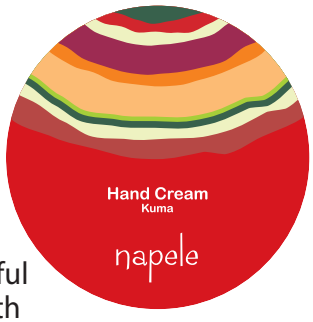
The 7 Current Elements to Cosmetic Label Guidelines

Since 1979, SixB Labels has continuously strengthened our expertise in Cosmetic Labels. SixB offers years of experience in making clients aware of necessary labeling regulations in order to help them comply with FDA Guidelines, while simplifying the intricacies of clients' programs. Here we offer an overview of the current labeling requirements.



The packaging and labeling of cosmetic products sold in the United States, whether manufactured domestically or imported from abroad, has been regulated since 1938. At that time, Congress passed the Federal Food, Drug and Cosmetic (FD&C) Act and the Fair Packaging and Labeling (FP&L) Act, to protect consumers from cosmetics containing harmful substances; bearing labels that are false, misleading, or lacking required information; or with containers made or filled in a deceptive manner.

After lengthy court proceedings and challenges, additional labeling requirements went into effect in 1977. While the most recent FDA Guidelines for transparency and safety in Cosmetic Labeling have been in place since 2012, if any new label requirements are put into effect, they will significantly impact both the Labeling and Cosmetic industries.

Meanwhile, here is a look at the Seven Expected Elements for Cosmetic Labels required by the FDA:

1. **The Legal Definition of a Cosmetic:** A cosmetic is a product, except soap, intended to be applied to the human body for cleansing, beautifying, promoting attractiveness, or altering the appearance. It is a product intended to exert a physical, not a physiological, effect on the human body. By law, the raw ingredients of cosmetic products are also cosmetics. Even for soap, if cosmetic claims, such as moisturizing or skin softening, are made on a label, the product is a cosmetic.

2. **Principal Display Panel (PDP)** (the part of a label that is most likely to be displayed, presented, shown, or examined under customary conditions of display for retail sale) must contain the Product Identity and the Net Weight Statement. Please note that only the panel of an outer container has a PDP panel. The label on a small bottle or jar inside of a box can provide less information than the box, because the box itself is considered the PDP.

3. **Requirements for Outer Container Labeling:** Under the FP&L Act, for cosmetics sold at retail, Ingredient Declarations are required only on the label of the outer container. When the outer container of the cosmetic product is a folding carton, box, or wrapper, the Ingredients Declaration, Allergen Statements, and Manufacturer Information may appear on any information panel of the package.

   Per the FD&C Act, any information that must appear on the immediate container label must also appear on the outside container of the retail package, or be readable through the outside container. If there is no outer packaging, as when the immediate container is small-sized, the Ingredient Declaration must appear firmly affixed on a tag, tape, or card.

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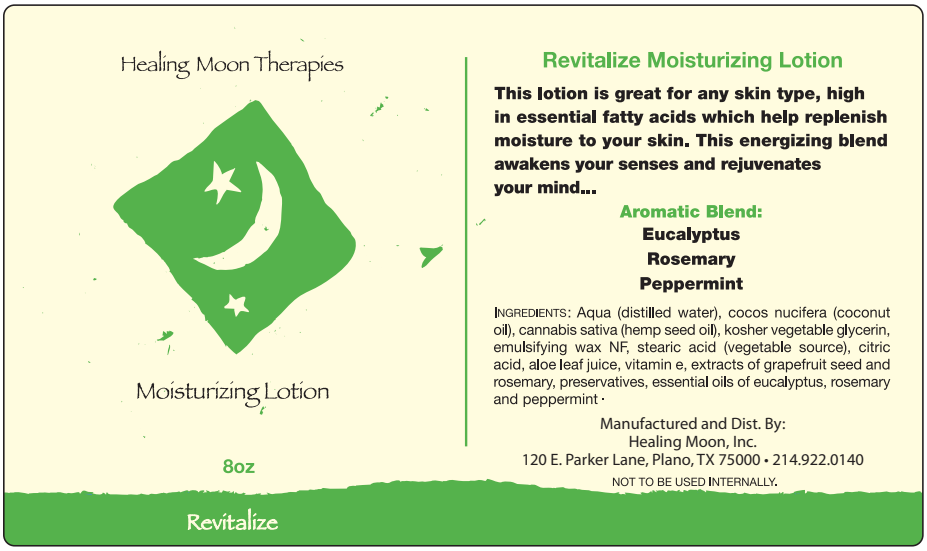
The Ingredients must be declared in descending order of predominance, and identified by the names established or adopted by regulations. Those accepted by the FDA as exempt from public disclosure, such as trade secrets, may be stated as "and other ingredients." Labels of cosmetics which are also drugs must first identify the drug ingredient(s) as "active ingredient(s)." Labeling may be considered misleading either because it presents statements that are deceptive or because it fails to reveal a material fact.

4. Type Point Size Components For the Net Contents:
Not less than 1/16" high if the PDP is less than 5 sq. inches
Not less than 1/8" high if the PDP is 5-25 sq. inches
Not less than 3/16" high if the PDP is 25-100 sq. inches

All Other Label Content: The Type Sizes of all other label content should be reasonably related to panel sizes. It should be not less than 1/32" high, if the total surface area to bear labeling is less than 12 square inches. This excludes the bottom, shoulder, neck, and flange, as well as any decorative or sculpted surfaces, of a container. The Type Size, consisting of upper and lower case letters, is determined by the height of the lower case letter "o".



5. Label Warnings: Under the FD&C Act, cosmetics which may be hazardous to consumers when misused must bear appropriate label warnings and adequate directions for safe use. A cosmetic not bearing a necessary Warning Statement, or one that violates the requirements of the Poison Prevention Packaging Act of 1970 (FD&C Act, sec. 602; 21 U.S.C. 362) may be considered misbranded. Warnings must be presented with prominent, conspicuous statements. The lettering must be in bold type on a contrasting background. The Type Size of the warnings must not be less than 1/16 inch in height, unless a smaller size is established by regulation. Some cosmetics, such as those in self-pressurized containers (aerosol sprays, for example) must bear label warnings or cautions prescribed by regulation.

Warning Statement Examples:

- **Safety:** Warning – Keep out of reach of children.
- **Unsubstantiated Safety:** Warning – The safety of this product has not been determined.
- **Aerosol Cans:** Avoid spraying in eyes. Contents under pressure. Do not puncture or incinerate. Do not store at temperatures above 120°F. Keep out of reach of children.
- **Foaming Detergent Bath Products:** Caution – Use only as directed. Excessive use or prolonged exposure may cause irritation to skin and urinary tract. Discontinue use if rash, redness or itching occurs. Consult your physician if irritation persists. Keep out of reach of children.

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6. **Legibility of Legally Required Label Statements:** All label statements required by law, including the Ingredient Declaration, must stand out enough to be readily noticed, and easily read and understood by ordinary individuals under normal purchasing conditions, with letters not obscured by design, vignettes, background or crowding. All statements required by U.S. law must be in English.

7. **Business ID** should include the corporate name, and principal place of business, and should provide the street address, city, state, and zip code. If the distributor is not the manufacturer or packer, the label should state a qualifying phrase such as "Manufactured for…" or "Distributed by…" or use similar appropriate wording.

SixB Labels has all the resources to help you with your Cosmetic Labeling projects. We can provide you with superior materials and top quality printing processes, including Hot Stamping, Cold Foiling and high-resolution color printing on both Flexo and Digital presses. Our production techniques, combined with our expertise developed over many years in the label printing industry, make SixB Labels the perfect place to bring your cosmetic label printing projects.

*For any further questions on the above information or general inquiries refer to the **www.fda.gov/Cosmetics/Labeling/Regulations** website.*

SixB Labels excels in producing effective Cosmetic Labels, so let us put our resources to work for you. If you are planning to change your current Cosmetic Labels or create new ones, call us for a consultation!

- ✔ Complimentary Phone Consultation + Project Quote
- ✔ Various Labels, Printers and Software Bundling Options
- ✔ Comparable Cosmetic Label Samples

**SixB Labels Corporation provides this quick reference for our clients and is not responsible for any errors. Please direct all questions to www.FDA.gov*