Questions and Answers Regarding Mandatory Cosmetics Recalls: Guidance for Industry

Draft Guidance

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Submit electronic comments to https://www.regulations.gov. Submit written comments to the Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. All comments should be identified with docket number FDA-2025-D-2246 as listed in the notice of availability that publishes in the *Federal Register*.

For questions or information regarding this draft guidance, contact the Office of Inspections and Investigations (OII), Office of Field Regulatory Operations (OFRO), Division of Inspectorate Policy (DIP), Food and Drug Administration at OIIPolicyStaffs@fda.hhs.gov.

U.S. Department of Health and Human Services
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I. Introduction

The purpose of this document is to provide guidance to industry on the implementation of the mandatory cosmetics recall provisions of section 611 of the Federal Food, Drug, and Cosmetic Act (the FD&C Act or the Act). The guidance in this document is in the form of Questions and Answers and provides answers to common questions that might arise about these mandatory recall provisions and FDA's current thinking regarding their implementation.

FDA's guidance documents, including this guidance, do not establish legally enforceable responsibilities. Instead, guidances describe the Agency's current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word *should* in Agency guidances means that something is suggested or recommended, but not required.

II. Background

On December 29, 2022, the President signed into law the Consolidated Appropriations Act, 2023 (Pub. L. 117-328), which included the Modernization of Cosmetics Regulation Act of 2022 (MoCRA). Among other provisions, MoCRA added section 611 to the FD&C Act, providing mandatory recall authority over cosmetics. Most recalls of FDA-regulated products, including cosmetics, have generally occurred voluntarily in accordance with 21 C.F.R. part 7, subpart C (§§ 7.40-7.59). FDA continues to encourage firms to voluntarily recall violative cosmetics and expects most violative cosmetics will continue to be voluntarily recalled. Section 611 of the FD&C Act gives FDA the authority to order a responsible person (as defined in section 604 of the Act) to cease distribution and recall a cosmetic if certain criteria are met.

III. Questions and Answers

This list of Questions and Answers is intended to provide answers to common questions about the cosmetic mandatory recall provisions in section 611 of the FD&C Act and FDA's current thinking regarding their implementation.

1. What cosmetics are subject to FDA's mandatory recall authority?

All articles that meet the definition of "cosmetic" in section 201(i) the FD&C Act are subject to FDA's mandatory cosmetic recall authority. The term "cosmetic" means (1) articles 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 attractiveness, or altering the appearance, and (2) articles intended for use as a component of any such articles; except that such term shall not include soap.

2. Are cosmetic products that are also drugs or devices subject to FDA's cosmetic mandatory recall authority?

Cosmetic products that are also subject to the requirements of Chapter V of the FD&C Act (i.e., requirements for drugs or devices) are not subject to section 611, but these products may be subject to other mandatory recall authorities. (See section 613 of the FD&C Act).[1]

3. Who is a "responsible person" under section 611 of the FD&C Act?

For purposes of MoCRA, the term "responsible person" is defined in section 604 of the FD&C Act as the manufacturer, packer, or distributor of a cosmetic product whose name appears on the label of such cosmetic product in accordance with section 609(a) of the FD&C Act or section 4(a) of the Fair Packaging and Labeling Act.

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

In order to use its cosmetic mandatory recall authority under section 611 of the FD&C Act, FDA must determine that the following criteria are met:

a. there is a reasonable probability that the cosmetic is adulterated under section 601 of the Act or misbranded under section 602 of the Act; and

b. there is a reasonable probability that the use of or exposure to the cosmetic will cause serious adverse health consequences or death (SAHCOD).

[1] See Is It a Cosmetic, a Drug, or Both? (Or Is It Soap?) for more information regarding cosmetics that are subject to drug requirements, and Aesthetic (Cosmetic) Devices for more information regarding cosmetics that are subject to device requirements.

5. What process will FDA follow before issuing an order for a mandatory recall?

If FDA determines that (1) there is a reasonable probability that the cosmetic is adulterated under section 601 of the Act or misbranded under section 602 of the Act and (2) there is a reasonable probability that the use of or exposure to the cosmetic will cause SAHCOD, FDA will provide the responsible person with an opportunity to voluntarily cease distribution and recall the cosmetic (section 611(a) of the FD&C Act). FDA will notify the responsible person of this opportunity in writing. If the responsible person refuses to or does not voluntarily cease distribution or recall such cosmetic within the time and manner prescribed by FDA, if so prescribed, FDA may, by order, require, as FDA determines necessary, the responsible person to immediately cease distribution of such cosmetic. FDA will provide the responsible person who is subject to such order with an opportunity for an informal hearing. If a hearing is granted by FDA, it will be held no later than 10 days after the date of issuance of the order and address whether adequate evidence exists to justify the order (section 611(b) of the FD&C Act). The informal hearing will be conducted in accordance with the procedures in 21 C.F.R. part 16, Regulatory Hearing Before the Food and Drug Administration.

6. What must a responsible person do after receiving an order to immediately cease distribution of a cosmetic?

Any responsible person subject to an order to immediately cease distribution of a cosmetic must comply with the order. If determined necessary, FDA may also require the responsible person to provide notice of such order to appropriate persons including persons who manufacture, distribute, import, or offer for sale such product that is the subject of the order and to the public. FDA generally intends to include this information in the order to immediately cease distribution and the responsible person must provide such notice as required by the order (see section 611(e) and 301(iii) of the FD&C Act).

7. After the order to immediately cease distribution of the affected cosmetic has been issued, does the responsible person have an opportunity for a hearing?

FDA shall provide the responsible person who is subject to an order to immediately cease distribution under section 611(a) with an opportunity for an informal hearing, to be held not later than 10 days after the date of issuance of the order (section 611(b) of the FD&C Act). The informal hearing will be conducted in accordance with the procedures in 21 C.F.R. part 16, Regulatory Hearing Before the Food and Drug Administration. If a hearing is granted, the hearing will provide an opportunity for the responsible person to address whether adequate evidence exists to justify the order.

8. After providing an opportunity for an informal hearing, what are the possible outcomes?

After providing an opportunity for an informal hearing, as described in section 611(b), FDA will:

- vacate the order, if FDA determines that inadequate grounds exist to support the actions required by the order;
- continue the order ceasing distribution of the cosmetic until a date specified in such order; or
- amend the order to require a recall of the cosmetic, including any requirements to notify appropriate persons, a timetable for the recall to occur, and a schedule for updates to be provided to FDA regarding such recall.

We note that the FDA Commissioner has the authority to order a recall or vacate a recall order issued pursuant to section 611(c)(3). This authority cannot be delegated to any other officer or employee (see section 611(g)).

9. When is a cosmetic considered adulterated under section 601 of the FD&C Act?

A cosmetic shall be deemed to be adulterated:

- If it bears or contains any poisonous or deleterious substance which may render it injurious to users under the conditions of use prescribed in the labeling thereof, or under such conditions of use as are customary or usual.[2]
- If it consists in whole or in part of any filthy, putrid, or decomposed substance.
- If it has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health.
- If its container is composed, in whole or in part, of any poisonous or deleterious substance which may render the contents injurious to health.
- If it is not a hair dye and it is, or bears or contains, a color additive which is unsafe within the meaning of 721(a) of the FD&C Act.[3]
- If it has been manufactured or processed under conditions that do not meet the good manufacturing practice requirements of section 606 of the FD&C Act.
- If it is a cosmetic product, and the cosmetic product, including each ingredient in the cosmetic product, does not have adequate substantiation for safety, as defined in section 608(c) of the FD&C Act.

10. When is a cosmetic considered misbranded under section 602 of the FD&C Act?

[2] We note that this provision does not apply to coal-tar hair dye if its label bears the following legend conspicuously displayed thereon: "Caution—This product contains ingredients which may cause skin irritation on certain individuals and a preliminary test according to accompanying directions should first be made. This product must not be used for dyeing the eyelashes or eyebrows; to do so may cause blindness.", and its labeling bears adequate directions for such preliminary testing. For the purposes of this provision, "hair dye" does not include eyelash or eyebrow dyes (section 601(a) of the FD&C Act).

[3] For purposes of this provision, "hair dye" does not include eyelash or eyebrow dyes (see section 601(a) of the FD&C Act).

A cosmetic shall be deemed to be misbranded:

- If its labeling is false or misleading in any particular.
- If it is in package form and does not bear a label containing: the name and place of business of the manufacturer, packer, or distributor; an accurate statement of the quantity of contents in terms of weight, measure, or numerical count;[4] and the information required under section 609 of the FD&C Act.
- If information required by the FD&C Act to appear on the label or labeling is not prominently and conspicuously placed and, in such terms, as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use.
- If its container is so made, formed, or filled as to be misleading.
- If it is a color additive that does not comply with the packaging and labeling requirements applicable to such color additive, as may be contained in the regulations issued under section 721 of the FD&C Act.[5]
- If its packaging or labeling is in violation of an applicable regulation issued pursuant to section 3 or 4 of the Poison Prevention Packaging Act of 1970.

11. What evidence or circumstances might FDA consider when deciding to move forward with a mandatory cosmetic recall under section 611?

FDA will evaluate all applicable evidence when determining whether there is a reasonable probability that the cosmetic is adulterated under section 601 of the FD&C Act or misbranded under section 602 of the FD&C Act, and that the use of or exposure to such cosmetic will cause SAHCOD. These circumstances or evidence may include:

- 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; and,
- whether the responsible person has failed to voluntarily cease distribution of the cosmetic or initiate a voluntary recall.

12. What are some examples of circumstances that FDA might consider to be

[4] We note that an exemption may apply to certain cosmetics that are to be processed, labeled, or repacked at an establishment other than where they were originally processed or packed, under 21 C.F.R. 701.9.

[5] We note that this provision does not apply to packages of color additives that are marketed and intended for use only in or on hair dyes (as defined in section 601(a) of the FD&C Act).

SAHCOD?

As explained above, FDA will consider all applicable evidence when determining whether there is a reasonable probability that the use of or exposure to an adulterated or misbranded cosmetic will cause SAHCOD. We note that section 604 of the FD&C Act defines "serious adverse event" 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 the outcomes previously described. Depending on the circumstances and available evidence, certain of these situations may represent a SAHCOD risk.

13. How will FDA ensure that appropriate persons or the public are notified about an order to cease distribution or mandatory recall order?

If determined necessary, FDA may require a responsible person to provide notice to appropriate persons, including persons who manufacture, distribute, import, and or offer for sale such product that is the subject of an order and the public, of an order to cease distribution of a cosmetic or an amended order to recall a cosmetic in accordance with 611(e) of the FD&C Act.

If an amended order to recall is issued pursuant to section 611(c)(3), FDA will ensure that a press release regarding the recall is published. The press release will include, at a minimum, the name of the cosmetic subject to recall, a description of the risk associated with such article and, to the extent practical, information for consumers about similar cosmetics that are not affected by the recall. FDA will also ensure publication, as appropriate, on its website of an image of the cosmetic that is the subject of the press release, if available.[6] Additionally, FDA will ensure that alerts (typically in the form of a notification letter or email) and public notices are issued, as appropriate. These communications are issued in order to provide notification to consumers and retailers to whom such cosmetic was, or may have been, distributed (see section 611(f) of the FD&C Act).

14. If an order to cease distribution of a cosmetic is continued, when would it end?

If an order to cease distribution of a cosmetic is continued under section 611(c)(2), the order stays in place until the date specified in the order.

15. When would a mandatory cosmetic recall order terminate?

[6] While mandatory recalls are not the subject of FDA's guidance, Public Warning and Notification of Recalls under 21 CFR part 7, Subpart C, it may provide some helpful background information relevant to press releases in the recall context (available at www.fda.gov/regulatory-information/search-fda-guidance-documents/public-warning-notification-recalls-under-21-cfr-part-7-subpart-c).

If FDA orders a recall under section 611(c)(3) of the FD&C Act, such recall will generally be terminated when FDA determines that all requirements of the recall order have been satisfied. FDA will generally follow the process for termination of the recall set forth in 21 C.F.R. 7.55. According to 21 C.F.R. 7.55, a recall will be terminated when FDA determines that reasonable efforts have been made to remove or correct the product in accordance with the recall strategy, and when it is reasonable to assume that the product subject to the recall has been removed and proper disposition or correction has been made commensurate with the degree of hazard of the recalled product. Written notification that a recall is terminated will be issued by the appropriate FDA office to the recalling firm.

16. What if the responsible person fails or refuses to cease distribution or recall the article as ordered?

The refusal or failure to follow an order under section 611 is a prohibited act (see section 301 of the FD&C Act). Therefore, a person who refuses or fails to follow such order could be subject to injunction and/or criminal prosecution (see section 302 and 303 of the FD&C Act).