Is This a Cosmetic or a Drug?

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Disclaimer

The opinions and conclusions expressed in this article are solely the views of the author(s) and do not necessarily reflect those of the Food and Drug Administration

Outline

- Introduction
- Regulation of Cosmetics and Drugs
- Labeling Claims
- Warning Letters

Cosmetics – Scope

- Used by most consumers every day
- Examples:
  - Moisturizers, other skin preparations
  - Hair care, hair dyes, hair straighteners
  - Makeup, nail polishes
  - Shaving preparations
  - Perfumes and colognes
  - Toothpastes, mouthwashes
  - Face and body cleansers, deodorants

- Multi-billion dollar industry
- Increasingly global industry

Cosmetics - Challenges

- Limited legal authorities
- Competing agency priorities

- Significant changes in past 5-10 years
  - Manufacturing more global
  - Alternatives to animal testing
  - Increasingly sophisticated technology and complex ingredients
    - Nanotechnology
    - “Active” ingredients
    - “Cosmeceuticals”
    - “Nutraceuticals”
    - Botanicals

What is a Cosmetic?

- Defined in the Federal Food, Drug, and Cosmetic Act (FD&C Act), Section 201 (i)

- Articles intended for:
  - Cleansing
  - Beautifying
  - Promoting attractiveness
  - Altering the appearance

** **Excludes "Soap" (alkali salt of fatty acid-CPSC)**

What is a Drug?

- Defined in FD&C Act, Section 201 (g)

- Articles intended
  - For use in the diagnosis, cure, mitigation, treatment, or prevention of disease
  - To affect the structure or any function of the body of man or other animals

OTC Drug vs. Cosmetic

- **OTC Drug**
  - Monograph or product-specific pre-market approval required
  - Pre-market evaluation of safety & efficacy
  - GMP regulations
  - Establishments & products must be registered
  - Serious adverse events must be reported
- **Cosmetic**
  - Pre-market approval not required
  - No pre-market clearance of safety or efficacy
  - GMP guidelines only (voluntary)
  - Establishments & products not required to be registered
  - Adverse events not required to be reported

Cosmetics – FDA's Authority

- Cosmetics must not be adulterated or misbranded
- The law does NOT provide for FDA pre-market approval
- FDA's authority is post-market only

Prohibited Under FD&C Act

- **Adulterated Cosmetics**
  - Harmful or injurious under labeled or customary conditions of use
    - Formulation
    - Container
    - Contamination
  - Manufactured or held under “insanitary” conditions
  - Unapproved color additive
    - “Coal Tar Hair Dye Exemption” (Sec. 601(a))
- **Misbranded Cosmetics**
  - False or misleading labeling
  - Required information missing or presented improperly
  - Deceptive container
  - Doesn’t comply with 1970 Poison Prevention Packaging Act (Child resistant)

Am I a Drug, Cosmetic, or Both?

Labeling

Significance of Labeling

- The Federal Food, Drug, and Cosmetic Act (FD&C Act)
- The Fair Packaging and Labeling Act (FPLA)

Labeling plays an important role in the safety of cosmetics

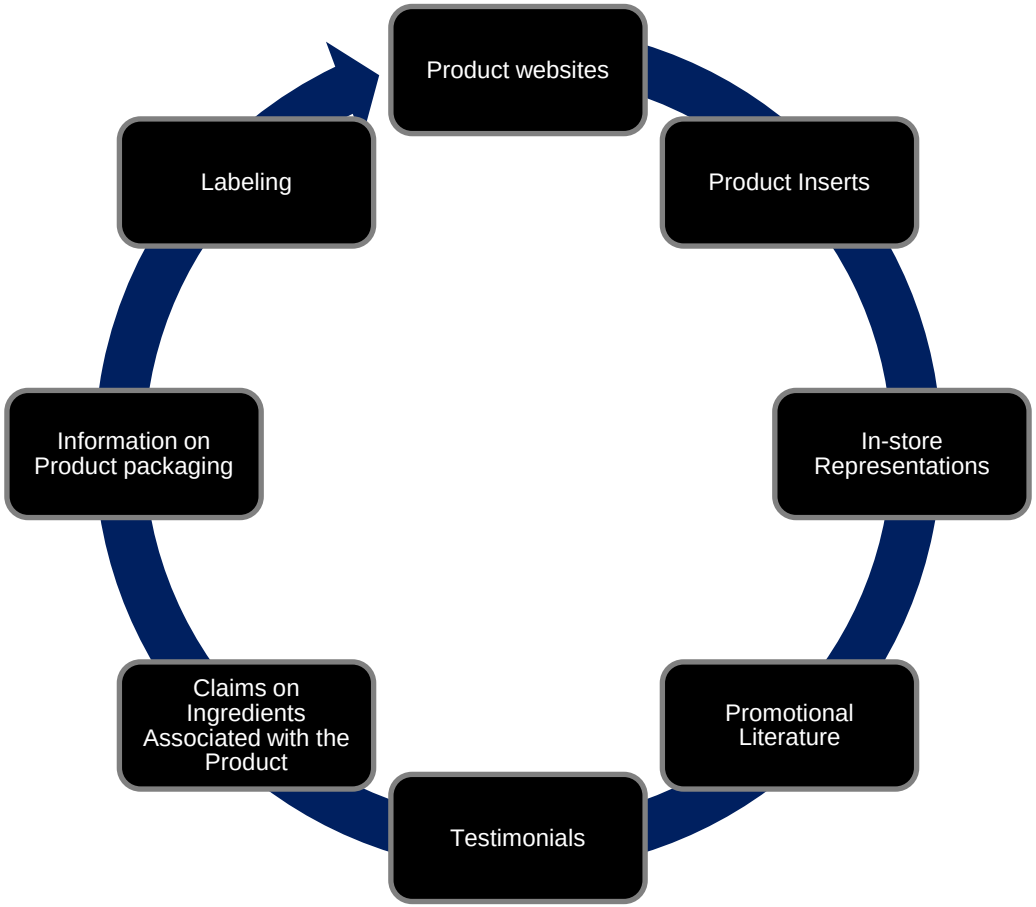
- To ensure proper use of product
- To allow consumers an opportunity to avoid ingredient that they may have known allergies
- To provide additional requirements for safe use such as “use in well ventilated area”
- To include warning statements to indicate a potential harm

Misbranded Cosmetic

- Improper packaging and labeling of color additives
- Labeling is false or misleading
- Package does not exhibit labeling information required by statute or regulation
- Required information is not conspicuousness or is illegible
- Misleading packaging - container is made or filled in a deceptive manner
- Improper packaging and labeling of color additives

What Constitutes Labeling?

FD&C Act Sec 201 (k) and (m)



Labeling Requirements

- Identity statement
- An accurate statement of the net quantity of contents
- Name and place of business
- Distributor statement
- Material facts
- Warning and caution statements
- Ingredient declaration

Cosmetic Claims

- FDA does not require pre-market clearance of cosmetic product claims
- FDA does not have a specific list of “acceptable” vs. “non-acceptable” cosmetic claims
- FDA evaluates cosmetic label claims in total context of all wording and images present in labels and collateral promotional literature (including print advertising and websites)

Cosmetic Label Review Check List

Principal Display Panel (PDP)

- Identity Statement
  - Indicates the intended use of the product.
    - May be expressed in terms of:
      - Common or usual name of the cosmetic
      - Descriptive name
      - Form of an illustration
- Net Contents
  - Weight is expressed in terms of avoirdupois pound and ounce.
  - Fluid measures are expressed in terms of the U.S. gallon, quart, pint and fluid ounce.
  - **Exceptions:** Cosmetics in packages containing less than 1/4 av. oz. or 1/8 fl. oz. are exempt, if affixed to a properly labeled display card or sold at retail in a properly labeled outer container

Information Panels

- Name and Place of Business
  - May be those of the manufacturer, packer or distributor.
    - If the name and address is not that of the manufacturer, the name must be preceded by phrases such as "Manufactured for ...", "Distributed by ...", or other appropriate wording
    - The name of the firm must be the corporate name, and the address may be that of the principal place of business.
    - The business address must include the street address, name of the city and state, and the ZIP code.
  - **Exceptions:** The street address may be omitted if the firm is listed in a current city or telephone directory.
  - The Tariff Act of 1930 requires that imported products state on the label the English Name of the country of origin.
- Ingredient Declaration
  - Declared in descending order of predominance.
  - Identified by the names established or adopted by regulation
  - Color additives are approved for use and certified, if required.
  - **Exceptions:** Free samples and cosmetics not customarily distributed for retail sale, e.g., cosmetics “For professional use only” are exempt from this requirement provided these products are not also sold to consumers.
- Directions for safe use
- Warning Statements

Warning Statements

- Required whenever necessary or appropriate to prevent a health hazard that may be associated with a product
- The warning statement must appear on both the inner and outer container labels
- Specific warning statements established by regulation that exist for a particular class of cosmetic products

Required Warning Statements

- Warning statements are required for the following cosmetics:
  - Cosmetics in self-pressurized containers (740.11)
  - Feminine deodorant sprays (740.12)
  - Foaming detergent bath products (740.17)
  - Sun tanning preparations (740.19) (those not containing a sunscreen ingredient)

Color Additives in Cosmetics

Color additives are primary ingredients in cosmetics

- To beautify the body
  - Lipsticks, eye shadows, mascaras, blushers
- To enhance the marketability of products
  - Shampoos, bath oils, skin fresheners
- To mask the colors of other ingredients in products
  - Lotions, creams

Color Additive Regulations

- Permitted color additives
  - 21 CFR Part 73
    - Listed under their common names
    - Exempt from certification
  - 21 CFR Part 74
    - “FD&C,” “D&C,” and “Ext. D&C” straight colors and a few lakes
    - Required to be batch certified
  - 21 CFR Part 82
    - Most “FD&C” and “D&C” color additive lakes
    - Required to be batch certified
- Most other color additive requirements
  - 21 CFR Parts 70, 71, 80, and 81

Labeling Requirements for Color Additives

- Color additives must be declared
  - *Either* by the names listed in 21 CFR Parts 73, 74, and 82
  - *Or* by their abbreviated names
  - *Examples:*
    - D&C Red No. 7 or Red 7
    - Ext. D&C Violet No. 2 or Ext. Violet 2
    - D&C Yellow No. 10 Lake or Yellow 10 Lake
    - Carmine, mica, manganese violet, ultramarines

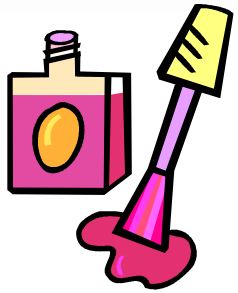
- Alternative names may be declared in parentheses
  - Colour Index or (C.I.) numbers, E numbers
  - *Example:*
    - FD&C Yellow No. 5 (C.I. 19140)

Color Additive Violations

- Adulteration
  - Uncertified material used in products
  - Non-permitted color additives used in products
- Misbranding
  - Color additives not declared by their listed names

"May Contain"

21 CFR 701.3(g)(1)



- Phrase is only permitted for use with color additives for products that may have the same formulation with several different shades. Ex. lipsticks and eye shadows.
- Not to be used to list all the color additives that comprise all batches
- Listed after the declaration of other color additives that are always present in each batch

Coal-tar Hair Dyes

- Synthetic organic dyes used for coloring the hair on the scalp
  - Not required to be listed as color additives
  - May not be used to dye the eyelashes or eyebrows
- Coal-tar hair dye package must contain
  - Caution statement about possible skin irritation
  - Directions for a preliminary patch test
  - See Chapter VI of the Federal Food, Drug, and Cosmetic Act
- Inorganic pigments and botanical extracts must be listed for use in hair dyes (Lead acetate, bismuth citrate, henna)
- Hair dyes include temporary coloring hairsprays

Required Labeling for Cochineal Extract and Carmine

- Both originate from *Coccus cacti L.*
  - Only carmine is permitted in cosmetics
- Must be declared on all FDA-regulated products
  - Both are possible allergens/sensitizers
- Final rule for labeling published on January 5, 2009
  - Effective date: January 5, 2011
  - Manufacturers were given two years for compliance with the final rule

Important Color Additive Requirements

- Only approved and listed color additives may be used in food, drugs, cosmetics, and medical devices marketed in the U.S. including purity requirements
- Color additives must be used appropriately
  - Manufacturers must consult the listing regulations
- Some color additives must be certified

Natural

- Not defined in the FD&C Act or in FDA regulations for cosmetics
- 'Natural' may be defined for other commodities
  - 'Minimal processing'
  - 'Natural', nature-identical, or nature-based (semi-synthetic)

Organic

- Not defined in the FD&C Act or in FDA regulations for cosmetics
- USDA regulations for “organic” do not supersede FDA labeling requirements.
- Organic defined by USDA for agricultural commodities and ingredients
  - National Organic Program (NOP), 7 CFR 205
  - ‘100% Organic’, ‘Organic’ , ‘Made with Organic Ingredients’

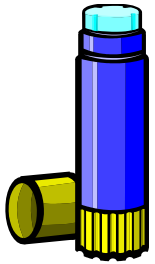
Cosmetic Labeling Claims
When do they cross the line?

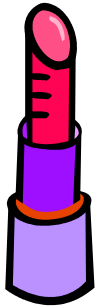
- Cosmetics marketed with drug claims are misbranded
- 6+ Warning Letters issued in autumn 2012 – generated strong industry and media response
- Another group of 16 WL's issued in 2015; still more to come

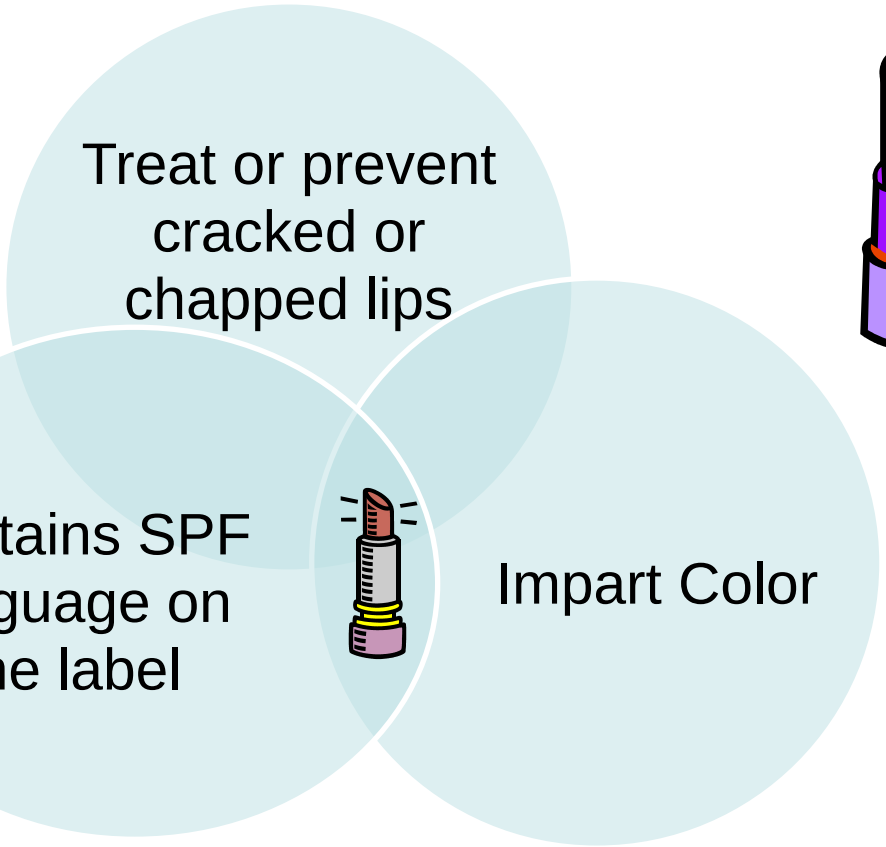
Examples of claims:

- Kills bacteria and reduces inflammation
- Prevents (or heals) scarring and stretch marks
- Stimulates the production of "youth proteins"
- Boosts the activity of genes
- Increases collagen production

Regulatory Category is Governed by "*Intended Use*"







OTC Products Inappropriately Marketed as Cosmetics

Skin Care

- Acne creams
- Topically Applied Hormones
- Wart Removers
- Muscle Cramps and Arthritis Creams

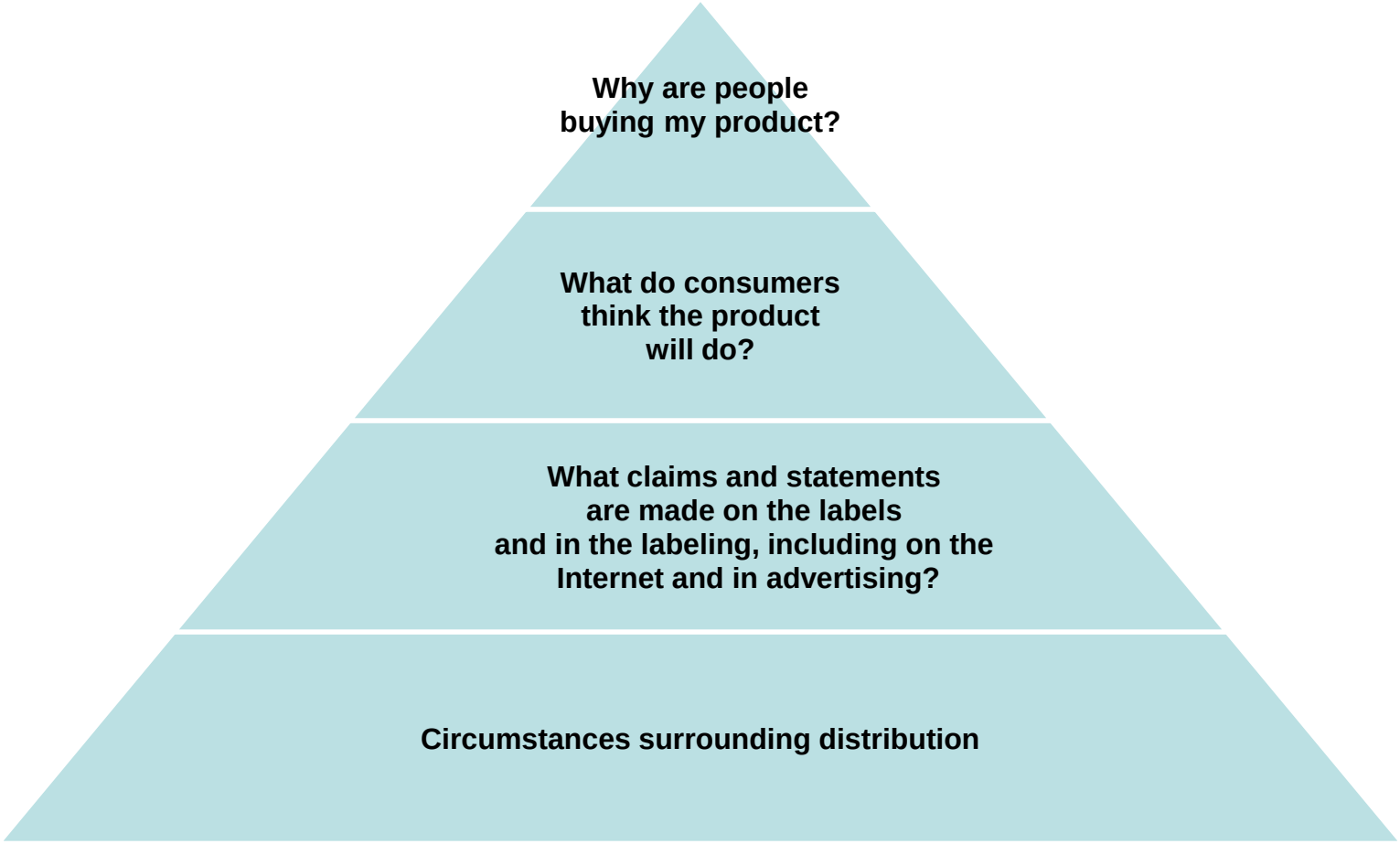
Personal Cleanliness

- Antibacterial Cleansers
- Antiperspirants
- Toothpaste & Mouthwashes containing fluoride
- Vaginal moisturizers
- Personal lubricants

Hair Preparations

- Lice Treatments
- Anti-dandruff
- Hair growth or loss products

Am I marketing a cosmetic, a drug or both?



Structure Claim

Function Claim

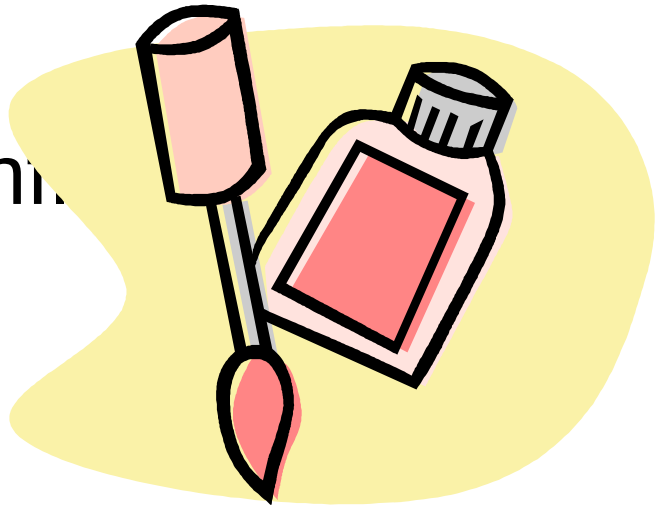
Prevention & Treatment Claim

Ease dry, flaking and cracking skin

by eliminating the int

of corns, calluses

and bunions.



Examples of claims that may go beyond intended cosmetic use

- "Stimulate growth…."
- "Anti-inflammatory…"
- "Treat or use on skin with Acne-eczema…"
- "Scar-wound treatment…"
- "Anti-bacterial/antiseptic…"
- "Treat or prevent Redness-sunburn…"
- "Anti-aging/anti-wrinkle…"
- "Skin bleaching/hyperpigmentation…"

Warning Letters

"[A]dvanced collagen boosters and botox alternatives that actually work"

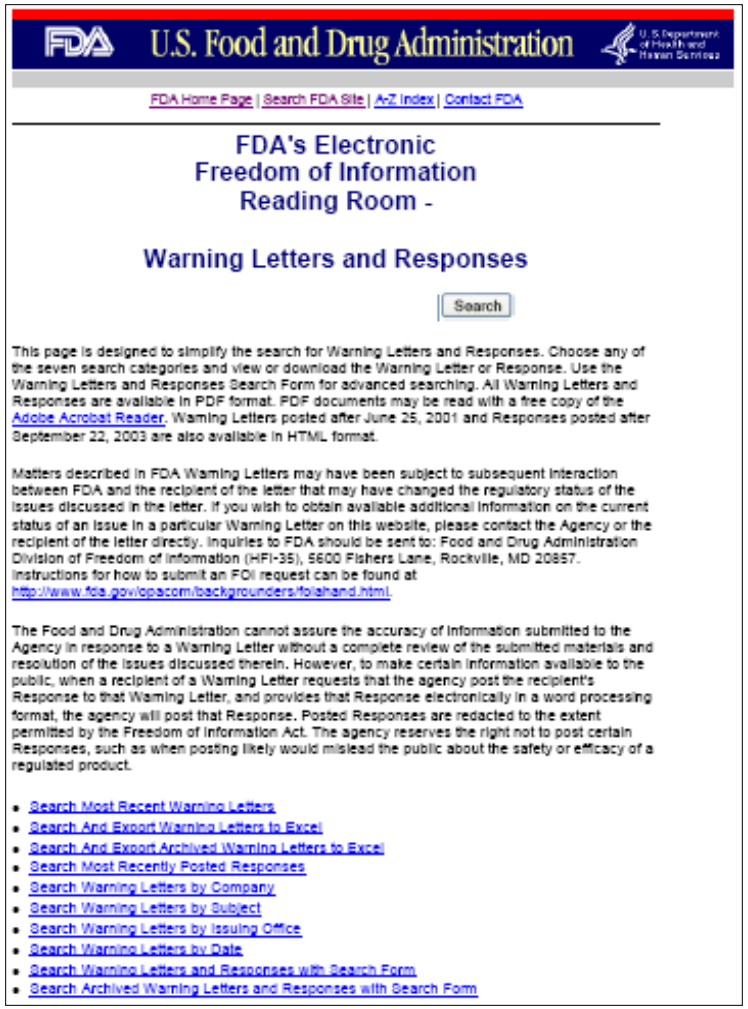
"Extensive new collagen production…"

"[H]elps breakdown fat deposits…"

"Treat it all—varicose veins, age spots… stretch marks, scars, bruises, rosacea and sun damage"

"[I]mprove the visible skin conditions associated with diabetes"

"[R]elieve the symptoms of psoriasis"



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Warning Letters and Responses

Search

This page is designed to simplify the search for Warning Letters and Responses. Choose any of the seven search categories and view or download the Warning Letter or Response. Use the Warning Letters and Responses Search Form for advanced searching. All Warning Letters and Responses are available in PDF format. PDF documents may be read with a free copy of the Adobe Acrobat Reader. Warning Letters posted after June 25, 2001 and Responses posted after September 22, 2003 are also available in HTML format.

Matters described in FDA Warning Letters may have been subject to subsequent interaction between FDA and the recipient of the letter that may have changed the regulatory status of the issues discussed in the letter. If you wish to obtain available additional information on the current status of an issue in a particular Warning Letter on this website, please contact the Agency or the recipient of the letter directly. Inquiries to FDA should be sent to: Food and Drug Administration Division of Freedom of Information (HFI-35), 5600 Fishers Lane, Rockville, MD 20857. Instructions for how to submit an FOI request can be found at http://www.fda.gov/opacom/backgrounders/foiahand.html.

The Food and Drug Administration cannot assure the accuracy of information submitted to the Agency in response to a Warning Letter without a complete review of the submitted materials and resolution of the issues discussed therein. However, to make certain information available to the public, when a recipient of a Warning Letter requests that the agency post the recipient's Response to that Warning Letter, and provides that Response electronically in a word processing format, the agency will post that Response. Posted Responses are redacted to the extent permitted by the Freedom of Information Act. The agency reserves the right not to post certain Responses, such as when posting likely would mislead the public about the safety or efficacy of a regulated product.

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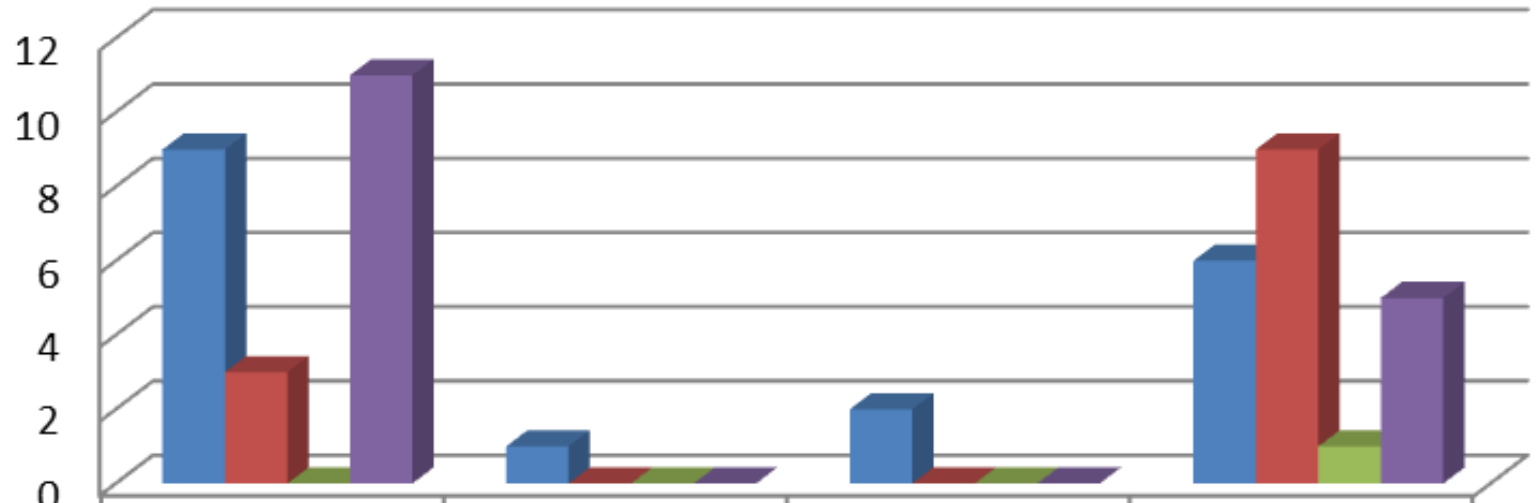
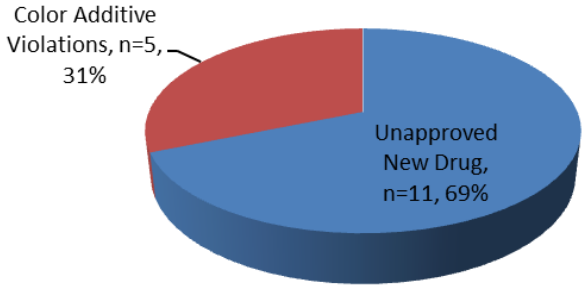
Warning Letters Issued by Year

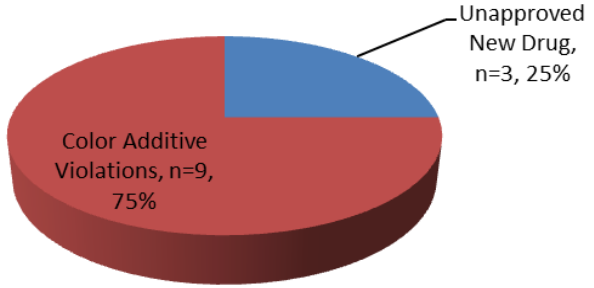


	Unapproved New Drug	Microbial Contamination	Misbranding	Color Additive Violations
2015	9	1	2	6
2014	3	0	0	9
2013	0	0	0	1
2012	11	0	0	5

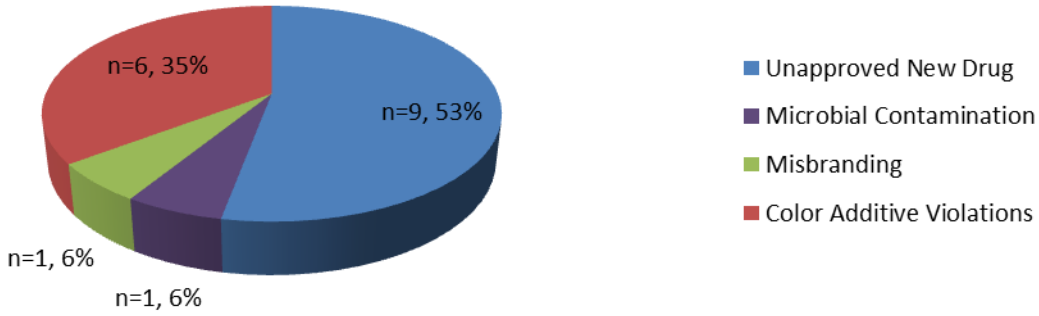
Warning Letters Issued in 2012 by Violation
Total=16



Warning Letters Issued in 2014 by Violation
Total=12



Warning Letters Issued in 2015 by Violation
Total=17



Regulatory Resources

- **CDER-CFSAN Cosmetic Agreement**

http://www.fda.gov/Cosmetics/GuidanceComplianceRegulatoryInformation/ComplianceEnforcement/ucm2005170.htm

- **Import Alert 66-41, “Detention Without Physical Examination of Unapproved New Drugs Promoted In The U.S.”**

http://www.accessdata.fda.gov/cms_ia/importalert_190.html

- **Import Alert 66-38, "Skin Care Products Labeled As Anti-Aging Creams"**

http://www.accessdata.fda.gov/cms_ia/importalert_188.html

- **Warning Letters Address Drug Claims Made for Products Marketed as Cosmetics**

http://www.fda.gov/Cosmetics/GuidanceComplianceRegulatoryInformation/ComplianceEnforcement/WarningLetters/ucm081086.htm

OTC Resources

Office of Compliance Over-the-Counter Drugs Branch:

- http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/EnforcementActivitiesbyFDA/ucm284122.htm
- Have a question? Submit to CDEROUDLCPMTRACK@CDER.FDA.GOV

Development and Regulation of OTC (Nonprescription) Drug Products:

- http://www.fda.gov/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/ucm209647.htm

Cosmetic Resources

- **Cosmetic Labeling and Label Claims**

http://www.fda.gov/Cosmetics/Labeling/Claims/UCM200520 0.htm

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

http://www.fda.gov/Cosmetics/GuidanceRegulation/LawsRegulations/ucm074201.htm

Resources

- **Cosmetic Labeling Manual**
  - Summary of Regulatory Requirements for Labeling of Cosmetics Marketed in the United States
  - Cosmetic Labeling Regulations as Published in Title 21, Code of Federal Regulations, Section 701, 740, and other Pertinent Sections
  - Cosmetic Labeling Guide

Color Additive Resources

Summary of Color Additives for Use in United States in Foods, Drugs, Cosmetics, and Medical Devices

http://www.fda.gov/ForIndustry/ColorAdditives/ColorAdditiveInventories/ucm115641.htm

Contact Information

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Thank You For Your Interest!
Questions?