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ALERT

FDA Explains Its Mandatory Cosmetics Recall Authority, Adhering Closely to 2022 Statutory Language

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The U.S. Food and Drug Administration (FDA, or the Agency) published a **draft guidance** explaining its mandatory recall authority for cosmetic products on December 18, 2025 (**90 FR 59129**). Entitled "Questions and Answers Regarding Mandatory Cosmetics Recalls: Guidance for Industry," the document provides FDA's thinking on how it will implement the mandatory cosmetics recall authority given to it by statute. FDA expounds on its recall-related policies, while also adhering closely to the language provided by Congress in 2022. FDA also describes the informal hearing process available to those who seek to challenge FDA's conclusion that there is a reasonable probability that the cosmetic will cause serious adverse health consequences or death.

Background

Statutory Authority: FDA can order a mandatory cosmetic recall under Section 611 of the Federal Food, Drug, and Cosmetic Act (the FD&C Act), as added by Section 3502 of the **Modernization of Cosmetics Regulation Act of 2022 (MoCRA)**.

Notice & Opportunity to Voluntarily Recall: The FDA must provide the responsible person (the manufacturer, distributor, or packer whose name is on the cosmetic label) with an opportunity to voluntarily cease distribution and recall the product.

Recall Standard: If the responsible person does not comply with FDA's initial request for a voluntary recall, then the Agency may, by order, require such person to immediately cease distribution of the product.

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Before issuing an order, the FDA must determine that there is a "reasonable probability" that:

(1) A cosmetic product is adulterated or misbranded under Sections 601 or 602, *and*

(2) The use of or exposure to such cosmetic will cause serious adverse health consequences or death (SAHCOD).

This MoCRA amendment significantly expanded FDA's recall authority. Most recalls of FDA-regulated products, including cosmetics, have occurred voluntarily in accordance with 21 C.F.R. §§ 7.40-7.59. FDA noted its expectation that most violative cosmetics will continue to be recalled as a voluntary company action despite its mandatory recall authority.

FDA's Draft Guidance – Questions and Answers on Mandatory Cosmetics Recalls

Although the draft guidance is relatively short at five pages, FDA discusses the following topics:

- Prior to issuing a mandatory recall order, the Agency will provide the responsible person, in writing, with an opportunity to voluntarily cease distribution of the cosmetic or component of the cosmetic. *See* Questions 1, 3, and 5.
- After issuing an order to cease distribution, FDA will provide an opportunity for an informal hearing within 10 days, under the procedures in 21 CFR part 16, to address whether adequate evidence exists to justify the order. *See* Question 5 and 7.
- Post-hearing outcomes – FDA may:
  - Vacate the order (if inadequate grounds exist to support the order),
  - Continue the order regarding ceasing distribution for a certain time period, *or*
  - Amend the order to add a requirement for a recall, which may include public notification, timetables for the recall, and a schedule for updating the Agency. *See* Question 8. In this case, FDA will issue its own press release and website notice describing the risk associated with the product and similar cosmetics not affected by the recall. *See* Question 13.

Overview of Informal Hearing Process:

- FDA may – and it intends to – require the responsible person to provide notice of the order to the public and to those who manufacture, distribute, import, or offer the product for sale. *See* Question 6.
- Under Questions 9 and 10, FDA lists the conditions under which a cosmetic is considered adulterated or misbranded under Sections 601 and 602 of the FD&C Act. FDA reminds the industry that a failure to have adequate substantiation of the safety of the product or its components can cause the product to be adulterated.
- Question 11 lists examples of evidence or circumstances that FDA may consider when pursuing a mandatory cosmetic recall, including:

  - Significant safety observations made during establishment inspections;
  - Results from sample analyses of raw materials or finished cosmetics, and sample swabs from the facility's manufacturing environment;
  - Epidemiological data (e.g., data directly related to the cosmetic that suggest disease or injuries have occurred from the use of/exposure to the product);
  - Vulnerability of the population that normally uses or is exposed to the cosmetic (e.g., infants, toddlers, the elderly, pregnant women, medically compromised individuals);
  - Serious adverse event (SAE) data;
  - Consumer and trade complaints; and
  - Whether the responsible person has failed to voluntarily cease distribution of the cosmetic or initiate a voluntary recall.
- When determining whether there is a reasonable probability that the cosmetic will cause SAHCOD, FDA states that it will consider "all applicable evidence," but then just recites the statutory definition of SAE. *See* Question 12.
- If the responsible person fails or refuses to cease distribution or recall the article as ordered, they could be subject to an injunction and/or criminal prosecution under Section 302 and 303 of the FD&C Act. *See* Question 16.
- A recall will terminate when FDA determines that all the requirements of the order have been met, and reasonable efforts have been made to remove or correct the product, commensurate with the degree of hazard associated with the product. *See* Question 15.
- FDA clarifies that cosmetic products that are also drugs or devices are not subject to mandatory recalls under Section 611. However, these products may be subject to other mandatory recall authorities. *See* Question 2.

Key Takeaways

FDA's mandatory cosmetics recall authority under the FD&C Act is still a relatively new extension of FDA's legal authority, although voluntary cosmetic recalls have occurred for decades. This draft guidance is a "first step" to help the industry prepare for, and hopefully avoid, the Agency's cease-distribution orders and mandatory recall orders.

In response to this information, cosmetics manufacturers, distributors and packers should (i) evaluate their customer complaint files and adverse event reports for possible recall-triggering risks; (ii) audit their product safety dossiers and good manufacturing practices for compliance with FDA expectations; (iii) ensure inspection readiness; and (iv) establish internal procedures covering rapid response for FDA inquiries and preparedness for engaging in the new notice order hearing recall process.

Stakeholders can submit comments and questions to FDA until **February 17, 2026**. Anyone interested can provide input on FDA's draft responses, express concerns, request clarifications, or propose additional questions for FDA to answer.

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Please do not hesitate to reach out to the authors of this alert if you have any questions about these or other requirements under MoCRA.