death complaint as this may impact the urgency of the response. An immediate follow-up may be warranted if there is illness, injury, death, or if directed by higher authority. All information should be obtained in the least intrusive, yet constructive, manner that allows the investigator to collect the evidence required to evaluate the validity of the complaint to determine if additional action is warranted.

8.4.3 - Complaints

FDA may receive information from various sources, such as a consumer, whistleblower, employee, other governmental agency, Congress, or competitor alleging a potential violation of the FD&C Act that must be followed up to confirm the information provided by the complainant. For medical devices, a complaint means any written, electronic, or oral communication that alleges deficiencies related to the identity, quality, durability, reliability, safety, effectiveness, or performance of a device after it is released for distribution.

As with all investigation types, report your findings in a memorandum and include all pertinent information and any attachments collected as evidence to support the complaint. Using eNSpect, create an operation 13, domestic investigation, or operation 15, foreign investigation, utilizing only one FEI and the Investigation Basis of Consumer Complaint, and complete all required fields. Upload all labeled attachments and submit for endorsement by your supervisor. Ensure the consumer complaints tab in eNSpect is completed. . If foreign, ensure the center is notified of the investigation and receives a copy of the investigation memorandum and any attachments.

If the complaint is an adverse reaction to a device, advise the complainant to visit FDA.gov, specifically the MedWatch Online Voluntary Reporting Form (fda.gov) to complete an FDA 3500, MedWatch Form; https://www.accessdata.fda.gov/scripts/medwatch/index.cfm (See IOM Exhibit 8-7) and discuss the need to have physician complete the form for submission. If the physician will not cooperate by completing the FDA-3500, request the complainant to do it. Note in the "Remarks" section of the CMS Consumer Complaints Report that the FDA 3500 was forwarded to the complainant.

8.4.4 - Reporting

The Medical Device Reporting (MDR) regulation and the changes mandated by the Safe Medical Devices Act of 1990 (SMDA) is a mandatory information reporting system. It requires manufacturers, importers, and device user facilities to report to FDA certain adverse experiences caused or contributed to by their devices.

This program is administered by the Center's MDR Policy Team in the Office of Regulatory Programs.

The regulation requires a report be submitted to FDA whenever a manufacturer or an importer becomes aware of information that its device: 1. May have caused or contributed to a death or serious injury, or 2. Has malfunctioned and this device or a similar device would be likely to cause or contribute to a death or serious injury, if the malfunction were to occur.

Under the Safe Medical Devices Act of 1990, user facilities must report device-related deaths to FDA and to the manufacturer, if known. User facilities must also report device-related serious illnesses and injuries to the manufacturer, or to FDA if the manufacturer is unknown. In addition, SMDA also requires user facilities to submit to FDA, on an annual basis, a summary of all reports submitted.

The CDRH Division of Industry and Consumer Education (DICE@fda.hhs.gov) and the MDR Team (MDRPolicy@fda.hhs.gov) in the Office of Regulatory Programs should be contacted for further guidance about the MDR regulation.

As of August 2018, the agency's Voluntary Malfunction Summary Reporting program was implemented. It permits certain manufacturers an alternative method to submit MDRs for eligible product codes in summary form on a quarterly basis; see 83 FR 40973.

8.4.5 – Medical Device Sampling

Obtain CDRH and WEAC concurrence prior to collecting any medical device samples.

8.5 - Biologics Investigations

8.5.1 - Illness/Injury

Reactions or symptoms of illness may occur in association with the administration of vaccines and other biological products. The Center for Biologics Evaluation and Research (CBER) is interested in all unexpected clinical responses to a biological product, as well as any expected responses of unusual frequency or severity. In some cases, a reaction or illness could occur because the product may:

- Vary from declared potency.
- Have been contaminated during manufacturing, shipment, or after shipment.
- Be mislabeled.
- Not have been given according to directions.
- Not have been stored under proper conditions.
- Have been provided to the wrong person.
- Contain substances innocuous to most people, but which the recipient is unable to tolerate (e.g., anti-Kidd, anti-Duffy), or contains substances not usually present in such a product which stimulate an adverse response in the recipient (e.g., HLA antibodies).

8.5.1.1 - Reporting

8.5.1.1.1 - Investigation/Reporting

When a biologics reaction/injury complaint is received by a CSO, they should forward the complaint to 'orabiobiologicsinspectionpoc@fda.hhs.gov. The Biologics POC will then forward it to the appropriate ORA Consumer Complaint Coordinator following SOP-000544.

All complaints received by the ORA BIO Biologics Inspection POC will be reviewed and upon determination of initial follow-up status entered into the ORA Consumer Complaint Initial Disposition Work Activity for that complaint.

When interviewing the complainant about a biologics complaint /injury, obtain:

- Complete description of the complaint/injury.
- Onset and duration of the reaction/injury.
- Name of product administered, include date and time of administration.
- Manufacturer and lot number of product(s), if available.

At this point, it is generally unnecessary to conduct interviews beyond the complainant, or obtain records, until a preliminary review has been conducted. It is important to rapidly communicate the basic information about the incident, implicated product, lot, license number, manufacturer, and presence of intact units to orabiobiologicsinspectionpoc@fda.hhs.gov.

Confidential complaints received during an inspection should be captured in a memorandum as an attachment to the EIR. The confidential source information should not be referenced in the EIR. Any findings related to complaints not involving confidential sources should be documented in the narrative to the EIR. The complaint number for all complaints should be written in the EIR coversheet in eNSpect. Complaint follow-up assignments will be issued in eNSpect as determined by OBPO.

If a complaint related to a vaccine product involves an adverse reaction of any kind, then a Form VAERS-1 (IOM Exhibit 8-6) should be completed online by complainant or their physician. If they cannot complete the form online, the VAERS Reporting Form can be mailed to them and they can send it to the address on the form. When you send a VAERS form to a complainant, note this fact in the Remarks Section of the CMS Consumer Complaint Report.

The Vaccine Adverse Event Reporting System (VAERS) is administered under a joint FDA/CDC contract. For reporting adverse events which occur subsequent to vaccine administration, the system utilizes a fillable online form (Form FDA VAERS 2.0) or can be directly submitted at: https://vaers.hhs.gov/reportevent.html See IOM Exhibit 8-6.

8.5.1.1.2 - Professional Reporting System for Vaccine Adverse Reactions

The National Childhood Vaccine Injury Act of 1986, 42 USC 201, was passed to achieve optimal prevention of childhood infectious diseases through immunization. At the same time, it was

intended to minimize the number and severity of adverse reactions to vaccines routinely administered to children. This law requires health care providers and vaccine manufacturers to report certain adverse events which occur following the administration of specific vaccines. The vaccines and reportable events are listed in the National Childhood Vaccine Injury Act Vaccine Injury Table. The Department of Health and Human Services (DHHS) has established a Vaccine Adverse Events Reporting System (VAERS) to accept all reports of suspected adverse events after the administration of any vaccine, in all age groups, including but not limited to those in the table.

If the complaint does not involve an adverse reaction, obtain the necessary information to allow the center to make an informed decision on follow-up at the manufacturer.

If the complaint is an adverse reaction to a biologics device, drug, or HCT/P product, an FDA 3500, MedWatch Form (See IOM Exhibit 8-7) must also be completed and forwarded to the complainant for completion by their physician. If the physician will not cooperate by completing the FDA-3500, request the complainant to do it. Assist the complainant in completing the FDA 3500, if necessary. Note in the "Remarks" section of the CMS Consumer Complaints Report that the FDA 3500 was forwarded to the complainant. MedWatch forms can be found at https://www.fda.gov/safety/medical-product-safety-information/medwatch-forms-fda-safety-reporting.

If the complaint does not involve an adverse reaction, obtain information necessary to permit OBPO make an informed decision on follow-up at the manufacturer. If a complainant desires further information, refer them to CBER, Office of Biostatistics and Epidemiology, Division of Epidemiology, at 301-827-3974.

If a CSO finds that there is a complaint of a fatality where blood or a blood component is implicated and that was not already reported to CBER, the CSO should notify their supervisor. The supervisor will then follow-up with OBPO management and CBER. Reporting a fatality is required of the collecting facility, in the event of a donor reaction, and by the facility which performed the compatibility tests, in the event of a transfusion reaction. An investigation of the incident shall be conducted by either Healthcare Finance Administration (HCFA) Centers for Medicare and Medicaid Services (CMS) or FDA, based on the type of facility involved, for example, transfusion service, blood bank, plasma center or hospital. OBPO CSOs may be assigned to investigate a fatality through an assignment from CBER.

CSOs should follow OBPO’s procedure as a guide for conducting the investigation. The CSO should also refer to the eNSpect assignment for additional information regarding the investigation. If the hospital, medical examiner, or other entity either refuses to provide or requires a written request in order to provide the CSO with medical history records, a death certificate, autopsy report, or other needed records, the CSO should complete and provide the firm with the Records Request Letter, that is referenced in OBPO’s procedure.

8.5.2 - Surveillance

OBPO CSOs should review OSAR Firm 360 to determine if an existing complaint exists in preparation for conducting an inspection assignment. The CSO will review all firm information in OSAR Firm 360, including reviewing all complaints and address all complaints that do not have entries under follow-up disposition and follow-up disposition dates during the inspection assignment. Complaints related to the FEI that have an initial evaluation of FDA Action Indicated, an initial disposition is entered, and no follow-up disposition is entered will automatically be listed into the inspection assignment following SOP-000544. CSO conducts the establishment inspection and investigates those issues identified in the complaint(s) and includes observations in the summary sections in the narrative of the EIR and completes the consumer complaints tab in eNSpect.

8.5.3 - Confidential Informants

In addition to this section, please refer to the general section on Confidential Sources (Section 8.1.5.7.2.3). Complaints can originate from public sources, including establishment employees at firm's we inspect, donors, donor family members, and industry. Confidential complaints can also come through CBER and through other agencies. If the complaint is from a confidential source, the complaint information is NOT documented in the EIR. Confidential Source complaint information is documented in an Investigation Memo and saved as an attachment to the EIR. Findings are considered in the initial classification of the inspection.

8.5.4 - Complaints

8.5.4.1 - BIOLOGICAL PRODUCTS

OBPO CSOs should follow the OBPO procedure on oversight of consumer complaints. If a consumer complaint coordinator receives a complaint on a biological product, they will follow SOP-000544 for proper escalation to the Biologics CMS team. If any ORA Office receives a complaint on a biological product, regardless of licensure status, the receiving office will notify OBPO at ORABIOBiologicsInspection@fda.hhs.gov. OBPO will provide direction on how to proceed, and next steps, including instructions on any CMS entries. For additional information or inquiries, send an email to the inspection POC address above or contact either of the OBPO division directors. OBPO staff receiving a complaint from external or internal sources should send the complaint to ORABIOBiologicsInspection@fda.hhs.gov. Confidential complaints received during an inspection should be captured in a memorandum as an attachment to the EIR. The confidential source information should not be referenced in the EIR.

Any findings related to complaints not involving confidential sources should be documented in the narrative to the EIR. The complaint number for all complaints should be written in the EIR coversheet in eNSpect. The consumer complaints tab in eNSpect must be completed for any assignments with complaints. Complaint follow-up assignments will be issued in eNSpect as determined by OBPO.

8.5.4.2 -Biological Samples

Do not collect samples of a suspect product without first consulting with the supervisor. An evaluation of the preliminary information on the injury/reaction by CBER (for licensed products)

and/or the home district division (for unlicensed products, plasma, and blood products) may be necessary to determine if a sample should be collected.

8.5.4.3 - BIOLOGICS INJURY/ADVERSE REACTION REPORTS

Submit biologics injury and adverse reaction narrative reports using encrypted email or mailing. If mailing, use this address:

Food and Drug Administration
White Oak Bldg71
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

NOTE: In addition, check the "Notify EO/EOMPS?" box in FACTS for all injury and adverse reaction complaints. For serious injury/illness reports, please notify the OEM/OEO immediately at 1 (866) 300-4374 and emergency.operations@fda.hhs.gov.

8.6 - Bioresearch Monitoring Investigations

8.6.1 - Illness/Injury

8.6.1.1 - Reporting

Submit drug complaints and injuries to:

MedWatch
The FDA Medical Products Reporting Program (HFD-410)
Food and Drug Administration
5600 Fishers Lane
Rockville, MD 20857
Fax Number: 1-800--322-0178

8.6.2 - Surveillance

For Cause assignments issued to OBIMO may require interviewing of subjects to verify their participation in the clinical trial. These activities would be conducted with supervisor approval. An OP13 (or OP15 for foreign) will be created in eNSpect, for the purpose of subject interviewing, with information correlating the OP12 (or OP11) For Cause assignment. An investigational memo will be uploaded as an "Attachment" as per Section 8.1.9 *General Investigation Reporting*. Additionally, the investigational memo will be included in the EIR as an "Attachment."

8.6.3 - Complaints

Complaints are received via assignment memo from the respective center. The memo will have specifics about the complaint and any special instructions. Reporting of complaints are the same as an inspection via an EIR unless otherwise instructed (see section regarding For Cause/Fact Finding/Information Gathering above). See IOM 5.14.2 – BIMO Assignments as complaint information will be included in the overarching assignment memo.

8.7 - Tobacco Investigations

8.7.1 - Investigations Coordination

Tobacco Products Samples: When collecting tobacco product samples as a result of a product complaint or adverse report investigation, see IOM 4-24, for sample collection guidance and contact CTP's Office of Compliance and Enforcement. (extract from IOM 8.4.7.6)

8.7.2 - Complaints

Anyone who encounters a problem with a tobacco product, such as a safety issue, undesired health problem, or product defect may report it online via the FDA Safety Reporting Portal (SRP) at www.safetyreporting.hhs.gov.

Potential tobacco product violations include (but are not limited to):

- Sales to minors.
- Flavored cigarette sales.
- Illegal marketing and advertising – The Tobacco Control Act gives the FDA the ability to regulate certain marketing and advertising activities by the tobacco industry, including describing tobacco products as "light," "mild," or "low" – or claiming a product is safer or less harmful without an FDA order.
- Distributing t-shirts or other promotional or novelty items with brand names of cigarette or smokeless tobacco products.
- Sponsoring events using the brand names of cigarette or smokeless tobacco products.
- Distribution of free samples of tobacco products except in limited circumstances.
- Placement of cigarette or smokeless tobacco product vending machines in prohibited areas (or providing access to self-service or direct access of tobacco products in prohibited areas).
- Sale of cigarettes in packages of less than 20.

If you see what you believe to be a violation of the Tobacco Control Act or other related regulations, you can:

- Submit online (https://www.accessdata.fda.gov/scripts/ptvr/index.cfm)
- Call the Tobacco Call Center using CTP's toll-free number: 1.877.CTP.1373
- Send an email: CTPCompliance@FDA.hhs.gov
- Print and mail:
  Paper form (Form FDA 3779, Potential Tobacco Product Violations Report) (https://www.accessdata.fda.gov/scripts/ptvr/index.cfm) to:

Potential Tobacco Products Violation Report
Food and Drug Administration
Center for Tobacco Products
Office of Compliance and Enforcement
Document Control Center
Building 71, Room G335
10903 New Hampshire Avenue
Silver Spring, MD 20993

EXHIBITS

8-1 FEDERAL ANTI-TAMPERING ACT FULL LANGUAGE

Federal Anti-Tampering Act

21 U.S.C. §1365. Tampering with consumer products

(a) Whoever, with reckless disregard for the risk that another person will be placed in danger of death or bodily injury and under circumstances manifesting extreme indifference to such risk, tampers with any consumer product that affects interstate or foreign commerce, or the labeling of, or container for, any such product, or attempts to do so, shall-

(1) in the case of an attempt, be fined under this title or imprisoned not more than ten years, or both;

(2) if death of an individual results, be fined under this title or imprisoned for any term of years or for life, or both;

(3) if serious bodily injury to any individual results, be fined under this title or imprisoned not more than twenty years, or both; and

(4) in any other case, be fined under this title or imprisoned not more than ten years, or both.

(b) Whoever, with intent to cause serious injury to the business of any person, taints any consumer product or renders materially false or misleading the labeling of, or container for, a consumer product, if such consumer product affects interstate or foreign commerce, shall be fined under this title or imprisoned not more than three years, or both.

(c)(1) Whoever knowingly communicates false information that a consumer product has been tainted, if such product or the results of such communication affect interstate or foreign commerce, and if such tainting, had it occurred, would create a risk of death or bodily injury to another person, shall be fined under this title or imprisoned not more than five years, or both.

(2) As used in paragraph (1) of this subsection, the term "communicates false information" means communicates information that is false and that the communicator knows is false, under circumstances in which the information may reasonably be expected to be believed.

(d) Whoever knowingly threatens, under circumstances in which the threat may reasonably be expected to be believed, that conduct that, if it occurred, would violate subsection (a) of this section will occur, shall be fined under this title or imprisoned not more than five years, or both.

(e) Whoever is a party to a conspiracy of two or more persons to commit an offense under subsection (a) of this section, if any of the parties intentionally engages in any conduct in furtherance of such offense, shall be fined under this title or imprisoned not more than ten years, or both.

(f)(1) Whoever, without the consent of the manufacturer, retailer, or distributor, intentionally tampers with a consumer product that is sold in interstate or foreign commerce by knowingly placing or inserting any writing in the consumer product, or in the container for the consumer product, before the sale of the consumer product to any consumer shall be fined under this title, imprisoned not more than 1 year, or both.

(2) Notwithstanding the provisions of paragraph (1), if any person commits a violation of this subsection after a prior conviction under this section becomes final, such person shall be fined under this title, imprisoned for not more than 3 years, or both.

(3) In this subsection, the term "writing" means any form of representation or communication, including hand-bills, notices, or advertising, that contain letters, words, or pictorial representations.

(g) In addition to any other agency which has authority to investigate violations of this section, the Food and Drug Administration and the Department of Agriculture, respectively, have authority to investigate violations of this section involving a consumer product that is regulated by a provision of law such Administration or Department, as the case may be, administers.

(h) As used in this section-

(1) the term "consumer product" means-

(A) any "food", "drug", "device", or "cosmetic", as those terms are respectively defined in section 201 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321); or

(B) any article, product, or commodity which is customarily produced or distributed for consumption by individuals, or use by individuals for purposes of personal care or in the performance of services ordinarily rendered within the household, and which is designed to be consumed or expended in the course of such consumption or use;

(2) the term "labeling" has the meaning given such term in section 201(m) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321(m));

(3) the term "serious bodily injury" means bodily injury which involves-

(A) a substantial risk of death;

(B) extreme physical pain;

(C) protracted and obvious disfigurement; or

(D) protracted loss or impairment of the function of a bodily member, organ, or mental faculty; and

(4) the term "bodily injury" means-

(A) a cut, abrasion, bruise, burn, or disfigurement;

(B) physical pain;

(C) illness;

(D) impairment of the function of a bodily member, organ, or mental faculty; or

(E) any other injury to the body, no matter how temporary.

8-2 LETTER TO HEALTHCARE PROVIDER FOR MEDICAL RECORDS

To access the word document, click here. Note: Link to the Letter to Healthcare Provider for Medical Records is only available to ORA users on the FDA intranet. The link is http://qmis.fda.gov:80/mc/main/index.cfm?event=showFile&ID=OMIJZHPT3ZE7FJRCSJ&static=false&mcuid=ANONYMOUS&mcsid=FPSFER5OBBABVCT55K. Users who need a copy of the template outside FDA should use the Freedom of Information Process described in Section 8.1.3 to get a copy of the template.



Click or tap to enter a date.

[Insert name of hospital or state medical examiner & address]

Dear [Insert name of hospital or state medical examiner]:

The United States Food and Drug Administration (FDA) requests copies of available medical records for [insert patient specifics], including [medical history records, a death certificate, autopsy report and other reports] and any other related medical records. FDA is not required to request this information from you in writing but is doing so at your request.

In providing the requested information, please note that the Health Insurance Portability and Accountability Act (HIPAA), Standards for Privacy of Individually Identifiable Health Information; Final Rule (Privacy Rule) permits disclosure of privacy information without a written patient authorization for specific public health purposes. Specifically, the Privacy Rule permits covered entities to disclose this type of information to "a public health authority that is authorized by law to collect or receive such information for the purpose of preventing or controlling disease, injury or disability, including . . . the conduct of . . . public health investigations." 45 C.F.R. § 164.512(b)(1)(i). Per the Privacy Rule, "public health authority means an agency or authority of the United States . . . including the employees or agents of such public agency . . . that is responsible for public health matters as part of its official mandate." 45 C.F.R. § 164.501. FDA, as a public health agency, meets this definition. Our authority to receive information related to FDA-regulated products comes from the Federal Food, Drug, and Cosmetic Act (FD&C Act), the Public Health Service Act, and regulations issued under those authorities.

The Privacy Rule permits covered entities to disclose protected health information (including personal privacy information) directly to FDA for certain public health activities, including activities related to preventing or controlling disease, injury, or disability and the conduct of public health surveillance, public health investigations, and public health interventions. As part of these public health activities, access to personal privacy information, including names and contact information, is necessary to ensure timely follow-up. FDA safeguards personal privacy information pursuant to the Freedom of Information Act and the Privacy Act, 5 U.S.C. §§ 552, 552a, and our information disclosure regulations, 21 C.F.R. Parts 20 and 21, and follows internal procedures to prevent its unauthorized disclosure.

Thank you for your assistance in this regard.

Sincerely,

|

U.S. Food and Drug Administration
XXX District
Street Address
City, State ZIP

www.fda.gov

8-3 INVESTIGATION MEMO

To access the word document, click here. Note: Link to the Investigation Memo is only available to ORA users on the FDA intranet. The link is http://qmis.fda.gov:80/mc/main/index.cfm?event=showFile&ID=C7ZQFEQOANEQ5JXMLX&static=false&mcuid=ANONYMOUS&mcsid=AQZ6DL5KXFHKBPWISH. Users who need a copy of the SOP outside FDA should use the Freedom of Information Process described in Section 8.1.3 to get a copy of the SOP.



Date: (Enter Date)

To: Recipient

From: Title and Division

Subject: Special Investigation (May be changed appropriately to the assignment)

Firm Information: ABC Firm **(May be N/A if no firm involved or you may list multiple firms)**
1st Avenue
City, State, Zip Code

FEI: 12345678

Text of Investigation (Do not use Bold Text in document)

NOTE: Be sure to update the footer with Division Address

Your Electronic Signature

(Your Name, Title, Division)

U.S. Food & Drug Administration
Address of Division

www.fda.gov

8-4 TABLE OF INCIDENT COORDINATION

Incident Type	*Coordinating Body*	*Points of Contact (POCs)*
Clusters and outbreaks of 2+ human illnesses	**CFSAN / CORE** (Coordinated Outbreak Response and Evaluation Network)	CORE Signals Team, CORESignalsTeam@fda.hhs.gov
Single human illness (this includes single case retrospective incidents but also individual consumer complaints)	**CFSAN / OC** (Office of Compliance)	CFSANOCSRT@fda.hhs.gov
Clusters and outbreaks of **human illness due to pet food/feed products**	**CVM** (Center for Veterinary Medicine)	David.Rotstein@fda.hhs.gov, Mark.Glover@fda.hhs.gov
Allergen issues (any and all)	**CFSAN / OC** (Office of Compliance)	Stefano.luccioli@fda.hhs.gov
Seafood toxin incidents* (All toxins; All domestic and international waters)	**CFSAN / OFS / DSS** (Division of Shellfish Safety and DSST, Division of Seafood Science and Technology)	Ronald.Benner@fda.hhs.gov Jonathan.Deeds@fda.hhs.gov Karen.Swajian@fda.hhs.gov
Molluscan shellfish outbreaks (single and multiple human illnesses)	**CFSAN / OFS / DSS** (Division of Shellfish Safety and DSST, Division of Seafood Science and Technology)	Melissa.Farrell@fda.hhs.gov (goes by Lizzie; OFS / DSS) Melissa.Abbott@fda.hhs.gov (OFS / DSS) Jessica.Jones@fda.hhs.gov (OFS / DSST)
Processed shellfish outbreaks (e.g., non-molluscan shellfish (crustaceans such as lobster, crab, crab meat, crawfish, shrimp, and processed molluscan shellfish))	**CFSAN / CORE** (Coordinated Outbreak Response and Evaluation Network)	CORE Signals Team, CORESignalsTeam@fda.hhs.gov
Kratom-related / CBD / psychoactive substance incidents	**OC / OO / OSEM / OEM / OEO** (Office of Emergency Operations)	FDA Emergency Operations list: emergency.operations@fda.hhs.gov
Hepatitis A positive samples (and subsequent coordination with CDC for PEP); no known associated HAV illnesses	**FDA Liaison to CDC**	FDA Liaison to CDC (Susan.Lance@fda.hhs.gov)

Infant illnesses* (*Salmonella, Cronobacter,* infant botulism with rule-out investigations for infant formula or related infant products such as gripe water or medicated foods)	**CFSAN / OC** (Office of Compliance) - Powdered Infant Formula (PIF) **CFSAN / ONFL** (Office of Nutrition and Food Labeling) **NCCC** National Consumer Complaint Coordinator	OC contact for PIF is Marjorie.Davis@fda.hhs.gov ONFL contact for infant formula are Andrea.Lotze@fda.hhs.gov and Carrie.Assar.@fda.hhs.gov NCCC in OEO is Sheila.vanTwuyver@fda.hhs.gov
Disasters (Natural and Manmade)	**OC / OO / OSEM / OEM / OEO** (Office of Emergency Operations)	FDA Emergency Operations list: emergency.operations@fda.hhs.gov
Food Defense incidents (Intentional Contamination)	**OC / OO / OSEM / OEM / OEO** (Office of Emergency Operations) *And* **CFSAN / OAO** (Office of Analytics and Outreach)	CFSAN/OAO/Food Defense and Emergency Coordination Staff contact is Leeanne.jackson@fda.hhs.gov

8-5 CIFOR OUE Agent List

Agent Name	Median Incubation Period (Range)[1]	Primary Signs and Symptoms	Primary Specimen(s)	KEI[§]-Special group(s)	KEI-Geographic Considerations	KEI-Notable Exposures
BACTERIAL						
Arcobacter butzleri	32 hrs (6-83 hrs)[2]	D (persistent and watery), abdominal cramps, N, V	Stool in Cary-Blair, raw stool			
Bacillus anthracis	Usually ≤1 week (Up to 60 days)	Severe abdominal pain, N, V, fever, D (may be bloody), ascites, sepsis, meningitis	Blood, stool in Cary-Blair, raw stool		Recent travel to endemic areas, tropical or sub-temperate regions	Undercooked meat or hides of herbivores
Bacillus cereus, diarrheal toxin	10-16 hours (6-24 hours)	Abdominal cramps, D (watery), N	Stool in Cary-Blair, raw stool			Time and/or temperature-abused foods
Bacillus cereus, pre-formed toxin	30 min- 6 hours	Sudden onset of severe N, V, D	Stool in Cary Blair			Time and/or temperature-abused foods
Brucella spp.	3-4 weeks (1 week to several months)	Flu-like symptoms including fever, chills, sweating, HA, joint pain, weakness; may cause recurrent fevers and chronic joint pain/fatigue; *may cause diarrhea and bloody stools in acute phase*	Blood, serum	Animal handlers, especially farm workers and veterinarians		Ingestion of raw milk and dairy products
Campylobacter spp.	2-5 days (1-10 days)	D (may be bloody), abdominal cramps, Fever, possible N & V, Guillain-Barre Syndrome[3]	Stool in Cary Blair, raw stool			Undercooked or raw meat or poultry; raw milk/ milk-products
Clostridium botulinum, foodborne[£]	12-72 hours (6 hours-10 days)	V, D, blurred vision, diplopia, dysphagia, "bilateral" descending muscle weakness, cranial nerve palsies (e.g., blurred vision, diplopia, dysphagia)	Raw stool, vomitus, or serum (specimens collected prior to anti- toxin administration)			Improperly processed and canned foods in airtight containers/packaging
Clostridium botulinum, infantile[£]	3- 30 days	Lethargy, weakness, poor feeding, constipation, hypotonia, poor head control, poor gag reflex and sucking reflex	Raw stool, serum	Infants		Honey; home canned vegetables, fruits; corn syrup
Clostridium perfringens	8-16 hours (6-24 hours)	D (watery), abdominal cramps, N; fever is rare	Stool in Cary-Blair, raw stool			Time and / or temperature abused foods
Cronobacter sakazakii	Less than 28 days	Bacteremia, meningitis, necrotizing enterocolitis	Blood, stool in Cary- Blair, raw stool	Premature infants		Infant formula
Coxiella burnetii (Acute Q fever)	2-3 weeks (3-39 days)	Fever, HA, fatigue, malaise, cough, anorexia, N, V, D, abdominal pain, pneumonia	Blood with EDTA/ serum, tissue	Pregnant women, immunosuppressed, and patients with a pre-existing heart valve defects		Consumption of raw cow or goat milk; contact with cows or goats
Enterohemorrhagic *E. coli* (EHEC) (including Shiga-toxin producing E. coli (STEC) and Verotoxin producing E. coli (VTEC))	3-4 days (1-10 days)	D (often bloody), abdominal cramps, V, hemolytic-uremic syndrome (HUS)	Stool in Cary-Blair, raw stool	Young children		Consumption of raw milk; contact with cattle/ruminants; undercooked ground beef; leafy greens
Enterotoxigenic *E. coli* (ETEC)	24-72 hours (10 hours- 6 days)	D (profuse watery), abdominal cramps, V	Stool in Cary-Blair, raw stool		Foreign travel especially to	Contaminated water and food sources

					developing countries	
Enteroinvasive *E. coli* (EIEC)	As short as 10-18 hrs	D (watery), fever, abdominal cramps, dysentery (in rare cases)- scant stools w/ evidence of blood, mucous or leukocytes in stool	Stool in Cary-Blair, raw stool		Foreign travel especially to developing countries	
Enteropathogenic *E. coli* (EPEC)	As short as 9-12 hrs	D (watery with mucous), fever, V	Stool in Cary-Blair, raw stool	Children < 2 years of age		
Enteroaggregative *E. coli* (EAEC)	Estimated at 20-48 hrs	Chronic or acute D (watery), V	Stool in Cary-Blair, raw stool			
Diffuse-Adherence *E. coli* (DAEC)		D	Stool in Cary-Blair, raw stool	Young children		
Leptospira interrogans	5-14 days (2-30 days)	**Anicteric disease** (no liver involvement)- Abrupt onset of fever, HA, abdominal pain, N, V, severe myalgia, malaise, **conjuctival petechiae and/or hemorrhage Icteric disease** (liver involvement)- Jaundice, upper right quadrant pain, N, V, decreased urine output, edema, hemorrhage, vascular collapse, severe altered mental status (AMS)	Blood, CSF, Urine	Farmers, veterinarians, slaughterhouse, and sewer workers		Water activities (swimming, kayaking)
Listeria monocytogenes	1 day- 3 weeks (3-70 days)	**Invasive disease**- Severe HA, N, V, stiff neck, confusion, and other neurological symptoms consistent with meningitis, sepsis, bacteremia, premature birth, or stillbirth **Gastrointestinal disease**- Fever, D, myalgia	Blood, CSF, Stool in Cary-Blair	Pregnant women€, immunosuppressed¥, elderly¥		Raw milk/dairy; soft cheeses; deli or RTE meats, raw produce
Mycobacterium bovis	Undetermined	**Gastrointestinal disease**- Abdominal pain, D **Lung disease**- Fever, weight loss, night sweats, cough	Stool in Cary-Blair, sputum	Foreign born, immigrants, immunocompromised, dairy workers		Raw milk/milk products; contact with cattle, bison, elk, and deer
Salmonella spp. (non-typhi)	12-36 hours (6- 72 hours)	D (can be bloody) fever, abdominal pain, N, V	Stool in Cary-Blair, raw stool			
Salmonella Typhi/ Paratyphi	**Typhi**- 7-14 days (3-60+ days) **Paratyphi**- 1-10 days	Fever, HA, malaise, chills, myalgia, weight loss, constipation or D, bacteremia, rash, cough	Stool in Cary-Blair, raw stool		Recent travel to endemic areas; Africa, Southeast Asia	Contaminated water and food sources
Shigella spp.	24-72 hours (1-7 days)	D (stools can have blood and mucus), abdominal cramps, fever, V, tenesmus	Stool in Cary-Blair, raw stool	Young children		Usually person to person, water or raw milk
Staphylococcus aureus (preformed toxin)	1-6 hrs (30 minutes-8hrs)	Severe N, V, abdominal cramps, prostration, D, drop in blood pressure	Stool in Cary-Blair, raw stool			Foods handled with bare hands especially those without further cooking or inadequate heating/ refrigeration, time and / or temperature abused foods

Streptococcus, Group A	1-5 days	Sore throat (pharyngitis, tonsillitis), fever, malaise, rash, cellulitis	Throat swab			Milk/ raw milk, eggs, raw produce
Vibrio parahaemolyticus	12-24 hours (2-96 hours)	D (watery), N, V, abdominal cramps, HA, fever, chills; Wound infections are possible	Stool in Cary-Blair, blood, wound culture	Immunocompromised, pre-existing liver conditions	Coastal, brackish waters, estuaries	Raw or undercooked seafood (oysters, clams, squid, mackerel, tuna, sardines, crab, shrimp)
Vibrio vulnificus	24-72 hours (1-7 days)	V, D, abdominal pain, wound infections, bacteremia, shock	Stool in Cary-Blair, blood, wound culture	Immunocompromised, pre-existing liver conditions	Coastal, brackish waters, estuaries	Raw or under-cooked seafood (oysters, clams, squid, mackerel, tuna, sardines, crab, shrimp), contaminated water, open wounds.
Vibrio cholerae, toxigenic	24-72 hours (few hours to 5 days)	D (profuse watery), abdominal cramps, N, V, dehydration, shock	Stool in Cary-Blair, rectal swab	Immunocompromised, esp. pre-existing liver conditions	Coastal, brackish waters, estuaries esp. Pacific Northwest	Seafood, raw or under-cooked oysters, contaminated water Recent travel to endemic areas
Yersinia enterocolitica	3- 7 days (1-14 days)	Fever, abdominal pain, D, V	Stool in Cary-Blair, raw stool; blood	Children and elderly more susceptible		Undercooked pork products, raw milk
Yersinia pseudotuberculosis	3- 7 days (1-14 days)	Fever, abdominal pain, D, V, (can have scarlatiniform rash)	Stool in Cary-Blair, raw stool; blood	Males		
FUNGAL						
Cryptococcus	2 to 14 months (*C. gattii*)	D, abdominal cramps	CSF, serum	Immunocompromised	Pacific Northwest, Australia, Africa	Inhalation
PARASITIC						
Angiostrongylus cantonensis or *A. costaricensis*	1-3 weeks (1 day- 6 weeks-cantonensis); weeks-1 year (costaricensis)	Severe HA, N, V, stiff neck, and other neurological symptoms consistent with meningitis (*A. canontensis*); Abdominal pain, fever, N, V (*A. costaricensis*)	CSF, blood, serum		Texas, Pacific Basin, SE Asia (A. cantonensis); Latin America, Caribbean (*A. costaricencis*)	Raw/undercooked snails, slugs; chopped vegetables contaminated with infected snails or slugs
Cryptosporidium	7 days (1-14 days)	D (severe watery; may be recurrent), abdominal cramps, N, fever	Stool (2-3 samples collected over several days)			Recreational water, drinking water, unpasteurized milk, contact with cattle, children in daycare settings (fecal-oral transmission)
Cyclospora cayetanensis	7 days (1-14 days)	D (watery), weight loss, anorexia, abdominal cramps, N, V and fatigue; fever rare	Stool, intestinal fluid, tissue biopsy		More common in tropical and subtropical countries, but occurs in other areas due to contaminated imported produce	Fresh fruit and vegetables (e.g., berries, basil, snow peas, lettuce), contaminated water
Entamoeba histolytica	1-4 weeks (from a few days to several months or years)	Fever, chills, lower abdominal pain, D, bloody D (amoebic dysentery), liver (or other organ) abscess	Stool (2-3 samples over several days), blood if	Invasive amoebiasis more common in young adults, liver	Tropical countries with poor sanitation (South and Central	Human reservoir, fecally contaminated food or water; person-to-person less common

			disseminated	abscess more common in males, dysentery rare before age 5	America, Africa, and Asia)	
Giardia lamblia	1-3 weeks (3 days- 3 weeks)	D, abdominal cramps, greasy stools, gas	Stool (2-3 samples collected over several days)			Drinking water, recreational water, children in daycare settings (fecal-oral transmission); occasional food contamination
Toxoplasma gondii	7 days (4-23 days)	Cervical lymphadenopathy, flu-like illness; if immunocompromised, central nervous system (CNS) disease, myocarditis, or pneumonitis can occur	Serum			Raw beef
Trichinella spiralis	GI symptoms- 1-2 days; 5 days- 8 weeks for other symptoms	Muscle soreness accompanied by fever and edema of eyelids are characteristic; eosinophilia, N, V, chills, D, abdominal cramps, fatigue and weakness possible	Serum; biopsy of tissue			Consumption of raw or undercooked meat (particularly bear, pork, wild feline, fox, dog, wolf, moose, horse, seal, or walrus)
VIRAL						
Adenovirus	1-10 days	D (prolonged), N, V, HA, fever, malaise, abdominal pain; Types 40 and 41 can cause GI outbreaks	Stool in Cary-Blair, raw stool, serum, naso-pharyngeal swab,	Children		
Astrovirus	1-4 days	D (watery), N, V, fever, malaise, abdominal pain, HA, anorexia	Stool in Cary-Blair, raw stool, serum	Children and immunocompromised		Childcare facilities, long-term care facilities
Hepatitis A	28 days (15-50 days)	Jaundice, dark urine, fatigue, anorexia, N, D, fever, HA, abdominal pain, weight loss	Stool in Cary-Blair, raw stool, Serum	Men who have sex with men, injection drug users, international adoptees	Foreign travel	Water contaminated with infectious human waste; raw, under-cooked mollusks harvested from contaminated waters
Hepatitis E	26-42 days (15- 64 days)	Jaundice, dark urine, D, fever, abdominal pain, arthralgia, rash, hepatomegaly, altered consciousness	Stool in Cary-Blair, raw stool, Serum		Foreign travel, especially Asia, Middle East, Africa, and Central America; exposure to pigs	Contaminated drinking water; oysters, mussels, and other shellfish; pork, pig liver; and raw/rare deer and boar
Norovirus	12-48 hours (10- 50 hours)	N, V, D, abdominal cramps, fever (low grade), HA, myalgia, malaise	Stool in Cary-Blair, raw stool	Institutionalized populations		
Parvovirus (Human Bocavirus, HBoV 2-4)	Unknown- emerging pathogen	D, V, fever, abdominal pain, coryza, cough	Stool in Cary-Blair, raw stool, serum, CSF	Children		
Rotavirus	1-3 days	D (watery), V, fever (low grade), abdominal pain	Stool in Cary-Blair, raw stool	Children		
Saffold virus (SAFV)	Unknown-emerging pathogen	D, V, respiratory symptoms (children); if invasive, then	Stool in Cary-Blair, raw stool,	Children		

		meningitis, encephalitis, myelitis, myocarditis, enanthema, exanthema, septicemia	naso- pharyngeal swab, CSF			
Sapovirus	12-48 hours	N, V, D, abdominal pain, fever, HA, myalgia	Stool in Cary-Blair, raw stool	Infants, young children, and institutionalized populations (esp. long-term care facilities)		
OTHER						
Brainerd D agent	Unknown	D (Profuse, watery, prolonged 2-36 months)	Stool in Cary-Blair, raw stool			
Toxins						
Azaspiracid Poisoning (AZP)	12-24 hours	N, V, D, abdominal cramps	Shellfish, toxin detection		Europe	Mussels, oysters
Carchatoxin	< 1-6 hours	N, V, D, and paresthesias	Food		Madagascar	Shark, particularly the liver
Ciguatera toxin	GI symptoms- 1-6 hours (few minutes-48 hours) Neurologic symptoms- few minutes- 48 hours	N, V, D, abdominal cramps, sweating, HA, muscle aches, paresthesia of lips, tongue, face or extremities and temperature sensation reversal (hot/cold sensation flip)	Fish for purification/ extraction and mouse bioassay		Tropical areas	Predatory fish like barracuda, grouper, sea bass, snapper, mullet
Scombroid	Few minutes- 3 hours	Rash, D, flushing, sweating, HA, V, burning/tingling sensation in mouth, swelling in mouth, abdominal pain, and metallic taste	Fish, histamine testing			Fish such as tuna and mackerel; (bacterial action in) Swiss cheese
Tetrodotoxin	< 30 minutes	Paresthesia of lips, tongue, face, or extremities often following numbness; floating sensation, V, D, abdominal pain, ascending paralysis, respiratory failure	Puffer fish, toxin testing			Puffer fish consumption
Mushroom toxin (short-acting)	Few minutes- 2 hours	V, D, confusion, vision problems, salivation, diaphoresis, hallucinations	Mushrooms, toxin detection			Mushroom consumption
Mushroom toxin (long-acting)	4-24 hours	D, abdominal cramps, liver and kidney failure	Mushrooms, toxin detection			Mushroom consumption
Shellfish toxin (diarrheic)	30 minutes- 2 hours	N, V, D, abdominal pain, chills, HA, fever	Shellfish, toxin detection			Mussels, oysters, scallops from Gulf of Mexico, FL
Shellfish toxin (neurotoxic)	Few minutes- 3 hours	Tingling and numbness of lips, tongue, and throat; muscle aches, dizziness and reversal of hot/cold sensation, D, V	Shellfish, toxin detection			Mussels, oysters, scallops from Gulf of Mexico, FL
Shellfish toxin (amnesic)	< 24 - 48 hours	V, D, abdominal pain and neurologic symptoms of confusion, memory loss, disorientation, seizure, or coma	Shellfish, toxin detection			Mussels, oysters, scallops

Shellfish toxin (paralytic poisoning)	30 minutes- 3 hours (15 minutes- 10 hours)	N, V, D, paresthesia of mouth and lips, weakness, dysphasia, dysphoria, respiratory paralysis	Shellfish or water, toxin detection			Scallops, mussels, clams, cockles
Chemicals						
Antimony	<1 hour (5 mins- 8 hours)	V, D, abdominal pain, metallic taste	Food or beverage			Metallic container
Arsenic	Few hours	N, V, D, pins and needles sensation, colic	Urine analysis			
Cadmium	<1 hour (5 mins- 8 hours)	N, V, D, myalgia, increased salivation, abdominal pain; often a metallic taste	Food			Seafood, oysters, clams, lobsters, grains, and peanuts
Chlorinated hydrocarbon insecticides (aldrin, chlordane, DDT, endrin, lindane, toxaphene)	30 minutes- 6 hours	N, V, paresthesia, dizziness, muscular weakness, anorexia, weight loss, confusion	Blood, urine, stools, gastric washings			Storing insecticides in same areas as foods; mistaking pesticides for powdered foods
Copper	<1 hour (5 mins- 8 hours)	N, V (blue or green), D; often a metallic taste	Food or beverage			Metallic containers
Mercury	<1 week	N, V, D, numbness, skin rash, eye irritation, weakness of legs, spastic paralysis, impaired vision, blindness, coma	Blood, hair			Fish; grains treated with mercury containing fungicides
Monosodium glutamate (MSG)	Few minutes to 1 hour	Tingling, flushing, dizziness, HA, N, burning sensation in back of neck, forearms; feeling of tightness in chest	N/A			Foods seasoned with MSG
Nicotinic acid/Niacin	Few minutes to 1 hour	Flushing, sensation of warmth, itching, abdominal pain, puffiness of face and knees	N/A			Meats or other foods with sodium nicotinate as color preservative; high doses of dietary supplements
Nitrite poisoning	1-2 hours	N, V, cyanosis/blue skin, HA, dizziness, weakness, fatigue, loss of consciousness, chocolate-brown colored blood	Blood, food			Cured meats and spinach
Organophosphates or carbamate pesticides (Diazinon, Malathion, Parathion, TEPP; Carbaryl, Sevin®, Lannate®, Aprocarb®)	Few minutes to few hours	N, V, abdominal pain, HA, nervousness, blurred vision, twitching, convulsions	Blood, food			Spraying foods just before harvesting; storing insecticides in same areas as foods; mistaking pesticides for powdered foods
Sodium fluoride	Few minutes to 2 hours	Irritation of skin, eyes, and respiratory tract, salty or soapy taste in mouth, numbness of mouth, V, D, dilated pupils, spasms, pallor, shock, collapse	Vomitus, gastric washes, and food			Dry goods (powdered milk, flour, baking powder, cake mix), insecticides and rodenticides
Thallium	Few hours	V, D, hair loss, neurologic manifestations (paresthesia, respiratory depression, bronchospasms, cranial nerve palsies)	Urine, hair			Centers for Disease Control and Prevention. Thallium Poisoning from Eating Contaminated Cake-- Iraq, 2008. MMWR. September 19,

						2008 / 57(37);1015-1018.
Tin	Few hours	N, V, D; often a metallic taste	Food			Metallic container
Triorthocresylphosphate	10 days (5-21 days)	N, V, D, leg pain, ungainly high stepping gait, food and wrist drop	N/A			Using compound to extract foods or as cooking or salad oil
Zinc	Few hours	Stomach cramps, N, V, D, myalgias; often a metallic taste	Blood, stool, saliva, urine, and food			Metallic container

Notes:

[1] Unless otherwise noted, the median incubation period and range were obtained from the following three sources: Heymann, D.L. (Ed.)(2008). **Control of Communicable Diseases Manual** (19th ed.). Washington, DC: American Public Health Association; Centers for Disease Control and Prevention (CDC) (March 26, 2014) A-Z Index for Foodborne Illness. Retrieved from http://www.cdc.gov/foodsafety/diseases/index.html.

[2] Victoria Lappi, John R. Archer, Elizabeth Cebelinski, Fe Leano, John M. Besser, Rachel F. Klos, Carlota Medus, Kirk E. Smith, Collette Fitzgerald, and Jeffrey P. Davis. Foodborne Pathogens and Disease. March 2013, 10(3): 250-255. doi:10.1089/fpd.2012.1307.

[3] B.R. Jackson, J. Alomia Zegarra, H. Lopez-Gatell, J. Sejvar, F. Arzate, S. Waterman, A. Sanchez Nunez, B. Lopez, J. Weiss, R. Quintero Cruz, D. Y. Lopez Murrieta, R. Luna-Gierke, K. Heiman, A. R. Vieira, C. Fitzgerald, P. Kwan, M. Zarate-Bermudez, D. Talkington, V. R. Hill and B. Mahon (2014). Binational outbreak of Guillain–Barré syndrome associated with Campylobacter jejuni infection, Mexico, and USA, 2011 . Epidemiology and Infection, 142, pp 1089-1099. doi:10.1017/S0950268813001908.

§- Key epidemiological information

£- Clinical consultation and testing recommendations (including lab collection recommendations) can be obtained through consultation with CDC.

€- Pregnant women may be more likely to present with mild, flu-like symptoms.

¥- Elderly or immunocompromised may be more likely to present with sepsis or meningitis.

N- nausea, D- diarrhea, V-vomiting, HA- headache

8-6 – VAERS Form

VAERS Vaccine Adverse Event Reporting System
www.vaers.hhs.gov

Adverse events are possible reactions or problems that occur during or after vaccination. Items **2, 3, 4, 5, 6, 17, 18 and 21** are **ESSENTIAL** and should be completed. Patient identity is kept confidential. Instructions are provided on the last two pages.

INFORMATION ABOUT THE PATIENT WHO RECEIVED THE VACCINE (Use **Continuation Page** if needed)

1. Patient name: (first) _____ (last) _____
Street address: _____
City: _____ State: ____ County: _____
ZIP code: _____ Phone: ( ) _____ Email: _____
2. Date of birth: (mm/dd/yyyy) _____ 3. Sex: ☐ Male ☐ Female ☐ Unknown
4. Date and time of vaccination: (mm/dd/yyyy) _____ Time: hh:mm ☐ AM ☐ PM
5. Date and time adverse event started: (mm/dd/yyyy) _____ Time: hh:mm ☐ AM ☐ PM
6. Age at vaccination: ___ Years ___ Months 7. Today's date: (mm/dd/yyyy) _____
8. Pregnant at time of vaccination?: ☐ Yes ☐ No ☐ Unknown
(If yes, describe the event, any pregnancy complications, and estimated due date if known in item 18)

9. Prescriptions, over-the-counter medications, dietary supplements, or herbal remedies being taken at the time of vaccination:

10. Allergies to medications, food, or other products:

11. Other illnesses at the time of vaccination and up to one month prior:

12. Chronic or long-standing health conditions:

INFORMATION ABOUT THE PERSON COMPLETING THIS FORM

13. Form completed by: (name) _____
Relation to patient: ☐ Healthcare professional/staff ☐ Patient (yourself) ☐ Parent/guardian/caregiver ☐ Other: _____
Street address: _____ ☐ Check if same as item 1
City: _____ State: ____ ZIP code: _____
Phone: ( ) _____ Email: _____
14. Best doctor/healthcare professional to contact about the adverse event: Name: _____ Phone: ( ) _____ Ext: _____

INFORMATION ABOUT THE FACILITY WHERE VACCINE WAS GIVEN

15. Facility/clinic name: _____
Fax: ( ) _____
Street address: ☐ Check if same as item 13
_____
_____
City: _____
State: ____ ZIP code: _____
Phone: ( ) _____

16. Type of facility: (Check one)
☐ Doctor's office, urgent care, or hospital
☐ Pharmacy or store
☐ Workplace clinic
☐ Public health clinic
☐ Nursing home or senior living facility
☐ School or student health clinic
☐ Other: _____
☐ Unknown

WHICH VACCINES WERE GIVEN? WHAT HAPPENED TO THE PATIENT?

17. Enter all vaccines given on the date listed in item 4: (Route is HOW vaccine was given, Body site is WHERE vaccine was given) Use **Continuation Page** if needed

Vaccine (type and brand name)	Manufacturer	Lot number	Route	Body site	Dose number in series
select			select	select	select
select			select	select	select
select			select	select	select
select			select	select	select

18. Describe the adverse event(s), treatment, and outcome(s), if any: (symptoms, signs, time course, etc.)
Use **Continuation Page** if needed

19. Medical tests and laboratory results related to the adverse event(s): (include dates)
Use **Continuation Page** if needed

20. Has the patient recovered from the adverse event(s)?: ☐ Yes ☐ No ☐ Unknown

21. Result or outcome of adverse event(s): (Check all that apply)
☐ Doctor or other healthcare professional office/clinic visit
☐ Emergency room/department or urgent care
☐ Hospitalization: Number of days (if known) _____
Hospital name: _____
City: _____ State: _____
☐ Prolongation of existing hospitalization (vaccine received during existing hospitalization)
☐ Life threatening illness (immediate risk of death from the event)
☐ Disability or permanent damage
☐ Patient died – Date of death: (mm/dd/yyyy) _____
☐ Congenital anomaly or birth defect
☐ None of the above

ADDITIONAL INFORMATION

22. Any other vaccines received within one month prior to the date listed in item 4: Use **Continuation Page** if needed

Vaccine (type and brand name)	Manufacturer	Lot number	Route	Body site	Dose number in series	Date Given
select			select	select	select	
select			select	select	select	

23. Has the patient ever had an adverse event following any previous vaccine?: (If yes, describe adverse event, patient age at vaccination, vaccination dates, vaccine type, and brand name)
☐ Yes _____ ☐ No ☐ Unknown

24. Patient's race: (Check all that apply) ☐ American Indian or Alaska Native ☐ Asian ☐ Black or African American ☐ Native Hawaiian or Other Pacific Islander ☐ White ☐ Unknown ☐ Other: _____

25. Patient's ethnicity: ☐ Hispanic or Latino ☐ Not Hispanic or Latino ☐ Unknown

26. Immuniz. proj. report number: (Health Dept use only) _____

COMPLETE ONLY FOR U.S. MILITARY/DEPARTMENT OF DEFENSE (DoD) RELATED REPORTS

27. Status at vaccination: ☐ Active duty ☐ Reserve ☐ National Guard ☐ Beneficiary ☐ Other: _____

28. Vaccinated at Military/DoD site: ☐ Yes ☐ No

FORM FDA VAERS 2.0 (03/21) SAVE

VAERS

CONTINUATION PAGE (Use only if you need more space from the front page)

17. Enter all vaccines given on the date listed in item 4 (continued):					Dose number in series
Vaccine (type and brand name)	Manufacturer	Lot number	Route	Body site	
select			select	select	select
select			select	select	select
select			select	select	select
select			select	select	select

22. Any other vaccines received within one month prior to the date listed in item 4 (continued):					Dose number in series	Date Given
Vaccine (type and brand name)	Manufacturer	Lot number	Route	Body site		
select			select	select	select	
select			select	select	select	
select			select	select	select	
select			select	select	select	
select			select	select	select	
select			select	select	select	

Use the space below to provide any additional information (indicate item number):

FORM FDA VAERS 2.0 (03/21)

SAVE

RETURN TO PAGE 1

COMPLETING THE VACCINE ADVERSE EVENT REPORTING SYSTEM (VAERS) FORM

GENERAL INSTRUCTIONS

- Submit this form electronically using the Internet. For instructions, visit www.vaers.hhs.gov/uploadfile/.
- If you are unable to submit this form electronically, you may fax it to VAERS at 1-877-721-0366.
- If you need additional help submitting a report you may call the VAERS toll-free information line at 1-800-822-7967, or send an email to info@vaers.org.
- Fill out the VAERS form as completely as possible and use the **Continuation Page** if needed. Use a separate VAERS form for each individual patient.
- If you do not know exact numbers, dates, or times, please provide your best guess. You may leave these spaces blank if you are not comfortable guessing.
- You can get specific information on the vaccine and vaccine lot number by contacting the facility or clinic where the vaccine was administered.
- Please report all significant adverse events that occur after vaccination of adults and children, even if you are not sure whether the vaccine caused the adverse event.
- Healthcare professionals should refer to the VAERS Table of Reportable Events at www.vaers.hhs.gov/reportable.html for the list of adverse events that must be reported by law (42 USC 300aa-25).
- Healthcare professionals treating a patient for a suspected vaccine adverse event may need to contact the person who administered the vaccine in order to exchange information and decide how best to complete and submit the VAERS form.

SPECIFIC INSTRUCTIONS

Items 2, 3, 4, 5, 6, 17, 18 and 21 are **ESSENTIAL** and should be completed.

- **Items 4 and 5:** Provide dates and times as specifically as you can and enter as much information as possible (e.g., enter the month and year even if you don't know the day). If you do not know the exact time, but know it was in the morning ("AM") or afternoon or evening ("PM"), please provide that information.
- **Item 6:** If you fill in the form by hand, provide age in years. If a child is less than 1 year old, provide months of age. If a child is more than 1 year old but less than 2 years old, provide year and months (e.g., 1 year and 6 months). If a child is less than 1 month of age when vaccinated (e.g., a birth dose of hepatitis B vaccine) then answer 0 years and 0 months, but be sure to include the patient's date of birth (item 2) and date and time of vaccination (item 4).
- **Item 8:** If the patient who received the vaccine was pregnant at time of vaccination, select "Yes" and describe the event, any pregnancy complications, and estimated due date if known in item 18. Otherwise, select "No" or "Unknown."
- **Item 9:** List any prescriptions, over-the-counter medications, dietary supplements, herbal remedies, or other non-traditional/ alternative medicines being taken by the patient when the vaccine(s) was given.
- **Item 10:** List any allergies the patient has to medications, foods, or other products.
- **Item 11:** List any short-term or acute illnesses the patient had on the date of vaccination AND up to one month prior to this date (e.g., cold, stomach flu, ear infection, etc.). This does **NOT** include the adverse event you are reporting.
- **Item 12:** List any chronic or long-standing health conditions the patient has (e.g., asthma, diabetes, heart disease).
- **Item 13:** List the name of the person who is completing the form. Select the "Check if same as item 1" box if you are the patient or if you live at the same address as the patient. The contact information you provided in item 1 will be automatically entered for you. Otherwise, please provide new contact information.
- **Item 14:** List the doctor or other healthcare professional who is the best person to contact to discuss the clinical details of the adverse event.
- **Item 15:** Select the "Check if same as item 13" box if the person completing the form works at the facility that administered the vaccine(s). The contact information provided in item 13 will be automatically entered for you. Otherwise, provide new contact information.
- **Item 16:** Select the option that best describes the type of facility where the vaccine(s) was given.

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- **Item 17:** Include only vaccines given on the date provided in item 4. The vaccine route options include:
  - Injection/shot (intramuscular, subcutaneous, intradermal, jet injection, and unknown)
  - By mouth/oral
  - In nose/intranasal
  - Other (specify)
  - Unknown

  For body site, the options include:
  - Right arm
  - Left arm
  - Arm (side unknown)
  - Right thigh
  - Left thigh
  - Thigh (side unknown)
  - Nose
  - Mouth
  - Other (specify)
  - Unknown

  For vaccines given as a series (i.e., 2 or more doses of the same vaccine given to complete a series), list the dose number for the vaccine in the last column named "Dose number in series."
- **Item 18:** Describe the adverse event(s), treatment, and outcome(s). Include signs and symptoms, when the symptoms occurred, diagnosis, and treatment. Provide specific information if you can (e.g., if patient had a fever, provide the temperature).
- **Item 19:** List any medical tests and laboratory results related to the adverse event(s). Include abnormal findings as well as normal or negative findings.
- **Item 20:** Select "Yes" if the patient's health is the same as it was prior to the vaccination or "No" if the patient has not returned to the same state of health prior to the vaccination, and provide details in item 18. Select "Unknown" if the patient's present condition is not known.
- **Item 21:** Select the result(s) or outcome(s) for the patient. If the patient did not have any of the outcomes listed, select "None of the above." Prolongation of existing hospitalization means the patient received a vaccine during a hospital stay and an adverse event following vaccination occurred that resulted in the patient spending extra time in the hospital. Life threatening illness means you believe this adverse event could have resulted in the death of the patient.
- **Item 22:** List any other vaccines the patient received within one month prior to the vaccination date listed in item 4.
- **Item 23:** Describe the adverse event(s) following any previous vaccine(s). Include patient age at vaccination, dates of vaccination, vaccine type, and brand name.
- **Item 24:** Check all races that apply.
- **Item 25:** Check the single best answer for ethnicity.
- **Item 26:** For health department use only.
- **Items 27 and 28:** Complete only for U.S. Military or Department of Defense related reports. In addition to active duty service members, Reserve and National Guard members, beneficiaries include: retirees, their families, survivors, certain former spouses, and others who are registered in the Defense Enrollment Eligibility Reporting System (DEERS).

GENERAL INFORMATION

- VAERS (www.vaers.hhs.gov) is a national vaccine safety monitoring system that collects information about adverse events (possible reactions or problems) that occur during or after administration of vaccines licensed in the United States.
- VAERS protects patient identity and keeps patient identifying information confidential.
- The Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule permits reporting of protected health information to public health authorities including the Centers for Disease Control and Prevention (CDC) and U.S. Food and Drug Administration (FDA) (45 CFR § 164.512(b)).
- VAERS accepts all reports without judging the importance of the adverse event or whether a vaccine caused the adverse event.
- Acceptance of a VAERS report by CDC and FDA does not constitute admission that the vaccine or healthcare personnel caused or contributed to the reported event.
- The National Vaccine Injury Compensation Program (VICP) is administered by the Health Resources and Services Administration (HRSA). The VICP is separate from the VAERS program and reporting an event to VAERS does not constitute filing a claim for compensation to the VICP (see www.hrsa.gov/vaccinecompensation/index.html).
- Knowingly filing a false VAERS report with the intent to mislead the Department of Health and Human Services is a violation of Federal law (18 U.S. Code § 1001) punishable by fine and imprisonment.

8-7 MedWatch Form

Reset Form

U.S. Department of Health and Human Services
Food and Drug Administration
MEDWATCH

FORM FDA 3500 (2/20)
The FDA Safety Information and Adverse Event Reporting Program

For VOLUNTARY reporting of adverse events, product problems and product use/medication errors

Page 1 of 2

Form Approved: OMB No. 0910-0291, Expires: 11-30-2021
See PRA statement on reverse.

FDA USE ONLY
Triage unit sequence #
FDA Rec. Date

Note: For date prompts of "dd-mmm-yyyy" please use 2-digit day, 3-letter month abbreviation, and 4-digit year; for example, 01-Jul-2018.

A. PATIENT INFORMATION

1. Patient Identifier
In Confidence

2. Age
☐ Year(s) ☐ Month(s) ☐ Week(s) ☐ Day(s)
or Date of Birth *(e.g., 08 Feb 1925)*

3. Gender *(check one)*
☐ Female ☐ Male ☐ Intersex ☐ Transgender ☐ Prefer not to disclose

4. Weight
☐ lb ☐ kg

5. Ethnicity *(check one)*
☐ Hispanic/Latino ☐ Not Hispanic/Latino

6. Race *(check all that apply)*
☐ Asian ☐ American Indian or Alaskan Native ☐ Black or African American ☐ White ☐ Native Hawaiian or Other Pacific Islander

B. ADVERSE EVENT, PRODUCT PROBLEM

1. Type of Report *(check all that apply)*
☐ Adverse Event ☐ Product Problem *(e.g., defects/malfunctions)* ☐ Product Use/ Medication Error ☐ Problem with Different Manufacturer of Same Medicine

2. Outcome Attributed to Adverse Event *(check all that apply)*
☐ Death *Date of death (dd-mmm-yyyy):*
☐ Life-threatening ☐ Disability or Permanent Damage
☐ Hospitalization (initial or prolonged) ☐ Congenital Anomaly/Birth Defects
☐ Other Serious or Important Medical Events
☐ Required Intervention to Prevent Permanent Impairment/Damage

3. Date of Event *(dd-mmm-yyyy)*

4. Date of this Report *(dd-mmm-yyyy)*

5. Describe Event, Problem or Product Use/Medication Error

(Continue on page 2)

6. Relevant Tests/Laboratory Data — Date *(dd-mmm-yyyy)*

(Continue on page 2)

7. Other Relevant History, Including Preexisting Medical Conditions *(e.g., allergies, pregnancy, smoking and alcohol use, liver/kidney problems, etc.)*

(Continue on page 2)

C. PRODUCT AVAILABILITY

1. Product Available for Evaluation? *(Do not send product to FDA)*
☐ Yes ☐ No ☐ Returned to Manufacturer on *(dd-mmm-yyyy)*

2. Do you have a picture of the product? *(check yes if you are including a picture)* ☐ Yes

D. SUSPECT PRODUCTS

1. Name, Strength, Manufacturer/Compounder *(from product label)*. Does this report involve cosmetic, dietary supplement or food/medical food? #1 ☐ Yes #2 ☐ Yes

#1 – Name and Strength	#1 – NDC # or Unique ID
#1 – Manufacturer/Compounder	#1 – Lot #
#2 – Name and Strength	#2 – NDC # or Unique ID
#2 – Manufacturer/Compounder	#2 – Lot #

2. Dose or Amount | Frequency | Route

#1			
#2			

3. Treatment Dates/Therapy Dates *(give best estimate of length of treatment (start/stop) or duration.)*
#1 Start
#1 Stop
Is therapy still on-going? ☐ Yes ☐ No
#2 Start
#2 Stop
Is therapy still on-going? ☐ Yes ☐ No

4. Diagnosis for Use *(Indication)*
#1
#2

5. Product Type *(check all that apply)*
#1 ☐ OTC ☐ Compounded ☐ Generic ☐ Biosimilar
#2 ☐ OTC ☐ Compounded ☐ Generic ☐ Biosimilar

6. Expiration Date *(dd-mmm-yyyy)*
#1
#2

7. Event Abated After Use Stopped or Dose Reduced?
#1 ☐ Yes ☐ No ☐ Doesn't apply
#2 ☐ Yes ☐ No ☐ Doesn't apply

8. Event Reappeared After Reintroduction?
#1 ☐ Yes ☐ No ☐ Doesn't apply
#2 ☐ Yes ☐ No ☐ Doesn't apply

E. SUSPECT MEDICAL DEVICE

1. Brand Name

2a. Common Device Name | 2b. Procode

3. Manufacturer Name, City and State

4. Model #	Lot #	5. Operator of Device ☐ Health Professional ☐ Patient/Consumer ☐ Other
Catalog #	Expiration Date *(dd-mmm-yyyy)*	
Serial #	Unique Identifier *(UDI)* #	

6a. If Implanted, Give Date *(dd-mmm-yyyy)* | 6b. If Explanted, Give Date *(dd-mmm-yyyy)*

7a. Is this a single-use device that was reprocessed and reused on a patient? ☐ Yes ☐ No

7b. If Yes to item 7a, Enter Name and Address of Reprocessor

8. Was this device serviced by a third party servicer?
☐ Yes ☐ No ☐ Unknown

F. OTHER (CONCOMITANT) MEDICAL PRODUCTS

1. Product names and therapy dates *(Exclude treatment of event)*

(Continue on page 2)

G. REPORTER *(See confidentiality section on back)*

1. Name and Address
Last Name: First Name:
Address:
City: State/Province/Region:
ZIP/Postal Code: Country:
Phone #: Email:

2. Health Professional? ☐ Yes ☐ No

3. Occupation

4. Also Reported to:
☐ Manufacturer/ Compounder ☐ User Facility ☐ Distributor/Importer

5. If you do NOT want your identity disclosed to the manufacturer, please mark this box: ☐

FORM FDA 3500 (2/20) Submission of a report does not constitute an admission that medical personnel or the product caused or contributed to the event.
* Please see Instructions

Reset Form

U.S. Department of Health and Human Services
Food and Drug Administration
MEDWATCH

FORM FDA 3500 (2/20) *(continued)*
The FDA Safety Information and Adverse Event Reporting Program

(CONTINUATION PAGE)
For VOLUNTARY reporting of adverse events, product problems and product use/medication errors

Page 2 of 2

B.5. **Describe Event or Problem** *(continued)*

Back to Item B.5

B.6. **Relevant Tests/Laboratory Data** *(continued)*

Date *(dd-mmm-yyyy)*	Relevant Tests/Laboratory Data	Date *(dd-mmm-yyyy)*

Additional comments

Back to Item B.6

B.7. **Other Relevant History** *(continued)*

Back to Item B.7

F.1. **Concomitant Medical Products and Therapy Dates** *(Exclude treatment of event) (continued)*

Back to Item F.1

ADVICE ABOUT VOLUNTARY REPORTING

Detailed instructions available at: https://www.fda.gov/safety/medwatch-forms-fda-safety-reporting/instructions-completing-form-fda-3500

Report adverse events, product problems or product use errors with:

- Medications (drugs or biologics)
- Medical devices (including diabetes glucose-test kit, hearing aids, breast pumps, and many more)
- Combination products (medication & medical devices)
- Blood transfusions, gene therapies, and human cells and tissue transplants (for example, tendons, bone, and corneas)
- Special nutritional products (dietary supplements, medical foods, infant formulas)
- Cosmetics (such as moisturizers, makeup, shampoos and conditioners, face and body washes, deodorants, nail care products, hair dyes and relaxers, and tattoos)
- Food (including beverages and ingredients added to foods)

Report product problems – quality, performance or safety concerns such as:

- Suspected counterfeit product
- Suspected contamination
- Questionable stability
- Defective components
- Poor packaging or labeling
- Therapeutic failures (product didn't work)

Report SERIOUS adverse events. An event is serious when the patient outcome is:

- Death
- Life-threatening
- Hospitalization (initial or prolonged)
- Disability or permanent damage
- Congenital anomaly/birth defect
- Required intervention to prevent permanent impairment or damage
- Other serious (important medical events)

Report even if:

- You're not certain the product caused the event
- You don't have all the details
- Just fill in the sections that apply to your report

How to report:

- Use section D for all products except medical devices
- Attach additional pages if needed
- Use a separate form for each patient
- Report either to FDA or the manufacturer (or both)

How to submit report:

- To report by phone, call toll-free: 1-800-FDA (332)-1088
- To fax report: 1-800-FDA(332)-0178
- To report online: www.fda.gov/medwatch/report.htm

If your report involves a serious adverse event with a device and it occurred in a facility outside a doctor's office, that facility may be legally required to report to FDA and/or the manufacturer. Please notify the person in that facility who would handle such reporting.

If your report involves an adverse event with a vaccine, go to http://vaers.hhs.gov to report or call 1-800-822-7967.

Confidentiality:

The patient's identity is held in strict confidence by FDA and protected to the fullest extent of the law. The reporter's identity, including the identity of a self-reporter, may be shared with the manufacturer unless requested otherwise.

The information in this box applies only to requirements of the Paperwork Reduction Act of 1995.

The burden time for this collection of information has been estimated to average 40 minutes per response, including the time to review instructions, search existing data sources, gather and maintain the data needed, and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

Please DO NOT RETURN this form to the PRA Staff e-mail above.

OMB statement:

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number."

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

8-8 Potential Tobacco Product Violations Form

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Potential Tobacco Product Violations Report

Form Approved: OMB No.: 0910-0716
Expiration Date: 07/31/2020
(See page 3 for PRA Statement)

Directions:

Use this form to report potential tobacco-related violations of the Federal Food, Drug, and Cosmetic Act and associated regulations. These submissions are reviewed by FDA's Center for Tobacco Products.

WHO can report? - Any member of the public.

Tell us:

WHEN did you see the potential violation?

WHERE did the potential violation occur?

WHAT is the potential violation?

WHY report? - Information we receive from the public is often very helpful in identifying problems with marketed products and possible violations of the laws that we enforce.

To submit your report, complete the form below:

Date and State Where Violation Occurred

Date potential violation occurred *(mm/dd/yyyy)*	I do not recall the date this potential violation occurred ☐	State in which potential violation occurred

Description of Product

Type	Tobacco Brand

Potential violation type *(choose all that apply)*

- ☐ Sales to minors
- ☐ Flavored cigarette sales
- ☐ Advertising/promotion/marketing
- ☐ Vending machine/direct access to cigarette or smokeless tobacco or covered tobacco products
- ☐ Free samples
- ☐ Self-service display/direct access to cigarette or smokeless tobacco
- ☐ Sale of cigarettes in packs of less than 20
- ☐ Unsure

Type of potentially violative promotional materials *(choose all that apply)*

- ☐ Newspaper
- ☐ Magazine
- ☐ Periodicals
- ☐ Billboard
- ☐ Direct mail
- ☐ In-store advertisements
- ☐ Price signage
- ☐ Posters
- ☐ Coupons
- ☐ Internet
- ☐ Unsure

Who potentially violated? *(choose all that apply)*

- ☐ Retailer
- ☐ Manufacturer
- ☐ Importer
- ☐ Distributor
- ☐ Unsure

FORM FDA 3779 (12/17) Page 1 of 3 PSC Publishing Services (301) 443-6740 EF

Potential Tobacco Product Violations Report

Description of potential violation

Name and physical address of the potential violator, if known

Retailer, manufacturer, importer, or distributor name

Street Address

Street Address Line 2

City	State/Province/Region	Postal/Zip Code

If report is about a website, insert website address:

All reports will remain private to the extent allowed by law. For more information about FDA's internet policies, please visit: http://www.fda.gov/AboutFDA/AboutThisWebsite/WebsitePolicies/default.htm

May we contact you if we need additional information?

☐ No, I want my report to be anonymous. *(Please note that if you submit this form by email, FDA will receive your email address. However, if you choose "no" FDA will not contact you.)*

☐ Yes, FDA may contact me. *(Please fill in contact information below.)*

Name

Affiliation *(such as company, school, or group)*

Street Address

Street Address Line 2

(continued on next page)

Potential Tobacco Product Violations Report

City	State/Province/Region
Postal/Zip Code	Phone Number

Email

Please email me to notify me that FDA got my complaint ☐ No ☐ Yes

In order to receive a response, please configure your email spam/junk filter to allow messages from ctpcompliance@fda.hhs.gov. In most cases, this is solved by adding our email address to your address book.

If you would rather submit your report to us in writing, along with any attachments, please do so at the the following address:

Food and Drug Administration
Center for Tobacco Products
Document Control Center
Building 71, Room G335
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

To reach us by telephone, please call 1-877-CTP-1373, and select option 3.
You may also email us at ctpcompliance@fda.hhs.gov.

Submit By Email Print Form Reset Form

An email message automatically will be produced when you click the SUBMIT BY EMAIL button. In the resulting email message, please don't forget to click the "Send" button or its equivalent when you are ready to send the email.

OMB Paperwork Reduction Act Statement

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

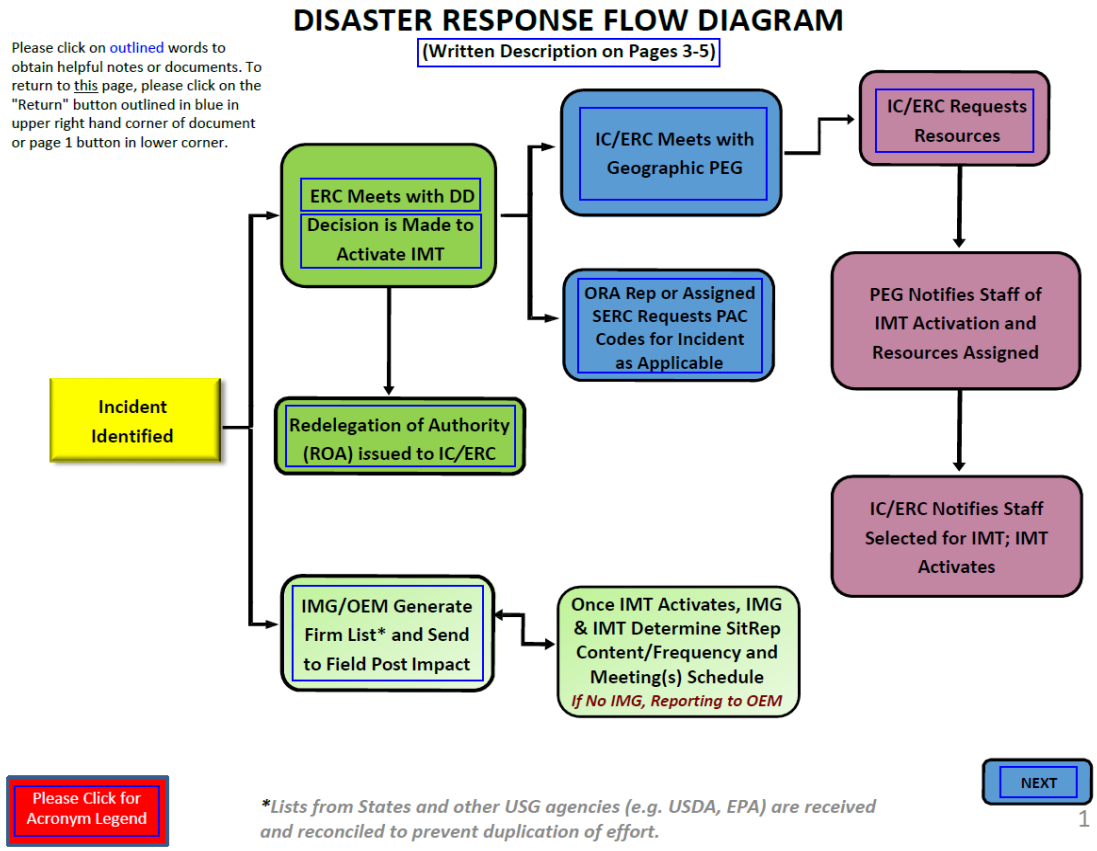
The burden for this collection of information is estimated to average 0.25 hour per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to the following address:

Department of Health and Human Services
Food and Drug Administration
Office of Operations
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

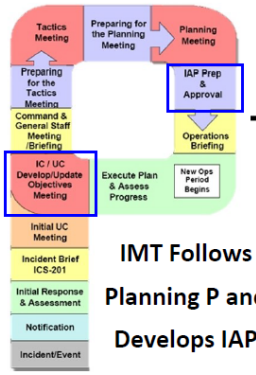
"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

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8-9 – Disaster Response Flow Diagram



DISASTER RESPONSE FLOW DIAGRAM



IMT Follows Planning P and Develops IAP

Please click on outlined words to obtain helpful notes or documents. To return to this page, please click on the"Return" button outlined in blue in upper right hand corner of document.

Operations Section Begins Telephone Assessments

Site Visits Using OP13 Conducted as Warranted *(Based upon Phone Assessment Intel)*

SitReps Issued per Agreed Upon Frequency

IMT Demobilizes Once Incident is Stabilized*

Uncontacted Firms Sent to Program(s) for Follow-up

Records Maintained per ORA Policy

After Action Review Conducted; Report Generated

Notes

- 2020 IMH
- For Expansion of IMT; Contact PEG or IMG for Additional Resources
- Reconcile Firm Lists Daily based on Work Accomplished
- SitRep Examples
- After Action Report Examples
- Additional Transition to Progam Email
- ROA Example

PAGE 1

2

* *Demobilization announced in last SitRep*

Disaster Response Flow Diagram

(Steps are Not Always Sequential)

1. Incident identified.
2. Initial notifications provided to DD/PDD or PEG based on incident.
3. ERC Meets with DD and decision is made to activate IMT. Local PDD may be in this initial meeting. *(Note: When an IMT is not activated, the ERC coordinates the disaster response with the Program Divisions.)*
   - Click link in flow diagram for discussion points for the ERC and DD/PDD meeting and AHOD or refer to page 6
   - Click link in Notes for DD/PDD meeting for Emergeny Response Resource and Funding Allocation Memo also referred to as All Hands on Deck (AHOD) memo
   - Click link in flow diagram to see IMT activation flow chart, and link in flow chart for example of PEG notification email
4. Redelegation of Authority issued to ERC/IC as applicable.
   - Click link for Redelegation of Authority (ROA) template. (Also see link of completed ROA example in Note Box on Page 2)
5. Initial communication between OEM or IMG (as applicable) and ERC/IC. *(Note: IMG is not activated for all storms; coordination is via OEM/OEO when there is no IMG.)*
   - ERC provides courtesy notification to OEM/IMG of IMT activation
   - OEM/IMG provides a map to ERC of projected area of impact prior to storm
   - OEM/IMG provides Center-vetted firm list for impacted area to PEG with copy to ERC post landfall
   - SitRep frequency and content are established with OEM/IMG. *(Note: When an IMT is not activated, ERC establishes with OEO Coordinator how updates will be provided.)*
6. DD/ERC meets with Geographic PEG to receive response priorities.
   - Click link in flow diagram for discussion points for PEG meeting or refer to page 7
   - Click link on PEG Meeting Notes page for "*Current Year" Program Priorities for Disaster Response* lists
7. Have ORA Rep or assigned SERC request PAC codes for incident if applicable. Otherwise, use General Disaster PAC Codes.
   - Click link in flow diagram for email with Natural Disaster and Emergencies PAC Codes
8. IC/ERC requests resources for IMT from PEG via Resource Request Form as warranted.
   - Click link in flow diagram for Resource Request form.

3

19. Telephone assessments and site visits are recorded as Op 13s in eNspect with the documents attached.
20. IMT records (IAP, Sitreps, emails, etc.) are stored in EON.
21. Hotwash is held prior to demobilization of IMT. A formal After Action Review is performed with IMT participants shortly after demobilization and an After Action Report generated.
    - Click link in flow diagram for Tips for Conducting an After Action Review (Also see link of After Action Report Examples in Note Box)

(Note: Click on Acronym Link on Page 1 for list of Acronyms used in document or refer to Page 8)

- Get IT assistance commitment
- Suggest initiation of *ALL HANDS ON DECK* as applicable
- Discuss number of resources and proposed length of activation
- Discuss Delegation of Authority

- Ensure PDD communicates resource commitment to supervisory level

Notes:

No completing of OEI forms. If a firm is OOB, an email or Disaster Telephone Assessment form will be sent to OEI coordinator.

Run ORADSS report prior to meeting for general picture of potential impact

RETURN

Acronym Legend

- AAR = After Action Report or After Action Review
- AHOD = All Hands on Deck
- DD = District Director
- EPA = Environmental Protection Agency
- ERC = Emergency Response Coordinator
- FSC = Finance Section Chief
- HQ = Headquarters
- IAP = Incident Action Plan
- IC = Incident Commander
- ICP = Incident Command Post
- ICS = Incident Command System
- IMG = Incident Management Group
- IMH = Incident Management Handbook
- IMT = Incident Management Team
- LSC = Logistics Section Chief
- OEM = Office of Emergency Management
- OEO = Office of Emergency Operations
- Op13 = Operation 13
- ORA = Office of Regulatory Affairs
- ORS = Office of Regulatory Science
- OSCP = Office of State Cooperative Programs
- PAC = Program Assignment Codes
- PD = Program Director
- PDD = Program Division Director
- PEG = Program Executive Group
- ROA = Redelegation of Authority
- SERC = Senior Emergency Response Coordinator
- SitRep = Situation Report
- UC = Unified Command
- USDA = United States Department of Agriculture
- USG = United States Government