Cosmetics – Regulatory and Testing Requirements

Cosmetics are preparations, such as powder or a skin cream, designed to beautify the body by direct application and/or something superficial that is used to cover a deficiency or defect. Cosmetic products are regulated by the FDA, and sometimes, depending on their "intended use", are regulated as OTC drug products.

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." 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.

A product's intended use is established in one of several ways, including

- 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.

The intended use of a product is what determines whether the product is regulated as a cosmetic or a drug.

The FDA does not have a pre-market approval system for cosmetic products or ingredients, with the important exception of color additives. If the product's intended use is both as a cosmetic and a drug, it is required to follow the pre-market process for OTC drugs (drugs must either receive pre-market

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approval by FDA or conform to final regulations specifying conditions whereby they are generally recognized as safe and effective, and not misbranded). The FDA maintains the Voluntary Cosmetic Registration Program (VCRP) for cosmetic establishments and formulations. This program is, of course, voluntary, so registering the cosmetic formulation is not required.

Cosmetic product labels must conform to the labeling regulations set forth in the Federal Food, Drug, and Cosmetic (FD&C) Act, the Fair Packaging and Labeling (FP&L) Act, and the regulations published by the Food and Drug Administration under the Authority of these two laws. These regulations state that the product's label must include the name of the product, a statement of identity, directions for safe use, warnings, net quantity of product, name and address of manufacturing, packaging, or distributing location, and a list of ingredients. (21 CFR 740.10) In a product that is both a cosmetic and a drug, the active ingredients must be clearly displayed as active ingredients.

Safety is, naturally, a priority for cosmetic companies. The FD&C Act requires that cosmetic and personal care products and their ingredients be substantiated for safety before going to market, and that they contain no prohibited ingredients. If the product or ingredients have not been substantiated, the product is considered misbranded unless the label conspicuously displays the statement "Warning- the safety of this product has not been determined." The industry supports an independent scientific body known as the Cosmetic Ingredient Review (CIR). The CIR thoroughly reviews and assesses the safety of ingredients used in cosmetics in an open, unbiased, and expert manner and publishes the results of its work in peer-reviewed scientific literature.

Stability testing is required to back up any expiration dating claims made by the label on the product. Other testing previous to marketing the cosmetic product is required to ensure that the ingredients used in the product are safe for the consumer to use. Microbial testing is typically done on all cosmetic products, but is not required.

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References

- FDA's Cosmetic Labeling Manual
- http://www.fda.gov/Cosmetics/default.htm
- cosmeticsinfo.org
- 21 CFR Section 701
- FD&C Act

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