

CHAPTER 29 - COLORS AND COSMETICS TECHNOLOGY

SUBJECT: COSMETICS PROGRAM; IMPORT AND DOMESTIC	IMPLEMENTATION DATE Upon Receipt
	COMPLETION DATE CONTINUING
DATA REPORTING	
PRODUCT CODES	PRODUCT/ASSIGNMENT CODES
INDUSTRY CODE : 53 USE APPROPRIATE PRODUCT CODES	29001 (for both domestic and import work)

FIELD REPORTING REQUIREMENTS

Note: To assist the reader in locating various topics in this document, please see Attachment A "Index".

1. Investigations Branches

a) Consumer adverse events or complaints, and trade complaints should be entered in FACTS. FDA Field Offices should handle cosmetic problems and emergencies on a case by case basis depending on the severity of the situation. However, since FACTS entries must be closed out before they can be downloaded into CFSAN's adverse event database, CAERS, there can be a significant length of time before FDA headquarters or the Office of Cosmetics and Colors might be informed of an unusual event. Therefore, in case of an unusual or high priority situation involving a cosmetic product, please contact the Office of Emergency Operations (OEO) at 301-796-8240 (24 hours) or email emergency.operations@fda.hhs.gov to report the situation (in addition to data entry into FACTS).

b) Within 30 days after completion of each inspection, electronically submit into CMS to HFS-608, CFSAN/OC/DE/Labeling and Dietary Supplement Branch, the following items:

- 1) a copy of the "Summary of Findings" for each inspection
- 2) a copy of the vendor/supplier list collected for each inspection.

2. Laboratory Branches

Report all analyses into the Field Accomplishment and Compliance Tracking System (FACTS) using the following Problem Area Flags (PAF) for the various types of analyses.

- | | |
|--------------------------|-------|
| Microbiological Analyses | - MIC |
| Toxic Elements | - ELE |
| Color Additive Analyses | - COL |

Food Economics and Standards (Label Reviews) - FDF
(Result Flag = FDL)

SPECIAL INSTRUCTIONS1. General

Do not collect surveillance samples. Only collect cosmetic samples under this program on a "for cause" compliance basis to document suspected adulteration or misbranding. The four areas for sample collection are as follows:

- o Collect product samples for color analysis and prohibited ingredients.
- o Collect samples of labeling to document suspect labeling violations.
- o Collect samples of eye area cosmetics, tattoo inks or skin care preparations and lotions for microbiological analysis when adequate challenge test documentation cannot be produced, the adequacy of preservation is in doubt or non-traditional preservative systems are used.
 - All samples under this program must be collected to support inspectional evidence or suspected product labeling violations
- o Collect samples of cosmetic products for screening of prohibited elements, as directed by CFSAN assignment.

Report only COSMETIC import label exams, inspections, sample collections under this program.

2. Domestic

Conduct routine surveillance inspections only at firms manufacturing or repacking eye area cosmetics, tattoo ink, skin care preparations and lotions, non-alcohol oral care products, and products intended for use by and on infants and children. These products present the greatest potential health hazard if they become contaminated with bacteria and fungi. However, once in the firm, conduct review of cosmetics according to instructions provided in Part III of this program.

3. Imports

In accordance with instructions provided in Part III of this program, import label examinations should emphasize four primary areas:

- review for compliance with mandatory labeling requirements, including, but not limited to, required warning statements;
- prohibited or restricted ingredients
- non-certified and non-permitted color additives; and
- Cosmetics containing bovine-derived tissues imported from BSE affected or at-risk countries.

PART I - BACKGROUND

Cosmetics are defined in section 201(i) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) as "(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." Soap meeting the criteria of 21 CFR 701.20(a)(1) and (a)(2) is excluded from the term "cosmetic" and is not subject to regulation under the FD&C Act.

Some products perceived by consumers to be cosmetics may also be drugs if, in addition to their cosmetic function, they are intended to cure, mitigate, treat or prevent disease, or to affect the structure or any function of the human body (see the definition of a "drug" in section 201(g) of the FD&C Act). For example, such products include anti-dandruff shampoos, toothpastes that contain fluoride, deodorants that are also antiperspirants, moisturizers, and lip balms and makeup marketed with sun-protection claims (including SPF values). Such products must comply with the requirements for both cosmetics and drugs.

In recent years there has been an increase in the number and type of cosmetic products sold annually, with a variety of new ingredients being introduced every year. The number of products targeting men's market has increased significantly. Likewise, the number of products marketed specifically for use by infants or children is following an upward trend.

The cosmetic industry is undergoing rapid technological changes, the manufacturing base becoming more global, and the ingredients ever more diverse. For some of these ingredients, there is little information available to substantiate safety. Ingredients, including nano-based chemicals, which may be subject to stringent drug and/or food pre-approval processes, are often incorrectly introduced into U.S. commerce through the cosmetic market due to its low regulatory barriers and may be cause a cosmetic to be adulterated if the safety of the ingredient has not been established.

Another change that the cosmetics industry is facing is consumer distaste for traditional preservatives. As an example, parabens, which are one of the most effective classes of preservatives, have been suspected of causing adverse effects to the endocrine system. In the European Union parabens are being phased out of all cosmetics because of this concern. As a result manufacturers are applying non-traditional preservative systems in order to assure the microbial safety of their products. FDA is concerned that cosmetic products that make a statement in labeling that the product is "green", "natural", "no parabens" and "no preservatives" may not be safe for consumers without appropriate safety testing. Companies and products that make such label statements should be given priority over traditionally manufactured cosmetics during inspection and sampling.

Adverse events have been associated with a variety of cosmetic products for several reasons including the following:

- color additive violations
- sensitivities to specific ingredients or the product formulation
- microbial contamination
- product misuse due to inadequate labeling

Surveillance of high risk cosmetics is a useful tool for identifying safety concerns related to a marketed product. Serious adverse events may warrant an inspection and/or sample collection. Examples of high risk cosmetic products that have been associated with serious adverse events include low- or no-alcohol mouthwash, eye area cosmetics, tattoo inks including permanent makeup, hair straighteners, and seasonal products (e.g. face paints and tanning products, which may be reported more frequently in the fall and summer seasons, respectively).

FDA has received reports from consumers, health care professionals, and salon experts that associate a loss of vision with the use of contaminated eye area cosmetics; rashes with the use of contaminated face paints; and local and systemic infections with the use of tattoo inks, all of which being contaminated with pathogenic microorganisms. FDA has also received reports of adverse events involving hair straightening products caused by product misuse due to inadequate labeling. Labeling may lack a clear statement of the intended use of the product, warning statements, and directions for safe use.

Some cosmetics are labeled as "professional use only" products, which require a trained and/or licensed professional to apply the cosmetic. Examples include hair straighteners and tattoos. Although FDA regulates cosmetic products, the facilities where these products are used, as well as the specific practices employed, are regulated by local and state authorities. FDA consults with the Occupational Safety and Health Administration (OSHA) and other regulatory agencies as appropriate.

PART II - IMPLEMENTATION1. Objectives

To ensure that imported and domestic cosmetics meet regulatory requirements through inspection, sample collection and analysis.

2. Program Management Instructions**Interaction with other compliance programs**

Include coverage of this program during inspections conducted under CDER's Drug Process Inspection Compliance Program when it is determined that the firm manufactures both cosmetics and drugs. Use the appropriate CFSAN and CDER Program Assignment Codes (PACS) when reporting time for these inspections.

Planning Instructions

Cover only cosmetics (see Part III, Section 1, for instructions in determining whether a product is a cosmetic, a drug, or a drug as well as a cosmetic).

Select firms for inspection in the following order of priority:

- a) Manufacturers who have recalled cosmetics because of microbial contamination during the previous 3-year period;
- b) Manufacturers of high-risk products that have had an OAI or VAI inspection within the previous 3-year period. High-risk products include:
 1. eye area cosmetics
 2. cosmetic non-alcohol oral care products
 3. wet wipes used by infants or children
 4. tattoo ink
 5. skin care preparations and lotions
- c) Firms that manufacture/repack high-risk products and firms that have serious Adverse Event reports or are manufacturers of recalled products. Refer to your district's cosmetic Official Establishment Inventory (OEI) to select these firms. To aid the districts in selecting firms, CFSAN will provide an inventory of firms that have been determined to be producing high-risk products. Use the firms provided on CFSAN's list to supplement OEI inspections.
- d) Any routine cosmetic surveillance inspection under this Compliance Program should be made only at firms' manufacturing or repacking locations.

PART III - INSPECTIONAL

A. General

The instructions in the program apply to *cosmetics only*. To determine if a product should be covered under this program, refer to its list of ingredients. The product should be covered as a cosmetic if no "active ingredient" is declared *and* there are no indications of intended drug use (i.e., labeling claims, promotional statements, etc.). If the product is determined to be a drug, it should not be covered under this program.

CDER and CFSAN have agreed to have concurrent jurisdiction, to assist FDA in implementing the cosmetic and drug provisions of the FD&C Act by clarifying program responsibilities in light of overlapping jurisdiction between CDER and CFSAN. Under this agreement, CDER and CFSAN have concurrent jurisdiction over a product which purports to be a cosmetic but meets the definition of drug. **Both CDER and CFSAN** may bring regulatory action relating to such product. CFSAN will not include drug charges in any such action without first notifying CDER of the charges that will be included. CDER will not include cosmetic charges in such an action without first obtaining CFSAN's concurrence.

In general, FDA does not have limits on elements allowed in cosmetics, with a few exceptions. When suspect cosmetics are identified, CFSAN/OCAC should be consulted prior to initiating further regulatory action, including sampling and testing.

B. Inspections

General guidelines for the areas to be covered during activities conducted under this program can be found in the document entitled "[Cosmetic Good Manufacturing Practice Guidelines](http://www.fda.gov/Cosmetics/GuidanceRegulation/GuidanceDocuments/ucm353046.htm)" (<http://www.fda.gov/Cosmetics/GuidanceRegulation/GuidanceDocuments/ucm353046.htm>). Items covered under this program include building and facilities, equipment, personnel, raw materials, production, laboratory controls, records labeling and complaints.

Note: Additional background information concerning topics related to cosmetics may also be found on the [FDA Cosmetic website](http://www.fda.gov/Cosmetics/default.htm) (<http://www.fda.gov/Cosmetics/default.htm>).

The following additional items should be covered during inspections of cosmetic manufacturers under this compliance program:

1. Cosmetics Making Drug Claims (DOMESTICS AND IMPORTS)

If product labels, packaging and inserts appear to make claims that would cause the product to be a drug, the labeling should be collected and submitted to the District Compliance Branch for evaluation. For general information on the differences between cosmetics and drug products, see "[Is It a Cosmetic, a Drug, or Both? \(Or Is It Soap?\)](#)." For

examples of Warning Letters sent to firms marketing cosmetics as drugs see [Warning Letters Address Drug Claims Made for Products Marketed as Cosmetics](http://www.fda.gov/Cosmetics/ComplianceEnforcement/WarningLetters/ucm081086.htm) (<http://www.fda.gov/Cosmetics/ComplianceEnforcement/WarningLetters/ucm081086.htm>).

General information on reviewing product labels for cosmetic products can be found at the [Summary of Labeling Requirements](http://www.fda.gov/Cosmetics/Labeling/Regulations/ucm126438.htm) website (<http://www.fda.gov/Cosmetics/Labeling/Regulations/ucm126438.htm>).

2. Prohibited/Restricted Ingredients (DOMESTICS AND IMPORTS)

By examination of labels for finished products and raw materials, determine whether any of the following *prohibited or restricted* ingredients are being used by the firm in the production of cosmetic products. Examination of batch records if provided, and other documents (e.g. product formulations, certificates of analysis), may also provide useful information. If these ingredients do not appear in any of the documents, query the firm directly.

Prohibited (Non-Permitted) Ingredients

- Bithionol (21 CFR 700.11)
- Halogenated Salicylanilides (21 CFR 700.15)
- Chloroform (21 CFR 700.18)
- Vinyl Chloride as an ingredient of aerosol products (21 CFR 700.14)
- Zirconium containing complexes in aerosol cosmetic products (21 CFR 700.16)
- Methylene chloride (21 CFR 700.19)
- Prohibited cattle material (21 CFR 700.27). See below for additional information.

Restricted Ingredients

- Hexachlorophene (21 CFR 250.250)
- Mercury Compounds (21 CFR 700.13)
- Sunscreen - must describe cosmetic benefit or be considered a drug (21 CFR 700.35(b))
- Chlorofluorocarbon Propellants (21 CFR 2.125)
 - o chlorofluorocarbon 11 (trichlorofluoromethane)
 - o chlorofluorocarbon 12 (dichloro-difluoromethane)
 - o chlorofluorocarbon 113 (trichlorotri-fluoroethane)
 - o chlorofluorocarbon 114 (dichlorotetra-fluoroethane)
 - o fluorocyclobutane C318 (octofluoro-cyclobutane).

Additional information on prohibited and restricted ingredients can be found on the [Prohibited & Restricted Ingredients](http://www.fda.gov/Cosmetics/GuidanceRegulation/LawsRegulations/ucm127406.htm) website: (<http://www.fda.gov/Cosmetics/GuidanceRegulation/LawsRegulations/ucm127406.htm>).

3. Prohibited Cattle Material(Coverage of Bovine Tissue and Tissue-Derived Ingredients for Bovine Spongiform Encephalopathy (BSE))

(DOMESTICS AND IMPORTS)

Bovine Spongiform Encephalopathy (BSE), commonly known as mad-cow disease, is a fatal disease in [cattle](#). The infectious agent has been linked to Cruetzfeldt-Jakob disease, a neurological disorder in humans. BSE is thought to be transmitted from infected cattle to humans via exposure to certain bovine tissues.

The cosmetic industry has historically been a user of bovine-derived raw materials. Human exposure to the infectious agent can occur through eye, mouth, or skin. Cosmetics containing infected bovine-derived materials may act as a vehicle capable of transmitting the infection to humans.

The agency has determined that certain raw materials from cattle are potentially highly infectious, and, if obtained from infected animals, may contain the BSE infectious agent. Cattle tissues prohibited from use in cosmetics are listed in 21 CFR 700.27, and include:

- The small intestine of all cattle except as provided in 21 CFR 700.27 (b) (2)
- material from non-ambulatory disabled cattle
- material from cattle not inspected and passed
- mechanically separated (MS) (Beef)
- "specified risk materials" identified in 21 CFR 700.27 (a) (5):
 - o brain
 - o skull
 - o eyes
 - o trigeminal ganglia
 - o spinal cord
 - o vertebral column (excluding the vertebrae of the tail, the transverse processes of the thoracic and lumbar vertebrae, and the wings of the sacrum)
 - o dorsal root ganglia of cattle 30 months and older
 - o tonsils and distal ileum of the small intestine of all cattle

Refer to 21 CFR 700.27 for more information, particularly for more information on the definition for cattle "inspected and passed" and a process for foreign countries to be exempted from provisions regarding prohibited cattle material.

A current listing of countries designated for exemption under paragraph (e) of 21 CFR 700.27 may be obtained from CFSAN OFS (Jeffrey Hamer (240)402-4188, or Jeffrey.Hamer@fda.hhs.gov).

BSE Record Keeping Requirements:

In accordance with 21 CFR 700.27(c), manufacturers and processors of a cosmetic that is manufactured from, processed with, or otherwise contains, material from cattle must establish and maintain records to demonstrate that the cosmetic is not manufactured from, processed with, or does not otherwise contain, prohibited cattle materials.

These records must be retained for 2 years at the manufacturing establishment or at a reasonably accessible location. Electronic records are acceptable if they are accessible from an onsite location.

These records must be available to FDA for inspection and copying.

Product labels and cosmetic raw materials, bulk cosmetic formulations, and finished cosmetic products and relevant records should be reviewed to determine if any of the products or ingredients contain prohibited cattle material.

If a firm manufacturing or importing cosmetic products or their ingredients uses any prohibited cattle material, document the following:

- The finished products containing the prohibited tissue
- The specific country of origin of the tissue
- The name and address of the importer or other responsible party.

The district compliance branch should consult with the CFSAN/OC/DE/Labeling and Dietary Supplements Compliance Branch (LDSCB) (HFS-608) for regulatory consideration.

Attachment B "Bovine Tissue and Tissue-Derived Ingredients, Materials with Suspected Risk of Infectivity" lists high-risk tissues to assist investigators in the identification of tissues and tissue-derived ingredients of concern. If a firm manufacturing or importing cosmetic products or their ingredients uses a tissue or tissue-derived ingredient listed in Attachment B but not otherwise listed as prohibited cattle material in 21 CFR 700.27, the FDA investigator should determine whether it has been exported from and/or originated from a BSE affected or at-risk country. If so, the investigator should contact CFSAN for further guidance.

A current list of BSE affected or at-risk countries can be found at: [USDA's Animal and Plant Health Inspection Service \(APHIS\) website](https://www.aphis.usda.gov/wps/portal/aphis/home/) (<https://www.aphis.usda.gov/wps/portal/aphis/home/>). Search "countries/regions affected by BSE."

Note: FDA labs do not conduct BSE analysis and thus no sampling guidance is issued for BSE. The basis for any regulatory action on a cosmetic product with respect to prohibited cattle material relies on review of records as described above, labeling and other documentation.

4. Adequacy of Preservation (DOMESTICS)

Numerous factors can influence a products susceptibility to microbial contamination. The choice of preservative system is important, along with other factors. In some instances, such as products dispensed from pressurized containers, there may be no need for added preservatives.

As appropriate, review the manufacturer's records and determine the identity and level of preservatives intended for each formulation. (See Attachment C "Preservation Systems for Cosmetics" for lists of common cosmetic preservatives, non-traditional preservatives and other considerations in evaluating a preservative system.) Verify that batch records indicate the addition of these preservatives to each formulation.

The susceptibility of a product to microbial contamination is often

determined through a microbial challenge test. This test involves inoculating the product with bacteria, molds, and yeast and determining the ability of the formulation to inhibit microbial growth. Ascertain if the manufacturer has conducted a challenge test on its formulations and ask for this documentation for verification. Ensure that the product challenged in this test actually reflects the ingredient composition of the formulation being produced at the facility. Note any inconsistencies between the product being manufactured and the product that was subjected to challenge testing. Since resistance to microbial contamination is especially important in the case of eye area products (especially those that are water-based), tattoo ink, skin lotions and no-alcohol mouthwash, collect samples of recently produced and retained products when the manufacturer is unable to produce challenge test documentation or the adequacy of preservation is otherwise in doubt [see *Section III on Import and Domestic sample collection*].

In order to determine adequacy of the testing criteria and results, when available, forward copies of challenge test results and criteria to the CFSAN/OCAC Microbiological Analytical Contact listed in the contacts section in PART VI.

5. Color Additives (DOMESTICS AND IMPORTS)

For an overview, see "[Color Additives and Cosmetics](http://www.fda.gov/ForIndustry/ColorAdditives/ColorAdditivesinSpecificProducts/InCosmetics/ucml10032.htm)" (<http://www.fda.gov/ForIndustry/ColorAdditives/ColorAdditivesinSpecificProducts/InCosmetics/ucml10032.htm>).

Color additives are subject to a strict system of approval under U.S. law [FD&C Act, sec. 721; 21 U.S.C. 379e]. Except in the case of coal-tar hair dyes, failure to meet U.S. color additive requirements causes a cosmetic to be adulterated [FD&C Act, sec. 601(e); 21 U.S. Code 361(e)]. Color additives used in cosmetics include both color additives exempt from certification (21 CFR Part 73) and color additives subject to certification (21 CFR Part 74 and Part 82 [Lakes]). Only color additives specifically permitted by regulation may be legally used in cosmetics, and then only in accordance with the provisions of the specific color additive regulation.

For a complete listing and permitted uses of each color additive approved for use in cosmetics, refer to "[Color Additives Permitted for Use in Cosmetics](http://www.fda.gov/Cosmetics/Labeling/IngredientNames/ucml09084.htm)" (<http://www.fda.gov/Cosmetics/Labeling/IngredientNames/ucml09084.htm>).

Click on the "CFR Section Number" on the right-hand side to view the actual regulation, including uses, specifications, and restrictions for each color additive.

Investigators should perform a label review of finished cosmetic products. Ensure that all color additives are listed on the product label, and that those being declared in the product as ingredients are permitted for use in that product type and that they are otherwise being used in conformance with the specifications in the listing regulations. Investigators should pay particular attention to color additives used in cosmetics intended for the area of the eye (see 21 CFR 70.3(s) for a definition of "area of the eye") as there are only a limited number that are specifically permitted by regulation for use in eye area cosmetics.

**Special Considerations for Color Additives Subject to Certification:
(DOMESTICS AND IMPORTS)**

Certifiable color additives, sometimes referred to as "synthetic-organic colors" must undergo batch testing by FDA. This process, known as color additive certification, assures the safety, quality, consistency and strength of the color additive prior to its use in cosmetics. Part 74, Subpart C and Part 82, Subparts B and C list the color additives permitted in cosmetics which are subject to batch certification. When FDA certifies a batch of bulk color additive, the color additive manufacturer is assigned a unique, six-digit lot number, beginning with two alpha characters followed by four number characters (e.g. XX1234). Finished-product manufacturers must ensure that they purchase certified color additives labeled with the batch certification lot number from color additive manufacturers.

Investigators may encounter certified color additives as raw material or as an ingredient listed on a product label. Each color additive included in a cosmetic product must be included in the product declaration of ingredients (using either the listed or abbreviated name e.g., Ext. D&C Yellow No. 7 or Ext. Yellow 7). Laboratory analysis of a cosmetic cannot determine whether a lot of color additive used was certified; therefore, investigators should ask manufacturers to provide FDA certification lot number(s) for color additives used in cosmetic products. Check the authenticity of each certification lot number by accessing FDA's [Color Certification database](http://inside.fda.gov:9003/CFSAN/OfficeofCosmeticsandColors/ucm406788.htm) (<http://inside.fda.gov:9003/CFSAN/OfficeofCosmeticsandColors/ucm406788.htm>) and keying in the six-digit lot number in the character field.

The information returned from the site includes:

- the name of the certified color additive
- the batch certification number of the original color additive that was manufactured
- the name of the company associated with the certified color additive
- the certification date

(Note: First time database users will be directed to click on the "Request Access" box for verification; permission is granted via email.)

In the case of color additive mixtures, the label should declare a control number that can be traced to the FDA certification lot number of the color additives present in the mixture.

6. Cosmetic Product Labeling Requirements- Ingredients (DOMESTIC AND IMPORTS)

Examine the declaration of ingredients on all cosmetic products intended for sale to consumers to determine compliance with 21 CFR 701.3. Note that products that are used *only* in salons and not sold to consumers (usually labeled "For Professional Use Only") or free samples where another purchase is not required to receive the free sample, are not required to bear an ingredient declaration under the FPLA (Section 1459). If, however, these products are customarily sold to consumers for their personal use, they are not exempt from ingredient labeling requirements and must bear an ingredient statement.

As the cosmetic marketplace has become more global, certain situations now arise with greater frequency and should receive special attention:

Use of a language other than English - All words, statements, and other information required by or under authority of the FD&C Act to appear on the label or labeling shall appear in the English language (except in the case of products distributed solely in Puerto Rico or in a U.S. Territory where the predominant language is other than English). If the label or labeling also contains any representation in a foreign language, then all words, statements, and representations must be made in that language.

"Dual declaration" of certain ingredients - In the mid-1990's correspondence between CFSAN Office of Cosmetics and Colors (OCAC) and the Cosmetic, Toiletry and Fragrance Association (CTFA) (since renamed the Personal Care Products Counsel (PCPC)) addressed several issues related to international harmonization of cosmetic labeling requirements and the use of "dual declaration" for certain types of cosmetic ingredients. These letters may be viewed online under [Cosmetic Ingredient Nomenclature: Industry Requests & FDA Responses](http://www.fda.gov/Cosmetics/Labeling/IngredientNames/default.htm#responses) (<http://www.fda.gov/Cosmetics/Labeling/IngredientNames/default.htm#responses>).

For color additives, FDA does not object to C.I. numbers being used in a dual declaration with the official FDA-sanctioned name, provided all of the requirements of the relevant color additive regulations have been met and the FDA-sanctioned name is listed first. An acceptable dual declaration will list the FDA-sanctioned name first followed by the C.I. number in parentheses.

Example: FD&C Blue No. 1 (C.I. 42090)

The Agency also does not object to a similar type of dual declaration for botanical ingredients where both the Linnaean taxonomic (genus/species) name and English "common or usual name" are listed, *provided* that the English "common or usual name" is listed first.

Example: Dandelion Leaf Extract (Taraxacum officinale Leaf Extract)

If there is no English "common or usual name" for a botanical ingredient, FDA does not object to the Linnaean name being used alone, per 21 CFR 701.3(c)(4).

Investigators should refer to Attachment D "Examples of Hypothetical Cosmetic Ingredient Label Declarations for Domestic and International Markets" of this compliance program for examples of nomenclature that may appear on the labels of cosmetic products marketed for domestic and/or international marketplaces, respectively.

7. Cosmetic Product Labeling Requirements- Warning Statements (DOMESTIC AND IMPORTS)

- a) Required warning statements on cosmetics packaged in self-pressurized containers (21 CFR 740.11). The wording for this statements is prescribed by regulation and must be correctly stated as follows:

"Warning-Avoid spraying in eyes. Contents under pressure. Do not puncture or incinerate. Do not store at temperature above 120°F. Keep out of reach of children."

In addition to the above warning statement, if the propellant used consists in whole or in part of a halocarbon or a hydrocarbon the

following additional warning statement must be used:

"Warning—Use only as directed. Intentional misuse by deliberately concentrating and inhaling the contents can be harmful or fatal."

- b) Required warning statement for "feminine deodorant spray" (any spray deodorant product whose labeling represents or suggest that the product is for use in the female genital area or for use all over the body) (21 CFR 740.12):

"Caution - For external use only. Spray at least 8 inches from skin. Do not apply to broken, irritated or itching skin. Persistent, unusual odor or discharge may indicate conditions for which a physician should be consulted. Discontinue use immediately if rash, irritation, or discomfort develops."

Use of the word "hygiene" or "hygienic" or a similar word or words renders any such product misbranded under section 602(a) of the FD&C Act. The use of any word or words which represent or suggest that such products have a medical usefulness renders the products misbranded under section 502(a) of the Act and renders them illegal new drugs marketed in violation of section 505 of the Act.

- c) Statement of appropriate warnings and directions for safe use of children's foaming detergent bath products, i.e., children's bubble bath products and all foaming detergent bath products not labeled as intended for use exclusively by adults (21 CFR 740.17). The product label must bear adequate directions for safe use and the following caution:

"Caution—Use only as directed. Excessive use or prolonged exposure may cause irritation to skin and urinary tract. Discontinue if rash, redness, or itching occur. Consult your physician if irritation persists. Keep out of reach of children."

- d) Required warning statement for sun tanning cosmetic products containing no sunscreen ingredients (21 CFR 740.19). The warning statement must read as follows:

"Warning--This product does not contain a sunscreen and does not protect against sunburn. Repeated exposure of unprotected skin while tanning may increase the risk of skin aging, skin cancer, and other harmful effects to the skin, even if you do not burn."

- e) Cautionary statement and adequate directions for use needed for the exception from adulteration on coal-tar hair dyes (i.e., hair dye color additives derived from coal tar or petroleum) as provided under section 601(a) of the FD&C Act. The labeling should also include adequate directions for such preliminary testing and use of the product. Note: these dyes cannot be used for dyeing the eyebrows or eyelashes.

"Caution- This product contains ingredients which may cause skin irritation on certain individuals and a preliminary test according to accompanying directions should first be made. This product must not be used for dyeing the eyelashes or eyebrows; to do so may cause blindness."

8. Directions for Safe Use (DOMESTICS AND IMPORTS)

Products described below are known to produce adverse reactions in individuals when not properly formulated or when improperly used by the consumer.

The firms' labeling of the products below warrants close attention during cosmetic inspections. Adequate instructions for use must be provided, including, but not limited to, any necessary time limits on application, instructions for washing off, or patch tests on small areas of the body, as appropriate. Questions about the adequacy of use instructions should be referred to CFSAN's Office of Cosmetics and Colors at 240-402-1130.

- Depilatories and hair straighteners;
- Permanent wave neutralizers;
- Nail builders, hardeners, and enamels;
- Artificial or sculptured fingernail glue; and
- Coal tar hair dyes (Under section 601 (a) the label *must* bear instructions for preliminary patch testing for possible skin irritation)

9. Cosmetic Product Packaging Requirements (DOMESTIC AND IMPORTS)

Determine whether cosmetic liquid oral hygienic products and all cosmetic vaginal products intended for retail sale comply with tamper-resistant packaging requirements and assure that the product label bears the statement alerting consumers to the tamper-resistant features (21 CFR 700.25).

10. Field Exam and/or Document Review (IMPORTS)

Note: Districts must refer to the FDA Import Alerts and active bulletins in the Compliance Management System for import alerts and bulletins for cosmetic products.

ORA includes resources for conducting label examinations of import entries under this program. Each label examination should cover five (5) focal areas:

1. Cover cosmetics only. (See Part I "Background," and Part III "Inspectional", Section 1. "General" in this Cosmetic Program Guidance Manual, for instructions in determining whether a product is a cosmetic, a drug, or drug as well as cosmetic. A listing of cosmetic product categories can be found at 21 CFR 720.4(c));
2. Include a review to ensure the product complies with mandatory labeling and packaging requirements, including required warning statements; prohibited/restricted ingredients; and non-certified or non-permitted color additives utilizing the instructions provided above under Part III, "Inspections";
3. Include a review of cosmetic labels with added "ingredient stickers" signifying possible re-labeling of a brand name (so called "gray market cosmetics" produced for markets outside of the U.S.) Cosmetics formulated for use in other countries may contain color additives not permitted in the U.S.

4. Include coverage of imported cosmetics containing color additives. Color additive violations are a common reason for detaining imported cosmetic products offered for entry into this country. See IA#53-06 "[Detention Without Physical Examination of Cosmetics Containing Illegal Colors](http://www.accessdata.fda.gov/cms_ia/importalert_130.html)" (http://www.accessdata.fda.gov/cms_ia/importalert_130.html).

When performing a field exam, please review Part III, Section 4, "Color Additives" for instructions in determining whether a product may contain non-certified or non-permitted color additives.

In addition, if the label of an imported cosmetic identifies color additives with their European name or ("E") color designation with a corresponding number (e.g., E104, E122, E123, and E124), a color index number (e.g., C.I. 15985) or the trade name of the color additive (e.g., Sunset Yellow FCF) alone without the U.S. approved designation, this suggests that the color additive used may not be certified or permitted. In these situations, districts should consider detaining without sampling based on the appearance of adulteration (i.e., the product appears to contain an uncertified color additive). These situations can be processed in OASIS using a violative label exam (Work Type LEX).

If the imported product appears to contain undeclared color additives, product samples should be obtained and sent to the designated laboratory for color analysis.

To confirm that a product contains certified color additives, request that the filer/importer provide a valid FDA certified Lot number for the color additive(s) used. Using the Color Additive Certification Database, "[Color Additives Permitted for Use in Cosmetics](http://www.fda.gov/Cosmetics/Labeling/IngredientNames/ucml09084.htm)," (<http://www.fda.gov/Cosmetics/Labeling/IngredientNames/ucml09084.htm>) confirm that the lot number provided can be validated. Then, the product can be released, provided the label declares the color additive(s) by the certified name, such as FD&C Yellow No. 6 or Yellow 6. If the product contains certified color additive(s), and the certified color additive(s) is not correctly declared on the label, process the entry for detention.

5. Include a review for prohibited cattle material. Please review Part III, Section 2 "Coverage of Bovine Tissue and Tissue-Derived Ingredients for Bovine Spongiform Encephalopathy (BSE)" for additional information.

OASIS screening criteria allow 100% entry review for any import entry of finished cosmetic products that may contain bovine tissue or tissue-derived ingredients. These include all products with industry code 53 R[[[]]].

Product labels and entry documentation of finished cosmetics should be reviewed to determine if the products contain any of the prohibited cattle material listed in 21 CFR 700.27. See above discussion under "Special Considerations Regarding Prohibited Cattle Material" for more information.

In addition, bulk shipments of bovine tissue and tissue-derived ingredients are flagged for review under Import Alert 17-04 "[Detention without Physical Examination of Bulk Shipments of High Risk Bovine Tissue from BSE Countries](http://www.accessdata.fda.gov/cms_ia/importalert_53.html)" (http://www.accessdata.fda.gov/cms_ia/importalert_53.html). Bulk shipments of bovine material intended for use in cosmetic products are product coded as 53P[][]01 and 53P[][]02. The specific bovine tissues and tissue derived ingredients of concern are listed in IA 17-04.

If a bulk shipment of a bovine tissue or tissue-derived cosmetic ingredient is detained under Import Alert 17-04 "Detention Without Physical Examination of Bulk Shipments of High Risk Bovine Tissue From BSE Countries," the importer or manufacturer may provide documentation that establishes the bovine tissue or tissue-derived ingredient is from BSE-free cattle or from a non-BSE affected country. See Import Alert 17-04 for more information.

Attachment B Bovines Tissue and Tissue-Derived Ingredients, Materials with Suspected Risk of Infectivity" contains a list of tissues to further assist investigators in identifying tissues and tissue-derived ingredients at high risk for infection with the agent that causes BSE. This list includes the "specified risk materials" specifically identified in 21 CFR 700.27 as well as additional bovine tissues with suspected infectivity. If a firm manufacturing or importing cosmetic products or their ingredients uses a tissue or tissue-derived ingredient listed in Attachment B but not otherwise listed as prohibited cattle material in 21 CFR 700.27, the FDA investigator should determine whether it has been exported from and/or originated from a BSE affected or at-risk country. If so, the investigator should contact CFSAN for further guidance.

A current list of BSE affected or at-risk countries can be found at: [USDA's Animal and Plant Health Inspection Service \(APHIS\) website](https://www.aphis.usda.gov/wps/portal/aphis/home/) (<https://www.aphis.usda.gov/wps/portal/aphis/home/>) and then typing in the search term "countries/regions affected by BSE" for an up-to-date list of countries.

11. Alpha Hydroxy Acids (AHAs) "Sunburn Alert" AHA Labeling Statement (DOMESTICS AND IMPORTS)

Because of the potential for increased sensitivity to the sun, manufacturers must use the following guidance labeling statement for topically applied cosmetic products containing AHAs (e.g., glycolic acid, lactic acid) as ingredients

Sunburn Alert: This product contains an alpha hydroxy acid (AHA) that may increase your skin's sensitivity to the sun and particularly the possibility of sunburn. Use a sunscreen, wear protective clothing, and limit sun exposure while using this product and for a week afterwards.

Investigators are requested to notify firms manufacturing cosmetics containing AHAs of "[Guidance for Industry: Labeling for Topically Applied Cosmetic Products Containing Alpha Hydroxy Acids as Ingredients](http://www.fda.gov/Cosmetics/GuidanceRegulation/GuidanceDocuments/ucm090816.htm)" (<http://www.fda.gov/Cosmetics/GuidanceRegulation/GuidanceDocuments/ucm090816.htm>).

12. Consumer and Trade Complaints (DOMESTICS)

The District Offices should use their own discretion concerning immediate follow-up on more serious or unusual consumer adverse reactions for cosmetic products, e.g., multiple or serious complaints for the same product. Prior to conducting follow-up on a cosmetic adverse event, including sampling, the district should contact Wendy Good (Wendy.Good@FDA.HHS.GOV) at 240-402-1146, Office of Cosmetics and Colors (OCAC), Cosmetics Staff (HFS-125). Many types of cosmetic products are known to cause adverse reactions under certain conditions, therefore automatic follow-up and sampling for adverse reaction reports on cosmetics may not be necessary. CFSAN can provide advice to the investigating district for appropriate follow-up.

The FACTS Consumer Complaint Cosmetic Report should be used for adverse events related to cosmetics (See Subchapter 8.4.5 of the IOM). If collection of cosmetic consumer complaint samples is necessary, follow the instructions provided in Subchapter 8.4.7 of the IOM. These samples will be analyzed by the appropriate district servicing laboratory or Center laboratory as discussed in Part IV of this compliance program.

13. Other coverage during Domestic Inspections (DOMESTICS):

a) Voluntary Registration (DOMESTICS)

During each inspection, determine whether the firm has registered its manufacturing establishment (21 CFR 710) and/or its cosmetic product formulations (21 CFR 720) under the [Voluntary Cosmetic Registration Program \(VCRP\)](http://www.fda.gov/Cosmetics/RegistrationProgram/default.htm) (<http://www.fda.gov/Cosmetics/RegistrationProgram/default.htm>). If not, encourage participation in these voluntary programs.

b) Fact Sheet for Cosmetic Manufacturers, Packers and Distributors

During an inspection, questions frequently arise as to products regulated by FDA and questions concerning cosmetics, such as labeling, BSE, color additives, voluntary registration, importing and exporting products and small business assistance. A fact sheet has been designed to answer some of these questions and provide the firm with helpful FDA links. At the closeout of each inspection, disseminate Attachment D "Food and Drug Administration, Office of Cosmetics and Colors Fact Sheet for Cosmetic Manufacturers, Packers and Distributors" to firm management.

c) Screening for toxic elements

X-ray fluorescence (XRF) can be used to identify prohibited elemental substances (I based colors, Hg in other than eye cosmetics, i.e., skin whiteners, Pb containing pigments used in religious celebrations and other facial decorations). XRF can detect up to 80 elements in the periodic table from a few ppm for some elements. XRF can detect Hg through the caps of closed vessels lessening the chance to exposure from volatile Hg from whitening creams containing volatile forms of Hg. In the lab a quantitative method to determine Hg in face cream has been developed (**Use of Field Portable XRF for Screening and Quantification of Mercury in Face Creams. Laboratory Information Bulletins (LIB) 4542**).

<http://inside.fda.gov:9003/downloads/PolicyProcedures/Laboratories/LaboratoryInformationBulletins/UCM353400.pdf>

Contact the CFSAN/Division of Field Programs, Program Assignment Monitoring Branch contact BEFORE employing a screening method for toxic elements in any situation other than as directed in a field assignment.

C. Sample Collections

For cosmetic color additive samples, consult Chapter 4 of the current edition of the IOM (Chart 9), "[Sample Schedule for Color Containing Product, Color Additive](http://www.fda.gov/ICECI/Inspections/IOM/ucm127693.htm)" (<http://www.fda.gov/ICECI/Inspections/IOM/ucm127693.htm>).

Note: Bulk color additives that are used as cosmetic ingredients should be collected under Industry Code 50. For straight colors, collect 28 gm (1 oz.) of powder. For color mixtures, collect 100 gm (4oz.) of liquid, paste or powder. If the color mixture contains over 50% pure dye, collect 55 gm (2oz.).

Color additive samples of finished cosmetics should be collected under Industry Code 53. If the product is strongly colored (e.g., lipsticks, hair coloring, products, eye mascara, eye liner, make-up, pencils of all types) collect four retail packages of the same lot code for each shade (color) in the product line. If the product is lightly colored (e.g., creams, lotions, shampoos, bath products, shaving preparations and perfumes), collect a sufficient number of retail packages to equal 1 lb (dry) or 1 pt (liquid) of sample. Always collect a minimum of two retail units of each product.

For bulk cosmetic products, collect samples for color additive analysis in the following quantities:

- Dry 454 gm (1 lb.);
- Liquids - Minimum of 36 fl. oz.

DOMESTICS:

For microbiological analysis, collect samples of eye area cosmetics, tattoo inks or skin care preparations and lotions when adequate challenge test documentation cannot be produced, the adequacy of preservation is in doubt or non-traditional preservative systems are used.

If uncertain whether to collect a sample, contact the appropriate CFSAN regulatory contact listed in Part VI of this program for additional instructions.

IMPORTS:

If product packaging and labeling indicates that a violation of the Act may exist, the field should collect samples to support potential regulatory action. The collected samples should be sufficient to ensure that the regulatory action is supportable. If the apparent violation is for micro contamination, undeclared colors, or heavy metals, etc. a physical sample and laboratory analysis would be appropriate.

Collect the following quantities as determined by the type of analyses required.

DOMESTIC AND IMPORTS:

Chemical Analysis – Collect in duplicate (as per specific assignment guidance)

Chemical analysis of cosmetics is not routine; however, it may be requested per specific assignment and/or during a for-cause inspection. The products and quantities listed are included for reference and should not be routinely collected for chemical analysis.

Aerosol products—680 gm (24 oz)
Bath Salts—680 gm (24 oz)
Bubble Baths—680 gm (24 oz)
Eye Make-up - 56 gm (2 oz)
Facial Make-up—225 gm (8 oz)
Mouthwashes—680 gm (24 oz)
Nail preparations—160 gm (6 oz)
Perfumes—160 gm (6 oz)
Pressed Powders—160 gm (6 oz)
Skin Lotion - 680 gm (24 oz)
Shampoos and conditioners - 680 gm (24 oz)

Microbiological analysisIndividual Retail Units

Collect at least ten (10) units [20 units if less than 14 gm (½ oz) each]

Bulk

One (1) 100 gm (4 oz) subsample from each of ten containers

Note: In the absence of specific sampling instruction **for tattoo ink**, contact the Program Analytical Contacts for guidance on adequate sample sizes.

Imports

All import lines sampled under this program must be held pending analysis. For entries that contain multiple lines of different product types that were not evaluated, the additional lines can be released if they do not appear to be violative.

SAMPLE SHIPMENT

Submit samples to your district's analytical laboratory or specialized CFSAN laboratory as appropriate to conduct the intended analysis as indicated in PART IV, Section A.

Important Note: For samples collected for field lab analysis, refer to the Servicing Laboratories section of the ORA Field Workplan. For this reason, for each type of analysis to be performed by CFSAN, a contact person is provided in Part IV, Section B. Collecting districts should contact that person by e-mail to confirm the shipping address prior to shipping any samples to CFSAN. For CFSAN, refer to CFSAN contact list.

PART IV - ANALYTICALImplementation

- a) To analyze samples of eye area cosmetics, tattoo ink and skin care preparations and lotions that could become contaminated with pathogenic microorganisms, due to a questionable preservative system or disregard for industry good manufacturing practices (see [Draft Guidance for Industry: Cosmetic Good Manufacturing Practices](http://www.fda.gov/cosmetics/guidanceregulation/guidancedocuments/ucm353046.htm) (<http://www.fda.gov/cosmetics/guidanceregulation/guidancedocuments/ucm353046.htm>)).
- b) To analyze cosmetics for color additives and prohibited ingredients and to conduct label reviews when suspected violations of the FD&C Act and the FPLA are encountered during inspections and import label examinations.

A. ANALYZING LABORATORIES

1. Fielda) Microbiological

General microbiological analysis will be performed by the district's customary microbiological analytical laboratory. (See the Servicing Laboratories section of the current ORA Field Workplan for a listing of servicing laboratories.)

NOTE:

Fungal sequencing performed by Pacific Regional Laboratory - Southwest will be used to identify yeast and mold isolates. When identification is needed, please make prior arrangements with the laboratory to ensure resources are available. All cultures will be shipped by UPS overnight delivery, and shipments will conform to the rules and regulations regarding the shipment of infectious agents.

Please send isolates to the following address:
Food & Drug Administration
Pacific Regional Laboratory - Southwest
19701 Fairchild
Irvine, CA 92612
ATTN: Dr. Donna Williams-Hill or Sample Custodian
Telephone: 949 608 3496 or 949 608 4432

b) Color Additives

[Servicing Laboratory Tables](#) are being used as an alternative system to the National Sample Distributer (NSD). However, if a specific laboratory has been indicated in a sampling assignment then that laboratory should be referenced during the C/R preparation process.

[Servicing Laboratory Tables](#)

http://qmis.fda.gov/MC/main/mastercontrol/vault/view_pdf.cfm?ui=092315124259&infocardID=2BC257D401BEA04613

NOTE: Initial analysis may be accomplished by the servicing district laboratory; however, either the original or check analysis for any potentially violative sample must be done by an analyst trained in certified color additive determination. Contact ORA/Office of Regulatory Science (HFC-141) at (301) 796-6600 with questions regarding servicing laboratories and analyses.

CFSAN/OCAC's Color Technology Team (HFS-106) Julie Barrows, 240-402-1119 is available to advise the district servicing laboratory on analyses involving difficult color samples.

c) Label Review

All servicing analytical laboratories will conduct review of the labeling (21 CFR Parts 700 and 701) for declaration of ingredients (21 CFR 701.3), and warning statements (21 CFR 740), and directions for use as necessary (see Part III 2. f. of this guidance document). For comprehensive material on cosmetic labeling requirements that should be used in conducting label review, refer to the resources listed at [Labeling](http://www.fda.gov/Cosmetics/Labeling/default.htm) (<http://www.fda.gov/Cosmetics/Labeling/default.htm>).

2. Center

The following may be performed by CFSAN. Investigations branches should e-mail the Center contact listed below before shipping any samples to the Center for analyses.

a) Species Identification

CFSAN/ORS/Division of Microbiology (HFS-712) is available to provide added support for the identification of yeast and mold isolates.

Contact Valerie Tournas at 240-402-1963 or via e-mail at valerie.tournas@fda.hhs.gov for support.

b) Chemical Analysis

CFSAN/ORS(HFS-700) will provide support for analysis of cosmetic products for prohibited or other potentially harmful ingredients or contaminants.

Contact Gregory Noonan at CFSAN/ORS/DBC (HFS-715) at 240-402-2250 or via e-mail at gregory.noonan@fda.hhs.gov prior to shipping samples.

c) Confirmation of Color Additives

The Division Color Certification and Technology, Color Technology Team (HFS-106) will provide color additive support

for samples of cosmetic products not amenable to the typical analytical methods.

Contact Dr. Julie Barrows via e-mail at Julie.Barrows@FDA.HHS.GOV (240-402-1119) for information prior to shipping samples.

d) Determination of Toxicity

The Office of Cosmetics and Colors, Division of Cosmetics (HFS-125) will provide support for evaluating topical toxicity or the potential for systemic toxicity as requested.

Contact Dr. Nakissa Sadrieh at (240) 402-2194 or via e-mail at Nakissa.Sadrieh@fda.hhs.gov for help with toxicity questions.

e) Label Review

CFSAN/OC/Division of Enforcement (HFS-608) will provide assistance for determining violations of cosmetic labeling requirements.

Contact Dehlia Young at e-mail Dehlia.Young@fda.hhs.gov or via phone at (240) 402-1626.

B. ANALYSIS

a) Microbiological

All method references to the e-BAM refer to the current edition of the Bacteriological Analytical Manual (<http://www.fda.gov/food/foodscienceresearch/laboratorymethods/ucm073598.htm>).

Refer to the e-BAM, Chapter 23 for methods to determine microbial contamination of cosmetics, except tattoo ink.

Tattoo ink and materials used to manufacture tattoo ink should be sent to Pacific Regional Lab (PRL-SW) for analysis. For the analysis of tattoo ink, refer to an appropriate validated method such as <http://inside.fda.gov:9003/downloads/PolicyProcedures/Laboratories/LaboratoryInformationBulletins/UCM413090.pdf>.

All Gram-positive and Gram-negative microbial isolates from aerobic plate counts or enrichments are to be identified to genus and species level using e-BAM, chapter 23 methods and commercial identification systems such as Vitek.

Prepare mold and yeast cultures for forwarding and further classification as follows:

- Potato Dextrose Agar (PDA- BAM Media M127) slants (screw cap tubes) can be used for culturing the mold isolates. The mold agar slants are incubated at 37°C to ensure proper growth before shipping (Reference: e-BAM, Chapter 23: Microbiological Methods for Cosmetics)
- Yeast isolates show optimal growth on Sabouraud's Dextrose Agar (SDA) plates incubated at 25°C, these isolates may need longer incubation time until growth is evident (Reference: e-BAM, Chapter 23: Microbiological Methods for Cosmetics).
- Media composition and growth conditions can sometimes vary depending on specific fungal species under which circumstances isolates need to be tested for optimal incubation temperatures and growth media such as PDA, SDA, malt extract agar (MEA- BAM Media M93) to ensure proper growth (Refer to e-BAM, Chapter 23: Microbiological Methods for Cosmetics)
- Pack, label and ship isolates in accordance with Federal Standards for Etiological Agents.

b) Color Additive Analysis

All determinations of color additives in cosmetic products will be performed in accordance with the instructions contained in Newburger's Manual of Cosmetic Analysis, 2nd Edition, Chapter 19, Determination of Color in Cosmetics, published by AOAC, 1977. For additional color additive analytical instructions refer to the AOAC, Official Methods of Analysis, 15th through 18th editions, Chapter 46, or most current edition. See also Compliance Program 7303.803 (Domestic Food Safety; Attachment C, Analytical Instructions); or 7309.006 (Imported Foods - Food and Color Additives; Part IV).

c) Toxic Elements (ELE) Analysis

All determinations of Toxic Elements Analysis in cosmetic products will be performed in accordance with the instructions contained in the Elemental Analysis Manual method 4.7 (EAM 4.7).

(<http://www.fda.gov/downloads/Food/FoodScienceResearch/LaboratoryMethods/UCM377005.pdf>)%20for%20the%20analytical%20method).

d) Label Review

Determine whether proper labeling practices are followed. See 21 CFR 701 for Cosmetic Labeling and 740 for cosmetic Product Warning Statements.

e) Reporting

Report analytical results into FACTS using the following Problem Area Flags (PAF):

- Use PAF "COL," for non-permitted color additives and identify the non-permitted color additives found.
- Use PAF "MIC," for microbiological examinations and identify the microorganisms(s) and level.
- Use PAF "ELE" for toxic elements
- Use PAF "FDF," Result Flag "FDL" for label reviews (Food Economics and Standards) and identify specific violation(s) found.

PART V - REGULATORY/ADMINISTRATIVE STRATEGY1. Situations Warranting CFSAN Contact

Contact CFSAN, Office of Compliance (OC), Division of Enforcement (DE), Dehelia Young, Labeling and Dietary Supplement Compliance Branch (HFS-608) at (240) 402-1626 for instructions in the following situations:

- a) If there is a suspected health hazard (see Part III for situations that may constitute a health hazard). In such cases, a health hazard evaluation should be requested from CFSAN/OC/DE. Refer to the [Regulatory Procedures Manual](#) (RPM) (<http://www.fda.gov/ICECI/ComplianceManuals/RegulatoryProceduresManual/default.htm>), Chapter 7 and [21 CFR 7.41\(a\)](#) for information regarding health hazard evaluations.

The receipt of a large number of adverse event reports for a particular product and/or adverse events involving severe chemical burns or severe eye injuries may also be indicative of a potential health hazard situation.

- b) If a product presenting a potential health hazard has been distributed.
- c) Cosmetic products are not expected to be aseptic; however, they must be completely free of high-virulence microbial pathogens, and the total number of microorganisms per gram must be low. CFSAN is currently using the following level of concern for aerobic plate counts (APCs):
- For eye-area products, counts should not be greater than 500 colony forming units (CFU)/g;
 - for non-eye-area products, counts should not be greater than 1000 CFU/g. Some examples of bacterial and fungal pathogens or opportunistic pathogens whose incidence would be of particular concern, especially in eye-area cosmetic products, include *Staphylococcus aureus*, *Streptococcus pyogenes*, *Pseudomonas aeruginosa*, *Aspergillus sps*, *Candida albicans*, *Klebsiella pneumoniae*, and other species.

The list of microorganisms noted above is not all-inclusive. When determining the pathogenicity of a specific microorganism and the potential health risk to consumers as a result of its presence in a cosmetic product, **OCAC microbiologists consider several factors.** Evidence in the available literature regarding cases of infection in healthy populations without intervening factors such as prior surgery or compromised immune systems is of primary significance. Mode and frequency of product application and container design, among other factors, are also taken into consideration when evaluating potential risk to the consumer. For example, some organisms are capable of causing eye diseases in healthy individuals when the eye, or area around the eye, is punctured or abraded. Questions regarding the pathogenicity and potential health risks of a given microorganism in a specific type of cosmetic product should be referred to CFSAN.

In addition, OCAC recognizes that the skin and ocular surface of healthy individuals inherently supports a moderate population of bacteria, typically coagulase-negative staphylococci (CNS), which are believed to exist as commensals. Under normal conditions, in healthy individuals, there is little or no opportunistic microbial colonization and infection resulting from these commensals, such as *Staphylococcus epidermidis*, *Staphylococcus hominis*, and *Micrococcus luteus*. As long as the overall microbial population in a cosmetic product is below regulatory limits, the sole presence of commensal microorganisms does not pose a significant health risk and does not render the product adulterated.

If a cosmetic appears to be making drug claims:

CDER and CFSAN have agreed to have concurrent jurisdiction to assist FDA in implementing the cosmetic and drug provisions of the FD&C Act by clarifying program responsibilities in light of overlapping jurisdiction between CDER and CFSAN. Under this agreement, CDER and CFSAN shall have concurrent jurisdiction over a product which purports to be a cosmetic but meets the definition of drug. **Both CDER and CFSAN** may bring regulatory action relating to such product. CFSAN will not include drug charges in any such action without first notifying CDER of the charges that will be included. CDER will not include cosmetic charges in such an action without first obtaining CFSAN's concurrence.

Districts may submit recommendations for advisory (e.g., Warning Letter) or enforcement action to CFSAN, and CFSAN will coordinate the action with CDER.

e) Contact CFSAN/OC/DE/ Labeling and Dietary Supplement Compliance Branch (HFS-608) if necessary for assistance when an import shipment is detained in accordance with I.A. #17-04 for bulk shipments of high-risk bovine tissues and tissue-derived ingredients.

If a cosmetic product contains or appears to contain prohibited cattle material, it should be detained. In order to obtain release of the product, the importer should provide records sufficient to demonstrate that the cosmetic is not manufactured from, processed with, or does not otherwise contain, prohibited cattle material. Examples of documents that may be useful to the reviewer in making a determination include:

- a relevant USDA/APHIS veterinary certificate
- a country of origin certificate
- relevant manufacturing records

2. Direct Reference Seizure Authority

Updated instructions regarding direct reference seizure authority for *Pseudomonas aeruginosa* contamination of cosmetics used in the eye area may be found in Section 590.300 of the Compliance Policy Guide Manual (CPG). The specimen charge is stated in the CPG.

SPECIMEN CHARGE:

The article (was adulterated while introduced into and while in interstate commerce) or (is adulterated while held for sale after shipment in interstate commerce) within the meaning of the Act, 21 U.S.C. 361(a) in that it contains a poisonous or deleterious substance, *Pseudomonas aeruginosa*, which may render it injurious to users under such conditions of use as are customary or usual.

Complete labeling and worksheets must accompany direct seizure recommendations when forwarded to the Office of Chief Counsel through the Division of Enforcement in the Office of Enforcement and Import Operations (HFC-210).

3. Seizure with Center Review

All other cases must be submitted to the Center for Food Safety and Applied Nutrition (CFSAN) through the electronic MARCS-CMS system. MARCS-CMS is a collection of modules supporting Agency compliance management and work flow for compliance-related activities. MARCS-CMS provides the mechanism to electronically send this information to the appropriate organizational unit based on individual organizations' business practices. It also provides the means to associate all evidence needed to support the Compliance Action. This evidence may contain enforcement, precedent scientific, or interpretive information relating to the Compliance Action.

Users can access the system by navigating through INSIDE.FDA.GOV. From this screen select MARCS-CMS link. A user's Guide is available within the application under the User's Guide link located at the top of the MARCS-CMS Main Screen.

If any of the situations below are encountered for domestic products, and the firm involved does not voluntarily recall all of the affected products districts should submit a recommendation for seizure (including sample analyses), electronic copy (e.g., .doc, .pdf files, etc.) through the [MARCS-CMS](#) system to HFS-608, CFSAN/OC/DE/Labeling and Dietary Supplement Branch. CFSAN will review to determine Center support for the recommended action.

a) Prohibited/ Restricted Ingredients. Determine whether prohibited or restricted ingredients (21 CFR 2.125, 21 CFR 250.250 and part 700) are being used. (Confirm status of ingredients at all 3 "bullets" below)

- Prohibited as cosmetic ingredients:

- i. bithionol (21 CFR 700.11);
 - ii. halogenated salicylanilides (di-, tri-, metabrom-salan and tetrachlorosalicylanilide) (21 CFR 700.15);
 - iii. chloroform (21 CFR 700.18); and
 - iv. methylene chloride (21 CFR 700.19).
- Prohibited as ingredients of cosmetic aerosol products:
 - i. vinyl chloride (21 CFR 700.14); and
 - ii. zirconium (21 CFR 700.16).
 - Restricted ingredients of cosmetic products unless used as specified in the regulations:
 - i. hexachlorophene (HCP) (21 CFR 250.250);
 - ii. mercury compounds (21 CFR 700.13); and
 - iii. chlorofluorocarbon propellants (21 CFR 700.23 and 2.125).

SPECIMEN CHARGE:

The article is adulterated within the meaning of Section 601(a) of the Act in that it bears or contains a poisonous or deleterious substance, namely [name of substance], which may render it injurious to users under the conditions of use prescribed in the labeling thereof or under such conditions of use as are customary and usual.

- b) Non-Certified or Non-Permitted Color Additives. Determine whether non-certified or non-permitted color additives (21 CFR 73, 74, 81, 82) are being used. Refer to [Color Additives Permitted for Use in Cosmetics](#) (<http://www.fda.gov/Cosmetics/Labeling/IngredientNames/ucml09084.htm>) for more information. If undeclared colors are identified in an imported product, process the entry for detention.

For cosmetics containing non-permitted color additives (for products other than hair dyes), if seizable size lots are not found, the district should consider a Warning Letter recommendation using the sample warning letter language found in Chapter 4 of the [Regulatory Procedures Manual](#) (<http://www.fda.gov/ICECI/ComplianceManuals/RegulatoryProceduresManual/default.htm>).

SPECIMEN CHARGE:

The article is adulterated within the meaning of Section 601(e) of the Act in that it bears or contains a color additive, namely [color], which is unsafe within the meaning of Section 721(a).

When a certifiable color additive is not declared on the label, FDA may or may not have certified it for use in cosmetic products. Without evidence that the color came from a batch that has been certified (e.g., FDA certification lot number), the appropriate charge would be a 601(e) adulteration charge.

- c) Tamper-Resistant Packaging. Cosmetic liquid oral hygiene products, e.g., mouthwashes and breath fresheners, and any kind of cosmetic vaginal product introduced into interstate commerce must be packaged in tamper-resistant packages if intended to be accessible to the

public while held for retail sale under 21 CFR 700.25. If not in tamper-resistant packaging, the product is adulterated under Section 601 of the Federal Food, Drug and Cosmetic Act (the Act). (See Section 4b Mandatory Labeling and Packaging Requirements for misbranding charges regarding tamper-resistant packaging and labeling requirements.)

SPECIMEN CHARGE: The article is adulterated within the meaning of Sections 601(a) and/or 601(c) of the Act in that it is not packaged in a tamper-resistant package as required in 21 CFR 700.25.

4. Other Findings

If the situations described in this section are found, enforcement action may be warranted. This is not an all-inclusive list of potential deviations. Districts should use their best judgment to determine the appropriate action (i.e., warning letter, seizure, etc.) and submit a recommendation to CFSAN. If additional assistance is needed, districts should contact the regulatory contacts listed in Part VI.

Mandatory Labeling and Packaging Requirements. Cosmetics must bear labeling as specified in the FD&C Act, the FPLA, and the cosmetic regulations (21 CFR Part 701). Failure to include necessary labeling elements may cause a product to be misbranded under section 602 of the Act.

- This article may also be misbranded within the meaning of section 1454(c)(3)(B) of the Fair Packaging and Labeling Act in that it appears that the label fails to bear an ingredient declaration in accordance with 21 CFR 701.3 (See Part III—Inspectional for additional information on ingredient declaration)

Some cosmetic products are also subject to the packaging provisions of the Poison Prevention Packaging Act of 1970 and the implementing regulations (16 CFR Part 1700 et. seq.). Products which do not comply with the regulations promulgated under this law are misbranded within the meaning of Section 602(f) of the FD&C Act.

- Appropriate Cautionary Statements and Directions for Safe Use.

The following products may be deemed adulterated or misbranded if the labeling does not contain an appropriate warning statement(s) and/or directions for safe use (see the appropriate section of the Act in parentheses):

- i. Depilatories and hair straighteners (Section 602(a) of the Act);
- ii. Cosmetic hair dye products containing lead acetate (21 CFR 73.2396), bismuth citrate (21 CFR 73.2110), and/ or henna (21 CFR 73.2190) (Sections 601(e) and 602(a) of the FD&C Act);
- iii. Coal-tar hair dyes (Section 601(a) of the Act); and
- iv. Nail builders, hardeners, and enamels (may require immediate CFSAN review depending on the facts involved (Section 602(a) of the Act).

- Child Resistant Packaging

The following products must be packaged in child-resistant packaging:

- i. Home permanent wave neutralizers containing sodium bromate or potassium bromate [16 CFR 1700.14(a)(19), Section 602(f) of the Act]; and
- ii. Artificial or sculptured fingernail glue removers containing acetonitrile [16 CFR 1700.14(a)(18), Section 602(f) of the Act].

- Sun-tanning Products

These products may be drugs and/or cosmetics, depending on the claims. If the product labeling includes any of the following claims, the product will be regulated as a drug:

- i. The labeling bears any direct or implied statement that the product screens out ultraviolet sunlight, prevents or treats sunburn, prevents wrinkles, or prevents premature aging of the skin;
- ii. The label bears a number representing the sun protection factor (SPF) value; or
- iii. The sunscreen ingredient is declared as an active drug ingredient and is listed before the listing of the cosmetic ingredients - Section 502(e)(1) of the Act and 21 CFR 701.3(d).

Suntan cosmetic products that do not contain a sunscreen must bear adequate directions for safe use and the warning statement required under 21 CFR 740.19. If the products do not comply with the regulation, they are misbranded under Section 602(a) of the Act.

There are "tanning pills" manufactured as capsules intended for ingestion. These products usually contain beta carotene and/or canthaxanthin. They act by entering the blood stream and are partially deposited in skin tissue, giving the skin a tan-like color. Neither beta carotene nor canthaxanthin is approved for this use, and tanning pill products containing these color additives are considered adulterated under Section 601(e). (NOTE: "Suntan accelerators" are new drugs within the meaning of Section 201(p) of the Act).

- Cosmetics Containing Sunscreen Ingredients

These products may contain a sunscreen ingredient for purposes other than sun protection (e.g., as a color additive or to protect the color of the product). Such products are required to be labeled with qualifying information in conjunction with the term "sunscreen" or other similar protection terminology used in the

labeling as required in 21 CFR 700.35. If the products do not comply with the regulation, they are misbranded under Section 602(a) of the Act.

- Cosmetics packaged in self-pressurized containers

Cosmetic aerosol products are misbranded unless the labeling bears the label statements required for cosmetics in self-pressurized containers (21 CFR 740.11, Sections 602(a) and 201(n) of the Act).

- Children's foaming detergent bath products

Such products (e.g., bubble bath products) are misbranded unless the labeling bears adequate directions for safe use and precautionary statement (21 CFR 740.17, Sections 602(a) and 201(n) of the Act).

- Feminine deodorant sprays

Such products are misbranded unless the labeling bears explicit warnings and directions for safe use (when applicable) (21 CFR 740.12, Section 602(a) of the Act). Additionally, these products may be considered misbranded under Sections 602(a) and 201(n) if the labeling contains the word "hygiene" or a similar word. If the product is represented to have a medical usefulness, it may be considered a drug and would be misbranded under Section 502(a) (21 CFR 740.12).

- Tamper-resistant packaging

Cosmetic liquid oral hygiene products and vaginal products are required to include a statement regarding the tamper-resistant features of the packages [21 CFR 700.25(c)]. If a product does not contain such statement, or if the labeling contains a statement that the package is tamper-proof, the product may be misbranded under Sections 602(a) and 201(n) of the Act. (See Section 3c Direct to Seizure with Center Review for an adulteration charge regarding tamper-resistant packaging requirements.)

- c) Insanitary conditions. Enforcement action may be warranted if the inspection finds that the product may become contaminated with filth or may be rendered injurious to health (Section 601(c) of the Act).

6. Imports

Refer to the [Regulatory Procedures Manual](http://www.fda.gov/ICECI/ComplianceManuals/RegulatoryProceduresManual/cml179264.htm) (RPM) Chapter 9 (<http://www.fda.gov/ICECI/ComplianceManuals/RegulatoryProceduresManual/cml179264.htm>) for instructions concerning recommendation for detention based on one violative sample found to contain illegal color additives, unsafe or prohibited ingredients, or that present a health hazard for other reasons as outlined in Part III of this program. Recommendations for Detention Without Physical Examination (DWPE) must be referred to

ORA/ORO Division of Import Operations (HFC-170) through the Compliance Management System (CMS). Recommendations must be accompanied by a complete regulatory package consisting of all analytical worksheets for original and check analyses (if required—see note below), and other appropriate documentation (e.g., entry paperwork, collection reports, original labels, etc.).

Note: In the case of cosmetic products bearing ingredient labels identifying colors with **ONLY** their European "E" color designation (e.g., E110), color index number (e.g., C.I. 15985), or a trade or common name of the color additive (e.g., Sunset Yellow FCF), FDA laboratory analysis to confirm the presence of the color is not necessary for Detention/DWPE Actions.

At this time, FDA is developing an enforcement strategy for cosmetics containing glitters and mica-based pearlescent pigments.

PART VI - ATTACHMENTS REFERENCES AND CONTACTS**1) ATTACHMENTS**

Attachment A--Index
Attachment B- Bovine Tissue and Tissue-Derived Materials with Suspected Risk of Infectivity
Attachment C- Preservation Systems for Cosmetics
Attachment D- Examples of Hypothetical Cosmetic Ingredient Label Declarations for Domestic and International Markets
Attachment E- FDA OCAC Fact Sheet for Cosmetic Manufacturers, Packers, and Distributors

2) REFERENCES

Online IOM--
<http://www.fda.gov/ICECI/Inspections/IOM/default.htm>
DFI Inspection Guide--
<http://www.fda.gov/ICECI/Inspections/InspectionGuides/default.htm>
Compliance Policy Guide--
<http://www.fda.gov/ICECI/ComplianceManuals/CompliancePolicyGuidanceManual/ucml19194.htm>
Regulatory Procedures Manual--
<http://www.fda.gov/ICECI/ComplianceManuals/RegulatoryProceduresManual/default.htm>

3) CONTACTSCompliance Program Inquiries:

Shannon Ingram, CFSAN/Office of Compliance/Division of Field Programs/Program Assignment Monitoring Branch (HFS-615), (240) 402-4885.

Regulatory Action Inquiries (both domestic and import):

Dehlia Young, CFSAN/Office of Compliance/Division of Enforcement/Labeling and Dietary Supplement Compliance Branch (HFS - 608), (240)402-1626 (or)

Latasha Robinson, CFSAN/Office of Compliance/Division of Enforcement/Labeling and Dietary Supplement Compliance Branch (HFS-608), (240)-402-1890.

Complaints/Consumers Question:

Kapal Dewan, Office of Cosmetics and Colors (OCAC) (HFS-125), (240)402-2908 (or)

Wendy Good, Office of Cosmetics and Colors (OCAC) (HFS-125), (240) 402-1146.

Inspectional procedures Inquiries:

Norman Fogg, ORA/OFFO/DFFPOI (HFC-130), (301) 796-5448.

Import Inquiries:

Matthew Brown, ORA/Division of Import Operations (HFC-172), at (301) 796-6690 (x 3885).

4) ANALYTICAL CONTACTS:BAM Chapter 23 Inquiries:

Jo Huang, Ph.D., Microbiologist, CFSAN/OCAC at (240)402-1344.

John Misock, Pharmacology, CFSAN/OCAC at 240-402-1423.

ORS Compliance Program Contact:

Terri McConnell, ORA/ORS at (404)253-1217.

Chemical Analyses Inquiries:

Mohammed Islam, ORA/ORS at (240)402-0552.

Microbiological Analyses Inquiries:

Toni Morales, ORA/ORS at (301)796-3589.

Color Additive Methodology Inquiries:

Julie Barrows, Ph.D. CFSAN/OCAC/Color Technology Team (HFS-106) at (240)402-1119.

Mold Species Identification Inquiries:

Dr. Donna Williams-Hill, Pacific Regional Laboratory - Southwest at (949)608-3496

or

Valerie Tournas, CFSAN/ORS/DM/MMSB at (240)402-1963.

PART VII - CENTER RESPONSIBILITYProgram Evaluation

During the course of this program, the Office of Cosmetics and Colors will monitor and evaluate the progress and results of the field operations conducted under this program.

INDEX

Adverse events and trade complaints - III
Analytical work - IV
Background - I
Bacteriological Analytical Manual (e-BAM) - IV
BAM (microbiology) inquiries - VI
BSE - III
Cautionary statements and product directions, violations - V
Chemical analyses inquiries - VI
Child resistant packaging - V
Color additive inquiries and analytical - VI
Color additives, about, check certification lot numbers - III
Compliance program inquiries - VI
Consumer adverse events and trade complaints - III
Contact CFSAN - V, VI
Cosmetics making drug claims - III
Domestic and import Inspections - III
Drug claim determination, Inter-Center agreement CFSAN/CDER - III, V
Field reporting requirements - page 1
Import inquiries - VI
Imports field exam - III
Inspectional procedures inquiries - VI
Inspections, general guidelines - III
Labeling, mandatory requirements - III
Labeling examples for ingredients - Attachment D
Microbiological analytical - IV
Planning cosmetics work - II
Product preservation - iii
Prohibited/restricted Ingredients - III, V
References, various topics - VI
Regulatory action inquiries - VI
Bovine Tissues and ingredients - Attachment B
Sample collection, Domestic - III
Sample collection, Imports - III
Seizure authority - V
Seizure with Center review - V
Selecting firms for inspection - II
Special field instructions (General, Domestic, Imports) - page 2
Sun-tanning products (not sunscreens) - V
Tattoo ink - III
Toxicity determination - IV
Violative products charges - V
Voluntary Cosmetic Registration Program (VCRP) - III
Warning statements - III, V

**BOVINE TISSUE AND TISSUE-DERIVED INGREDIENTS
MATERIALS WITH SUSPECTED RISK OF INFECTIVITY**

Adrenal gland	Rowamyelin
Basal ganglia/basal ganglion	Sciatic nerve
Bone marrow	Sphingosine phosphatide
Brain	Sphingomyelin
Brain extract	Sphingolipid
Ceramide B-lactoside	Spinal cord
Ceramide dihexoside	Spleen
Cerebellum	Suprarenal gland
Cerebroside (sulfate)	Tetraglycosylceramide
Cerebrospinal fluid	Thymus gland (sweet-bread)
Cranial nerves	Tonsil
Collagen (soluble)	Triglycosylceramide
Colon (proximal and distal)	Trinitrophenylaminolauroylglucocerebroside
Disialoganglioside	Trinitrophenylaminolauroylgalactocerebroside
Dura mater	Trisialoganglioside
Elastin (source: oxen neck ligaments)	
Eye	
Galactocerebroside	
Galactosylcerebroside (sulfate ester)	
Ganglioside	
Glucosylcerebroside	
Glycerophospholipid	
Glycosaminoglycan	
Glycosphingolipid	
Glycosylceramide	
Hypothalamus	
Ileum	
Intercellular Lipids (ICL's)	
Lactocerebroside	
Lactosylceramide	
Liposomes	
Liver	
Lung	
Lymph nodes	
Monoglycosylceramide (cerebroside)	
Monosialoganglioside	
N-Nervonoyl cerebroside	
N-Oleoyl cerebroside	
N-Palmitoyl cerebroside	
Nasal mucosa	
Olfactory bulb or gland	
Pancreas (including pancreatin)	
Phospholipids	
Pineal gland	
Pituitary gland	
Placenta	

NOTE: If any bovine tissues or tissue derived ingredients are offered for import or being used as an ingredient in cosmetics, if the ingredient is from a BSE affected or at-risk country, refer to Part III of this program for additional instructions.

Preservation Systems for CosmeticsPreservative Compounds Commonly Used in Cosmetics:

Parabens (methyl, ethyl, propyl, and butyl)
Quaternium 15 (aka "Dowicil")
Diazolidinyl urea
Imidazolidinyl urea
DMDM Hydantoin
2-bromo-2-nitropropane-1,3-diol (aka "Bronopol")
Sodium hydroxyglycinate
Phenoxyethanol
Sorbic acid / Potassium sorbate
Methylisothiazolinone (aka "MI")
Methylchloroisothiazoline (aka "CMI" often in combination with MI as
Kathon CG)
Sodium benzoate
Caprylyl glycol
Sodium dehydroacetate
Formaldehyde

Non-traditional Preservatives (examples):

Non-traditional preservatives are typically extracts of botanicals, organic acids, alcohols and glycerols. Fermentation products are also used as preservatives. The presence of these types of chemicals in a cosmetic, in the absence of traditional chemicals, indicates they may be used a part of a preservative system. This list is a small sample.

Glyceryl caprylate
Levulinic acid
p-anisic acid
Eucalyptus globulus
Glycyrrhiza Glabra (Licorice) Root Extract
Salvia officinalis
Citrus grandis (organic grapefruit) extract
Arnica montana (organic arnica) extract
Boraxitrus seed extracts
Leuconostoc/Radish Root Ferment Filtrate
Goldseal (Hydrastis canadensis root extract)
Citrus Medica Limonum (Lemon) Peel Extract
Caprylhydroxamic acid

Other Important Factors in Evaluating a Preservation System:

1. Appropriate packaging - Is product packaging and closure consistent with the preservative system of the product? For example, a product dispensed with a pump, a container with a flip cap, or a single use container would require a much less vigorous preservative system than a product in a wide mouth jar or mascara that the consumer can contaminate with every use.
2. Water activity - Products such as powders with little or no water do not require as strong a preservative system as aqueous emulsions.

3. pH control - Microorganisms grow best between pH 6.5 to 7.5. Products with pH in this range require more microbial control than products outside this range.

Often described as "self-preserving":

Ethanol - when present at >15%
Butylene glycol - when present at >10%
Propylene glycol - when present at >20%

Other Substances Used as Preservatives in Cosmetics:

MDM Hydantoin
Sodium hydroxymethylglycinate
Benzisothiazolinone
Benzyl Alcohol
Dehydroacetic acid
Benzoic acid
Salicylic Acid
Iodopropynyl Butylcarbamate
Chloroxylenol
Methyldibromo Glutaronitrile
Chlorphenesin
Triclosan
Benzalkonium Chloride
Chlorhexidine
Polyaminopropyl Biguanide
5-Bromo-5-Nitro-1,3-Dioxane (Bronidox)
Hexamidine Diisethionate
Pentylene Glycol
1,2-Hexanediol
1,2-Octanediol
Ethylhexylglycerin
Triclocarban
Glyceryl Caprylate
o-Cymen-5-ol
Chlorphenesin
Glyceryl Monolaurate

Examples of Hypothetical Cosmetic Ingredient Label Declarations For Domestic and International Markets

Examples of hypothetical cosmetic ingredient label declarations are provided, as they might appear under current regulations PCP on international harmonization of ingredient nomenclature.

a) Cocoa Butter and Coconut Oil Lotion for Extra Dry Skin

Caveat: It has been proposed (and we currently allow) that FDA listed color additives be permitted to be declared in cosmetic ingredient labels by abbreviated names (c.f., 61 FR 8372 @ 8417, March 4, 1996)

Current Cosmetic Ingredient Label Declaration:

INGREDIENTS: Water, Cocoa Butter, Coconut Oil, Glyceryl Stearate, Mineral Oil, Propylene Glycol, Glycerin, Petrolatum, Cetyl Alcohol, PEG-8 Stearate, Tocopheryl Acetate, Methylparaben, Propylparaben, FD&C Yellow No. 5, D&C Orange No. 4.

Proposed Interim Harmonization Cosmetic Ingredient Label Declaration:

INGREDIENTS: Water (Aqua), Cocoa (Theobroma cacao) Butter, Coconut (Cocos nucifera) Oil, Glyceryl Stearate, Mineral Oil (Paraffinum liquidum), Propylene Glycol, Glycerin, Petrolatum, Cetyl Alcohol, PEG-8 Stearate, Tocopheryl Acetate, Stapyrium Chloride, Methylparaben, Propylparaben, Yellow 5 (CI 19140), Orange 4 (CI 15510).

b) Moisturizing Herbal Shampoo

Caveat: Certain botanical (plant) ingredients may have Linne System (Latin genus/species) names that have no English language 'common or usual name' equivalents (e.g., "Sambucus nigra Extract"). Semi-synthetic derivatives of botanical (plant) ingredients are not subject to the Interim Harmonization Proposals (e.g., "PEG-40 Hydrogenated Castor Oil").

Current Cosmetic Ingredient Label Declaration:

INGREDIENTS: Water, Sodium Laureth-7 Sulfate, Lauramide DEA, Cocamidopropyl Betaine, Disodium Laureth Sulfosuccinate, Fragrance, Panthenol, Quaternium-75, Sambucus Nigra Extract, Yarrow Extract, Comfrey Extract, Boysenberry Extract, Sweet Grass Extract, Sweet Cherry Pit Oil, Butylene Glycol, PEG-40 Hydrogenated Castor Oil, Benzophenone-4, Disodium EDTA, Citric Acid, Sodium Chloride, Methylchloroisothiazolinone, Methylisothiazolinone, Ext. D&C Violet No. 2.

Proposed Interim Harmonization Cosmetic Ingredient Label Declaration:

INGREDIENTS: Water (Aqua), Sodium Laureth-7 Sulfate, Lauramide DEA, Cocamidopropyl Betaine, Disodium Laureth Sulfosuccinate, Fragrance (Parfum),

Panthenol, Quaternium-75, Sambucus Nigra Extract, Yarrow (Achillea millefolium) Extract, Comfrey (Symphytum officinale) Extract, Boysenberry (Rubus deliciosus) Extract, Sweet Grass (Hierochloa odorata) Extract, Sweet Cherry (Prunus avium) Pit Oil, Butylene Glycol, PEG-40 Hydrogenated Castor Oil, Benzophenone-4, Disodium EDTA, Citric Acid, Sodium Chloride, Methylchloroisothiazolinone, Methylisothiazolinone, Ext. Violet 2 (CI 60730).

Abbreviated names for color additives (e.g., Ext. D&C Violet No. 2 can be stated as Violet 2, and the lake of FD&C Yellow No. 5 can be stated as Yellow 5 Lake) specified in the 1996 Federal Register proposed rule Permanent Listing of Color Additive Lakes (March 4, 1996, 61 FR 8372, at page 8417).

**Food and Drug Administration, Office of Cosmetic and Colors
FACT SHEET FOR COSMETIC MANUFACTURERS, PACKERS AND DISTRIBUTORS**

This fact sheet provides answers to some frequently asked questions and lists some useful Web resources.

For more information, please visit FDA's homepage at www.fda.gov. You can access Cosmetics from the list in the upper right-hand corner, or go directly to the Cosmetics home page (<http://www.fda.gov/Cosmetics/default.htm>). You can access Color Additives resources by going to the A-Z Subject Index, selecting "C," and scrolling down to Color Additives, or going directly to the Color Additives page (<http://www.fda.gov/ForIndustry/ColorAdditives/default.htm>).

Are cosmetics regulated by FDA?

Yes. For information on FDA's regulation of cosmetics, see "FDA Authority Over Cosmetics"
<http://www.fda.gov/Cosmetics/GuidanceRegulation/LawsRegulations/ucm074162.htm>
"Inspection of Cosmetics"
<http://www.fda.gov/Cosmetics/ComplianceEnforcement/ComplianceResources/ucm136455.htm>

When is a cosmetic considered a drug?

Some products perceived by consumers to be cosmetics may also be drugs if, in addition to their cosmetic function, they are intended to cure, mitigate, treat or prevent disease, or to affect the structure or any function of the human body (see the definition of a "drug" in section 201(g) of the FD&C Act). Some products can be both a drug and cosmetic, in which case, the product must comply with both the drug and cosmetic regulations. Typical examples of drug/cosmetic claims are: antiperspirant/deodorant products; sunscreen/suntan products; fluoridated toothpaste/toothpastes; antidandruff shampoos/cleansing beautifying shampoos; an SPF claim on a moisturizer or other cosmetics.

For more information, see "Is It a Cosmetic, a Drug, or Both? (or Is It Soap?)"
<http://www.fda.gov/Cosmetics/GuidanceRegulation/LawsRegulations/ucm074201.htm>

For information regarding drug registration and listing, see "Drug Registration and Listing System:
<http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/DrugRegistrationandListing/default.htm>.

Where can I find information related to cosmetics?

See FDA's Cosmetics home page: <http://www.fda.gov/Cosmetics/default.htm>

For a quick-reference list of resources often requested by industry, see Cosmetic Manufacturers, Packagers, and Distributors: <http://www.fda.gov/Cosmetics/ResourcesForYou/Industry/default.htm>

Where can I find safety and regulatory information on Bovine Spongiform Encephalopathy (BSE)?

Resources are listed under Bovine Spongiform Encephalopathy (BSE):
<http://www.fda.gov/cosmetics/productsingredients/potentialcontaminants/ucm136786.htm>

Where can I find guidance documents?

See the resources listed at

<http://www.fda.gov/Cosmetics/GuidanceRegulation/default.htm>

Where can I find information related to color additives used in cosmetics?

Information on FDA's regulation of color additives for use in all FDA-products is listed at "Color Additives":
<http://www.fda.gov/ForIndustry/ColorAdditives/default.htm>.

For information specifically on color additives for use in cosmetics, see "Color Additives in Cosmetics"
<http://www.fda.gov/ForIndustry/ColorAdditives/ColorAdditivesinSpecificProducts/InCosmetics/default.htm>.

For a quick-reference list with links to the regulations, see "Color Additives Permitted for Use in Cosmetics"
<http://www.fda.gov/Cosmetics/Labeling/IngredientNames/ucm109084.htm>.

What is the Voluntary Cosmetic Regulation (VCRP) Database?

The Voluntary Cosmetic Registration Program (VCRP) is an FDA post-market reporting system for use by manufacturers, packers, and distributors of cosmetic products that are in commercial distribution in the United States. There are two parts to the VCRP, one for registering establishments and another for filing formulations. You may participate in both parts of the program or only one part. No fees are required to participate in this voluntary program.

The VCRP does not apply to cosmetic products for professional use only, such as products used in beauty salons, spas, or skin care clinics. It also does not apply to hotel samples or free gifts or cosmetic products you make in your home to sell to your friends.

To learn more and participate in the VCRP, see "Voluntary Cosmetic Registration Program (VCRP)"
<http://www.fda.gov/Cosmetics/RegistrationProgram/default.htm>

Where can I find information on importing and exporting cosmetics?**Importing:**

For an overview, see "Cosmetic Imports"
<http://www.fda.gov/Cosmetics/InternationalActivities/Importers/default.htm>

Additional resources listed at this page include "Federal Agencies Issue Draft Guidance for Industry Good Importer Practices" <http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm109063.htm> and Import Surveillance <http://www.fda.gov/Cosmetics/InternationalActivities/Importers/ucm2005216.htm>, for links to Import Alerts and recent Import Refusals related to cosmetics.

Exporting:

For answers to regulatory questions and information about export certificates, see "Cosmetic Exports"
<http://www.fda.gov/Cosmetics/InternationalActivities/Exporters/default.htm>

Does FDA offer assistance to small businesses?

Yes. For information, visit "Small Business Assistance"
<http://www.fda.gov/ForIndustry/SmallBusinessAssistance/default.htm>