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Law expands FDA's authority to regulate cosmetics

November 1, 2023

from the Food and Drug Administration

Article type: FDA Update

Topics: Pharmacology

Children and adolescents use cosmetic products every day. Cosmetics include makeup and other products such as skin moisturizer, shower gel, deodorant, nail polish, hair dye and certain mouthwashes, shampoos and toothpastes.

While companies and individuals who market cosmetics have a responsibility to ensure the safety of their products, the law has not imposed specific requirements for safety testing. In addition, cosmetic products and ingredients, other than color additives, are not required to receive approval from the Food and Drug Administration (FDA) before they are marketed.

"We want health care providers to understand what the FDA can and cannot do, so providers know how to guide patients and families about the safety of cosmetics," said Linda M. Katz, M.D., M.P.H., director of the FDA's Office of Cosmetics and Colors.

The Modernization of Cosmetics Regulation Act of 2022 enhanced the FDA's authority over cosmetics. Dr. Katz called it "the most significant expansion of the FDA's authority to regulate cosmetics since the Federal Food, Drug, and Cosmetic Act was passed in 1938."

Although the law still does not require premarket approval for cosmetics, it will require companies and individuals who manufacture or market cosmetics to do the following:

- follow good manufacturing practice standards,
- substantiate the safety of their products,
- report serious adverse events to the FDA,
- provide contact information on the product labeling for consumers to report adverse events,
- make changes to labeling, including disclosure of specified fragrance allergens,
- register their manufacturing facilities with the FDA, and
- provide a listing of products and ingredients.

The law also gives the FDA new enforcement authorities, including an ability to mandate product recalls if the FDA has concerns about serious adverse health consequences related to a cosmetic product or ingredient.

“To take action against a cosmetic for safety reasons, the FDA must have reliable scientific information showing that the product or ingredient is harmful when consumers use it according to directions on the label or in the customary way,” Dr. Katz said.

The safety of some cosmetic ingredients, such as parabens, per- and polyfluoroalkyl substances, phthalates and talc, has been questioned. The FDA monitors the scientific literature and conducts research on cosmetic products and ingredients to help address safety concerns, but it’s also important for patients and families to do their own research when purchasing a cosmetic. The FDA has a listing of certain cosmetic ingredients and the available safety information at https://bit.ly/3PMdaAR.

“The cosmetic industry is always evolving and, like other industries, has been impacted by the wide reach of social media,” Dr. Katz said. “Young children and adolescents may be excited about trying new makeup or personal care products, so it’s important to teach them to be mindful about what they’re putting on their skin.”

Patients, families and health care providers should report any problems or adverse reactions experienced when using a cosmetic product to the FDA at https://bit.ly/460dYYC.

Dr. Katz also recommends that consumers beware of companies promising too much. Any claims that a product will affect the structure or function of the body or will prevent or treat certain medical conditions generally require the FDA’s approval as a drug, but some companies cross the line when marketing their products.

“If a product seems too good to be true,” she said, “it probably is.”

The FDA’s Office of Pediatric Therapeutics, Office of New Drug’s Division of Pediatrics and Maternal Health, and Office of Cosmetics and Colors contributed to this article.

Resources

- Information from the FDA on cosmetics
- Information from the FDA on cosmetic ingredients
- How to report a cosmetic-related complaint to the FDA
- FDA article “Are Some Cosmetics Promising Too Much?”
- Modernization of Cosmetics Regulation Act of 2022