

Labeling of Cosmetics in the US

Although in the US manufacturers and importers of cosmetics are not required to have their products approved by the FDA (Food & Drug Administration) before they go on the market, all cosmetic products must be in compliance with the provisions of the FD&C Act (Federal Food, Drug & Cosmetic) and the FP&L Act (Fair Packaging & Labeling). This article gives a brief overview about the requirements for labeling based on excerpts of the FDA labeling manual (www.cfsan.fda.gov/~dms/cos-lab1.html).

Definition of Cosmetics

FDA defines cosmetics as articles intended to be applied to the human body for cleansing, beautifying, promoting attractiveness, or altering the appearance without affecting the body's structure or functions. Included in this definition are: skin creams, lotions, perfumes, lipsticks, fingernail polishes, eye & facial make-up preparations, shampoos, permanent waves, hair colors, toothpastes, deodorants, and any material intended for use as a component of a cosmetic product.

Soaps Are Not Cosmetics

Soaps consisting primarily of an alkali salt of fatty acid & making no claim other than cleansing are not considered cosmetics under law.

Cosmetics That Are Also Drugs

Cosmetics that are also intended to treat or prevent disease, or affect the structure or functions of the human body, are considered also drugs and must comply with both the drug and cosmetic provisions of the law. Examples of products which are drugs and cosmetics are:

- Anticaries toothpastes (e.g. fluoride pastes)
- Hormone creams
- Suntanning preparations intended to protect against sunburn
- Antiperspirants that are also deodorants
- Antidandruff shampoos

Cosmetic Labeling

Labeling means all labels and other written or graphic matter on or accompanying a product. Under law the label statements must appear on the inside and any outside container or wrapper. The principal display panel (part of the label most likely displayed under customary conditions of display for sale), must state the name of the product, identify by descriptive name or illustration the nature or use of the product, and bear an accurate statement of the net quantity of contents of the cosmetic in the

package in terms of weight, measure, numerical count, or a combination of numerical count and weight or measure.

The declaration must be distinct, placed in the bottom area of the panel in line generally parallel to the base on which the package rests, and in a type size commensurate with the size of the container.

The net quantity of contents statement of a solid, semisolid or viscous cosmetic must be in terms of the avoirdupois pound and ounce, and a statement of liquid measure must be in terms of the US gallon of 231 cubic inches and the quart, pint, and fluid ounce subdivisions thereof. If the net quantity is one pound or one pint or more, it must be expressed in ounces, followed in parenthesis by a declaration of the largest whole units (i.e., pounds and ounces or quarts and pints and ounces). The net quantity may additionally be stated in terms of the metric system.

The name and place of business of the firm marketing the product must be stated on an information panel of the label. The address must state the street address, city, state, and zip code. If a firm is listed in a current city or telephone directory, the street address may be omitted. If the distributor is not the manufacturer or packer, this fact must be stated on the label by the qualifying phrase "Manufactured for..." or "Distributed by..." or similar wording.

Cosmetics Labels Must Include:

- Name of the product
- Nature or use of the product
- Net quantity of contents in terms of weight, measure, numerical count, or both
- Declaration of the ingredients listed in descending order of predominance
- List of active ingredients (=drug ingredients) if the cosmetic product is also a drug
- Label warnings if the products may be hazardous if misused
- Name & place of manufacturer or distributor

Declaration of Ingredients

Cosmetics made for retail sale to consumers for their personal care are required to declare the ingredients. This declaration must be conspicuous so that it is likely to be read at the time of purchase. It may appear on any information panel of the package (folding carton, box wrapping if the immediate container is so packaged, and may also appear on a firmly affixed tag, tape or card.

The letters must not be less than 1/16 of an inch in height. If the package surface available to bear labels is < 12 square inches, the letters must not be < 1/32 of an inch in height. Off-package ingredient labeling is permitted if the cosmetic is held in tightly compartmented trays or racks, it is not enclosed in a folding carton, and the package surface area is < 12 square inches.

The ingredients must be declared in descending order of predominance. Color additives and ingredients present at 1% or less may be declared without regard for predominance. The ingredients must be identified by the names established or adopted by regulation (e.g. INCI names); those accepted by the FDA as exempt from public disclosure may be stated as "and other ingredients".

Cosmetics that are also drugs must first identify the drug ingredients as "active ingredients" before listing the cosmetic ingredients. All label statements required by regulation must be in the English language and must be placed on the label with such prominence and conspicuousness that they are readily noticed and understood by consumers under customary conditions of purchase.

Label Warnings

Cosmetics that may be hazardous when misused must bear appropriate label warnings and adequate directions for safe use. The statements must be prominent and conspicuous. Some cosmetics must bear label warnings or cautions prescribed by regulation (e.g. cosmetics in self-pressurized containers as aerosol products, feminine deodorant sprays, bubble bath products for children).

Although the FD&C Act does not require that cosmetic manufacturers or marketers test their products for safety, the FDA strongly urges cosmetic manufacturers to conduct whatever toxicological or other tests are appropriate to substantiate the safety of their cosmetics. If the safety of a cosmetic is not adequately substantiated, the product may be considered misbranded unless the label bears the following statement: Warning--The safety of this product has not been determined.

Law Enforcement

FDA may conduct examinations and investigations of products, inspect establishments in which products are manufactured or held, and seize adulterated (harmful) or misbranded (incorrectly or deceptively labeled or filled) cosmetics. Adulterated or misbranded foreign products may be refused entry into the United States.