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February 16, 2026

The Honorable Martin Makary, MD, MPH
Commissioner
Food and Drug Administration
5630 Fishers Lane, Rm 1061 (HFA-305)
Rockville, MD 20852

Submitted electronically via https://regulations.gov/

RE: Questions and Answers Regarding Mandatory Cosmetics Recalls: Draft Guidance for Industry; Availability [Docket No. FDA-2025-D-2246]

Dear Commissioner Makary,

On behalf of the American Academy of Dermatology Association (AADA), we write to express our support for the Food and Drug Administration's (FDA) draft guidance, *Questions and Answers Regarding Mandatory Cosmetics Recalls: Draft Guidance for Industry; Availability*. This guidance promotes timely public safety communications, which are critical to ensuring appropriate oversight of cosmetic products that pose a public health risk, and **we urge the FDA to make information on mandatory recalls, supporting data, and related reports publicly available in a timely manner to enhance transparency and strengthen consumer protection.**

As the leading society in dermatological care representing nearly 17,500 dermatologists nationwide, the AADA is committed to excellence in the medical and surgical treatment of skin disease; advocating for high standards in clinical practice, education, and research in dermatology; and driving continuous improvement in patient care and outcomes while reducing the burden of skin disease.

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Dermatologists are uniquely qualified to identify and report serious adverse events and cosmetic product safety concerns, given their expertise in managing skin conditions and understanding how to prevent and mitigate adverse responses to cosmetic ingredients. Consumers in the United States are exposed to more than 100 unique chemical ingredients in personal care products each day, with the greatest sources of exposure stemming from body care, skin care, and cosmetic products.[1] Many of these chemicals—including parabens, phthalates, and per- and polyfluoroalkyl substances (PFAS)—are known or suspected endocrine disruptors or carcinogens.[2] Potential health risks underscore the importance of robust cosmetic product safety efforts and their direct implications for public health.

Product safety efforts, including mandatory cosmetic recalls, remain a necessary regulatory mechanism to protect consumers and prevent serious adverse health consequences.[3] Furthermore, dermatologists are uniquely positioned to support the FDA's public safety efforts by identifying and reporting adverse events, supporting the FDA when it decides to recall harmful cosmetic products, educating critical health professionals along the care continuum, and collaborating with other stakeholders to reduce hazardous chemical exposures.

In particular, dermatologists improve consumer safety through patient education and robust pharmacovigilance, including the reporting and monitoring of adverse events that require medical attention. These efforts are critical for identifying risks to patient populations that may be uniquely vulnerable to certain chemicals and ingredients.[4] Continued education for "responsible persons"[5] regarding adverse event reporting, such as implementing robust documentation systems and improving the regulatory framework around adverse event reporting will further strengthen epidemiologic and serious adverse event data used to identify potentially hazardous ingredients.

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[1] Harris KJ, Munoz G, Woo V, Sauvé S, Rand AA. Targeted and Suspect Screening of Per- and Polyfluoroalkyl Substances in Cosmetics and Personal Care Products. Environ Sci Technol. doi: 10.1021/acs.est.2c02660

[2] Faber S. The Toxic Twelve Chemicals and Contaminants in Cosmetics. Environmental Working Group. Published May 5, 2020. Accessed February 6, 2026. https://www.ewg.org/the-toxic-twelve-chemicals-and-contaminants-in-cosmetics

[3] Venkatesh KP, Kadakia KT, Ashkan Akbarpour, Nambudiri VE. US Food and Drug Administration recalls of cosmetic and personal products from 2011 to 2023: A cross-sectional study. J Am Acad Dermatol. Published October 1, 2024. Accessed February 6, 2026. doi: https://doi.org/10.1016/j.jaad.2024.09.040

[4] Nguyen HP, Bergfeld WF, Forman HP, Belsito DV, Bolognia JL. Modernizing regulation of cosmetic products: Reintroduction of the Personal Care Products Safety Act. J Am Acad Dermatol. Published April 3, 2018. Accessed February 6, 2026. doi: https://doi.org/10.1016/j.jaad.2018.03.045

[5] Under section 604 of the FD&C Act, a "responsible person" is a manufacturer, packer, or distributor of a cosmetic product whose name appears on the label of a cosmetic product in accordance with section 609(a) of the FD&C Act or section 4(a) of the Fair Packaging and Labeling Act.

Consumers have a right to understand potential risks associated with the cosmetic products they use. Accordingly, their dermatologists also rely on accurate and timely adverse event information from the FDA and cosmetic manufacturers to effectively advise and treat patients, given dermatologists' clinical expertise in managing skin disease and cosmetic-related reactions. **We therefore urge the FDA to finalize this guidance to ensure timely and robust public notification of adverse events to support the identification, reporting, and mitigation of emerging cosmetic product safety concerns.**

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Thank you again for the opportunity to comment on the FDA's draft guidance on mandatory recalls for cosmetic products. If you have any questions or need additional information, please contact Nija Chappel, JD, MPH, Manager, Regulatory Policy at nchappel@aad.org.

Sincerely,

Susan C. Taylor, MD, FAAD
President, American Academy of Dermatology Association