FDA Authority Over Cosmetics

What does the law say about cosmetic safety and labeling?

The two most important laws pertaining to cosmetics marketed in the United States are the Federal Food, Drug, and Cosmetic Act (FD&C Act) and the Fair Packaging and Labeling Act (FPLA).

The FD&C Act prohibits the marketing of adulterated or misbranded cosmetics in interstate commerce. Violations of the Act involving product composition--whether they result from ingredients, contaminants, processing, packaging, or shipping and handling--cause cosmetics to be adulterated and subject to regulatory action. Under the FD&C Act, a cosmetic is adulterated if--

- "it bears or contains any poisonous or deleterious substance which may render it injurious to users under the conditions of use prescribed in the labeling thereof, or under conditions of use as are customary and usual" [with an exception made for hair dyes];
- "it consists in whole or in part of any filthy putrid, or decomposed substance";
- "it has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health";
- "its container is composed, in whole or in part, of any poisonous or deleterious substance which may render the contents injurious to health"; or
- except for hair dyes, "it is, or it bears or contains, a color additive which is unsafe within the meaning of section 721(a)" of the FD&C Act. (FD&C Act, sec. 601)

Improperly labeled or deceptively packaged products are considered misbranded and subject to regulatory action. Under the FD&C Act, a cosmetic is considered misbranded if--

- "its labeling is false or misleading in any particular";
- its label does not include all required information;
- the required information is not adequately prominent and conspicuous;
- "its container is so made, formed, or filled as to be misleading";
- it is a color additive, other than a hair dye, that does not conform to applicable regulations issued under section 721 of the FD&C Act; and
- "its packaging or labeling is in violation of an applicable regulation issued pursuant to section 3 or 4 of the Poison Prevention Packaging Act of 1970." (FD&C Act, sec. 602)

In addition, under the authority of the FPLA, FDA requires an ingredient declaration to enable consumers to make informed purchasing decisions. Cosmetics that fail to comply with the FPLA are considered misbranded under the FD&C Act.

It is important to understand that Congress passes the laws that govern the United States. To put those laws into effect, Congress authorizes certain government agencies, including FDA, to create and enforce regulations, but only as authorized under the law. A change in FDA's statutory authority over cosmetics would require Congress to change the law.

Does FDA approve cosmetics before they go on the market?

FDA's legal authority over cosmetics is different from other products regulated by the agency, such as drugs, biologics, and medical devices. Cosmetic products and ingredients are not subject to FDA premarket approval authority, with the exception of color additives. However, FDA may pursue enforcement action against violative products, or against firms or individuals who violate the law.

Who is responsible for substantiating the safety of cosmetics?

Cosmetic firms are responsible for substantiating the safety of their products and ingredients before marketing. Failure to adequately substantiate the safety of a cosmetic product or its ingredients prior to marketing causes the product to be misbranded unless the following warning statement appears conspicuously on the principal display panel of the product's label:

"Warning--The safety of this product has not been determined." (21 CFR 740.10)

In addition, regulations prohibit or restrict the use of several ingredients in cosmetic products and require warning statements on the labels of certain types of cosmetics.

In general, except for color additives and those ingredients which are prohibited or restricted from use in cosmetics by regulation, a manufacturer may use any ingredient in the formulation of a cosmetic provided that the ingredient and the finished cosmetic are safe, the product is properly labeled, and the use of the ingredient does not otherwise cause the cosmetic to be adulterated or misbranded under the laws that FDA enforces.

Can FDA order the recall of a hazardous cosmetic from the market?

Recalls of cosmetics are voluntary actions taken by manufacturers or distributors to remove from the marketplace products that represent a hazard or gross deception, or that are somehow defective. FDA categorizes a firm's action as a recall (as opposed to a market withdrawal) when it determines that the product hazard or defect represents a violation of the FD&C Act.

FDA is not authorized to require recalls of cosmetics but does monitor companies that conduct a product recall and may request a product recall if the firm is not willing to remove dangerous products from the market without FDA's written request. Recalls are addressed in Title 21 of the Code of Federal Regulations (CFR), sections 7.40 through 7.59.

What actions can FDA take against firms that market adulterated or misbranded cosmetics?

FDA may take regulatory action if it has information to support that a cosmetic is adulterated or misbranded. The agency can pursue action through the Department of Justice in the federal court system to remove adulterated and misbranded cosmetics from the market. To prevent further shipment of an adulterated or misbranded product, the agency may request a federal district court to issue a restraining order against the manufacturer or distributor of the violative cosmetic. Violative cosmetics may be subject to seizure. FDA also may initiate criminal action against a person violating the law.

In addition, FDA works closely with the U.S. Customs and Border Protection to monitor imports. Under section 801(a) of the FD&C Act, imported cosmetics are subject to review by FDA at the time of entry through U.S. Customs. Products that do not comply with FDA laws and regulations are subject to refusal of admission into the United States. Violative products must be brought into compliance (if feasible), destroyed, or re-exported.

FDA takes regulatory action based upon agency priorities, consistent with public health concerns and available resources.

Can FDA inspect cosmetic manufacturers?

FDA can and does inspect cosmetic manufacturing facilities to assure cosmetic product safety and determine whether cosmetics are adulterated or misbranded under the FD&C Act or FPLA.

Does FDA test cosmetics?

The FD&C Act does not subject cosmetics to FDA premarket approval in order to be marketed legally. However, FDA collects samples for examination and analysis as part of its plant inspections, import inspections, and follow-up to complaints of adverse reactions. FDA may also conduct research on cosmetic products and ingredients to address safety concerns.

The agency does not function as a private testing laboratory, and in order to avoid even the perception of conflict of interest, does not recommend private laboratories to consumers or manufacturers for sample analysis. Testing laboratories are listed in your telephone directory.

Must cosmetic manufacturers register with FDA?

Manufacturers are not required to register their cosmetic establishments, file data on ingredients, or report cosmetic-related injuries to FDA. However, companies are encouraged to register their establishments and file Cosmetic Product Ingredient Statements with FDA's Voluntary Cosmetic Registration Program (VCRP).