



FDA's views on cosmetics vs. drugs

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173rd Expert Panel Meeting, Cosmetic Ingredient Review (CIR)
June 9, 2025

Outline

- **Who am I and why am I here?**
- **Definitions**
- **How to establish a product's intended use**
- **Examples of cosmetics from real life**
- **Examples of unapproved drug claims from recent warning letters**
- **Questions and discussion**

Outline

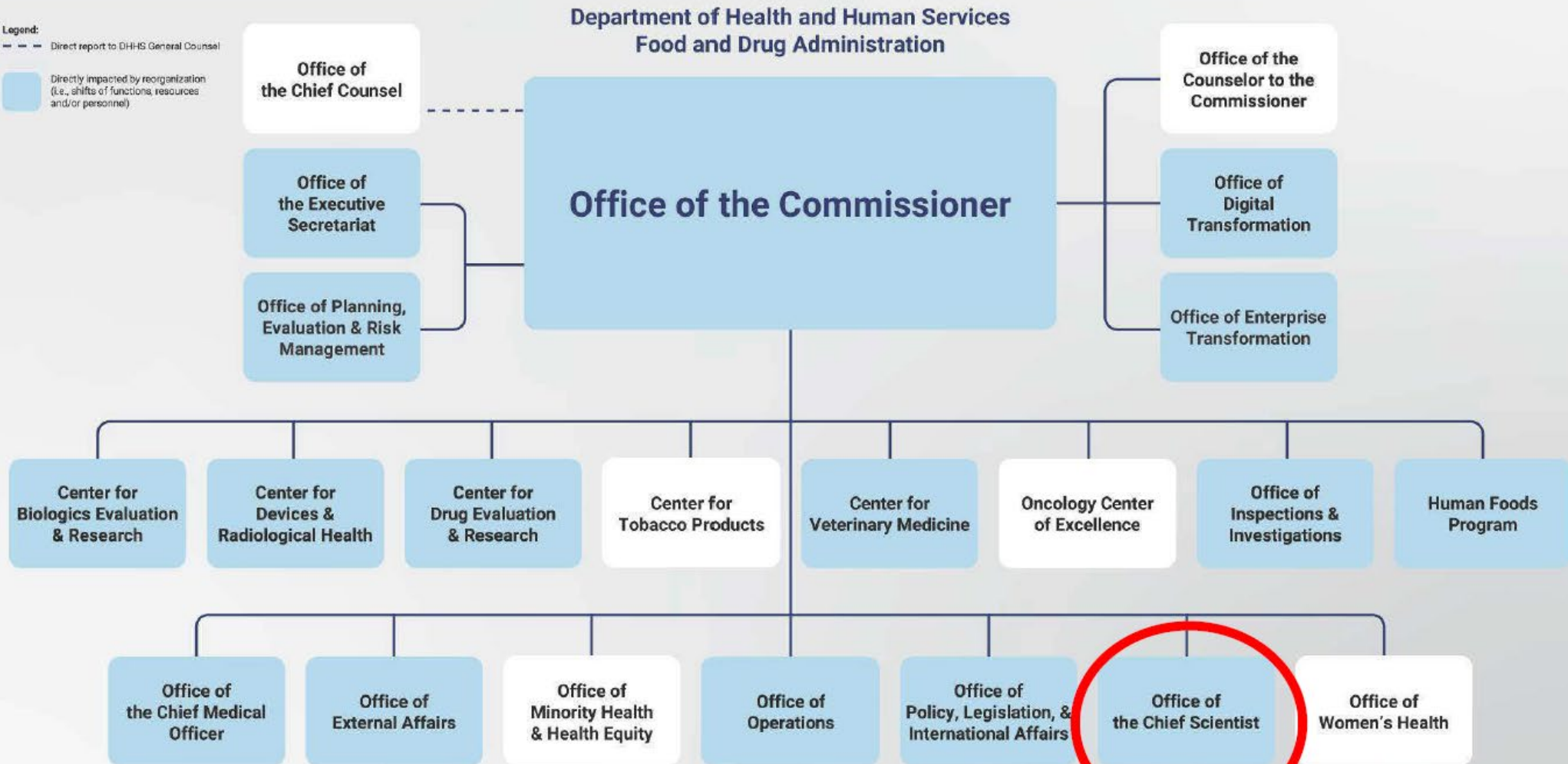
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Organizational Structure

Legend:

--- Direct report to DHHS General Counsel

Directly impacted by reorganization (i.e., shifts of functions, resources and/or personnel)



†The elements of the reorganization are the same as those proposed in December 2023.

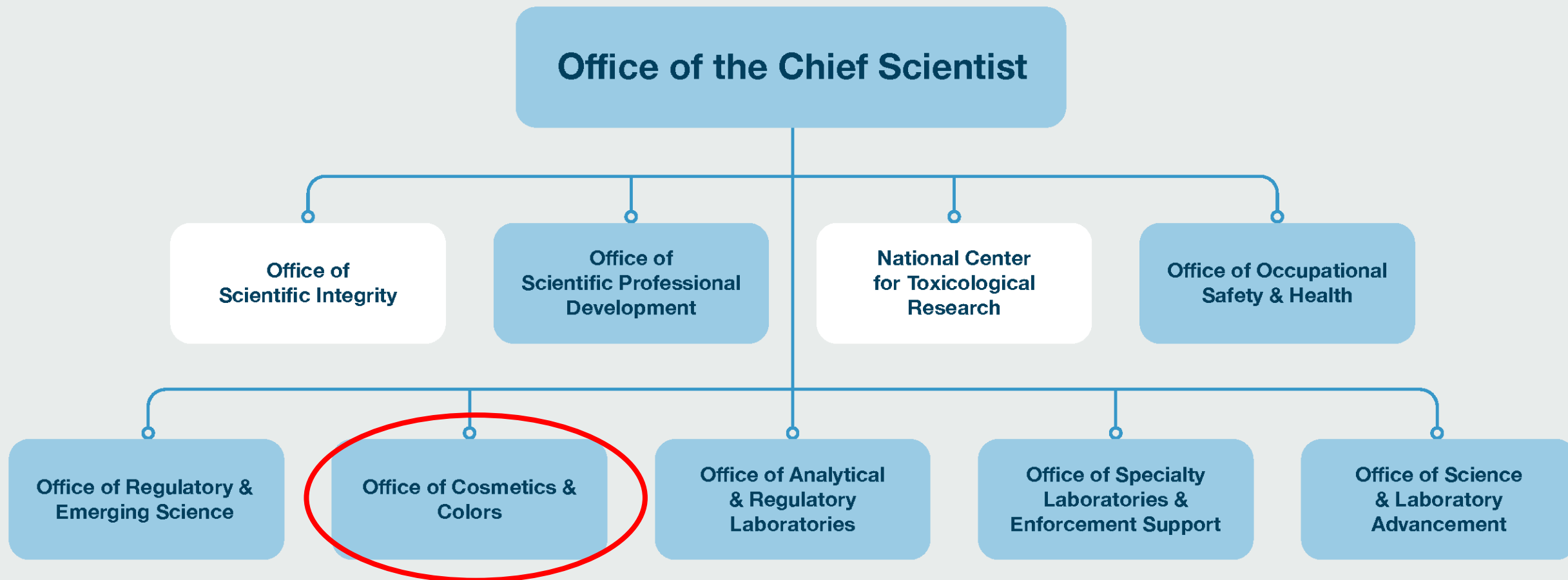
‡The changes reflected here will be implemented when all required reorganization steps have been met.

Effective Oct. 1, 2024

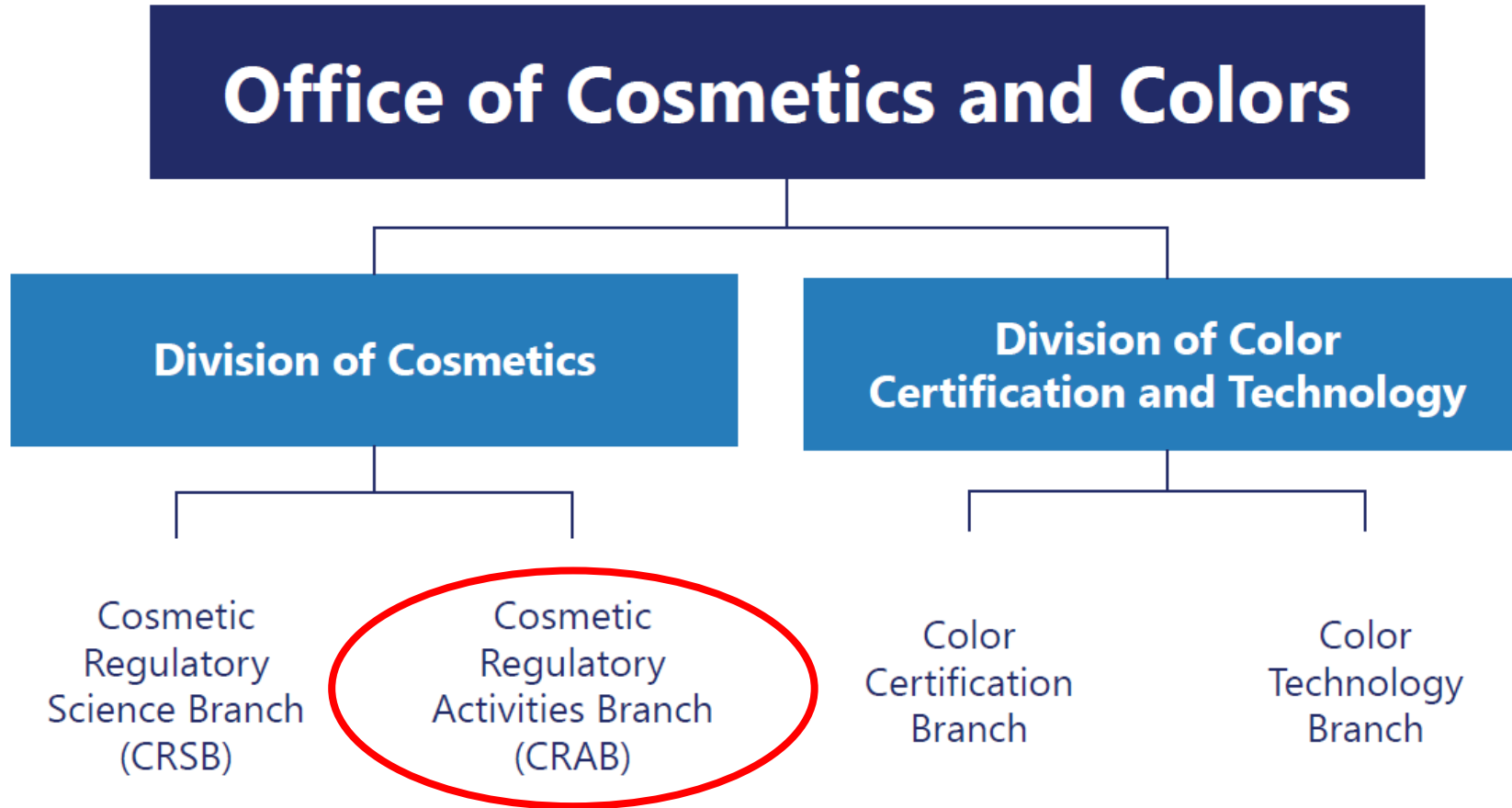
Legend:

Directly impacted by reorganization that took effect on Oct. 1, 2024 (i.e., shifts of functions, resources and/or personnel)

Department of Health And Human Services
Food and Drug Administration
Office of the Chief Scientist



Organizational Structure



Based in the Office of the Chief Scientist as of October 1, 2024

Outline

- Who am I and why am I here?
- **Definitions**
 - **What is a cosmetic?**
 - **And what is soap?**
 - **What is a drug?**
- How to establish a product's intended use
- Examples of cosmetics from real life
- Examples of unapproved drug claims from recent warning letters
- Questions and discussion

What is a cosmetic?

Section 201(i) of the Federal Food, Drug & Cosmetic Act (21 U.S.C. 321)

- The term “cosmetic” means
 - (1) articles intended to be rubbed, poured, sprinkled, or sprayed on, introduced into, or otherwise applied to the human body or any part thereof for cleansing, beautifying, promoting attractiveness, or altering the appearance, and
 - (2) articles intended for use as a component of any such articles;
- except that such term shall not include soap.



And what is soap?

21 CFR 701.20

- In administering the act, the Food and Drug Administration interprets the term “soap” to apply only to articles that meet the following conditions:
 - (1) The bulk of the nonvolatile matter in the product consists of an alkali salt of fatty acids and the detergent properties of the article are due to the alkali-fatty acid compounds; and
 - (2) The product is labeled, sold, and represented only as soap.



What is a drug?

Section 201(g)(1) of the Federal Food, Drug & Cosmetic Act (21 U.S.C. 321)

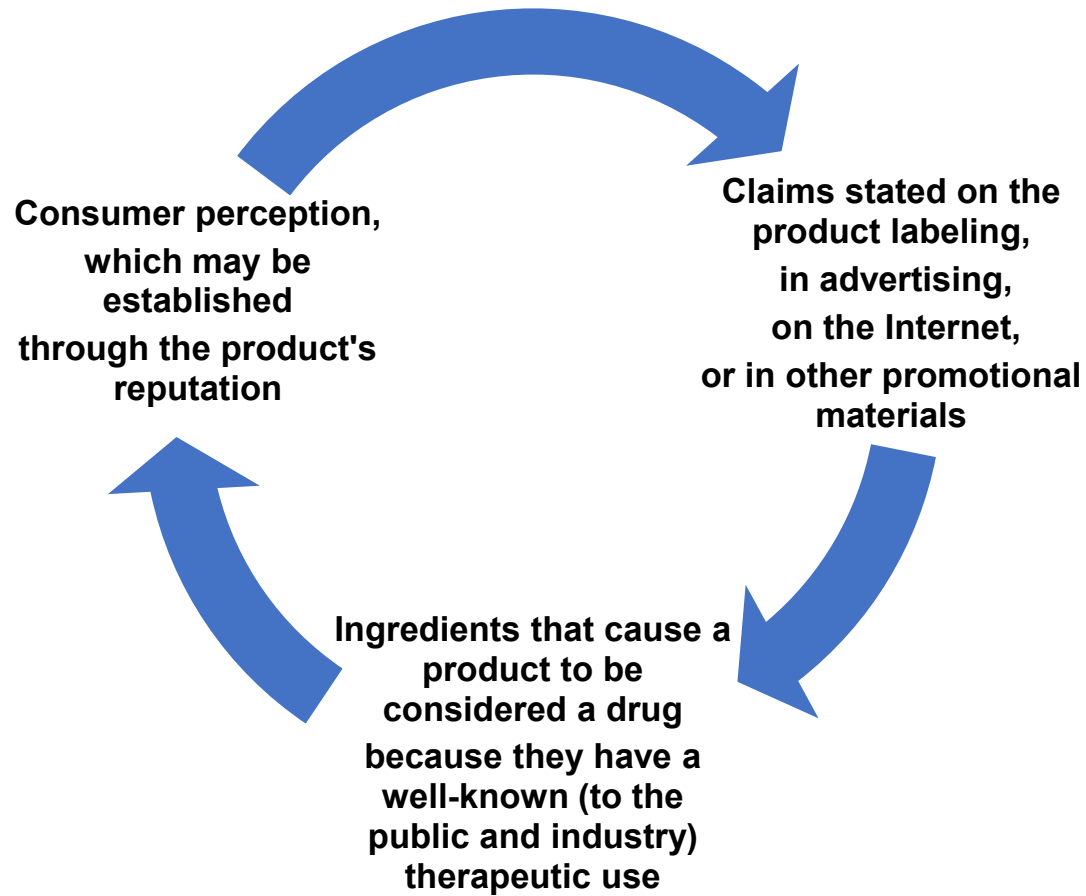
- The term “drug” means...
 - (B) articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals; and
 - (C) articles (other than food) intended to affect the structure or any function of the body of man or other animals...



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How is a Product's Intended Use Established?



Is It a Cosmetic, a Drug, or Both? (Or Is It Soap?)

Cosmetics Laws & Regulations

Key Legal Concepts for Cosmetics Industry: Interstate Commerce, Adulterated, and Misbranded

Regulations Related to Cosmetics from Title 21 of the Code of Federal Regulations (21 CFR)

Prohibited & Restricted Ingredients in Cosmetics

[Cosmetics & U.S. Law](#)

[En Español \(Spanish\)](#)

[Français \(French\)](#)

[한국어 \(Korean\)](#)

[中文 \(Simplified Chinese\)](#)

[英語 \(Traditional Chinese\)](#)

NOTE on antibacterial soaps: For the latest information, see [FDA issues final rule on safety and effectiveness of antibacterial soaps](#).

Whether a product is a cosmetic or a drug under the law is determined by a product's intended use. Different laws and regulations apply to each type of product. Firms sometimes violate the law by marketing a cosmetic with a drug claim or by marketing a drug as if it were a cosmetic, without adhering to requirements for drugs.

- [How does the law define a cosmetic?](#)

Content current as of:

09/11/2024

Regulated Product(s)

Cosmetics

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Warning Letters

- Warning Letters
- About Warning and Close-Out Letters

Content current as of:
05/12/2025

[Learn about the types of warning letters on FDA's website.](#)

- Matters described in FDA warning letters may have been subject to subsequent interaction between FDA and the letter recipient that may have changed the regulatory status of issues discussed in the letter.
- To obtain additional available information, contact FDA. Requests to FDA for agency records should be sent to: Food and Drug Administration Division of Freedom of Information (HFI-35), 5630 Fishers Lane, Rockville, MD 20857. Instructions for how to submit an FOI request can be found at [How to Make a FOIA Request](#).

Search

Filter by ^

Issuing Office

Letter Issue Date **Letters with Response or Closeout**

- Any - - Any -

Posted Date **Year**

- Any - - Any -

Clear Filters

Showing 1 to 10 of 3,326 entries

Export Excel Show 10 entries

Letter

Examples of drug claims

- “[M]olluscum away healing ointment for inflamed skin”
- customer review: “My 3 year old daughter’s pediatrician said there was nothing we could do for her molluscum. . . . the Molloscum [sic] Away ointment cleared it up right away! Within a couple of weeks there was hardly any more bumps left! I was skeptical that it was going to work but was amazed at the results!”
- “#MolluscumAway healing ointment . . . relieving skin irritation & soothe #MolluscumContagiosum symptoms!”
- “Treat your little one’s skin with our #MolluscumAway healing ointment . . . help with #MolluscumContagiosum”
- “Our healing ointment is amazing for helping #MolluscumContagious bumps.”



Examples of drug claims

- **“How does Zinc Oxide work in terms of UV protection?...Zinc Oxide is an excellent sunscreen because it has the broadest UV protective spectrum and cannot be absorbed into your blood... effectively providing a layer of armor against damaging UV rays ...“Try our zinc oxide Sunscreens!”**
- **“Customers Say...I have a tendency to not use any kind of UV protection at all...I've used the body wash particularly... on my head for about 2 weeks and have noticed a definite increase in UV protection when I'm under the sun...My head has not been burned once this year.”** [from the Customers Say section at the bottom of the product page]
- **“Body Wash UV...I've been using Body Wash UV every day in the shower for about three weeks...I had about 3 hours of direct sun exposure, which was definitely in burn area ... I couldn't believe it. I was like – how did I not get burned? Then it hit me – Body Wash UV! I use it everyday... The fact that it protects me from getting roasted when I don't put sun block lotion on is awesome.** [from the Testimonial page on your website]



Examples of drug claims

- “Revitalizing TCA Skin Peel: Customize Your Strength from 15% to 100% - Target Wrinkles, Acne, and Imperfections . . .
 - TCA Skin Peel Kit Uses: Tattoo removal, warts, moles, skin tags, aging, scars”
 - Renew aging skin with our DIY at-home skin peel...
 - Reduce fine lines and wrinkles
 - Stimulate collagen production
 - Reveal softer, more youthful skin
 - Visibly fade freckles, scars, and hyperpigmentation”
- “START REBUILDING YOUR COLLAGEN TODAY WITH A TCA PEEL!”
 - **“TCA & GLYCOLIC PEEL INDICATIONS: . . .**
 - Fine lines, Wrinkles, Crepey Skin
 - Stimulates Collagen & Elastin
 - Hyper-pigmentation / Age Spots / Sun Damage
 - Enlarged Pores, Acne Scars & Stretch Marks
 - Lightens & Brightens
 - Actinic Keratosis
 - Fades Tattoos
 - Skin Tags”
- “Versatile Glycolic Acid Peel Range 25%-70% - Professional Formula for Age-Defying Skin . . . removes the outer layer of the epidermis and dermis. Professionally formulated to reduce wrinkles, fine lines, crepey skin, acne, large pores, age spots and hyper-pigmentation. It dramatically reverses the visible signs of aging.”



Examples of drug claims

- “Colloidal Silver is an all natural anti-bacterial, anti-viral and anti-fungal solution that is a safer alternative to antibiotics and will not cause future bacterial resistance. Colloidal Silver had been used in medicine as an antiseptic for centuries and as a cure-all anti-microbial for everything from tuberculosis, herpes, staph and yeast infections.”
- “Our 500 ppm Colloidal Silver Eye Drops are the highest potency available eye drop for ocular infections. Research suggests it works by attaching to proteins on the cell walls of microorganisms, damaging their cell membranes Can also be used to control sinus infections.”
- “MSM Eye Drops are a natural anti-inflammatory and an alternative to steroid drops (which can elevate intraocular pressure.)”
- “When MSM (a sulfur-based compound) is applied into the eye, the antioxidant sulfur plus vitamin C aids in pushing out metabolicwaste [sic] away from ocular tissues of the cornea, intraocular lens and the retina to minimize free radical damage.”
- “[A]pply MSM eye drops topically [and] these nutrients will be able to go the extra mile because of the improved cellular permeability. The retina has one of the highest metabolic needs in the body, and the macula actually has the highest metabolic need of the retina. In Macular Degeneration, there is a nutrient starvation going on in the macula.”
- “For Ocular Repair”
- “Naturally improve dry-eye symptoms by reducing tear evaporation, encouraging lipid production, and adding a protective layer of fatty acids over the eyes to lock in moisture.”
- “These drops have the highest lipid concentration indicated for dry, itchy or irritated eyes, cataracts, allergy symptoms, and post lasik [sic] surgery. The drops contains [sic] a range of powerful fatty acids and other antioxidants that can benefit your eyes, with additional antibacterial, antifungal and antiviral support.”



Examples of drug claims

- “Lighten & Brighten Dark Your Eye Color, Speed Up the Eye Color Changing Process.”
- Customer review : “I’ve had brown eyes for years, and they were blue when I was born! Now, after 5 months, I bought it hoping for green eyes and it works well. It has changed my eyes, and now having green eyes is what I’m most excited about.”
- “Our Eye Color treatments harness the natural properties of plants that work in tandem with proven science to promote clean and gentle color changing process.”
- “We are committed to creating thoughtful, modern Color Changing treatments that serve to empower and embrace natural beauty.”
- “Our...products work by inhibiting the production of Melanin, other pigmentation, and Tyrosinase. But that's not all, our products go beyond this, working at cellular level to Inhibit the enzymes and underlying mechanisms responsible for producing and stimulating pigment-producing cells, [g]iving you a new eye color based on new lower levels of pigmentation.”
- “By inhibiting the expression of Melanin and other pigmentation, you increase the color expression of lighter tones, (such as blues, greens, hazels, and light honey shades) and the overall lightness of your eyes.”



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Questions



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240-402-1324

Extra Slides

What is a cosmetic product?

Section 604(2) of the Federal Food, Drug & Cosmetic Act (21 U.S.C. 321)

- The term “cosmetic product” means a preparation of cosmetic ingredients with a qualitatively and quantitatively set composition for use in a finished product.



Examples of drug claims

- “Scalp Sunscreen...Our Zinc Shampoo provides your hair and skin with daily UVA/UVB/UVC protection, creating a barrier against the sun's harsh rays...”
- Embrace the Waxhead Experience... Boosts daily UVA/UVB/UVC protection: Safeguard your face, skin, and hair from incidental sun exposure.”
- “Waxhead Zinc Body Wash and Shampoo is the game-changer you've been waiting for...With our innovative scalp sunscreen and zinc body wash combination, you can effortlessly protect your skin from the sun's harmful rays without the need for sunscreen lotions...”
- “Added Layer of UV Protection... Our Zinc Body Wash and Shampoo boosts UV protection for the face, skin, and hair and helps protect areas difficult to cover with sunscreen, such as the scalp and ears.”



Examples of drug claims

- “[T]reating skin problems like blemishes...and acne”
- “[C]ontrol acne”
- “Comfrey Root Powder [an ingredient in the product] (restructuring and pain relief from acne or cystic acne)”



Examples of drug claims

- “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...”



Examples of drug claims

- “Gently Nourishing Molluscum Away Body Wash”
- customer review by Asya L: “I bought this for my daughter. We have been dealing with these bumps for more than 6 months. This body wash and the patches cleared her skin in less than 3 weeks!! This works!”

