MoCRA Update: FDA's Draft Q&A on Cosmetics Recall Authority

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The Modernization of Cosmetics Regulation Act of 2022 (MoCRA) is considered the most significant expansion of the U.S. Food and Drug Administration's (FDA) authority to regulate cosmetics since the enactment of the Food, Drug and Cosmetic Act (FDCA) in 1938. For example, in addition to the various substantive requirements for industry and rulemaking directives to the FDA, MoCRA granted the Agency mandatory recall authority over cosmetics. Three years after receiving such authority, in December 2025, the FDA issued a draft guidance addressing anticipated questions about MoCRA's mandatory recall provisions and the Agency's current thoughts on their implementation.

The FDA's draft, "Questions and Answers Regarding Mandatory Cosmetics Recalls," covers key considerations, such as the circumstances under which the FDA may use its mandatory recall authority and what factors and evidence will be considered in deciding whether to do so. While it may be helpful for cosmetic companies to review the questions and answers addressing such considerations to ensure they are effectively addressed in their respective compliance policies, the rest of the draft guidance largely echoes MoCRA's provisions.

Key Questions and Answers:

Below are highlights from some of the key questions and answers that may provide helpful insight for companies subject to MoCRA. For a refresher on the broader requirements of MoCRA, see our prior overview here.

What determination must the FDA make to invoke its mandatory recall authority?

To invoke its authority to issue a mandatory recall, the FDA must determine that:

1. There is a reasonable probability that the cosmetic is adulterated under Section 601 of the FDCA or misbranded under Section 602 of the FDCA, *and*
2. There is a reasonable probability that the use of or exposure to the cosmetic will cause serious adverse health consequences or death (SAHCOD)

What are some examples of information that the FDA might consider in deciding whether there is a reasonably probability of SAHCOD?

A "serious adverse event" is defined as: "death; a life-threatening experience; inpatient hospitalization; a persistent or significant disability or incapacity; a congenital anomaly or birth defect; an infection; significant disfigurement (including serious and persistent rashes, second- or third-degree burns, significant hair loss or persistent or significant alteration of appearance), other than as intended, under conditions of use that are customary or usual; or based on reasonable medical judgment, requires a medical or surgical intervention" to prevent any of these outcomes.

Whether the use of or exposure to a cosmetic is reasonably likely to result in SAHCOD depends on the applicable circumstances and available evidence, including, for example:

- Significant cosmetic safety observations made during establishment inspections
- Results from sample analyses, which may include those for raw materials or finished cosmetics, and sample swabs from the cosmetic facility manufacturing environment
- Epidemiological data (e.g., data directly related to the cosmetic that suggest disease or injuries have already occurred from the use of/exposure to the product)
- Vulnerability of the population that normally uses or is exposed to the cosmetic (the assessment of the hazard will consider the segment of the population, e.g., infants, toddlers, the elderly, pregnant women, medically- compromised individuals)
- Available serious adverse event data
- Consumer and trade complaints
- Whether the responsible person has failed to voluntarily cease distribution of the cosmetic or initiate a voluntary recall

What process will the FDA follow in issuing a mandatory recall under MoCRA?

Once the FDA has determined that there is a reasonable probability that the cosmetic is adulterated or misbranded and that SAHCOD is reasonably likely to result from use or exposure, the FDA plans to, first, allow the responsible person an opportunity to voluntarily cease distribution of the cosmetic and initiate a voluntary recall. If the responsible person declines or does not halt distribution or voluntarily recall the cosmetic in the time and manner that the FDA prescribed, the FDA may, then, compel the recall.

After ordering a responsible person to immediately cease distribution of a cosmetic, the FDA will hold a hearing within 10 days. The hearing will provide an opportunity for the responsible person to address whether there is adequate evidence to justify the order.

After providing the opportunity for a hearing, the FDA will vacate the order if the grounds for the order prove to be inadequate, continue the order to cease distribution of the cosmetic until a date specified, or amend the order to require a recall of the cosmetic. Refusal or failure to follow an order to cease distribution or recall the cosmetic could result in an injunction and/or criminal prosecution.

What's next?

The deadline to submit comments to the draft guidance is February 17, 2026. The FDA will consider comments submitted by such date before issuing a final version.[1] While the FDA final guidance documents often mirror the draft form, it may be worthwhile to submit critical questions that the draft guidance does not address or identify issues that need further clarification from the Agency while the comment window is open.

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[1] 90 Fed. Reg. 59129.