

**STATEMENT
OF
SUSAN T. MAYNE, PHD
DIRECTOR
CENTER FOR FOOD SAFETY AND APPLIED NUTRITION
FOOD AND DRUG ADMINISTRATION
DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**BEFORE THE
SUBCOMMITTEE ON HEALTH
COMMITTEE ON ENERGY AND COMMERCE
UNITED STATES HOUSE OF REPRESENTATIVES**

**“BUILDING CONSUMER CONFIDENCE BY EMPOWERING FDA TO IMPROVE
COSMETIC SAFETY”**

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Introduction

Good morning, Chairwoman Eshoo, Ranking Member Burgess, and Members of the Subcommittee. I am Dr. Susan Mayne, Director of the Center for Food Safety and Applied Nutrition (CFSAN) at the Food and Drug Administration (FDA or the Agency), which is part of the U.S. Department of Health and Human Services (HHS). Thank you for the opportunity to appear before you today to discuss FDA's role in the regulation of cosmetics.

The cosmetics industry is undergoing rapid expansion and innovation. The industry looks very different than it did in 1938 when FDA was given regulatory authority over cosmetics. These changes help bring new opportunities and choices to consumers. There are now more varieties of cosmetic products available to consumers than ever before, and consumers enjoy this wide variety of cosmetic products offered at many price points. We are aware of estimates that the U.S. cosmetics industry may be larger than \$ 80 billion in terms of annual sales. But at the same time, our authority over cosmetics has not modernized even as the industry has undergone rapid evolution.

Each day, cosmetic products are sold to consumers across the United States. These products are frequently used as part of daily beauty and cleansing routines, often on the most sensitive areas of the skin, such as the face, eyelids and lips. They may also be used in caring for infants and children, who are still in the early years of development. Given widespread usage by U.S. consumers, including vulnerable populations, it is very important that cosmetic products are safe, properly labeled, and free of contamination.

We believe that most cosmetics on the market in the United States are indeed safe, and in our experience, most firms are responsible actors – they care about consumer safety and the reputations of their brands, and in those rare cases when safety issues do arise, many firms work with us cooperatively to address them. We also understand that most ingredients used in cosmetic products have been used in cosmetics for many decades, and we are not aware of safety concerns regarding most ingredients.

The Current Regulatory State of Play

The Federal Food, Drug, and Cosmetic Act (FD&C Act) defines a cosmetic as an “article intended to be rubbed, poured, sprinkled, or sprayed on, introduced into, or otherwise applied to the human body or any part thereof for cleansing, beautifying, promoting effectiveness, or altering the appearance.” The definition includes articles intended for use as a component of any such articles. Under the FD&C Act, cosmetic products and ingredients (with the exception of color additives) are not subject to FDA premarket approval or premarket notification to FDA. Cosmetics firms are responsible for the safety of their products and ingredients. However, they are not required to provide any safety information to the Agency, even if requested by FDA during an inspection.

In general, except for color additives and those ingredients that are prohibited or restricted from use in cosmetics by regulation,¹ a manufacturer may use any ingredient in a cosmetic, provided that the ingredient does not adulterate the finished cosmetic and the finished cosmetic is properly labeled.

To take an enforcement action against a cosmetic, FDA must demonstrate that the cosmetic is adulterated or misbranded. For example, if there are safety concerns with a product, FDA would need to determine that the cosmetic contains a substance that is poisonous or deleterious and that may render the cosmetic injurious to the user before FDA can take action against such product as an adulterated cosmetic.

Regulations are also in place that specify the labeling requirements for cosmetics. These requirements include:

- An identity statement indicating the nature and use of the product (for example, “shampoo” or “lip gloss”);
- The name and place of business of the manufacturer, packer, or distributor;
- A net quantity of contents statement in terms of weight, measure, or numerical count (e.g., “net wt. 4 oz.”) to inform consumers of the quantity of the cosmetic in the package;

¹ FDA regulations prohibit or restrict the use of 10 types of ingredients in cosmetic products due to safety concerns. Some examples are chloroform, methylene chloride, and mercury-containing compounds.

- Material facts about the product and its use (for example, directions for safe use, if a product could be unsafe if used incorrectly);
- Warning and caution statements for products that are required to bear such statements by the FD&C Act and FDA's regulations (for example, coal tar hair dyes); and
- A list of ingredients, in descending order of predominance; however, the specific ingredients in a fragrance or flavor are not required to be listed.

Challenges

The provisions in the FD&C Act – the law governing FDA's oversight of cosmetic products — were enacted in 1938. The cosmetics industry has and continues to undergo rapid expansion and innovation; the industry looks very different in 2019 than it did in 1938. For example, in Fiscal Year (FY) 2018, 2,727,847 lines of cosmetics products were imported into the United States from 177 countries.² For comparison, in FY 2008, there were 1,588,066 lines of cosmetics imported into the United States. That is an increase of more than one million lines of annual cosmetic imports in just the past decade.

In recent years, our program for cosmetics is approximately \$10 million and has represented about three percent of CFSAN's total \$327 million budget.

Companies and individuals who market these products in the U.S. are responsible for the safety and labeling of their products. As stated above, the current law does not require cosmetics to be reviewed and approved by FDA prior to being sold to American consumers.

FDA's Efforts to Address These Challenges

FDA is taking steps to ensure the safety of consumers, consistent with our authorities and using our available resources, to the greatest extent possible.

FDA encourages companies to register their establishments through the Voluntary Cosmetic Registration Program (VCRP) and file cosmetic product ingredient statements with FDA;

² An entry line simply represents an individual shipment, no matter of what size. For example, an entry line could be for 10 cartons of lipstick or 10,000 cartons of lipstick.

however, there is no requirement in the FD&C Act for firms to do either. The Agency established the VCRP and the cosmetic product ingredient statement program to gain more information about cosmetics that are being manufactured and marketed to consumers in the United States. The VCRP currently has almost 4,300 domestic and foreign registered cosmetics establishments, and cosmetic product ingredient statements have been filed for over 68,000 products; however, we estimate that only one-third of cosmetics manufacturers voluntarily file cosmetic product ingredient statements for their products with FDA.

We also continue to encourage companies to proactively report adverse events involving cosmetic products to CFSAN's Adverse Event Reporting System. Although not required by current law, we believe serious adverse event reporting is an important component of responsible marketing and facilitates our oversight of these products. FDA faces challenges in identifying and analyzing safety signals due to our lack of reliable, complete adverse event report data. We note that cosmetic product labels are not required to provide information on how consumers and health care professionals can report adverse events to the manufacturer, packer, or distributor.

FDA works to gain voluntary cooperation from cosmetics firms to access records during an inspection and to initiate recalls when FDA becomes aware of adulterated or misbranded cosmetic products on the market, though firms are not required to do so under current law. FDA has also issued a draft guidance on good manufacturing practices for cosmetics products, though firms are not required to follow GMPs.

FDA evaluates concerns about ingredients or products based on currently available science and data, much of which is publicly available as FDA does not have authority to require companies to provide it with safety, compositional and other relevant information about cosmetics. FDA also supports and conducts research related to cosmetics safety to support our regulatory activities, as allowed by our resources. When we have safety concerns about ingredients we will act swiftly to inform and advise consumers of any identified public health risks.

Ensuring the safety of cosmetics is a high priority for us.

Conclusion

FDA is committed to protecting Americans from unsafe products and will continue our efforts to regulate cosmetics with our available resources and authorities.

Thank you for the opportunity to discuss FDA's cosmetics program. FDA appreciates the Committee's interest in the program and looks forward to providing feedback on the legislation and answering any questions.