미국 FDA 경고 서한(Warning Letter) 사례집

(2024년 개정판)

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식품의약품안전처 대한화장품협회

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1 경고 서한(Warning Letter)의 유형

□ 경고 서한이란?

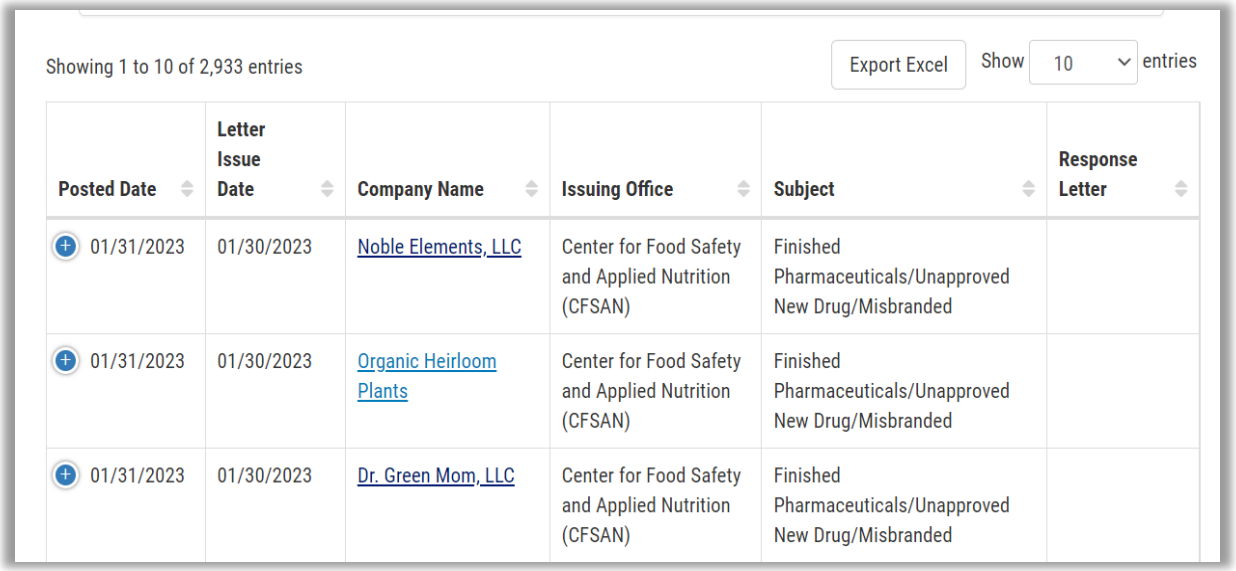
- 제품이 미국 법규를 준수하지 않았을 경우에는 FDA가 제조소 실사(inspection)를 하지 않더라도 먼저 경고 서한(Warning letter)을 FDA 웹사이트에 게재하여 해당 업체에 경고를 하기도 함

- "경고 서한(Warning letter)"이란 일종의 public information이라고 보면 되는데, FDA 웹사이트에 올라가며, 회사명과 무엇을 잘못했는지에 대한 정보가 공개됨

  · FDA에서 발행한 경고 서한은 아래 사이트에서 검색이 가능함

  ※ Warning Letters

  https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/compliance-actions-and-activities/warning-letters



Showing 1 to 10 of 2,933 entries Export Excel Show 10 entries

Posted Date	Letter Issue Date	Company Name	Issuing Office	Subject	Response Letter
01/31/2023	01/30/2023	Noble Elements, LLC	Center for Food Safety and Applied Nutrition (CFSAN)	Finished Pharmaceuticals/Unapproved New Drug/Misbranded	
01/31/2023	01/30/2023	Organic Heirloom Plants	Center for Food Safety and Applied Nutrition (CFSAN)	Finished Pharmaceuticals/Unapproved New Drug/Misbranded	
01/31/2023	01/30/2023	Dr. Green Mom, LLC	Center for Food Safety and Applied Nutrition (CFSAN)	Finished Pharmaceuticals/Unapproved New Drug/Misbranded	

- "Warning letter"를 받은 제조소에서 제조한 제품에 대해서는 억류(detention) 및 반입 거부(refusal)로 이어질 수 있음

- FDA가 “Warning letter”를 발행하는 이유는 이러한 조치로 가기 전에 “업체가 자발적으로 시정할 것”을 기대하기 때문임

- 화장품과 관련하여 발행된 경고 서한의 대표적인 예시는 FDA 웹사이트에서 볼 수 있음

※ Warning Letters Related to Cosmetics

https://www.fda.gov/cosmetics/cosmetics-compliance-enforcement/warning-letters-related-cosmetics



Warning Letters Related to Cosmetics

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□ 경고 서한을 받게 되는 대표적인 유형

- 미국 FDA로부터 경고 서한(Warning letter)를 받게 되는 대표적인 유형은 다음과 같음

· 유형 1 : 화장품으로 판매한 제품에서 의약품의 효능효과를 클레임한 경우

· 유형 2 : 색소 규정 위반

· 유형 3 : 미생물에 오염된 불량 화장품

· 유형 4 : 의료기기로 허가를 받고 팔아야 하는데, 이를 화장품으로 판매한 경우

· 유형 5 : 화장품 및 의약품 규정을 위반

· 유형 6 : 안전성 및 라벨링 위반

· 유형 7 : 의약품 GMP 미준수

□ 유형 1 : 화장품으로 판매한 제품에서 의약품의 효능효과를 클레임한 경우

- 미국 FDA로부터 경고서한을 받게 되는 첫 번째 유형은 “화장품으로 판매한 제품에서 의약품의 효능효과를 클레임한 경우”임

  ※ Warning Letters Address Drug Claims Made for Products Marketed as Cosmetics

  https://www.fda.gov/cosmetics/warning-letters-related-cosmetics/warning-letters-address-drug-claims-made-products-marketed-cosmetics

- 『연방 식품, 의약품 및 화장품법(FD&C Act)』에서는 화장품을 “외관을 세정, 미화, 호감도 증진 또는 수정하기 위해… 인체에 바르거나 붓거나 뿌리거나 분무하거나 더하거나 기타 도포하는 용도의 품목” 이라고 그 용도를 정의하고 있음(FD&C 법, 섹션201(i))

- FD&C Act에서 의약품은 "질병의 진단, 치유, 경감, 치료 또는 예방하는 용도의 품목" 및 “인간 및 기타 동물의 신체 구조나 일체 기능에 영향을 미칠 용도의 (식품이 아닌) 품목”으로 정의하고 있음. 만약 이러한 제품이 라벨에 표시된 대로 사용될 때 안전하고 효과적이라고 일반적으로 인정(Generally Recognized As Safe and Effective)되지 않는 경우, 이 제품은 “신약(New Drug)”에 해당하며, 미국에서 합법적으로 시판되기 위해서는 신약 신청(NDA)을 하여 승인을 받아야 함

- 의약품(Drug)에서만 허용되는 클레임을 화장품 라벨에 표기하거나, 유튜브, 페이스, 웹사이트, 브로셔, 제품 홍보자료 등에서 이러한 클레임을 하는 경우, 미국 FDA로부터 경고 서한(Warning letter)을 받게 됨 이러한 클레임의 예시는 다음과 같음

  · acne treatment (여드름 트리트먼트)

  · cellulite reduction (셀룰라이트 감소)

  · stretch mark reduction (스트레치 마크 감소)

  · wrinkle removal (주름 제거)

· dandruff treatment (비듬 트리트먼트)

· hair restoration (모발 복원)

· eyelash growth (속눈썹 성장)

- 업체가 FDA로부터 경고 서한(Warning letter)을 받게 된다면, 제품 포장, 광고 문구, 웹사이트 등에 사용된 과대표현을 수정해야 함

- 이러한 행위를 지속적으로 한다면 FDA의 후속 조치가 있음

사례 1

- "Treating skin problems like blemishes...and acne"
- "Control acne"
- "Comfrey Root Powder [an ingredient in your product] (restructuring and pain relief from acne or cystic acne)"

※ 자료 : Warning Letter - Earthworks Health June 7, 2019

https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/earthworks-health-560772-06072019

사례 2

- "A unique ... blend of our original anti-inflammatory herbs with the added therapeutic benefit of five essential oils that assist in relieving ... migraines..."
- "Ailments such as eczema, psoriasis, ... burns, wounds, bug bites and any skin irritation and eruptions..."
- "These organic herbs can reduce inflammation..."
- "The anti-inflammatory herb blend...can help with Arthritis, tendonitits [sic], bursitis, ..."
- "Ailments such as eczema, psoriasis,...burns, wounds, bug bites and any skin irritation and

eruptions…"

- "A blend of oils known to assist the body with sinus congestion & inflammation. Opens airways & alleviates…allergies…"
- "An amazing product for a vast variety of skin ailments, such as: Eczema, …Wounds, …Rashes…including Diaper Rashes, Psoriasis, Cracked Lips, Irritated and/or Itchy Skin, Burns, Acne, Rosacea,…and More!.."
- "This blend of pure, therapeutic grade essential oils is perfect for migraine headaches…"
- "Our No More Aches Line encourages the body to repair naturally by applying to any area with pain and inflammation…"
- "The organic herbs…are known for inflammation reduction…"
- "PLUS: Our amazing cream blended with Therapeutic Grade Essential Oils to offer…while assisting with…Plantar Fasciitis, Swelling & Inflammation, arthritis and tendonitis…"
- "Sciatica…
- "Use as an expectorant, immune booster and for it's [sic] antiviral properties…"
- "CREAM: …soothing cream that protects and alleviates the skin from the itchiness, pain and irritation of skin ailments such as psoriasis, eczema and rashes…"
- "PLUS CREAM: …blended with Therapeutic Grade Essential Oils beneficial for burns and cuts…break outs from acne to rashes…."
- "OIL [Roll-On]: …great for fungal infections, warts, acne, scalp…."

아래 예시는 OTC Drug으로 등록하지 않고 자외선차단 효과를 클레임한 경우임

- "Formulated with…SPF containing oils, it provides…sun protection…"
- "SPF…"
- "Equivalent to 30+ SPF…"
- "Provides Natural and Mild Sun Protection…"
- "Provides safe, effective, chemical free, broad spectrum UVA-UVB protection for all ages…"
- "These minerals [Zinc Oxide and Titanium Dioxide] provide a physical barrier, reflecting and scattering damaging UVB and UVA rays before they reach your skin…"

※ 자료 : Warning Letter - Green Water, LLC January 31, 2019

https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/green-water-llc-564081-01312019

사례 3

- "Anti-bacterial and anti-microbial . . . Sanitizes . . ."
- The product name, "Hand Sanitizer"
- "Helps to reduce inflammation & minimize breakouts. . . Beneficial for acne, cuts, burns & rashes. . .."
- "Protect from Bacteria and Infection. . ."
- "Reduce Pain, Inflammation, Scarring and Scar Tissue. . ."
- "Stimulate Production of Stem Cells. . ."
- "Rebuild Damaged Tissue. . ."
- "Uses: Abrasions, Acne, Bites, Blisters, Boils, Burns, Cold Sores . . . Diseased Skin . . . Germ Protection, Infections (Bacterial, Fungal, Viral or Parasitic), Inflammation, Irritations, Itching, Rashes, Skin Conditions, Sores, Sunburn, Post Surgical, Topical Antibiotic, Ulcers, Warts, Wounds, etc. . ."

※ 자료 : Silver Armor Inc. May 17, 2018

https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/silver-armor-inc-543786-05172018

사례 4

"Rapha Remedy can be used as a soothing salve for treatment of the symptoms resulting from:

- o "Eczema and Rosacea
- o "Cracked, Dry, Itching and Burning Skin
- o "Dandruff
- o "Bed Sores and Sores from quadriplegic conditions

- o "Chicken Pox, Shingles and Blisters
- o "Diaper Rash
- o "Cold Sores and Canker Sores
- o "Psoriasis
- o "Dermatitis
- o "Sunburn and Peeling Skin from tanning
- o "Athlete's Foot and Nail Fungus
- o "Sore, Dry Heels. Helps soften tough, rough skin on feet
- o "Warts, Moles, Skin Tags
- o "Cuts, Bruises and Spider Veins
- o "Skin Discoloration, Brown spots (hormonal, pregnancy and liver spots)
- o "Elasticity to Scars and Skin
- o "Sagging, Wrinkled, Aging Skin
- o "Red and Blood Spots, White Spots, Sties and Dry Eye Lids
- o "Stretch Marks (also aids in prevention), Scarring, Deep cuts in cuticles and Hangnails
- o "Burns from Radiation
- o "Frost Bite and can help protect your skin from the cold weather
- o "Muscle fatigue and tension
- o "Measles, Hives and Insect Bites
- o "Jock Itch
- o "Nasal Polyps
- o "Strengthens Dry Nails"

※ 자료 : Long Life Unlimited January 31, 2018

https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/long-life-unlimited-533282-01312018

사례 5

- "Deeply penetrate into muscles and joints to warm and comfort sore areas"
- "Massage into over-taxed muscles, sprains, strains, arthritic joints, or any other aches and pains..."
- "Deeply penetrate into sore muscles and joints to warm and comfort sore areas"
- "Deeply penetrate into sore muscles and joints to stimulate circulation and relieve minor aches and pains."
- "Our Recipe for Tending Minor Wounds"
- "Soothe recuperating cuts, minor burns and abrasions"
- "It is free of any stinging ingredients..."
- "Apply to affected area of minor cuts, burns and infections. Great for healing tattoos..."
- "Soothe skin inflammation..."
- "Pain-relieving and anti-inflammatory..."
- "Massage into sore areas of your feet..."
- Review by customer on 04/14/17, "Soothed my sunburn and my psoriasis"

※ 자료 : Moon Valley Natural Products, LLC August 11, 2017

https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/moon-valley-natural-products-llc-522934-08112017

사례 6

- "Caffeine Extract, known for increasing circulation ... "
- "ROSE HIP SEED OIL [(an ingredient in your product)]: Supports the keratin migration cycle that is responsible for the natural regeneration of skin cells and can increase renewed cells in the epidermis."
- "CUCUMBER PEEL EXTRACT [(an ingredient in your product)]: ... has anti-inflammatory ... properties."
- "Hyaluronic Acid has recently been used to create Hylaform Gel, an FDA Approved injectable material that aestheticians and plastic surgeons predict will replace collagen injections

because the risk of reaction is lower (most collagen being of bovine origin) and Hylaform Gel is more effective, and the results last longer than those of collagen injections."

- "Addition of CLOVE [(an ingredient in your product)], an antiseptic, and CAYENNE [(an ingredient in your product)], an anti-inflammatory ingredient that helps soothe redness, fade dark spots and promotes healing of Acne scars."
- "Also includes WILLOW BARK [(an ingredient in your product)], a 100% pure and natural way to help stop Acne in its tracks! Willow Bark, or Salicin, is a derivative of Salicylic Acid, the key additive in many skin-care products for the treatment of acne."
- "WILLOW BARK [(an ingredient in your product)] ... reduce inflammation, soothes pain."
- "PINK GRAPEFRUIT ESSENTIAL OILS [(an ingredient in your product)] ... reduce oil production."
- "CLOVE [(an ingredient in your product)] ... Has antibacterial properties, and some of its primary components are known to be toxic to Propionibacterium Acnes bacteria."
- "CAYENNE [(an ingredient in your product)] ... anti-inflammatory."
- "WITCH HAZEL [(an ingredient in your product)] ... reduces oil production. "
- "ORGANIC ROSE HYDROSOL [(an ingredient in your product)] ... helps to regulate sebum, and its antibacterial properties can be helpful in the prevention of acne."
- "ORGANIC ALOE [(an ingredient in your product)] ... reduce inflammation and swelling. Aloe vera also reduces redness."
- "LAVENDER ESSENTIAL OIL [(an ingredient in your product)] ... Balances oil production ... "
- "TEA TREE OIL [(an ingredient in your product)] ... Destroys bacteria that cause Acne flare-ups. "
- "LICORICE ROOT [(an ingredient in your product)], which has excellent anti-inflammatory properties ... "
- "ROSE HIP SEED OIL [(an ingredient in your product)] ... Supports the keratin migration cycle that is responsible for the natural regeneration of skin cells and can increase renewed cells in the epidermis."
- "VITAMIN C [(an ingredient in your product)] ... skin whitening agent ... "
- "Licorice extract [(an ingredient in your product)] can inhibit the melanogenesis and is thus used also as skin whitening agent."

※ 자료 : Skin 2 Spirit, LLC August 10, 2017

https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/skin-2-spirit-523208-08102017

사례 7

- "…Calendula is known to be antiseptic, anti-inflammatory, and immune stimulating. These properties are suitable for treating various types of dermatitis such as eczema."
- "Chamomile, lemongrass, edelweiss and milk thistle [(ingredients in your product)] calm irritated skin with anti-inflammatory properties, …"
- "Calming and anti-inflammatory"
- "Chamomile Hydrosol- Just as chamomile tea can soothe the stomach and nerves, topically applied chamomile hydrosol has great skin soothing benefits. It has anti-inflammatory and anti-allergenic properties that can help reduce the redness and irritation of sensitive or damaged skin."
- "Rose [(an ingredient in your product)] Distillate – … roses have anti-inflammatory and antibacterial properties."
- "Lactobacillus/Kelp Ferment Filtrate [(an ingredient in your product)] -… Reduces inflammation."
- "Calendula [(an ingredient in your product)] – Contains flavonoids for anti-inflammatory activity…Calendula also promotes skin healing and brightening and cell regeneration. It is noted for its ability to soothe eczema, psoriasis, diaper rash, acne and burns"
- "CoenzymeQ10 (aka Ubiquinone) -… is used by the cells to make ATP which provides energy to carry out their metabolic functions at an optimal rate"
- "Aloe Vera Leaf Juice [(an ingredient in your product)] - Research has shown aloe vera's unique ability to regenerate cellular membranes and boost the production of fibroblast cells (responsible for collagen production) six to eight times faster than the rate of normal cellular function.
- "Shea Butter [(an ingredient in your product)] -…chemical constituents offer anti-

inflammatory…benefits."

- "Rose Flower Water [(an ingredient in your product)] -… roses have anti-inflammatory and antibacterial properties."
- "Witch Hazel Distillate [(an ingredient in your product)] –… benefits include the reduction of inflammation and promotion of wound healing."
- "Acai Fruit Extract [(an ingredient in your product)] -… acai berries to be one of the most beneficial natural ingredients for the treatment of hyperpigmentation (darkening of the skin)."
- "Edelweiss Extract [(an ingredient in your product)] – ….anti-inflammatory… properties."
- "Boosts circulation and helps drain lymph nodes by increasing blood flow to the skin's surface"
- "Stimulates new healthy cell production and growth"
- "Squalane [(an ingredient in your product)] -… it is antibacterial and has been scientifically proven to clear up difficult skin problems (eczema, dermatitis, rashes, etc.)."
- "Decreases hyperpigmentation from age spots and acne…"
- "Stimulates new skin cell production; increases collagen and elastin production"
- "Helps destroy acne causing bacteria"
- "Stimulates blood flow, …"
- "Rooibos Tea Extract [(an ingredient in your product)] - Helps prevent skin disorders like acne and rashes. Also possesses strong antibacterial properties."
- "It also has antibacterial properties and helps to prevent the formation of brown age spots. Research has shown that squalane is beneficial for clearing up difficult skin problems such as eczema, dermatitis, rashes and certain types of acne."
- "Aspen Bark Extract [(an ingredient in your product)] -…treating burns to reducing fevers to relieving eczema. The bark is rich in salycin, which is considered to be analgesic, anti-inflammatory, calming and healing."
- "Red Raspberry Seed Oil [(an ingredient in your product)] - natural SPF properties (especially against UVB rays). It enhances the barrier function and repair of the outer layer of each cell…"

※ 자료 : Be Natural Organics July 19, 2017

https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/be-natural-organics-523615-07192017

사례 8

- "Pure and potent botanicals deliver dramatic healing benefits that are powerful enough to combat eczema…"
- "Patchouli essential oil [(an ingredient in this product)] relieves inflammation and combats bacteria."
- "Chamomile essential oil [(an ingredient in this product)] is packed with azulene, a powerful anti-inflammatory agent, for diminished scars and redness."
- "Powerful anti-inflammatory and anti-bacterial agents combat redness…"
- "Natural antibacterial agents like turmeric, clove and neem [(ingredients in this product)] destroy acne-causing bacteria…"
- "Prevent future breakouts and eliminate blackheads."
- "Orange peel and cinnamon [(ingredients in this product)] stimulate cellular regeneration to fade acne scarring, while nourishing botanicals like natural camphor and mint [(ingredients in this product)] minimize inflammation."
- "Killing acne-causing bacteria…"
- "Formula of tea tree, juniper berry, and clary sage essential oils [(ingredients in this product)] to target blemishes by penetrating the skin's surface and killing bacteria at its source. Its anti-inflammatory and mildly numbing properties diminish swelling and redness, reduce cystic acne pain, and accelerate healing."
- "Use this treatment at the first sign of a blemish, as it is very effective at every stage — even on blemishes that have not fully surfaced."

※ 자료 : Vedame Oils LLC dba UMA Oils July 18, 2017

https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/vedame-oils-llc-dba-uma-oils-525122-07182017

사례 9

- "The result is a nutritious concoction rich in anti-inflammatory Omega fatty acids …"
- "Hemp [(an ingredient in your product)] … reduces redness and is recommended for the treatment of psoriasis and eczema."
- "Organic Tamanu [(an ingredient in your product)] oil has proven antibacterial, anti-inflammatory and skin rebuilding properties …"
- "Beta glucans … are anti-inflammatory"
- "Organic oils of Baobab, Pomegranate, Perilla, and Pumpkin [(ingredients in your product)] make a synergy to soothe irritations whether they be from sun, wind, allergies, or chronic inflammatory conditions. Each of these oils is known to be helpful for eczema, dermatitis, chapping, and dryness."
- "St. John's wort [(an ingredient in your product)] is anti-inflammatory and analgesic for skin irritations and damage."
- "100% natural, botanical recipe anti-redness and anti-inflammatory …"
- "Marshmallow [(an ingredient in your product)] provides soothing mucilage and Plantain leaf infuses reknowned anti-redness abilities. Self Heal comes packed with gentle but effective antimicrobial properties to keep acne and other skin disturbers at bay."
- "Heather Flowers [(an ingredient in your product)] provide the anti-allergenic flavonoid Quercetin which also helps synthesize new collagen."
- "Cold-extracted Olive Leaf [(an ingredient in your product)] offers a fraction called Oleuropein known for its potent antibacterial and anti-inflammatory effects."
- "Niacinamide [(an ingredient in your product)] is included at 4% which is a level proven in studies to be more effective than a 1% clindamycin antibacterial gel at preventing acne breakouts. It maintains ceramide levels …, synthesizes collagen, and evens coloration of the skin."
- "Organic Evening Primrose oil and Pomegranate Oil [(ingredients in your product)] are rich in omega 5, 6, and 9 essential fatty acids including GLA which helps balance hormones, …"
- "Omega 5 is a rare fatty acid that acts as an… anti-inflammatory,…"
- "Pomegranate oil [(an ingredient in your product)] also has phytoestrogen to assist with

hormone balancing, …"

- "Tamanu [(an ingredient in your product)] has been used … for its anti-inflammatory, antibacterial, and regenerative properties."

※ 자료 : Irie Star, LLC July 6, 2017

https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/irie-star-llc-524242-07062017

사례 10

- "This Face Serum is a custom combination of…Evening Primrose oil…(a wonderful source of gamma linoleic acid-with powerful anti-inflammatory…properties…and"
- "sea buckthorn oils…(which…alleviate eczema, rosacea and sensitive skin rashes.)"
- "French green clay [(an ingredient in this product)] gently stimulates blood flow…"
- "Rosewood and cedarwood essential oils … helping prevent break-outs and balancing oil/combination skin while alleviating acne, scars, eczema, psoriasis and wrinkles."
- "Combined with kaolin clay [(an ingredient in this product)], which gently stimulates blood flow…"
- "Ground green cardamom [(an ingredient in this product)] provide a … effective antiviral and antimicrobial barrier."
- "Moringa and prickly pear seed oils [(ingredients in this product)] repair tissue damage…"
- "Arnica [(an ingredient in this product)] reduces swelling, inflammation and bruising."
- "Horse chestnut [(an ingredient in this product)] minimizes varicose veins and leads to improved circulation."

※ 자료 : Soapwalla Inc. June 15, 2017

https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/soapwalla-inc-519062-06152017

사례 11

- "Coconut oil … is known to help treat eczema, psoriasis, and can even help treat and prevent acne."
- "Rosemary Leaf Extract … is helpful in treating skin issues such as acne, eczema, and chronic dry skin."
- "Sunflower seed oil … is effective in combating acne, eczema, inflammation, redness, and irritation."
- "Mango Seed Butter also aids in cellular regeneration and is excellent for soothing sunburns…"
- "Eucalyptus oil functions as an anti-inflammatory, antiseptic, and antibacterial ingredient. The oil is also a skin-conditioning agent used to treat skin infections and help alleviate skin irritation."
- "Peppermint oil is used to relieve skin irritation, itchiness, and redness where inflammation is present. The high menthol content of the oil is also known to allow blood vessels to relax and improve circulation."
- "Tea tree Oil, also known as Melaleuca Oil, has anti-microbial, anti-viral, and anti-fungal properties which help with the treatment of acne, dandruff, rashes, sunburns, and other skin conditions."
- "Lavender Oil has anti-inflammatory and antimicrobial properties and can soothe minor burns and insect bites."
- "Green or White Tea Extract has strong antimicrobial … and anti-inflammatory … properties."
- "Safflower Seed Oil … is known for its ability to treat psoriasis, eczema, and acne."
- "Caffeine… acts as an anti-inflammatory… and can help protect the skin against sun damage."
- "Shea Butter… is effective in improving or treating skin inflammation and irritation such as burns and acne, dark spots, eczema, and psoriasis."

※ 자료 : Perfectly Posh, LLC June 2, 2017

https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/perfectly-posh-520135-06022017

사례 12

- "Sculpting Crème eliminates and prevents the accumulation of fats and wastes that become trapped in the susceptible cells just below the skin."
- "Stimulates microcirculation to help your body reduce fat deposits."
- "Natural Botox Alternative"
- "Stimulate collagen growth…reduction of deep wrinkles…"
- "Prevent aging of the skin …"
- "Emu Oil contains…healing properties…known to repair skin damage."
- "Suppresses inflammatory enzymes, decreasing puffiness and swelling"
- "Strengthens capillaries, arteries and veins…"
- "It promotes collagen formation, thereby increasing capillary blood circulation, retards capillary leakage, reduces melanin production…to reduce swelling…"
- "Vitamin K…stimulates Epithelial growth…"
- "Vitamin C – Helps to protect against damaging UVA/UVB rays…and stimulates collagen production…"
- "Hexapeptide 3… reduces wrinkles… Also has been shown to prevent aging of the skin…"
- "Marine Collagen…helping cells to renew themselves… "
- "Emu Oil - … Vitamin E: anti-oxidant and healing agent…."
- "Vitamin E…healing agent, Vitamin A…skin repairer, Terpines: an antiseptic…"
- "Women…their first choice in addressing PMS and other hormone related issues."
- "Users experience less PMS symptoms, reduced stress and increased vitality."
- "To relieve cramping… apply the cream to the abdomen each half hour until the cramping subsides."
- "With hot flashes…apply…cream each time they have a hot flash."
- "Stimulates epithelial growth and promotes…clarification of the damaged skin."
- "Helps eliminates (sic) spider veins (dilated or broken capillaries) and bruising…"
- "Cosmetic surgeons…use it for pre & post operative treatment to reduce post operative bruising, swelling, and to speed up the healing process and diminish scarring."
- "Clots the blood…"
- "Boost Immune Function"

- "Increase Lean Muscle Mass"
- "Reduce Body Fat"
- "Reduce Stress"
- "Combat Depression"
- "Enhance Sexual Drive & Desire"
- "Improve Memory"
- "Helps Prevent Osteoporosis & Cardiovascular Disease"
- "Increase estrogen and testosterone levels… increase IGF-1, increase lean body mass, and decrease appetite."
- "Improve quality of sleep, decrease joint pain…"
- "Contains phyto-hormones thatare identical to the human estrogens estradiol, estriol, and estrone…"
- "It has a stabilizing effect on the entire endocrine system, calming hot flashes and night sweats, and restoring normal sleep patterns…"
- "Exhibits dh-Testosterone blocking qualities to help reduce … facial hair growth."
- "Black Cohosh Known….To restore healthy menstrual activity."
- "Stimulates estrogen, cortisone and aldosterone production…"
- "Assists with menopausal symptoms, helps to regulate menstruation and PMS."
- "Helps liver problems, heart palpitations, high blood pressure, hypoglycemia and chronic bronchitis."
- "Used to dissolve blood clots, strengthen the central nervous system and nourish the brain."
- "Is helpful for hormonal balancing, PMS, weight control…"
- "Stimulates fat cells below lip tissue increasing the size of your lips."
- "Expand the cellular substructure of your lips…"
- "Provide healing…benefits to the skin…"
- "Known to protect again (sic) infections with its antibacterial and antiviral properties."
- "Assist the body's ability to utilize oxygen on a cellular level."
- "Fuller Thicker Hair In As Little As Two Months"
- "A natural alternative to combat hair loss…"

- "Restore thinning hair with visible results"
- "Restores and maintains healthy hair."
- "Proven to prevent DHT…from attaching to the hair follicle…"
- "Works to balance the hormones in the follicle…"
- "To restore thickness and prevent more hair from falling out."
- "Nugen HP – The All-Natural Hair Restoration System?
- "Revitalizes your hair follicles stimulating fuller, thicker hair."

※ 자료 : Star Health & Beauty, LLC May 26, 2017

https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/star-health-beauty-llc-516206-05262017

사례 13

- "Stimulation of collagen synthesis"
- "Wound healing"
- "Immunostimulant"
- "Treat skin conditions like acne…poison ivy…"
- "Useful for conditions such as cancer, high cholesterol and heart disease too."
- "Has also been found to help acne scars, rosacea, warts, and dermatitis"
- "To lighten… & even skin tone"
- "Has also been found to help acne scars, rosacea, warts, and dermatitis"
- "To lighten and even skin tones, age spots and freckles"

※ 자료 : Cape Fear Naturals March 2, 2017

https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/cape-fear-naturals-512768-03022017

사례 14

- "It stimulates cell-cell interaction, assists in the formation of collagen, and increases skin elasticity..."
- "Stimulates cell-cell interactions, and accelerates cell renewal"
- "Helps to preserve cellular energy, assists the formulation of collagen and strengthens in structural proteins"
- "Reduce transepidermal waterloss...assists in skin regeneration ..."
- "Giga White™ is a skin lightener developed by seven Alpine plants with synergistic ratio maximizing the tyrosinase-inhibiting activity."
- "Assists in skin regeneration..."
- "Biofactor8000™ A skin respiratory factor that helps skin cells to promote the healing process through the uptake of oxygen. It accelerates the cellular metabolism of sugar, stimulates cell reproduction and collagen."
- "Induces signal transduction...reconstructs protein structure...acts as a topical Botox..."
- "Stimulates cell respiration and increases cell turnover."
- "A biosafe alternative to Botox, it relaxes muscle contraction..."
- "Increase Microcirculation"
- "Anti-Inflammatory...Anti-Fungal...Rosacea Treatment...Anti-Bacterial ...Anti-Viral*** Facilitates collagen production ...Reduces scar tissue...Promotes wound healing...relieves symptoms of acne and rosacea..."
- "Provides powerful healing...promotes healing and reduces symptoms of acne and rosacea... "
- "Anti-Inflammatory • Anti-Fungal • Rosacea Treatment"
- "Provides extraordinary...protection against UV damage"
- "Facilitates collagen production ..."
- "Promotes wound healing..."
- "Powerful Anti-Inflammatory...Provides extraordinary anti-inflammatory and anti-viral properties...Relieves the symptoms of psoriasis..."
- "SUPERHEAL O-live Leaf Extract promotes wound healing, relieves the symptoms of rosacea, eczema, and psoriasis..."

- "Powerful Anti-Inflammatory..."
- "Suitable for all types of skin, including psoriasis"
- "Provides extraordinary anti-inflammatory and anti-virus properties"
- "Relieves the symptoms of psoriasis..."
- "Enhances the skin immune system ..."
- "Scar Tissue Reducing...Anti-Cellulite...Facilitates collagen production ...Reduces scar tissue...Promotes wound healing... "
- "Anti-Acneic...Protection against harmful UV rays..."
- "Anti-Acne..."
- "Provides extraordinary ...protection against the damage from UV radiation"
- "Facilitates collagen production ..."
- "Reduces scar tissue..."
- "Reduces Scar Tissue• Anti-Cellulite"
- "Provides extraordinary ...protection against Photodamage"
- "Promotes wound healing"
- "Strong anti-cancer effects...Promotes DNA repair...prevents skin cell mutation... Relieves the symptoms of melanoma...reduces the risk of skin cancer...stimulates collagen production...Addresses skin concerns of Photoaging...Melanoma...Skin Cancer..."
- "SELENIUM, an essential trace element that our bodies use to produce glutathione peroxidase, it has been shown to have strong anti-cancer effects, related to its catalytic role in antioxidant enzymes... Facilitates collagen production..."
- "PHYTO-C Selenium in C Serum provides powerful healing antioxidants to restore and protect skin against UV damage..."
- "Anti-photoaging..."
- "Provides extraordinary... protection against UV damage"
- "Essentialto catalytic role in antioxidant enzymes and protects cells and tissues from oxidation"
- "Promotes DNA repair, prevents skin cell mutation and reduces the risk of skin cancer"
- "Facilitates collagen production and improves signs of photoaging"
- "Stimulates the synthesis of melanocytes...activate melanin production ...restores skin

pigment ... Treatment for Vitiligo ...Fungal Infection and Inflammation ..."

- "A natural choice for Vitiligo...Stimulates the synthesis of melanocytes..."
- "A medical prescription line to treat the common dermatological conditions, such as Acne, Rosacea, Dry skin, Vitiligo and Fungal Infections, etc... Vitivera contains apple pectin which helps to utilize the UV rays to initiate the melanin to be active and come back to the normal function ..."
- "Acne Treatment"
- "A medical prescription line to treat the common dermatological conditions, such as Acne, Rosacea, Dry skin, Vitiligo and Fungal Infections, etc. . ."
- "Strengthens the protective skin tissue"
- "Treat acne...Hyperpigmentation Treatment...Anti-Inflammatory...Reduces scar tissue...Anti Cellulite...Anti-Allergic...Active ingredients work synergistically to restrain melanin formation..."
- "Discoloration Treatment...restrain melanin formation...prevents formation of melanin from Tyrosine by deactivating the tyrosinaze enzyme...Kojic Acid Inhibits skin melanin formation and educes pigmentation..."
- "Skin Discoloration Treatment"
- "It contains anti-inflammatory and anti-bacterial herbal extracts to smooth and calm irritated skin, at the same time reduces the post-treatment redness..."
- "waterproof, sweat proof'
- "help prevent sunburn and other skin damage caused by the sun"

※ 자료 : PhytoCeuticals, October 18, 2016

https://web.archive.org/web/20190908161951/https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/phytoceuticals-inc-499623-10182016

사례 15

- "Our Ultra 20% Anhydrous Vitamin C Serum supports the skin's use of oxygen to boost the natural cell metabolism…and capillary function…"
- "Replenishes Vitamin C levels to support the continued production of collagen and elastin"
- "…Serum RV performs better than cosmetic injections…"
- "Easy, natural alternative to pricey injections!"
- "An all-natural powerful defense against damaging sun rays…"
- "Works all day to protect your skin from harmful…DNA damage…"
- "Promotes the production of collagen and elastin"
- "Promotes blood microcirculation…"
- "Banish bruises and prevent unsightly scars with Serum K1"
- "The BOTOX alternative that packs a peptide punch"
- "Argireline, a peptide that serves as a natural muscle relaxant, builds up in facial muscles over time…This key ingredient destresses facial muscles beneath the deepest layer of skin to reduce tightening around cavities caused by collagen and elastin deterioration, stopping the process that furrows and puckers the outer layer of skin into wrinkles."
- "Better than a needle? You betcha.—Get all the benefits without invasive toxins, the potential risk, and the high price tag. Plus, Serum XL goes where paralyzing injections can't."
- "#1 Botox TM Alternative, 30% multipeptide serum."
- "Collagen-stimulation superstar…"
- "Best collagen producer—Vitamin C is essential to the active production of collagen. And CPlus really revs up your skin cells…"
- "A…antiaging serum that utilizes…Intensive Penetrating Complex…which helps activate collagen and elastin and repairing damaged proteins…Intensive Penetrating Complex encourages healthier skin cell replication for long-term repair and help protect healthy cells from future damage…"

※ 자료 : Bioque Technology, Inc & Vouray, October 7, 2016

https://web.archive.org/web/20190908160514/https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/bioque-technology-inc-vouray-inc-506050-10072016

사례 16

- "Healing blend of Cypress, Juniper, and Rosemary essential oils, known for their antibacterial, antiseptic and anti-inflammatory properties."
- "Blemish Balm reduces inflammation..."
- "A proprietary base of three seaweeds combined with a unique blend of Cypress, Juniper, and Rosemary essential oils...reduces inflammation, regulates sebum production, heals..."
- "Rosemary [an ingredient in the product] helps strengthen the capillaries...It helps to prevent age-related skin damage by safeguarding a protective protein called HSP70. The role of this protein is to reduce damage to skin caused by stress, free radicals, and other toxins."
- "Saccharomyces/Copper Ferment [an ingredient in the product]...It has been shown to stimulate tissue-repair..."
- "Saccharomyces Zinc Ferment [an ingredient in the product]...Saccharomyces/Zinc ferment peptide...promotes wound healing."
- "Contains Tea Tree, White Thyme and Juniper which all have powerful natural antiseptic and antibacterial properties."
- "How it Works: A naturally antibacterial, anti-fungal, and antiseptic complex to effectively treat blemishes, cold sores, insect bites and ingrown hairs."
- "Essential Oil of Tea Tree [an ingredient in the product] has antiseptic properties that make it a gentle method of controlling skin irritations and infections such as acne, cold sores, athlete's foot, insect bites and minor cuts, scrapes, and scratches."
- "White Thyme [an ingredient in the product] helps stimulate circulation and has powerful antiseptic, bactericidal and insecticidal properties."
- "How it Works: Bearberry Leaf is a natural skin lightener that works by actively inhibiting skin's melanin production. It has been proven to be highly effective for lightening age spots, freckles, sun spots, Melasma..."
- "USDA Certified Organic Gigartina Algae bolsters immune response ...It also has been found effective for skin ailments such as psoriasis, eczema, and herpes."
- "Pomegranate Extract has been shown to boost collagen production..."
- "Red Wine Extract, loaded with resveratrol...contains anti-viral and anti-fungal properties."

- "Wine Polyphenols Proline (Red Wine Extract) [an ingredient in the product]…stimulate the production of elastin and collagen cells…bioactive polyphenols…prolong cell life for a dual preventative and curative…action."

※ 자료 : Osea International External Link Disclaimer September 27, 2016

https://web.archive.org/web/20190908161635/https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/osea-internacional-506246-09272016

사례 17

- "Lemon, a powerhouse of vitamin C…with its antibacterial properties, and boosts collagen production…It also lightens age spots…"
- "Limes …reduce bacteria, which greatly improves the skin's immunity against infection."
- "Another benefit oranges includes their antidepressant qualities…"
- "Organic vanilla has antibacterial properties to provide relief from abrasions by killing germs that facilitate acneic growth. It also soothes burns, wounds, and cuts…"
- "Organic chocolate contains antioxidants called flavinols, which aid your skin in protecting itself from harmful UV rays, …"
- "By increasing blood flow…"
- "Organic shea butter is a powerhouse… has natural anti-inflammatory properties that can take the sting out of insect bites."
- "Its antibacterial properties fight off fungi, bacteria, and viruses…with a strong immunity to deflect environmental damage"
- "Organic chai offers its anti-inflammatory properties that help heal skin abrasions, as well as antioxidants that fight skin cancer…"
- "Fennel has anti-carcinogenic agents…"
- "Organic pomegranate contains compounds that inhibit the enzymes responsible for cartilage destruction."
- "Peppermint has anti-inflammatory, antiseptic …antimicrobial properties…"
- "Tea tree oil, a powerful immune stimulant, fights off bacteria, fungi, and viruses…"

- "It also relieves itchiness, and treats acne and the irritation caused by poison ivy or chicken pox."
- "It offers relief for conditions such as rashes, eczema, psoriasis, and burns."

※ 자료 : Face Naturals September 20, 2016

https://web.archive.org/web/20190908161454/https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/face-naturals-501680-09202016

사례 18

- "Removes Wrinkles Instantly"
- "The Sea Fennel stem cell has the effect of lightening the skin..."
- "Tests using a 0.5% concentration of the culture have shown a clear reduction of uneven pigmentation and obvious lightening if the skin."
- "This marine ingredient ...offering protection against UVB induced free radicals."
- "It provides amazing benefits to our skin by ... stimulating regeneration of cell tissues..."
- "DHP(Dimethylmethoxy chromanyl palmitate) is a new synthetic peptide that has revolutionized the process of skin lightening."
- Eliminating the harsh effects that were once associated with previous lightening procedures. DHP...reverses the signs of aging caused by UV rays."
- "POPT7(Palmitoyl oligopeptide & palmitoyl tetrapeptide 7)... increases cell communication and gene activation for the skin healing, thus it plays a fundamental role in the reconstruction of the skin tissue."
- "Acetyl Hexapeptide8... works in a similar way to Botox treatments."
- "AH8 blocks the message that commands the face to tense up, thus interfering with the message being sent the brain. In doing so, the facial muscles remain relaxed, and wrinkles are kept at bay."
- "A super anti-oxidant ...eliminates age spots, contains protection from ultraviolet A and B and

boosts collagen synthesis."

※ 자료 : Hollywood Skincare International, April 14, 2016

https://web.archive.org/web/20190908133602/https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/hollywood-skincare-international-inc-04142016

사례 19

- "Localized Redness Intensive Serum"
- "RECOMMENDED FOR: Redness-prone skin, experiencing overall redness, flushing and sensations of discomfort"
- "Reduces visible redness and sensations of discomfort"
- "Formula combining 3 effective ingredients to help reduce redness with a long lasting efficacy"
- "I have rosaceaon my neck when I get warm or under stress. This product really works to keep it under control!!!"
- "I have broken capillaries and generalized redness on several areas of my face. I was told laser treatment was the only fix. Then…the miracle of Rosalic AR!"
- "With powerful Ambophenol [0.5%] to visibly reduce redness"
- "Concentrated Dark Spot Correcting Serum"
- "Use to treat dark spots and discolorations"
- "Recommended For: Hyperpigmentation and Dark Spots"
- "With 2% Kojic Acid to visibly reduce the intensity of dark spots"

※ 자료 : L'Oréal USA February 12, 2015

https://web.archive.org/web/20190908022651/https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/loreal-usa-440851-02122015

사례 20

- "TGF-b(1-3) (Transforming Growth Factor Beta) to help stimulate collagen, to help inhibit cellular breakdown…"
- "PDFG (Platelet Derived Growth Factor) to help activate wound healing fostering new skin growth, to help reduce scar tissue, and to help form stronger blood vessels."
- "GM-CSF (Granulocyte-Macrophage Colony- Stimulating Factor) to help restore blood cell response to the breakdown of skin structure, to help counteract infection (e.g., acne), to help even-out discolored appearance (e.g., hyperpigmentation), to help reduce inflammation (e.g., Rosacea)…"
- "Interleukins (IL3, IL6-8) …improve anti-inflammatory response."
- "Skin Growth Factors / Human Fibroblast Conditioned Media- Four essential skin proteins stimulate collagen, inhibit cellular breakdown, increase cell growth, and enable cells to locate nutrients fostering faster skin growth, stronger blood vessel formation, reduce infection, calm inflammation…"
- "Glycolic Acid - Helps open follicles and reduce oil production."
- "Green Tea Extract - Potent anti-inflammatory agent helps reduce inflammation and prevents collagen breakdown by inhibiting the collagenase enzyme."
- "Vitamin D3 (cholecalciferol) – Helps reduce inflammation, calm irritation…"
- "Oligopeptide Complex –Inhibits tyrosinase activity which is a leading cause of spots and uneven skin tone."
- "Vitamin K - Stimulates blood flow to reduce inflammation…"
- "Retinol (.01%) - …collagen stimulator."
- "Vitamin K - Stimulates blood flow…"
- "Arnica - Reduces swelling…"
- "Green Tea Extract - Potent anti-inflammatory agent helps reduce inflammation and prevents collagen breakdown by inhibiting the collagenase enzyme."
- "Ginseng Root Extract & Bioflavoids - Strengthen capillaries to increase microcirculation blood flow. Strengthen elastin and the collagen structure for firmer texture while reducing inflammation and redness."

- "Ginko Biloba - Helps stimulate and improve circulation…"
- "Decrease the formation of cellulite while tightening and shrinking blood vessels to help reduce the appearance of spider veins."
- "Coffea Arabatica (Coffee) Seed Powder - Micronized coffee effectively stimulates circulation…"
- "Caffeine - Stimulates lipolysis in the cellulite cells…"
- "Zea Mays (Corn) Cob Powder - …improves microcirculation…"
- "Olea Europaea (Olive) Seed Powder - …vasodilatation properties to increase circulation and promote detoxification."
- "Stimulate circulation…"
- "Aloe Barbadensis (Aloe Vera) Extract - Calms inflammation with an anesthetizing response."
- "Panax Ginseng Root Extract - Strengthen capillaries to increase microcirculation blood flow. Strength elastin and the collagen structure for firmer texture while reducing inflammation and redness."
- "Further invigorate the circulatory and lymphatic system…"

※ 자료 : Skin Authority, LLCExternal Link Disclaimer March 25, 2015

https://web.archive.org/web/20190908032520/https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/skin-authority-llc-03252015

사례 21

- "The at-home answer to wrinkle-filling injections. Start rebuilding collagen in just 48 hours."
- "4D WRINKLE-REVERSE TECHNOLOGY IS DESIGNED TO:

  o Rebuild collagen to help plump out lines and wrinkles.

  o Stimulate elastin to help improve elasticity and resilience.

  o Regenerate hydroproteins to help visibly minimize creasing."
- "Formulated to boost shock-absorbing proteins to help strengthen skin's support layers."
- "Improve fine & deep wrinkles up to 50%. Immediately plumps out wrinkles and fine lines.

Within 48 hours begins boosting collagen production."

- "Wrinkles are a result of micro-injuries to the skin, so AVON studied how skin heals. As part of the repair process, the body produces Activin . . . . Exhaustive research, testing & review have resulted in an unprecedented discovery by AVON scientists: how to activate this key repair molecule. . . . Designed to boost Activin, ANEW's Activinol Technology helps reactivate skin's repair process to recreate fresh skin & help dramatically reverse visible wrinkles."
- "Our effective lifting treatment is formulated to fortify damaged tissue with new collagen. In just 3 days, see tighter, firmer, more lifted skin."
- "Help tighten the connections between skin's layers."
- "Formulated with pomegranate and fennel extracts to help boost production of collagen and elastin."

※ 자료 : Avon Products, Inc.,External Link Disclaimer October 5, 2012

https://wayback.archive-it.org/7993/20171115075932/https:/www.fda.gov/ICECI/EnforcementActions/WarningLetters/2012/ucm323738.htm

사례 22

- "Boosts the activity of genes and stimulates the production of youth proteins."
- "Boosts the activity of genes."
- "A powerful combination of unique ingredients – Reconstruction Complex and Pro-Xylane™, a patented scientific innovation-- has been shown to improve the condition around the stem cells and stimulate cell regeneration to reconstruct skin to a denser quality."
- "See significant deep wrinkle reduction in UV damaged skin, clinically proven."
- "A powerful combination of unique ingredients – Reconstruction Complex and Pro-Xylane™, a patented scientific innovation-- has been shown to improve the condition around the stem cells and stimulate cell regeneration to reconstruct skin to a denser quality."
- "Immediate lifting, lasting repositioning. Inspired by eye-lifting surgical techniques . . . helps recreate a younger, lifted look in the delicate eye area."

- "Unique R.A.R.E. oligopeptide helps to re-bundle collagen."

※ 자료 : Lancôme USA,, September 7, 2012

https://wayback.archive-it.org/7993/20171115075937/https:/www.fda.gov/ICECI/EnforcementActions/WarningLetters/2012/ucm318809.htm

사례 25

- "I had two cysts on my face that would not heal . . .. I finally ordered BioHeal and applied it. . . . The wounds turned darker and started to close up. Within a week, they were healed even though a crater type scar remained. . . . My grandmother had a horrible case of shingles. Nothing the doctor gave her worked even after months of treatment. I brought down some BioHeal for her to use and 7 to 10 days later it was completely healed."
- "I had been burned by very hot coolant from my cars radiator after I opened the radiator cap. The physicians at the hospital thought I would need skin transplants but I started using BioHeal four days after the burn and had complete healing."
- "'It Worked for Me' . . . Problem: Eczema (a painful skin inflammation) on her index fingers and thumbs. What she did: tried a Copper-Peptide lotion (CP Serum) meant to be a skin care product, after reading a newspaper story about non-surgical ways to reduce wrinkles. . . . How she did it: Dawson's hands were so affected that 'there would be cracks and splits, and they' d be bleeding.' The story about Copper-Peptide creams mentioned that the creams were originally developed for burn victims and diabetics whose wounds wouldn't heal. . . . Small studies had shown that skin treated with Copper-Peptides had less pigmentation, reduced wrinkling . . .."
- "Had a patch of psoriasis on the side of one eye for years. Dermatologists gave me medicines for years without success. Four nights of the Emu Oil for Skin cleared the psoriasis."

- "After just 3 applications of the Folligen Spray and Shampoo and Conditioner, I am thrilled to see my hair growing thicker and longer. The biggest bonus though is truly amazing - My hair is now returning to its original youthful brunette color . . .."
- "My 89 year old mother's hair was shedding and she had developed a bald spot. After she used Folligen Spray, the shedding stopped."
- "The TriReduction has done wonders . . . in reducing some flat warts elsewhere on my body . . .."
- "I live in Florida and have been using your copper peptides [an ingredient in this product] for three years. When I started my face had extensive sun damage. Recently, my face was examined with sun damage detection system (ultraviolet photography) and found to be free of sun damage except for a small area around my lips where I do not use the copper peptide creams."
- "P&R cleared up the eczema on my hands in three days."
- "I have been trying your products with amazing results. I developed severe cystic acne once reaching the age of 35. I am having wonderful results with P & R #3. I would like to add, I have been to numerous dermatologists for years! There has never been one treatment that can compare to your product."
- "The key for reducing the appearance of pitted acne seems to be gently massaging LacSal Serum or Exfol Serum into the pitted scar on a daily basis to help slowly dissolve and remove scar tissue. . .. As scar tissue is replaced with healthy skin, the skin's surface seems to pull itself flat like a balloon."
- "Squalane/Squalane . . . compounds have some anti-cancer properties (Lee and Langer 1983) . . .. In animal studies, mice were protected against the toxicity and injury of radiation when fed a diet supplemented with 2% Squalane (Storm et al, 1993). The compounds also have some anti-fungal properties and enhances the effects of Amphotericin B (Fungizone) against a variety of candida species Masuda et al, 1982)."
- "I was amazed to see enough improvement on the first squalane application to apply makeup relatively smoothly, and within three days, I saw a 97% improvement in my dermatitis . . .. I highly recommend replacing at least one of the daily corticosteroid applications with squalane.

It's more effective and carries none of the insidious medical risks of steroids."

- "Many of our customers have reported that the combination of Folligen and emu oil often help revitalize hair. Recently, Dr. Michael Holick (Boston University Medical Center) reported a clinical study that found emu oil accelerated skin regeneration and also stimulated hair growth. He wrote - 'The hair follicles were more robust, the skin thickness was remarkably increased... Also, we discovered in the same test that over 80 percent of hair follicles that had been 'asleep' were awakened, and began growing hair.'"

※ 자료 : Skin Biology, Inc., October 11, 2012

https://wayback.archive-it.org/7993/20170406090852/https:/www.fda.gov/ICECI/EnforcementActions/WarningLetters/2012/ucm324935.htm

사례 23

- "Frankincense essential oil has antibacterial and anti-inflammatory benefits to the skin, making it ideal for acne-prone skin."
- "Lavender essential oil...helps regenerate skin cells so is great for ...sun spots, and scarring."
- "Myrrh essential oil... has strong anti-inflammatory properties... Myrrh can also help heal sun damage, chapped skin, rashes, and eczema."
- "Specially formulated shampoo for those who have Eczema or Psoriasis in the scalp area."
- "The essential oils are "essential" to help control eczema or psoriasis and heal the scalp."
- "Neem is anti-viral, anti-fungal, and anti-inflammatory."
- "Neem produces pain-relieving, anti-inflammatory and fever-reducing compounds that can aid in the healing of cuts, burns, sprains, earaches, and headaches, as well as fevers."
- "Several studies of Neem extracts in suppressing malaria have been conducted, all supporting its use in treatment."
- "These essential oils can lower your blood pressure and help hypertension."
- "Use of this blend may help prevent and/or reduce the symptoms of many heart disease related conditions, including atherosclerosis, angina, neuritis, neuralgia, rheumatism, liver problems, arteriosclerosis, prevent coronary heart disease, congestive heart disease..."

- "Hawthorn berry—boasts a century of effective use in cardiovascular disease. Helps dilate the blood vessels away from the heart, lowering blood pressure and reducing the heart's burden."
- "Motherwort—A hypotensive..."
- "Cayenne—Helps lower blood cholesterol levels; to reduce blood pressure, cardiac problems, lipid levels."
- "These herbs help the body lower high serum cholesterol and to help prevent the deposition of dietary cholesterol on arterial walls."
- "Apple Pectin [an ingredient in your product]—Decreasing cholesterol..."
- "Hawthorn berries [an ingredient in your product]—Slowly eats away cholesterol deposits and provides relief from concurrent hypertension."
- "Black Cohosh [an ingredient in your product]– Reduces hypertension through vasodilation of peripheral veins."
- "Promotes the body's ability to reduce high blood sugar."
- "For Hyperglycemia: 3 capsules, 3 times per day."
- "Bilberry [an ingredient in your product]—Used by many naturopathic doctors to treat sugar diabetes and ailments of the kidneys and gallbladder."
- "Raspberry Leaf [an ingredient in your product]—Has a proven hypoglycemic action."
- "Gymnema sylvestre [an ingredient in your product]—The leaves are said to be used as a remedy for diabetes...and to cure diabetes and stress related disorders."
- "Parsley...the herb is very effective in remedying liver diseases."
- "Uva Ursi [an ingredient in your product]—Urinary antiseptic action. Relieves cystitis, nephritis and kidney stones."
- "Bladderwrack [an ingredient in your product]—Effective against nephritis, bladder inflammation, cardiac degeneration, obesity, thyroid problems."
- "To help provide systematic relief of prostate problems. Helps the body overcome the effects of an enlarged and/or inflamed prostate."
- "USE: Inflamed prostate: 2–8 capsules daily...Enlarged prostate: 3–6 capsules daily."
- "This blend helps fight prostatitis and enlargement in at least four ways. 1. Stimulates urine flow. 2. Reduces inflammation and infection. 3. Decreases the size of the enlarged prostate.

4. Prevents these conditions."

- "Parsley [an ingredient in your product]—Diuretic recommended for enlarged prostate, painful and incomplete urination. Stimulates urination and provides relief."
- "Saw Palmetto Berry [an ingredient in your product]—Acts directly on the enlarged prostate to reduce inflammation, pain and throbbing.
- "Corn Silk [an ingredient in your product]—Reduces painful symptoms and swelling from several inflammatory conditions of the bladder, kidneys, female system and well as hepatitis and all edematous conditions."
- "Mullein [an ingredient in your product]—A demulcent to soothe irritated mucous membranes. Reduces swelling and pain. Kills bacteria."
- "Buchu leaf [an ingredient in your product]—Known to reduce swelling of the prostate. Soothe the lining membrane of the urethra and alleviate painful urination. It has been proven to help control bladder and kidney problems and the incontinence that is associated with prostate problems."
- "Bladderwrack [an ingredient in your product]—Effective against nephritis, bladder inflammation, cardiac degeneration, obesity, thyroid problems."
- "Kelp [an ingredient in your product]—To treat disorders of the genital urinary tract, including kidney, bladder, prostate and uterine problems. Normalizes and remedies the enlarged prostate. Daily kelp ingestion gradually reduces the prostate in older men to the point that urination becomes painless."
- "Purpose: Helps the body reduce high blood pressure (hypertension)… Helps lower serum cholesterol. Other applications: hives, shingles, erysipelas, insomnia."
- "USE: High blood pressure: 23 capsules, 34 times per day… High Cholesterol: 4 capsules daily…"
- "Skullcap…Used to help normalize cholesterol and blood pressure levels… helps with sleep disorders…"
- "Garlic… Regularly eating garlic could have dramatic benefits in heart disease due to atherosclerosis."
- "Black Cohosh… hypotensive effects…"
- "Kelp… antibiotic and hypotensive… Can give significant improvement in blood pressure

readings…"

- "Cayenne [an ingredient in your product]—Helps lower blood cholesterol levels, to reduce blood pressure, cardiac problems, lipid levels."
- "Purpose: To relieve the distress of respiratory ailments such as pneumonia, asthma, bronchitis, croup, tuberculosis, colds, flus, hay fever, emphysema… Also for allergies, fevers, colitis, cancer."
- "Lungwort… Good treatment for chronic bronchitis. Helps to treat coughs from whooping cough and other infections. It also works to treat problems with asthma. Was used to treat tuberculosis."
- "Pleurisy root [an ingredient in your product]—Treatment of colds, flu, bronchitis, tuberculosis, pleurisy… Healing in pneumonic fevers, colds, catarrh."
- "Slippery Elm bark… remarkably effective against sore and inflamed mucous membranes."
- "Plantain [an ingredient in your product]-Used in cases of chronic bronchitis…"
- "Chickweed [an ingredient in your product]—Gives relief for bronchitis, whooping cough, colds, sore throats, flu, and tuberculosis. Has antibiotic properties against respiratory pathogens. Useful against blood diseases, gout, joint disease."
- "IBS, Colitis, Crohns, Diverticulitis, Indigestion, Inflammation…Diarrhea, Ulcers"
- "Purpose: Soothe and heal gastrointestinal tract disorders."

※ 자료 : Healing-Scents July 29, 2016

https://web.archive.org/web/20190908151332/https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/healing-scents-499219-07292016

사례 24

- "Improve recovery from extreme stress and illness like burn, surgery, and cancer."
- "Nopal…several human studies show possible lowering of blood sugar levels"
- "Essential oil with proven natural antiseptic against a wide range of bacteria and fungi."

- "Protects skin against ...UV aggression."
- "Stimulate Root!"
- "Helps to grow hair fast"
- "Formula made from ginseng, dong quai, rosemary and horsetail, which have been known to help circulation and stimulate hair growth."
- "Helps reduce swelling..."
- "Quinol is a face whitening cream that contains alpha hydroxy acid and a fading agent to help lighten skin... Helps lighten dark spots, liver spots..."

※ 자료 : Beauty & Health International, Inc. February 5, 2016

https://web.archive.org/web/20190908132011/https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/beauty-health-international-inc-02052016

사례 26

- "Organic Cedarwood ... helps to strengthen hair growth ... and combat ... hair loss."
- "Eucalyptus also offers antibacterial, anti-inflammatory benefits and can help to stimulate blood circulation on the scalp, encouraging hair growth..."
- "Organic Lavender ... Human clinical studies have reported that lavender essential oil may be beneficial in ... alopecia (hair loss) and as an antibacterial agent."
- "Blemish Free Skin in Just 3 Days!"
- "Clinically proven to reduce breakouts and blemishes by 84%"
- "Reduces white heads and black heads by 92%"
- "Organic Lime...has bactericidal...anti-inflammatory...properties."
- "Lavender can...protect the skin while helping to prevent blemishes."
- "Palmarosa...helps in treating a range of skin infections..."
- "Organic Patchouli ...It also works aggressively to help prevent scarring."
- "Organic Petigraine...antiseptic properties help to clear...blemishes..."
- "Organic Thyme, a potent antimicrobial, antibacterial, and antifungal...recommended for many types of skin disorders."

- "Organic Geranium … effective cell regenerator …"
- "Organic Lavender … antiseptic … properties …"
- "Organic Rosewood … cell stimulant and tissue regeneration properties …"
- "Organic Palmarosa … anti-infectious botanical, as well as an antifungal … also helps in treating a range of skin infections while offering antiseptic … benefits …"
- "Organic Rosemary Verbenone … Accelerates the cell's natural regenerative powers."
- "Organic Everlasting … Cell-regenerative for skin, healing for scars (increases production of new cells)."
- "Organic Thyme Linalool … Accelerates the cell's natural regenerative powers."
- "Organic Neroli … prevents scarring and stretch marks."
- "Organic Patchouli … known as … an antimicrobial ingredient …"
- "Organic Plant Stem Cells … reactivate your body's own dormant and weak skin stem cells, pushing them to regenerate."
- "Organic Lemon Verbena … Acts as an … antiseptic and bactericide … It also improves circulation and removes toxins, ensuring optimum circulation."
- "Organic Cedarwood … used … to ward off infections …"
- "A safe and effective alternative to Botox®."
- "Jasmine oil is known for its anti-inflammatory properties"
- "Chamomile…celebrated for its…anti-inflammatory properties…"
- "Skin treatment with avocado oil significantly increases water soluble collagen."
- "Organic Neroli Oil … used … against plague and fevers."
- "Zingibain is an enzyme in ginger that has anti-inflammatory properties."
- "Helps promote the development of collagen."
- "Organic Chamomile …anti-inflammatory properties …"

※ 자료 : Greek Island Labs, September 7, 2012

https://wayback.archive-it.org/7993/20170723000427/https:/www.fda.gov/ICECI/EnforcementActions/WarningLetters/2012/ucm318805.htm

사례 27

- "it increases copper dependent enzyme activity that is essential in the production of elastin...This production may help minimize sagging..."
- "Copper also facilitates the increased growth of collegan (sic) an active ingredient of skin tissue.
- "According to the Centers for Disease Control, 'In cell cultures, copper complexes cause some types of cancer cells to revert to non-cancerous growth patterns'."
- "Our formulation is pH balanced to maintain proper delivery of particles into the skin creating a...healing benefit."
- "This product also helps to remove scars, wrinkles, old age and skin blemishes, skin color problems and fights the worst of skin burns, hydrofluoride acid burns."
- "Vitamin C is good for reestablishing new collagen growth...helps keep the skin from sagging..."
- "Vitamin C has been proven to increase collagen synthesis..."
- "Topical Vitamin C protects skin against harm caused by exposure to sunlight,"
- "It helps to correct sun damage and brown spots..."
- "Vitamin C has Anti-inflammatory benefits which reduce redness and irritation..."
- "Oxygen is a catalyst and energy source for most cellular functions." "Oxygen is vital for all cells to sustain proper metabolism (skin includes (sic))."
- "Oxygen is important in helping to maintain healthy tissues."
- "Oxygen is important as a fuel source for metabolism and removing of old tissue and producing new tissues."
- "Oxygen has a significant role in wound healing, being essential to provide the additional energy source for the repair process."
- "Oxygen is...component of the immune function...component of blood flow...functional element in hormonal mediators...required...during tissue repair process,"
- "Tissue damage...from the sun, wind, environment, aging...is why everyone should use Raahj Facial Oxygen."
- "Helps the skin to produce new skin tells and-rejuvenate damaged cells."
- "Relief from: Cuts, burns, sunburns, abrasion, rash, diaper rash, bug bites, shaving, waxing and

many types of skin irritations."

- "Hydrofluoric Acid burns are treated with procedures that include Calcium Gluconate...Cailcium Gluconate used in Facial Spritzer and/or Sunburn Relief Spray...is in nano particle size creating a Most effective product for sun burn, skin burns and other skin irritations."
- "It combats adult acne and helps to reverse pre-mature aging."
- "It is excellent for burns, sunburn, and rashes."
- "Spray...on the sunburn and feel immediate relief."
- "Stops the pain experienced with bikini waxing."
- "HG/EF is a strong weapon against thinning...slow growing and depleated (sic) hair."
- "HG/EF...stops hair loss from continuing."
- "It has been shown to help new hair growth..."
- "Dr. Gunderson...states that his hair is growing back and he is no longer finding hair in the sink after combing."
- "Acne, pimples, zits, blemishes and scars are significantly reduced or totally eliminated with the 'CRS' Acne Purge Skin Care Program."
- "Proven to work effectively on your skins (sic) worst difficulties by topically bringing to your skin the ingredients necessary for it to repair or heal itself."
- "Through...DNA synthesis skin problems such as acne, pimples, blemishes, scars and zits are gradually minimized or eliminated...by cell repair and new cell growth."
- "The ingredients in the...products...promote functional activity at the cell level allowing for a more permeable membrane which helps the skin tissue heal itself of wrinkles, aging lines, pimples, blemishes, scars, zits and acne."
- (Testimonial) "I had a stubborn outbreak of acne on my chin that persisted for 3 months...The acne seems to just be disappearing..."
- "CRS stands for Cell Regeneration System and as you use it the aging skin is repairing and healing itself at the cell level."
- "The ingredients of the CRS formula are being transported directly to the damaged cells and through DNA synthesis new cells are being generated and damaged cells are being restored.

The damaged skin is gradually rebuilt and the effects of aging, wrinkles, scars, pimples, acne and blemishes are reduced to insignificance or eliminated."

- "The CRS system is a unique and effective method of preventing or reversing aging. "
- "Thus anti-aging is enhanced as the aging process is stopped and reversed as your unwanted wrinkles and age lines fade away with these products fighting the signs of aging."
- (Testimonial) "CRS Acne Purge Skin Care, WOW...My two teenagers...have experienced about a 90% improvement...Prior to this program they used Accutane and Retin-A with marginal results..."

※ 자료 : Freedom Plus Corporation,, March 29, 2007

https://wayback.archive-it.org/7993/20170111100910/http:/www.fda.gov/ICECI/EnforcementActions/WarningLetters/2007/ucm076343.htm

사례 28

- "(b)(4), is a unique, cosmetically elegant roll-on gel formulated for ingrown hairs, razor burn, and bumps resulting from shaving, waxing, tweezing, electrolysis and laser hair removal. (b)(4) contains exfoliating and moisturizing ingredients to maximize your results . . . ."
- "vanish" juxtaposed with the following conditions: "Ingrown Hair . . . Waxing/Razor Bumps . . . Razor Burn . . . Roll-On For Men and Women . . . ."
- "Ingredients: SDA-408, Isopropyl Alcohol, Purified Water, Willow Bark Extract, Propylene Glycol, Lactic Acid . . . ."
- "NATURAL PROGESTERONE . . . Because Change Is The Only Constant In A Woman's Life . . . (b)(4) . . . ."
- "SUGGESTED USE: . . Twice a day, morning and night with a heavier dose at night to help induce sleep. Apply to inner thigh & arms, face, neck, upper chest or abdomen. Rotate site with every application . . . Each pump of the dispenser contains approximately 32 MG of natural progesterone . . . ."
- "INGREDIENTS: . . . 2,625 MG. USP natural progesterone powder, aloe vera gel in distilled water, vitamin E, glyceryl stearate, Isopropyl alcohol, avocado oil, vitamin B complex factor,

amino acids, emulsifying wax, fragrance . . . ."

- "Natural progesterone's most important and powerful role in the woman's body is to balance or oppose estrogen.
- "Estrogen dominance leads to dangerous side effects, severe PMS and menopausal symptoms, and the promotion of cancer . . . ."
- "PROGESTERONE . . . Protects against breast fibrocysts . . .Natural anti-depressant . . . Prevents endometrical (sic) cancer . . . Helps prevent breast cancer. . . ."
- "Low progesterone levels in women results in estrogen dominance, PMS, early perimenopause onset, low libido, excessively heavy bleeding during a period, weight-gain, migraine like headaches, primary dysmenorrheal or cramps, increases the risk of endometrial cancer . . . ."
- "Failing to apply (b)(4) when a woman is estrogen dominant will simply lead to greater estrogen dominance . . . Apply (b)(4) as often as necessary to rid yourself of symptoms . . . ."
- "Taken orally progesterone is transported to the liver where 80 to 90% of it is removed from the body. . . Transdermal creams are the safest and effective way to get the proper physiologic dose of progesterone .
- (product label) "This eyelash enhancer . . . stimulates follicle growth and strength."
- (www. (b)(4).com) "Nourish lash follicles and promote fuller, longer, healthier eyelashes."
- (www. (b)(4).com) "Prevents alopecia from progressing"
- (product label) "Stimulates eyelash follicles which can improve the length and strength of lashes"
- (product label) "Stimulates hair follicles resulting in longer, fuller and more youthful eyelashes."
- (pamphlet) "Eyelash Growth Promoter Complex stimulates hair follicles to improve the length and thickness of eyelashes."
- (www. (b)(4).com) "One of the main complaints he had was his hair had thinned and his eye lashes had also thinned and fallen out. I thought I would try (b)(4) on him. I started applying the (b)(4) every night on the top and bottom eye line. Within 2 weeks his lashes were visible again. Within 4 weeks his eyelashes had come back thicker and longer."
- (www. (b)(4).com) "(b)(4) is amazing. . . My lashes grew longer and thicker!"

- (www. (b)(4).com) "(b)(4) (I cut my lashes to see how much it grows and its grown!!)"
- (pamphlet) "Stimulate hair follicles for full and lengthy lashes. . .."
- (pamphlet) "STIMULATES FOLLICLES Eyelash Growth Promoter Complex stimulates hair follicles to improve the length and thickness of eyelashes."

※ 자료 : Allure Laboratories, Inc., May 24, 2011

https://wayback.archive-it.org/7993/20170111100912/http:/www.fda.gov/ICECI/EnforcementActions/WarningLetters/2011/ucm257013.htm

사례 29

- (website) "After 84 days of daily use, RapidLash induced a significant increase in the length of eyelashes"
- (website video) "This formula is designed to lengthen and thicken lashes in 30 days. Your lashes and your eyebrows grow thicker and faster."
- (website video) "RapidLash, which is this eyeliner type stuff that you paint on your eyes, and your lashes grow. . ."
- (website video) "There are brands like RapidLash that really grow your lashes."
- (website) "When I reached about age 50, my eyelashes had seemed to shrink to nothing and wearing mascara was senseless. Then along came Rapid Lash! I began to notice a change with my eyelashes in less then 4 weeks of using it. In 6 weeks, my eyelashes were back to the original length of my younger days."
- (website audio) "...I have been using RapidLash for probably going on three months now, and let me tell you this stuff is awesome. . . .My eyelashes have grown . . .."
- (promotional pamphlet) "I went to the salon and they asked me if I wanted my eyebrows trimmed. I never had any eyebrows before RapidLash"
- (website) "I lost my eyelashes during chemotherapy and had none for three years. When I heard about products to help lengthen and thicken lashes, I was skeptical but chose to try neuLash because of its great customer reviews. . .. After eight weeks, my lashes were curlier, darker, longer, and thicker than ever before."

- (magazine image from website) "NeuLash®, an active eyelash technology strengthens and lengthens eyelashes in as little as two weeks."
- (website) "Helps promote cell regeneration"
- (promotional pamphlet) "Helps accelerate the length of the hair shaft, while promoting fuller, thicker, and healthier looking brows."
- (promotional pamphlet) "neuveauBrow [sic] features our exclusive (b)(4) which effectively renews and regenerates skin cells. . .."
- (website) "It took about 6 weeks for me to see anything, but, lo and behold, I looked in the mirror one morning and saw MANY new hairs filling in my brows. I could not believe it."
- (website) "It's easy to apply and you do get growth where you put it."

※ 자료 : Lifetech Resources, LLC, April 18, 2011

https://wayback.archive-it.org/7993/20170111100914/http:/www.fda.gov/ICECI/EnforcementActions/WarningLetters/2011/ucm251951.htm

사례 30

- "BEST . . . age spot remover . . . lightening perfection crème"
- "Lightens dark spots in the skin such as freckles, age spots and liver spots."
- "An advanced lightening skin cream containing maximum strength hydroquinone to gently fade skin discolorations"

※ 자료 : M & M Beauty and Wellness, LLC April 13, 2022

https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/m-m-beauty-and-wellness-llc-628392-04132022

사례 31

- "Dark Spot Fade Gel is the ultimate skin brightening treatment for hyperpigmentation, skin

discoloration and age spots."

- "Uses For the gradual fading of 'dark spots' 'freckles' 'age spots' 'brownish skin discolorations'"
- "Dark Spot Fade Gel is the ultimate skin brightening treatment for hyperpigmentation, skin discoloration, and age spots."
- "This product will help balance uneven skin tone from sun damage, age spots, and hyperpigmentation that have formed on the skin's surface over the years."

※ 자료 : True Earth Health Products, LLC April 13, 2022

https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/true-earth-health-products-llc-628383-04132022

사례 32

- "Get Tattooed Without ANY Pain"
- "STOP PAIN - Our Painless Tattoo Numbing Cream relieves pain anywhere it's applied for 3+ hours"

※ 자료 : Sky Bank Media, LLC dba Painless Tattoo Cream Co. March 25, 2024

https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/sky-bank-media-llc-dba-painless-tattoo-cream-co-666693-03252024

사례 33

- "Oxygenating Hydro-Matrix . . . (37% ceravitae complex) . . . Acne Control . . . anti-inflammatory . . . antimicrobial . . . DRUG FACTS . . . USES: . . . TREATS ACNE, HELPS PREVENT DEVELOPMENT OF NEW ACNE BLEMISHES"
- "CERAVITAE COMPLEX . . . Ceravitae allows your skin to absorb more oxygen, stimulating skin cell production and helping to heal."

- oxygenetix® Oxygenating Foundation Acne Control:
- "Acne Control . . . ceravitae pro-oxygen complex . . . DRUG FACTS . . . USES: . . . TREATS ACNE, HELPS PREVENT DEVELOPMENT OF NEW ACNE BLEMISHES"
- "Oxygenating Acne Control Foundation clears not causes acne, giving you confidence even on your worst skin days. And the aloe vera base, instead of water or oils that attract bacteria to your skin, is antibacterial and soothing."

※ 자료 : Colonial Dames Company, Ltd December 5, 2023

https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/colonial-dames-company-ltd-659151-12052023

사례 35

- "ULTRA BRIGHT LIGHTENING CREAM Maximum Strength Hydroquinone" "With a maximum strength of Hydroquinone in the highest allowable amount, the Ultra Brightening Skin Lightener from SkinPro's Medical Grade Skin Care line of products works fast to eradicate dark spots and prevent future occurrences of hyperpigmentation and uneven skin tone."

※ 자료 : SkinPro APRIL 13, 2022

https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/skinpro-628398-04132022

□ 유형 2 : 색소 규정을 위반한 경우

- 경고 서한을 받게 되는 빈번한 사유 중 하나가 바로 “색소 규정 위반” 임

  ※ Warning Letter Cites Lime Crime, Inc. Regarding Color Additives

  https://web.archive.org/web/20201218170326/https:/www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/lime-crime-07292015

- FDA에서는 미국으로 수입되는 화장품의 라벨을 검토하여 표기된 색소가 관련 규정을 준수하고 있는지를 판단하는데, 라벨에 색소 표기가 없어도 제품을 실험실로 보내 색소가 첨가되어 있는지 확인하기도 함

- 해당 규정을 준수하지 않은 제품은 추후에 수입이 거절되거나 수입금지 리스트에 올라갈 수도 있음

- 따라서 색소가 함유된 제품을 미국에 시판하기 전에 주의해야 할 사항을 정리해 보면

  ① 우선 해당 색소가 용도에 대해 승인을 받았는지 여부를 확인하는 것이 필수적임

> <예시>
>
> - 예를 들어 Ferric ferrocyanide는 “Externally applied cosmetics(외용 화장품)” 용도로 사용하도록 승인된 색소임. 이러한 색소가 만약 립스틱에 사용되었다면 이는 미국 FDA에서 정한 규정을 위반한 것으로 간주됨
> - 색소가 “Externally applied cosmetics” 용도로 사용하도록 승인된 경우, 규정상 특별히 허가받지 않는 한 립스틱 같은 제품에서는 사용할 수 없기 때문임 [21 CFR 70.3 (v)].
>
> https://web.archive.org/web/20201218170326/https:/www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/lime-crime-07292015

  ② 두 번째로, 사전허가를 받은 성분임을 확인하였다면 배치 인증(Batch Certification)이 필요한 색소인지 여부를 확인해야 함

  ③ 또한 전성분 표기시 색소의 이름이 FDA 규정에 맞게 표기되었는지 여부를 확인해야 함

<예시>

- FD&C Yellow No. 5(FD&C 황색 5 호)는 타르트라진(Tartrazine)이 FDA로부터 인증 받은 형태이고, 이는 일반적으로 화장품에 대한 사용이 허가되어 있음
- 그러나 FDA로부터 배치 인증(Batch Certification)을 받지 않은 타르트라진을 FD&C 황색 5 호 대신 사용하거나 전성분 표기시 표시해서는 안 됨

□ 유형 3 : 미생물에 오염된 불량 화장품일 경우

- 연방 식품, 의약품 및 화장품법에 따라 주(州) 간 상거래에서 불량 화장품(adulterated cosmetic)을 판매하는 것은 불법임[21 U.S.C. 331(a)]
- "라벨링에 규정된 사용 조건 또는 관습적이거나 일상적인 사용 조건에서 소비자에게 해로울 수 있는 독성 또는 유해 물질이 제품에 포함되어 있는 경우" 불량 화장품으로 간주됨
- 이러한 "독성 또는 유해 물질"에는 미생물 오염이 포함될 수 있음

※ Warning Letters Cite Cosmetics as Adulterated Due to Microbial Contamination

https://www.fda.gov/cosmetics/warning-letters-related-cosmetics/warning-letters-cite-cosmetics-adulterated-due-microbial-contamination

사례 1

- FDA는 타투 잉크 제조 시설을 실사하여 샘플을 취한 후, 이를 분석하였는데, 미생물 오염이 관찰됨
- 발견된 미생물은 독소와 박테리아 모두 감염을 일으키는 Clostridium species(클로스트리디움속)이었으며, 타투 잉크 제품은 매우 비위생적인 환경에서 제조되고 있었음
  - Clostridium species: Clostridium clostridioforme, Clostridium ramosum, Bacillus pumilus, and B. megaterium
- 이에 FDA는 이 회사에게 warning letter를 받은 날로부터 근무일 기준 15일 이내에 서면으로 회신할 것을 요청함

- 서면 회신에는 warning letter에 명시된 위반 사항과 관련하여, 향후 재발방지를 위해 어떠한 시정 조치를 할 것인지 각 단계별로 설명하는 내용이 포함되어야 함

※ 자료 : Color Art, Inc. dba Solid Ink September 18, 2019

https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/color-art-inc-dba-solid-ink-587248-09182019

사례 2

- FDA는 타투 잉크 제조 시설을 실사하여 샘플을 취한 후, 이를 분석하였는데, 미생물 오염(Bacillus cereus, Staphylococcus equorum, Kocuria kristinae)이 관찰됨
- 이에 FDA는 이 회사에게 warning letter를 받은 날로부터 근무일 기준 15일 이내에 서면으로 회신할 것을 요청함
    - 서면 회신에는 warning letter에 명시된 위반 사항과 관련하여, 향후 재발방지를 위해 어떠한 시정 조치를 할 것인지 각 단계별로 설명하는 내용이 포함되어야 함

※ 자료 : Dynamic Color September 18, 2019

https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/dynamic-color-inc-587250-09182019

사례 3

- FDA는 타투 잉크 제조 시설을 실사하여 샘플을 취한 후, 이를 분석하였는데, 미생물 오염(Pseudomonas andersonii, Oligella ureolytica, and unidentified members of the genus Methylobacterium)이 관찰됨
- 또한 제품 포장에 "멸균된(sterile)"이라는 클레임을 하고 있으나, 미생물 오염이 발견되었기 때문에, 허위 및 소비자 오인성 광고(false and misleading)에 해당함
- 이에 FDA는 이 회사에게 warning letter를 받은 날로부터 근무일 기준 15일 이내에 서면으로 회신할 것을 요청함

- 서면 회신에는 warning letter에 명시된 위반 사항과 관련하여, 향후 재발방지를 위해 어떠한 시정 조치를 할 것인지 각 단계별로 설명하는 내용이 포함되어야 함

※ 자료 : Intenze Products Inc. September 18, 2019

https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/intenze-products-inc-587251-09182019

사례 4

- FDA는 호텔 어메니티 제품(샤워젤, 샴푸, 로션, 컨디셔너)을 생산하는 제조 시설을 실사하여 샘플을 취한 후, 이를 분석하였는데, 미생물 오염(P. aeruginosa)이 관찰됨
- FDA의 가이드라인에서는 총 호기성 생균수가 눈가용 화장품의 경우 500 CFU/g(mL), 기타 모든 제품의 경우 1,000 CFU/g를 초과해서는 안 된다고 정하고 있음
- 그러나 해당 제품에서는 최대 210,000,000 CFU/m의 호기성 생균이 검출되었으며, 이러한 미생물이 최종 제품에 존재하면 사용자의 감염 위험이 증가할 수 있기 때문에 사용자에게 해를 끼칠 수 있음
- 이에 FDA는 이 회사에게 warning letter를 받은 날로부터 근무일 기준 15일 이내에 서면으로 회신할 것을 요청함
    - 서면 회신에는 warning letter에 명시된 위반 사항과 관련하여, 향후 재발방지를 위해 어떠한 시정 조치를 할 것인지 각 단계별로 설명하는 내용이 포함되어야 함

※ 자료 : Gilchrist & Soames, Inc. March 16, 2016

https://web.archive.org/web/20191001013235/https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/gilchrist-soames-485833-03162016

사례 5

- FDA는 아이 섀도우 제품을 생산하는 제조 시설을 실사하여 샘플을 취한 후, 이를 분석하였는데, 미생물 오염(Bacillus cereus)이 관찰됨
- FDA의 실사 결과, 이 회사는 미생물 오염이 없음을 확인하기 위한 원료 규격 검사를 하지 않았고, 유통기한이 지난 원료를 사용하고 있었으며, 원료 관리를 문서화하고 있지 않았음이 발견됨
- 이에 FDA는 이 회사에게 warning letter를 받은 날로부터 근무일 기준 15일 이내에 서면으로 회신할 것을 요청함
    - 서면 회신에는 warning letter에 명시된 위반 사항과 관련하여, 향후 재발방지를 위해 어떠한 시정 조치를 할 것인지 각 단계별로 설명하는 내용이 포함되어야 함

※ 자료 : Gemdo Cosmetics Inc. External Link Disclaimer April 16, 2015

https://web.archive.org/web/20190908040049/https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/gemdo-cosmetics-inc-04162015

사례 6

아래 예시는 OTC Drug에 해당하는 사례임

- FDA는 어떤 회사가 불순물 함유 의약품을 판매하고 있다는 것을 알게 되었음
- 회사는 제품을 안약 및 점안액으로 판매하고 있었음
- 해당 제품의 무균 상태를 분석하기 위해 분석된 샘플로부터 Exophiala sp.와 Bacillus spp가 검출됨. 이보다 더 많은 균들이 포함되어 있을 가능성이 있음
- 이러한 사항으로 인해 제품 리콜을 실시하고 있고, 소비자에게 구매와 사용을 중단할 것을 요구하는 메시지를 발표함. 그리고 FDA 홈페이지에 이와 관련된 사항을 공지함
- FDA는 15일 이내에 위반 사항에 대한 시정 조치 계획 제출을 요구함
- 이러한 사항들이 시정되지 않을 경우 법적 조치, 압류, 금지 명령 등이 있을 수 있음을 경고함

※ 자료 : Dr. Berne's Whole Health Products NOVEMBER 22, 2023

https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/dr-bernes-whole-health-products-665456-11222023

□ 유형 4 : 의료기기로 허가를 받고 팔아야 하는데, 화장품으로 판매한 경우

- 의료기기로 허가를 받고 팔아야 하는데, 이를 화장품으로 판매한 경우에 경고 서한을 받게 됨

※ Warning Letters Highlight Differences Between Cosmetics and Medical Devices

https://www.fda.gov/cosmetics/warning-letters-related-cosmetics/warning-letters-highlight-differences-between-cosmetics-and-medical-devices

의료기기의 정의

"...an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component, part, or accessory, which is – (1) recognized in the official National Formulary, or the United States Pharmacopeia, or any supplement to them, (2) 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 (3) 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." [FD&C Act, section 201 (h)]

사례 1

- FDA는 마이크로 니들 제품에 대해 경고 서한을 발행함
- FDA에서는 이 제품의 웹사이트와 브로셔, 팜플렛, 그리고 라벨링을 검토하였고, 이 제품이 피부에서 새로운 콜라겐의 합성을 유도하며, 깊은 주름과 스트레치 마크를 트리트(treat)하고 있기 때문에 이 제품은 의료기기로 허가를 받아야 한다고 결론 내림
- 또한 이 제품이 혈관과 신경에 손상(damage)을 줄 가능성, 즉 안전성과 관련한 우려가 있

으므로, 사전 허가를 받아야 하는 제품이라고 결론 내림

- 이에 FDA는 이 회사에게 즉각적으로 시정 조치를 하지 않을 경우에는 압수(seizure), 명령(injunction), 민사상 벌금(civil money penalties)에 처해질 것이라고 경고함

※ 자료 : Eclipse Aesthetics LLC March 28, 2016, October 27, 2015

https://web.archive.org/web/20190908131450/https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/eclipse-aesthetics-llc-03282016

https://web.archive.org/web/20190908104554/https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/eclipse-aesthetics-llc-10272015

사례 2

- FDA는 어떤 회사가 미국 FDA의 인허가를 받지 않은 필러(dermal fillers)를 판매하고 있다는 것을 알게 되었음
- 해당 제품은 다음과 같은 광고를 하고 있었음
  - to treat wrinkles, add contour to facial features, enhance the lips, and to eliminate the appearance of aging. (주름을 치료하고, 얼굴 윤곽을 또렷하게 하고, 입술을 확대하고, 노화되어 보이는 것을 없애 줍니다.)
- 해당 제품은 미국 FDA로부터 사전 시판 승인(premarket approval : PMA)를 받지 않았으므로, 부정표시 제품(misbranded product)로 간주되었음
- 또한 법 위반의 심각성을 고려할 때 해당 제품(피부 필러)이 불량 제품(adulterated)으로 보이며, 그 결과 이러한 위반 사항이 시정될 때까지 FDA는 해당 제품을 DWPE(물리적 검사 없는 억류) 조치에 취할 것이라고 경고함

※ 자료 : Medica Outlet June 1, 2015

https://web.archive.org/web/20190908045033/https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/medica-outlet-06012015

사례 3

- FDA는 어떤 회사가 미국 FDA의 인허가를 받지 않은 하이드로겔 제품(Hydrogel products)을 판매하고 있다는 것을 알게 되었음. 이 제품은 100% 폴리아크릴아마이드(Polyacrylamide)와 테오시알 제품(Teosyal products)으로 구성되어 있으며, 해당 제품은 미국에서는 의료기기에 해당함
- 해당 제품은 웹사이트에서 아래와 같은 광고를 하고 있었음
  - shaping the face, genitals, mammary glands, and buttocks; elimination of deep deforming scars; and endoprosthetics of vocal chords in cases of paralytic stenosis of the larynx (얼굴, 생식기, 유선, 엉덩이의 모양을 잡습니다. 깊은 변형 흉터 제거; 마비성 후두 협착증의 경우 성대의 관내 인공 삽입물)
  - Teosyal is being marketed as an aesthetic medicine which is "among the top 3 fillers in the world today.(터시알은 "오늘날 세계 3대 필러 중 하나"인 미용의학으로 판매되고 있습니다.)
- FDA는 해당 회사의 웹사이트를 검토하였으며, 해당 제품이 dermal filler로 판매되고 있다고 결론 내림.
- 또한 법 위반의 심각성을 고려할 때 해당 제품(피부 필러)이 불량 제품(adulterated)으로 보이며, 그 결과 이러한 위반 사항이 시정될 때까지 FDA는 해당 제품을 DWPE(물리적 검사 없는 억류) 조치에 취할 것이라고 경고함

※ 자료 : Dr. Ashley Minas May 29, 2015

https://web.archive.org/web/20190908044929/https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/dr-ashley-minas-05292015

사례 4

- FDA는 미국에 소재한 회사를 실사(inspection)하여, 문제가 된 제품을 해당 회사가 수입한 것을 확인함
- FDA는 제품 포장 및 라벨, 사용자 매뉴얼, 브로셔, 회사 웹사이트, 그리고 실사 결과를 검

토한 결과, 해당 제품이 불량(adulterated) 제품이라고 결론 내리고, 해당 제품은 사전 허가를 받아야 하는 의료기기에 해당한다고 보았음

- 해당 제품은 웹사이트에서 아래와 같은 광고를 하고 있었음

  - "Can help to lighten the appearance of hyper-pigmentation."
  - "Use the pen on your face or body to reduce the appearance of acne scars, fine lines, wrinkles and stretch marks."
  - "You can even use it on your scalp to stimulate hair growth."
  - "We suggest using with Relumins Intensive Brightening Serum to treat stretch-marks"
  - "1 PIN TIPS: 5 PACK – This single needle tip allows precise treatment of deep lines or wrinkles"
  - "What makes this pen stand apart from the rest is the adjustable needle head (varying in length from 0.25 mm to 2 mm), and the built-in vibration mechanism that provides deeper needle penetration."
  - "Various needle modules to stimulate skin: for treating fine lines, scars or large areas"
  - "More than 50% of stretch marks and acne scar improvement"
  - "Reduce the Appearance of Indented Acne Scars, Wrinkles and Lines"
  - "Clinically shown to be effective in reducing scarring in 94% of patients"
  - "Anti-aging, skin regeneration and skin tightening"
  - "Improves skin texture and reduces the appearance of wrinkles"
  - "Reduces the appearance of hyperpigmentation and scars, creating smooth, even skin"
  - "0.05mm (click for Relumins Roller in this size!)- Fine lines, Light Wrinkles, Open Pores, Pigmentation Marks, Acne Scars, Mild Ice Pick Scars, Face Rejuvenation"
  - "1.00mm (click for Relumins Roller in this size!)- Mild Wrinkles, Deep Acne Scars, Surgery Scars, Chicken Pox Scars, Ice Pick Scars, Strong Black Heads"
  - "1.5mm - Deep scars, Deep stretch marks"
  - "Lighten Acne Scar Hyper-pigmentation to Reduce the Appearance of Indented Acne Scars, Wrinkles and Lines"
  - "Clinical studies have shown that over 94% of patients using the DermaRoller/MicroNeedling Treatment System achieved a reduction in the severity of their scarring by one or two grades. More than 80% of patients assessed their

treatment as 'excellent' on a 10-point scale."

- "Target areas include under-eye pouches, crow's feet, wrinkles around the nose and mouth, chin skin, frown lines and improving the appearance of neck wrinkles"
- "Solar panel provides microcurrent to stimulate the body's tissue"

- 또한 의료기기의 최초 수입자(initial importer)는 FDA에 매년 등록(annual registration)해야 하는데, 해당 회사는 등록 의무를 준수하지 않은 것으로 밝혀짐. 이 외에도 여러 가지 문제점이 발견됨
- 이에 FDA는 이 회사에게 시정 조치를 하지 않을 경우에는 압수(seizure), 명령(injunction), 민사상 벌금(civil money penalties)에 처해질 것이라고 경고함
- FDA는 이 회사에게 warning letter를 받은 날로부터 근무일 기준 15일 이내에 서면으로 회신할 것을 요청함

※ 자료 : Flawless Beauty and Skin. AUGUST 05, 2022

https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/flawless-beauty-and-skin-630567-08052022

사례 5

- FDA는 어떤 회사가 미국 FDA의 인허가를 받지 않은 불량 의료기기(adulterated device),
- 불법 표시 의료기기(misbranded device)를 판매하고 있다는 것을 알게 되었음
- 회사는 제품을 의료기기로 간주되는 미용 및 개인용 케어 제품으로 판매하고 있었음
- 문제가 된 제품은 3 Levels Injection Insulin Gun Hyaluronic Acid Skin Injection Needle Free Pen여러 종류의 Derma Pens, LED 마스크 제품들, 650nm 레이저 모발 성장 헬멧, 가정용 지방 냉동 슬리밍 기기, 전기영동 메조테라피 무침 주입 뷰티 기기 등임
- 해당 회사는 피부 깊숙이 침투하여 효과를 발휘한다는 주장, 여드름, 흉터, 주름 개선 등의 의료적 효능 주장, 콜라겐 생성 촉진, 지방 분해 등 신체 기능에 영향을 미친다는 주장, 탈모 예방 및 모발 성장 촉진 주장을 함
- 해당 회사는 FDA 승인 없이 의료기기로 간주되는 제품을 판매함
- 의료기기 등록 및 리스팅 요구사항을 미준수 함

- 제품에 대한 과장된 의료 효능을 주장함
- FDA는 15일 이내에 위반 사항에 대한 시정 조치 계획 제출할 것을 요구함
- FDA는 위반 사항 재발 방지를 위한 구체적인 계획을 제시함
- FDA는 시정 조치에 대한 문서화된 증거를 제출할 것을 요구함
- FDA는 해당 제품이 미국 내 수입이 거부될 수 있다고 경고함
- FDA는 지속적인 위반 시 추가적인 규제 조치가 있을 수 있음을 이야기함

※ 자료 : Ostar Beauty Sci-Tech Co Ltd. DECEMBER 04, 2023

https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/ostar-beauty-sci-tech-co-ltd-667871-12042023

□ 유형 5 : 화장품 및 의약품 규정을 위반한 경우

- 아래는 화장품 및 의약품 규정을 위반하여 경고서한을 받은 사례임

사례 1

- FDA에서는 OTC Drug의 해외 제조소를 실사하였는데, 의약품 GMP(CGMP)를 심각하게 위반하였음을 발견했음

> ※ 미국 FDA가 말하는 CGMP란?
>
> ☞ 여기에서 "C"는 화장품(cosmetics)이 아니라 "현행(Current)"의 약자임.
>
> 미국 FDA 규정에서 CGMP 라 함은 의약품 현행 GMP를 뜻하므로, 주의할 것

- 경고 서한(warning letter)의 내용을 자세히 살펴보면 다음과 같음
- FDA는 이 회사의 본사를 실사(inspection)하였음. 그때 이 회사에서는 OTC Drug의 공급자 또는 계약 제조자 중 한 곳이 경고 서한(warning letter)을 받았음을 인지하고 있었으며, 앞으로 그 곳에서는 제품을 공급받지 않을 것이라고 FDA에 약속하였음. 그리고 그 회사는 만약 해당 OTC Drug가 수입 경보(import Alert)를 받게 된다면, 해당 해외 제조소에서 제품을 수입하는 것을 중단하겠다고 서면으로 FDA에 약속함. 그러나, 추후 FDA에서 이 회사의 수입 기록을 뒤져본 결과, 거짓말임이 드러남
- 그리고 의약품 GMP를 위반한 해외 제조소로부터 이 회사가 수입하고 있던 제품 중 일부는 화장품이면 동시에 의약품인 제품(예를 들면 자외선차단제)이었음
- 위생적이지 않은 환경에서 제조, 포장된 제품은 불량(adulterated) 제품으로 간주되어 경고서한(Warning letter)이 발행되었음
- FDA에서는 이 회사에 이러한 위반사항을 어떻게 시정할 것인지 15일이내에 답변할 것을 요청함

※ 자료 : Greenbrier International, Inc dba Dollar Tree, NOVEMBER 06, 2019

https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/greenbrier-international-inc-dba-dollar-tree-574706-11062019

사례 2

- FDA는 어떤 회사가 불법 의료기기(시판 전 승인 없이 판매)를 판매하고 있다는 것을 알게 되었음
- 회사는 제품을 상처 치료용 제품으로 판매하고 있었음
- 해당 제품은 다음과 같은 광고를 하고 있었음
  - "Banda-SiL's chelated silver, derived from natural sources, prevents infection, stimulates wound healing, and promotes skin matrix repair."
- 해당 회사는 Banda-SiL Silver Wound Care Gel과 Banda-Sil Silver Liquid Gel Spray를 FDA 승인 없이 판매함. 이는 시판 전 승인 없이 의료기기를 판매한 것임
- 2021년 3월 1일까지 510(k) 제출 약속을 이행하지 않음
- 해당 회사는 제품에 허가받지 않은 효능 주장 (감염 예방, 상처 치유 촉진 등)
- UDI(Unique Device Identifier) 라벨링 요구사항을 준수하지 않음
- 해당 회사는 의료기기 등록 및 리스팅 요구사항을 미준수 하였음
- FDA는 15일 이내에 위반 사항에 대한 시정 조치 계획 제출을 요구함
- FDA는 위의 사항이 시정되지 않을 경우 추가 통지 없이 법적 조치, 압류, 금지 명령, 민사상 벌금 등의 가능성을 경고함

※ 자료 : AG Essence, Inc. JUNE 14, 2024

https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/ag-essence-inc-678344-06142024

□ 유형 6 : 안전성 및 라벨링을 위반한 경우

- 아래는 "안전성 및 라벨링 위반"으로 인해 경고 서한을 받은 사례임

사례 1

- 이 제품은 헤어제품이며 사용법에 "본 제품을 바른 후, 열을 가하고 고데기를 하세요" 라고 되어 있었음
- 라벨링에 명시된 사용법, 즉 일반적이고 관습적인 사용법을 따랐을 때, 소비자에게 해를 주는 독성 성분이 있다면, 불량 화장품으로 간주됨
- 이 제품은 메틸렌 글리콜(Methylene glycol)을 함유하고 있었는데, 이 성분이 들어간 제품을 헤어에 바르고, 열을 가한 후 고데기를 하면 포름알데하이드가 배출됨
- 이러한 사용법 하에서 메틸렌 글리콜은 유해성분(deleterious substance)이므로, 이 제품은 불량 화장품(adulterated cosmetics)에 해당함
- 또한 이 제품은 라벨에 기재된 사용법이 잘못되었기 때문에 부정표시 화장품(misbranded cosmetics)으로도 간주되었음

※ 자료 : Van Tibolli Beauty Corp, SEPTEMBER 02, 2015

https://web.archive.org/web/20201218172727/https:/www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/van-tibolli-beauty-corp-09022015

사례 2

- 회사는 제품을 OTC 의약품 (Dr. Numb® Lidocaine Cream 4% - Topical Anesthetic, Dr. Numb® Lidocaine Cream)로 판매하고 있었음
- 해당 제품은 제품 라벨과 웹사이트에서 승인되지 않은 적용 부위 (문신, 피어싱 등)을 표시, 사용 방법이 위험할 수 있는 정보를 포함 (두꺼운 층으로 도포, 플라스틱 필름으로 덮기 등)하고 있기 때문에 불법 표시사항임
- 추가적으로 해당 회사는 불완전한 실험실 기록 유지, 부적절한 실험실 관리, 부적절한 안정성 시험 프로그램, 부적절한 규격 이탈(OOS) 결과 조사로 문제제기 됨

- FDA는 15일 이내에 위반 사항에 대한 시정 조치 계획 제출 요구함
- 또한 CGMP 컨설턴트를 고용할 것을 권고함
- 데이터 무결성 개선 계획을 요구함
- 시정되지 않을 경우 신약 승인 보류, 제품 수입 거부 등의 조치가 될 수 있음을 경고함

※ 자료 : Cosmaceutical Research Lab Inc. 2020년 5월 29일

https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/cosmaceutical-research-lab-inc-600121-05292020

□ 유형 7 : 의약품 GMP를 준수하지 않은 경우

- 아래는 "의약품 GMP 미준수"로 인해 경고 서한을 받은 사례임

사례 1

- FDA는 이 회사의 의약품 제조 시설을 실사하였음
- 의약품 제조 방법, 설비, 제조 관리, 가공, 포장 등 모든 면에서 미국 FDA가 정한 의약품 GMP를 심각하게 위반한 것이 관찰되었기 때문에, 해당 회사의 의약품은 불량(adulterated) 의약품으로 간주되었음. 이에 FDA에서는 경고 서한(Warning letter)을 발행함
- 이 회사는 "시정 조치가 완료되기 전에는 미국에 수출하지 않겠습니다" 라고 약속했음. 그러나 이것은 거짓임이 드러나게 됨. 이에, FDA는 수입 경보(import alert)를 발행함
- FDA 실사 결과, 해당 회사는 아래 사항을 준수하지 않았음이 드러남
  - □ 회사의 품질 관리 부서는 제조된 의약품이 CGMP를 준수하고 의약품의 확인, 용량, 품질 및 순도에 대해 확립된 규격을 충족하는지 확인해야 함(21 CFR 211.22).
    - 배치 출하 전에 모든 테스트를 수행하고 검토한다. (all testing was performed and reviewed prior to batch release)
    - 계약 테스트 실험실은 적절한 자격을 갖춘다. (contract testing laboratory was adequately qualified)
    - 직원이 수행한 활동에 대해 정확히 기록한다. (staff completed records accurately and contemporaneously for activities they performed)
    - 불량품 및 원료의 보관을 위한 적절한 통제를 한다. (adequate controls were in place

for storage of rejects and raw materials)

- 안정성 프로그램을 수립한다. (stability program was established.)

> 미국 Title 21 CFR Part 211
>
> Subpart B 조직 및 작업원
>
> sec. 211.22 품질관리조직의 책임
>
> (a) 모든 원료, 의약품 용기, 마개, 공정 중 물품, 포장 자재, 라벨, 의약품의 적/부 판정 권한 및 책임과 제조 공정 중에 어떤 오류도 발생하지 않았거나 오류가 발생했더라도 이를 충분하게 조사했는지 확인하기 위해 생산 기록서의 검토 권한을 갖춘 품질관리조직(QCU)이 있어야 한다. 또한 품질관리조직(QCU)은 계약에 의거하여 다른 회사가 제조, 가공, 포장 또는 보관한 의약품의 적/부를 결정할 책임이 있다.
>
> (b) 원료, 의약품 용기, 마개, 포장 자재, 공정 중 물품, 의약품의 시험과 적/부 판정을 위한 적절한 실험실 시설을 품질관리조직(QCU)에서 사용할 수 있어야 한다.
>
> (c) 품질관리조직(QCU)은 의약품의 확인, 함량, 품질, 순도에 영향을 주는 모든 절차와 규격을 승인 또는 기각할 책임이 있다.
>
> (d) 품질관리조직(QCU)에 적용되는 책임 및 절차는 서면으로 작성되어야 한다. 그러한 서면 절차를 따라야 한다.

□ 의약품의 특성에 따라, 안전성, 확인, 용량, 품질 또는 순도를 공식적으로 또는 기타 확립된 요구사항을 초과하여 바뀌게 하는 오작동 또는 오염을 방지하기 위해 적절한 간격으로 장비 및 기구를 세척, 유지 및/또는 멸균해야 함(21 CFR 211.67(a)).

미국 Title 21 CFR Part 211

Subpart D-설비

Sec. 211.67-설비 세척 및 유지 관리

(a) 설비와 기구를 적절한 주기로 청소, 유지관리, 그리고 의약품 특성을 감안하여 적절하게 소독 및/또는 멸균하여, 의약품의 안전성, 확인, 함량, 품질, 또는 순도가 공식 또는 기타 설정된 기준을 벗어나 변화되도록 할 수 있는 오염이나 오작동을 방지해야 한다.

(b) 의약품의 제조, 가공, 포장 또는 보관에 사용되는 기구를 포함한 설비의 세척과 유지관리에 대한 절차 문서가 확립되어 있어야 하며 이를 따라야 한다. 절차 문서는 다음 사항을 포함하여야 하나 이에 국한되는 것은 아니다.

(1) 설비 세척과 유지 관리 업무의 분장.

(2) 적절한 경우에는 위생 처리 일정을 포함한 유지 관리 및 세척 일정

(3) 세척 및 유지 관리 작업 방법, 사용 설비 및 물품에 대한 상세한 설명과 적절한 세척 및 유지 관리를 위해 필요한 설비의 분해와 조립 방법.

(4) 이전 작업 배치 표시물의 제거 또는 말소.

(5) 사용 전까지 깨끗한 설비가 오염되지 않도록 하기 위한 보호 조치.

(6) 사용 직전에 설비의 청결도 검사.

(c) 211.180 및 211.182항에 규정된 바에 따라 유지 관리, 세척, 위생 처리 및 검사에 대한 기록서를 보관하여야 한다.

□ 컴퓨터 또는 관련 시스템에 대한 적절한 통제권을 행사하여 인증된 직원만이 마스터 생산 및 제어 기록 또는 기타 기록의 변경을 수행하도록 보장해야 함(21 CFR 211.68(b)

미국 Title 21 CFR Part 211

Sec. 211.68. 자동식, 기계식, 전자식 설비

(b) 컴퓨터 또는 관련 시스템을 적절하게 관리하여, 허가 받은 작업원만 마스터 생산 및 관리 기록서 또는 기타 기록서를 변경할 수 있게 한다. 컴퓨터 또는 관련 시스템에 공식이나 기타 기록 또는 데이터를 입출력할 때는 정확성을 점검한다. 입출력 확인의 주기와 정도는 컴퓨터 또는 관련 시스템의 복잡성 및 신뢰성에 따라 결정한다. 컴퓨터 또는 관련 시스템에 입력된 데이터의 백업 파일을 유지하여야 하나, 시험분석과 관련하여 실시한 계산 같이 일부 데이터가 컴퓨터 처리 과정 또는 기타 자동처리 과정에서 없어지는 경우는 예외로 한다. 이와 같은 경우에는 적절한 밸리데이션 데이터와 함께 프로그램에 대한 기록 문서를 유지한다. 백업 데이터를 정확하고 완벽하게 유지하며 변형, 부주의에 의한 삭제 또는 손실로부터 보호하기 위하여, 복제본, 테이프 또는 마이크로필름 같은 대체 시스템이나 하드 카피를 유지하여야 한다.

- 이외에도 부정표기(misbranded) 등의 정황도 드러남
- 이 회사에서는 화장품도 생산하고 있었으므로, 화장품 관련 규정 준수 여부 확인을 위해, 화장품 제조 공정을 검토해 보라고 FDA에서 해당 회사에 권고함
- FDA는 해당 회사가 모든 위반 사항을 완전히 시정하고 CGMP 준수 여부를 확인할 때까지 해당 회사에서 제조된 모든 의약품, 건강보조제의 인허가 신청이 보류될 수 있으며, 이러한 위반 사항을 시정하지 않으면 FDA가 해당 제조소에서 제조한 물품의 승인을 계속 거부할 수도 있다고 경고 서한(Warning Letter)에 명시함
- FDA는 이 회사에게 경고 서한(Warning Letter)을 받은 날로부터 근무일 기준 15일 이내에 서면으로 회신할 것을 요청함

※ 자료 : Glint Cosmetics Pvt Ltd. MAY 31, 2019

https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/glint-cosmetics-pvt-ltd-573468-05312019

사례 2

- FDA는 OTC Drug인 손 세정제(hand sanitizer)를 생산하는 업체의 제조시설을 실사하였고, 제조 방법, 설비, 제조 관리, 가공, 포장 등 모든 면에서 미국 FDA가 정한 의약품 GMP를 심각하게 위반한 것이 관찰되었기 때문에, 경고 서한(Warning letter)을 발행함
- Form FDA 483(미국 FDA가 제조시설을 실사하여 발견한 위반 사항을 정리한 문서)에 대해 해당 회사가 응답을 하긴 했으나, 의약품 GMP 준수를 위한 시정 조치에 대한 충분한 세부 정보나 증거를 제공하지 않았기 때문에 FDA는 해당 회사의 응답이 부적절하다고 간주함
- FDA 실사 결과, 해당 회사는 아래 사항을 준수하지 않았음이 드러남

□ 의약품 구성요소, 의약품 용기 및 마개의 시험과 승인 또는 부적합 판정 (21 CFR 211.84(d)(1) and 211.84(d)(2)).

- 구성요소, 의약품 용기 및 마개에 대한 시험을 수행해야 함

> Subpart E-원료, 의약품 용기 및 마개의 관리
>
> Sec. 211.84-원료, 의약품 용기 및 마개의 시험과 승인 또는 부적합 판정
>
> (d) 검체의 검사 및 시험은 다음과 같이 실시한다.
>
> (1) 의약품의 각 성분의 동일성을 확인하기 위하여 최소한 1회 이상의 시험을 실시하여야 한다. 특정 확인 테스트가 있는 경우 이를 사용해야 한다.
>
> (2) 각 구성 요소는 순도, 강도 및 품질에 대한 모든 적절한 서면 규격을 준수하는지 테스트해야 한다. 제조업체의 이러한 테스트 대신 구성 요소 공급자의 분석 보고서를 수락할 수 있는 경우는 △ 제조업체가 해당 구성 요소에 대해 최소한 하나의 특정 확인 테스트를 수행하는 경우, 그리고 △ 제조업체가 적절한 간격으로 공급업체의 테스트 결과를 적절하게 검증하여 공급업체 분석의 신뢰성을 확립하는 경우에 한한다.

□ 유통 전 검사 및 출하(21 CFR 211.165)

- 의약품 배치별로 제품 출하 승인에 앞서 각 유효성분의 확인과 함량시험을 포함하여 의약품이 최종 규격에 적합한지 시험을 통해 적절하게 판정해야 함

미국 Title 21 CFR Part 211

Subpart I 시험 관리

sec. 211.165 시험 및 출하 승인

(f) 확립된 표준 또는 규격 및 기타 관련 품질 관리 기준에 부합하지 못한 의약품은 부적합 처리해야 한다. 재가공을 실시할 수도 있다. 이들 재가공품은 수용하고 활용하기에 앞서 적절한 표준, 규격 및 기타 관련 기준을 충족시켜야 한다.

□ 품질 시스템 절차(21 CFR 211.22)

- 품질관리조직(QCU)에 관한 요구사항을 준수하기 위해 품질시스템 절차를 확립하고, 경영을 책임지는 경영진은 확립된 품질정책과 품질목표의 이행 여부 확인을 포함하여 품질시스템의 적합성과 유용성을 정기적으로 검토해야 함

미국 Title 21 CFR Part 211

Subpart B 조직 및 작업원

sec. 211.22 품질관리조직의 책임

(a) 모든 원료, 의약품 용기, 마개, 공정 중 물품, 포장 자재, 라벨, 의약품의 적/부 판정 권한 및 책임과 제조 공정 중에 어떤 오류도 발생하지 않았거나 오류가 발생했더라도 이를 충분하게 조사했는지 확인하기 위해 생산 기록서의 검토 권한을 갖춘 품질관리조직(QCU)이 있어야 한다. 또한 품질관리조직(QCU)은 계약에 의거하여 다른 회사가 제조, 가공, 포장 또는 보관한 의약품의 적/부를 결정할 책임이 있다.

(b) 원료, 의약품 용기, 마개, 포장 자재, 공정 중 물품, 의약품의 시험과 적/부 판정을 위한 적절한 실험실 시설을 품질관리조직(QCU)에서 사용할 수 있어야 한다.

(c) 품질관리조직(QCU)은 의약품의 확인, 함량, 품질, 순도에 영향을 주는 모든 절차와 규격을 승인 또는 기각할 책임이 있다.

(d) 품질관리조직(QCU)에 적용되는 책임 및 절차는 서면으로 작성되어야 한다. 그러한 서면 절차를 따라야 한다.

- 2022년 1월 26일에 FDA는 손 소독제 제조 작업과 관련된 FD&C법 섹션 704(a)(4)에 따라

기록 및 기타 정보를 요청함. 그러나 해당 회사는 메탄올이 포함된 에탄올 로트 COA(Certificate of Analysis)를 제공했음

- 2022년 5월 17일에 FDA는 이 로트의 에탄올로 제조된 모든 손 소독제 의약품에 대한 유통 기록을 요청했음. 그러나 해당 회사는 응답하지 않았음
- FDA는 2022년 7월 21일부터 27일 사이에 이 제품과 관련하여 해당 회사 또는 그 회사의 컨설턴트와 원격 회의를 하기 위해 추가 시도를 하였으나, 아무런 응답을 받지 못함
- 이에, 2022년 8월 3일에 FDA는 해당 제품의 메탄올 함량을 FDA 웹사이트를 통해 대중에게 공지함

※ 게시글 제목 : FDA updates on hand sanitizers consumers should not use

https://www.fda.gov/drugs/drug-safety-and-availability/fda-updates-hand-sanitizers-consumers-should-not-use

- 실사를 받은 후, 해당 회사는 기준치 초과 메탄올을 함유한 손 소독제를 전량 폐기하겠다고 약속했음. FDA의 입회 하에, 2022년 11월 10일 해당 회사의 시설에서 이러한 제품이 폐기되었음
- FDA는 이 회사에게 의약품 GMP 전문 컨설턴트의 도움을 받을 것을 권고함
- 해당 회사에서는 의약품 생산을 중단하겠다고 했음. 이에 FDA는 본 경고서한(Warning Letter)에 대한 회신으로 향후 이 시설에서 의약품 제조를 재개할 것인지 여부를 명확히 할 것을 요청함. 그리고 의약품 제조를 재개할 계획이라면 적절한 시정 조치가 마련되어 있는지 확인하고 작업을 재개하기 전에 회의 일정을 잡기 위해 FDA에 연락할 것을 요구함

※ 자료 : Clean Cosmetics LLC. JANUARY 30, 2023

https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/clean-cosmetics-llc-643205-01302023

사례 3

- FDA는 2021년 9월 27~10월 15일에 이 회사의 의약품 제조 시설을 실사하였음
- 의약품 제조 방법, 설비, 제조 관리, 가공, 포장 등 모든 면에서 미국 FDA가 정한 의약품 GMP를 심각하게 위반한 것이 관찰되었기 때문에, 해당 회사의 의약품은 불량(adulterated) 의약품으로 간주되었음. 이에 FDA에서는 경고 서한(Warning letter)을 발행함
- Form FDA 483(미국 FDA가 제조시설을 실사하여 발견한 위반 사항을 정리한 문서)에 대해 2021년 11월 2일자로 이 회사는 답변을 보냈으며, FDA에서 이를 자세히 검토함
- FDA 실사 결과, 해당 회사는 아래 사항을 준수하지 않았음이 드러남

□ 회사의 품질 관리 부서는 제조된 의약품이 CGMP를 준수하고 의약품의 확인, 용량, 품질 및 순도에 대해 확립된 규격을 충족하는지 확인해야 함(21 CFR 211.22).

- 의약품의 각 배치별로 출시 전에 미생물 테스트를 수행하고 검토해야 함 (Microbiological testing was performed and reviewed prior to release for each batch of drug product (21 CFR 211.165(b)).
- 규격 외(OOS) 결과에 대한 적절한 조사 및 철저한 조사를 수행하기 위한 서면 절차 (Adequate investigations of out-of-specification (OOS) results and written procedures to conduct thorough investigations (21 CFR 211.192)).
- 적절한 문서화 및 변경 평가 (Appropriate documentation and assessment of changes (21 CFR 211.100(a)).
- 적절하고 지속적인 안정성 프로그램 수립 (Establishment of an adequate, ongoing stability program (21 CFR 211.166(a)).
- 적절한 연간 제품 검토 수행 (Performance of appropriate annual product reviews (21 CFR 211.180(e)).

미국 Title 21 CFR Part 211

Subpart B 조직 및 작업원

sec. 211.22 품질관리조직의 책임

(a) 모든 원료, 의약품 용기, 마개, 공정 중 물품, 포장 자재, 라벨, 의약품의 적/부 판정 권한 및 책임과 제조 공정 중에 어떤 오류도 발생하지 않았거나 오류가 발생했더라도 이를 충분하게 조사했는지 확인하기 위해 생산 기록서의 검토 권한을 갖춘 품질관리조직(QCU)이 있어야 한다. 또한 품질관리조직(QCU)은 계약에 의거하여 다른 회사가 제조, 가공, 포장 또는 보관한 의약품의 적/부를 결정할 책임이 있다.

(b) 원료, 의약품 용기, 마개, 포장 자재, 공정 중 물품, 의약품의 시험과 적/부 판정을 위한 적절한 실험실 시설을 품질관리조직(QCU)에서 사용할 수 있어야 한다.

(c) 품질관리조직(QCU)은 의약품의 확인, 함량, 품질, 순도에 영향을 주는 모든 절차와 규격을 승인 또는 기각할 책임이 있다.

(d) 품질관리조직(QCU)에 적용되는 책임 및 절차는 서면으로 작성되어야 한다. 그러한 서면 절차를 따라야 한다.

□ 의약품의 확인, 함량, 품질 및 순도를 갖도록 설계된 생산 및 공정 관리를 위한 적절한 서면 절차를 확립해야 함(21 CFR 211.100(a)).

미국 Title 21 CFR Part 211

Subpart F 생산 및 공정 관리

sec. 211.100 ; 절차 문서 일탈

(a) 의약품이 목표로 하거나 보유하는 것으로 표시한 확인 함량 품질 및 순도를 확보하도록 생산 및 공정 관리에 대한 절차문서를 구비해야 한다 절차 문서는 이 서브파트에 제시된 모든 기준을 포함해야 한다 이들 절차문서와 이의 변경은 적절한 조직 단위에서 초안을 작성하고 검토 및 승인을 거쳐 품질관리조직의 (QCU)검토와 승인을 받아야 한다.

(b) 생산 및 공정 관리 문서 절차에 따라 각종 생산 및 공정 관리 업무를 수행해야 하며 업무 행위 당시에 기록을 하여야 한다. 문서 절차에서 벗어난 모든 일탈 사항을 기록하고 그의 타당성을 증명해야 한다.

□ 시설 청소 및 유지 관리를 위한 적절한 서면 절차를 확립하고 따라야 함(21 CFR 211.67(b)).

> 미국 Title 21 CFR Part 211
>
> Subpart D-설비
>
> Sec. 211.67-설비 세척 및 유지 관리
>
> (b) 의약품의 제조, 가공, 포장 또는 보관에 사용되는 기구를 포함한 설비의 세척과 유지관리에 대한 절차 문서가 확립되어 있어야 하며 이를 따라야 한다. 절차 문서는 다음사항을 포함하여야 하나 이에 국한되는 것은 아니다.
>
> (1) 설비 세척과 유지 관리 업무의 분장.
>
> (2) 적절한 경우에는 위생 처리 일정을 포함한 유지 관리 및 세척 일정
>
> (3) 세척 및 유지 관리 작업 방법, 사용 설비 및 물품에 대한 상세한 설명과 적절한 세척 및 유지 관리를 위해 필요한 설비의 분해와 조립 방법.
>
> (4) 이전 작업 배치 표시물의 제거 또는 말소.
>
> (5) 사용 전까지 깨끗한 설비가 오염되지 않도록 하기 위한 보호 조치.
>
> (6) 사용 직전에 설비의 청결도 검사.

□ 실험실 관리 메커니즘을 문서화하고 필수 실험실 관리 메커니즘으로부터의 편차를 기록하고 타당성을 증명해야 함(21 CFR 211.160(a)).

> 미국 Title 21 CFR Part 211
>
> Subpart I-시험 관리
>
> Sec. 211.160-일반사항
>
> (a) 모든 규격, 표준, 검체 채취 방법, 시험 절차 또는 이 서브파트에서 요구되는 기타 시험 관리 메커니즘의 변경을 포함하여 이들 규격, 표준, 검체 채취 방법, 시험 절차 또는 기타 시험 관리 메커니즘을 적절한 조직 단위에서 초안을 작성하고 품질 관리 조직(QCU)의 검토와 승인을 받아야 한다. 이 서브파트의 기준을 준수하고 실행 시점에 문서화해야 한다. 문서화된 규격, 표준, 검체 채취 방법, 시험 절차 또는 기타 시험 관리 메커니즘에서 벗어나는 모든 일탈 사항을 기록하고 타당성을 증명해야 한다.

- FDA는 이 회사에게 의약품 GMP 전문 컨설턴트의 도움을 받을 것을 권고함
- FDA는 이 회사에게 즉시 시정할 것을 요구함. 이 문제를 신속하고 적절하게 해결하지 못하면 추가 통지 없이 압수(seizure), 명령(injunction) 등의 법적 조치를 취할 것이라고 경고함

※ 자료 : Verde Cosmetic Labs LLC, MARCH 30, 2022

https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/verde-cosmetic-labs-llc-622534-03302022

사례 4

- FDA는 어떤 회사가 부적합 의약품을 판매하고 있다는 것을 알게 되었음
- 회사는 제품을 OTC 손 소독제, 글리세린 함유 의약품, 이소프로필 알코올 함유 의약품을 판매하고 있었음
- 해당 회사는 품질관리부서의 책임 이행을 제대로 하고 있지 못함 (21 CFR 211.22)
- 각 의약품에 대한 적절한 실험을 진행하지 않음 (21 CFR 211.165(b))
- 생산 공정 관리를 위한 절차를 확립하지 않음 (21 CFR 211.100(a))
- 장비 청소 및 유지보수 절차를 준수하지 않음 (21 CFR 211.67(a) 및 (b)). 특히 다른 제품의 생산에 동일한 장비를 사용할 시 생길 수 있는 오염 방지를 위한 청소 프로세스의 검증을 실시하지 않음.
- 제품 출하 전 미생물 오염 테스트를 시행하지 않음
- 연간 제품 품질 검토를 실시하지 않음.
- 위와 같은 사항들을 봤을 때, 제품의 품질, 안전성, 효능을 보장할 수 없다고 판단하고 CGMP규정을 위반하고 있다고 판단함
- 이에 FDA는 15일 이내에 위반 사항에 대한 시정 조치 계획 제출을 요구하였음
- 추가적으로 CGMP 컨설턴트의 고용을 권고함
- 위와 같은 사항들이 시정되지 않을 경우 추가 통지 없이 법적 조치, 압류, 금지 명령 등이 있을 수 있음을 경고함
- 또한 수출 인증서 발급이 보류될 수 있고 시정조치 확인을 위한 재검사가 있을 수 있음을

경고함

※ 자료 : Art of Beauty Company, Inc. MAY 22, 2024

https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/art-beauty-company-inc-674144-05222024

사례 5

- FDA는 어떤 회사가 부적합 의약품을 판매하고 있다는 것을 알게 되었음
- 회사는 선크림, 진통제, 여드름 치료제 등의 OTC제품을 판매하고 있었음
- 해당 제품은 출하 전 미생물 검사에 대한 결과가 없고, 적절한 안정성 프로그램을 확립하고 있지 않아 품질관리에 문제가 있다고 판단함
- 각 제품별로 진통제 제품에 대한 공정 검증 프로토콜 부재, 일부 선크림 제품에 대해 공정 검증 문서 검토 및 서명 누락 등의 문제가 발견되었음
- 장비 청소와 유지 보수에 대한 적절한 절차가 부족하다 판단함.
- 정제수 시스템의 샘플링, 압력 게이지 모니터링 기록 누락 등 실험실 관리 메커니즘을 준수하지 않음.
- 이에 FDA는 15일 이내에 위반 사항에 대한 시정 조치 계획을 제출할 것을 요구함
- CGMP 컨설턴트의 고용을 강력하게 권고함
- 위와 같은 사항이 시정되지 않을 경우 법적 조치, 압류, 금지 명령 등의 조치와 계약 체결 시 불이익이 있을 수 있음을 경고함
- 또한 수출 인증서의 발급이 보류될 수 있고 시정 조치 확인을 위한 재검사가 있을 수 있음을 언급함

※ 자료 : Verde Cosmetic Labs LLC MARCH 30, 2022

https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/verde-cosmetic-labs-llc-622534-03302022

사례 6

- 회사는 제품을 여드름 치료, 주름 제거, 피부 미백, 피부 톤 개선을 가진 제품이라고 광고 및 판매하고 있었음
- 해당 제품은 다음과 같은 문제를 가지고 있었음
- 안정성 시험 절차 미준수
- 원료 공급업체 신뢰성 검증 미실시
- 변경 관리 절차 미준수
- 정제수 시스템의 미생물 오염 관리 부족
- 청소 검증 프로그램 부적절
- FDA는 15일 이내에 위반 사항에 대한 시정 조치 계획 제출을 요구함
- FDA는 CGMP 컨설턴트 고용을 권고함
- FDA는 시정되지 않을 경우 추가 통지 없이 법적 조치, 압류, 금지 명령이 있을 수 있음을 경고함
- FDA는 위반 사항 해결되지 않을 경우 수출 인증서 요청 승인 보류 및 신약 신청 또는 보충 자료의 승인이 보류될 수 있음을 경고함

※ 자료 : Cosmetic Solutions, LLC MAY 31, 2024

https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/cosmetic-solutions-llc-670486-05312024