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

The legal difference between a cosmetic and a drug is determined by a product's intended use. Different laws and regulations apply to each type of product. Firms sometimes violate the law by marketing a cosmetic with a drug claim, or by marketing a drug as if it were a cosmetic, without adhering to requirements for drugs.

How does the law define a cosmetic?

The Federal Food, Drug, and Cosmetic Act (FD&C Act) defines cosmetics by their intended use, as "articles intended to be rubbed, poured, sprinkled, or sprayed on, introduced into, or otherwise applied to the human body...for cleansing, beautifying, promoting attractiveness, or altering the appearance" [FD&C Act, sec. 201(i)]. Among the products included in this definition are skin moisturizers, perfumes, lipsticks, fingernail polishes, eye and facial makeup preparations, shampoos, permanent waves, hair colors, toothpastes, and deodorants, as well as any material intended for use as a component of a cosmetic product.

How does the law define a drug?

The FD&C Act defines drugs, in part, by their intended use, as "articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease" and "articles (other than food) intended to affect the structure or any function of the body of man or other animals" [FD&C Act, sec. 201(g)(1)].

How can a product be both a cosmetic and a drug?

Some products meet the definitions of both cosmetics and drugs. This may happen when a product has two intended uses. For example, a shampoo is a cosmetic because its intended use is to cleanse the hair. An antidandruff treatment is a drug because its intended use is to treat dandruff. Consequently, an antidandruff shampoo is both a cosmetic and a drug. Among other cosmetic/drug combinations are toothpastes that contain fluoride, deodorants that are also antiperspirants, and moisturizers and makeup marketed with sun-protection claims. Such products must comply with the requirements for both cosmetics and drugs.

What about "cosmeceuticals"?

The FD&C Act does not recognize any such category as "cosmeceuticals." A product can be a drug, a cosmetic, or a combination of both, but the term "cosmeceutical" has no meaning under the law.

How is a product's intended use established?

Intended use may be established in a number of ways. Among them are:

- **Claims stated on the product labeling, in advertising, on the Internet, or in other promotional materials.** Certain claims may cause a product to be considered a drug, even if the product is marketed as if it were a cosmetic. Such claims establish the product as a drug because the intended use is to treat or prevent disease or otherwise affect the structure or functions of the human body. Some examples are claims that products will restore hair growth, reduce cellulite, treat varicose veins, or revitalize cells.
- **Consumer perception, which may be established through the product's reputation.** This means asking why the consumer is buying it and what the consumer expects it to do.
- **Ingredients that may cause a product to be considered a drug because they have a well known (to the public and industry) therapeutic use.** An example is fluoride in toothpaste.

This principle also holds true for essential oils in fragrance products. A fragrance marketed for promoting attractiveness is a cosmetic. But a fragrance marketed with certain "aromatherapy" claims, such as assertions that the scent will help the consumer sleep or quit smoking, meets the definition of a drug because of its intended use.

How are the laws and regulations different for cosmetics and drugs?

The following information is not a complete treatment of cosmetic or drug laws and regulations. It is intended only to alert you to some important differences between the laws and regulations for cosmetics and drugs in the areas of approval, good manufacturing practice, registration, and labeling. You should direct questions regarding laws and regulations for drugs to FDA's Center for Drug Evaluation and Research (CDER).

How approval requirements are different

FDA does not have a premarket approval system for cosmetic products or ingredients, with the important exception of color additives. Drugs, however, are subject to FDA approval. Generally, drugs must either receive premarket approval by FDA or conform to final regulations specifying conditions whereby they are generally recognized as safe and effective, and not misbranded. Currently, certain -- but not all -- over-the-counter (OTC) drugs (that is, non-prescription drugs) that were marketed before the beginning of the OTC Drug Review (May 11, 1972) may be marketed without specific approval pending publication of final regulations under the ongoing OTC Drug Review. Once a regulation covering a specific class of OTC drugs is final, those drugs must either -

- Be the subject of an approved **New Drug Application (NDA)** [FD&C Act, sec. 505(a) and (b)], or
- Comply with the appropriate **monograph**, or rule, for an OTC drug.

What do these terms mean?

- An **NDA** is the vehicle through which drug sponsors formally propose that FDA approve a new pharmaceutical for sale and marketing in the U.S. FDA only approves an NDA after determining, for example, that the data are adequate to show the drug's safety and effectiveness for its proposed use and that its benefits outweigh the risks. The NDA system is also used for new ingredients entering the OTC marketplace for the first time. For example, the newer OTC products (previously available only by prescription) are first approved through the NDA system and their 'switch' to OTC status is approved via the NDA system.
- FDA has published **monographs**, or rules, for a number of OTC drug categories. These monographs, which are published in the Federal Register, state requirements for categories of non-prescription drugs, such as what ingredients may be used and for what intended use. Among the many non-prescription drug categories covered by OTC monographs are -
    - acne medications
    - treatments for dandruff, seborrheic dermatitis, and psoriasis
    - sunscreens

A note on "new drugs": Despite the word "new," a "new drug" may have been in use for many years. If a product is intended for use as a drug, no matter how ancient or "traditional" its use may be, once the agency has made a final determination on the status of an OTC drug product it must have an approved NDA or comply with the appropriate OTC monograph to be marketed legally in interstate commerce. Certain OTC drugs may remain on the market without NDA approval pending final regulations covering the appropriate class of drugs.

Where to learn more about NDAs and OTC monographs: If you have questions about NDAs and OTC monographs, you should address them to CDER.

How good manufacturing practice requirements are different

Good manufacturing practice (GMP) is an important factor in assuring that your cosmetic products are neither adulterated nor misbranded. However, no regulations set forth specific GMP requirements for cosmetics. In contrast, the law requires strict adherence to GMP requirements for drugs, and there are regulations specifying minimum current GMP requirements for drugs [Title 21 of the Code of Federal Regulations (CFR), parts 210 and 211]. Failure to follow GMP requirements causes a drug to be adulterated [FD&C Act, sec. 501(a)(2)(B)].

How registration requirements are different

FDA maintains the Voluntary Cosmetic Registration Program, or VCRP, for cosmetic establishments and formulations [21 CFR 710 and 720]. As its name indicates, this

program is voluntary. In contrast, it is mandatory for drug firms to register their establishments and list their drug products with FDA [FD&C Act, sec. 510; 21 CFR 207].

How labeling requirements are different

A cosmetic product must be labeled according to cosmetic labeling regulations. See the Cosmetic Labeling Manual for guidance on cosmetic labeling. OTC drugs must be labeled according to OTC drug regulations, including the "Drug Facts" labeling, as described in 21 CFR 201.63. Combination OTC drug/cosmetic products must have combination OTC drug/cosmetic labeling. For example, the drug ingredients must be listed alphabetically as "Active Ingredients," followed by cosmetic ingredients, listed in order of predominance as "Inactive Ingredients."

And what if it's "soap"?

Soap is a category that needs special explanation. That's because the regulatory definition of "soap" is different from the way in which people commonly use the word. Products that meet the definition of "soap" are exempt from the provisions of the FD&C Act because -- even though Section 201(i)(1) of the act includes "articles...for cleansing" in the definition of a cosmetic -- Section 201(i)(2) excludes soap from the definition of a cosmetic.

How FDA defines "soap"

Not every product marketed as soap meets FDA's definition of the term. FDA interprets the term "soap" to apply only when --

- The bulk of the nonvolatile matter in the product consists of an alkali salt of fatty acids and the product's detergent properties are due to the alkali-fatty acid compounds, and
- The product is labeled, sold, and represented solely as soap [21 CFR 701.20].

If a cleanser does not meet all of these criteria...

If a product intended to cleanse the human body does not meet all the criteria for soap, as listed above, it is either a cosmetic or a drug. For example:

If a product --

- consists of detergents or
- primarily of alkali salts of fatty acids and
- is intended not only for cleansing but also for other cosmetic uses, such as beautifying or moisturizing,

it is regulated as a cosmetic.

If a product --

- consists of detergents or
- primarily of alkali salts of fatty acids and
- is intended not only for cleansing but also to cure, treat, or prevent disease or to affect the structure or any function of the human body,

it is regulated as a drug.

If a product --

- is intended solely for cleansing the human body and
- has the characteristics consumers generally associate with soap,
- does not consist primarily of alkali salts of fatty acids,

it may be identified in labeling as soap, but it is regulated as a cosmetic.