Cosmetics Labeling Regulations

This section provides resources on regulatory requirements for cosmetic labeling. For a thorough explanation of cosmetic labeling regulations, see FDA's Cosmetic Labeling Guide and the cosmetic labeling regulations themselves (21 CFR parts 701 and 740). Firms also may wish to discuss their labeling needs with a consultant.

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In this section:

- Cosmetic Labeling Guide: Step-by-step labeling help, with examples
- Summary of Regulatory Requirements for Cosmetic Labeling
- List of Labeling Regulations for Cosmetics in Title 21 of the Code of Federal Regulations
- Required Warning Statement for Tanning Products Without Sunscreen

More Resources:

- Color Additives Permitted for Use in Cosmetics
- Country of Origin Marking: From U.S. Customs and Border Protection
- "Made in U.S.A." Claims: From the U.S. Federal Trade Commission
- Labeling Regulations Applicable to Cosmetics
- Current Issues in the Safety and Labeling of Cosmetics: VideoExternal Link Disclaimer
- Guidance: Labeling for Cosmetics Containing Alpha Hydroxy Acids
- Guidance for Industry: Cochineal Extract and Carmine: Declaration by Name on the Label of All Foods and Cosmetic Products That Contain These Color Additives; Small Entity Compliance Guide

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Overview of Labeling Requirements

The following information is a brief introduction to labeling requirements. For a more thorough explanation of cosmetic labeling regulations, refer to FDA's Cosmetic Labeling Guide and the cosmetic labeling regulations themselves (21 CFR parts 701 and 740). Firms also may wish to discuss their labeling needs with a consultant.

Proper labeling is an important aspect of putting a cosmetic product on the market. FDA regulates cosmetic labeling under the authority of both the Federal Food, Drug, and Cosmetic Act (FD&C Act) and the Fair Packaging and Labeling Act (FPLA). These laws and their related regulations are intended to protect consumers from health hazards and deceptive practices and to help consumers make informed decisions regarding product purchase.

It is illegal to introduce a misbranded cosmetic into interstate commerce, and such products are subject to regulatory action. Some of the ways a cosmetic can become misbranded are:

- its labeling is false or misleading,
- its label fails to provide required information,
- its required label information is not properly displayed, and
- its labeling violates requirements of the Poison Prevention Packaging Act of 1970 [FD&C Act, sec. 602; 21 U.S.C. 362].

Does FDA pre-approve cosmetic product labeling?

No. FDA does not have the resources or authority under the law for pre-market approval of cosmetic product labeling. It is the manufacturer's and/or distributor's responsibility to ensure that products are labeled properly. Failure to comply with labeling requirements may result in a misbranded product.

Some labeling terms to know

Before proceeding with a discussion of labeling requirements, it is helpful to know what some labeling terms mean:

- **Labeling.** This term refers to all labels and other written, printed, or graphic matter on or accompanying a product [FD&C Act, sec. 201(m); 21 U.S.C. 321(m)].
- **Principal Display Panel (PDP).** This is the part of the label most likely displayed or examined under customary conditions of display for sale [21 CFR 701.10].
- **Information Panel.** Generally, this term refers to a panel other than the PDP that can accommodate label information where the consumer is likely to see it. Since the information must be prominent and conspicuous [21 CFR 701.2(a)(2)], the bottom of the package is generally not acceptable for placement of required information, such as the cosmetic ingredient declaration.

Is it permitted to label cosmetics "FDA Approved"?

No. As part of the prohibition against false or misleading information, no cosmetic may be labeled or advertised with statements suggesting that FDA has approved the product. This applies even if the establishment is registered or the product is on file with FDA's Voluntary Cosmetic Registration Program (VCRP) (see 21 CFR 710.8 and 720.9, which prohibit the use of participation in the VCRP to suggest official approval). False or misleading statements on labeling make a cosmetic misbranded [FD&C Act, sec. 602; 21 U.S.C. 362].

What about therapeutic claims?

Be aware that promoting a product with claims that it treats or prevents disease or otherwise affects the structure or any function of the body may cause the product to be considered a drug. FDA has an Import Alert in effect for cosmetics labeled with drug claims. For more information on drug claims, refer to Is It a Drug, a Cosmetic, or Both? (Or Is It Soap?).

How should products be labeled if they are both drugs and cosmetics?

If a product is an over-the-counter (OTC) drug as well as a cosmetic, its labeling must comply with the regulations for both OTC drug and cosmetic ingredient labeling [21 CFR 701.3(d)]. The drug ingredients must appear according to the OTC drug labeling requirements [21 CFR 201.66(c)(2) and (d)] and the cosmetic ingredients must appear separately, in order of decreasing predominance [21 CFR 201.66(c)(8) and (d)]. Contact the Center for Drug Evaluation and Research (CDER) for further information on drug labeling.

What languages are acceptable?

All labeling information that is required by law or regulation must be in English. The only exception to this rule is for products distributed solely in a U.S. territory where a different language is predominant, such as Puerto Rico. If the label or labeling contains any representation in a foreign language, all label information required under the FD&C Act must also appear in that language [21 CFR 701.2(b)]. For information on dual declaration of ingredients, see Ingredient Names.

What labeling information is required?

The following information must appear on the principal display panel:

- **An identity statement,** indicating the nature and use of the product, by means of either the common or usual name, a descriptive name, a fanciful name understood by the public, or an illustration [21 CFR 701.11].
- **An accurate statement of the net quantity of contents,** in terms of weight, measure, numerical count or a combination of numerical count and weight or measure [21 CFR 701.13].

The following information must appear on an information panel:

- **Name and place of business.** This may be the manufacturer, packer, or distributor. This includes the street address, city, state, and ZIP Code. You may omit the street address if it is listed in a current phone directory or city directory [21 CFR 701.12(a)].
- **Distributor statement.** If the name and address are not those of the manufacturer, the label must say "Manufactured for..." or "Distributed by...," or similar wording expressing the facts [21 CFR 701.12(c)].

- **Material facts.** Failure to reveal material facts is one form of misleading labeling and therefore makes a product misbranded [21 CFR 1.21]. An example is directions for safe use, if a product could be unsafe if used incorrectly.
- **Warning and caution statements.** These must be prominent and conspicuous. The FD&C Act and related regulations specify warning and caution statements related to specific products [21 CFR part 700]. In addition, cosmetics that may be hazardous to consumers must bear appropriate label warnings [21 CFR 740.1]. An example of such hazardous products is flammable cosmetics.
- **Ingredients.** If the product is sold on a retail basis to consumers, even it it is labeled "For professional use only" or words to that effect, the ingredients must appear on an information panel, in descending order of predominance. [21 CFR 701.3]. Remember, if the product is also a drug, its labeling must comply with the regulations for both OTC drug and cosmetic ingredient labeling, as stated above. To learn more, see "Ingredient Names," "Color Additives and Cosmetics," "Fragrances in Cosmetics," and "'Trade Secret' Ingredients."