Notifying FDA of a Permanent Discontinuance in the Manufacture or an Interruption of the Manufacture of an Infant Formula: Guidance for Industry

Draft Guidance

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For questions regarding this guidance, contact the Human Foods Program at 240-402-1200.

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U.S. Department of Health and Human Services
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This draft guidance, when finalized, will represent the current thinking of the Food and Drug Administration (FDA or we) on this topic. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations. To discuss an alternative approach, contact the FDA staff responsible for this guidance at the phone number listed on the title page.

I. INTRODUCTION

Section 424(a)(1) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 350m(a)(1)) requires manufacturers of a critical food[2] to notify FDA of a permanent discontinuance in the manufacture or an interruption of the manufacture of a critical food that is likely to lead to a meaningful disruption in the supply of such food in the United States, and the reasons for such discontinuance or interruption, as soon as practicable, but not later than 5 business days after such discontinuance or such interruption.

The notification requirements apply to all manufacturers (foreign and domestic) that manufacture critical foods for sale in the United States, regardless of manufacturer size or market share. This guidance discusses the notification requirements under section 424(a)(1) of the FD&C Act as they pertain to infant formula,[3] as well as FDA's interpretation of key terms in the statute and provides recommendations for the content of and procedures for submitting such notifications. These recommendations are informed by FDA's recent experience involving manufacturer interruptions of these products and our work to improve the resiliency of the infant formula market. This guidance covers all infant formulas, including those that are also medical foods

[1] This guidance has been prepared by the Office of Surveillance, Strategy, and Risk Prioritization; the Office of Critical Foods; and the Office of Policy, Regulations, and Information in the Human Foods Program at the U.S. Food and Drug Administration.
[2] Section 201(ss) of the FD&C Act (21 U.S.C. 321(ss)) defines a "critical food" as a food that is (1) an infant formula or (2) a medical food as defined in section 5(b)(3) of the Orphan Drug Act [21 U.S.C. 360ee(b)(3)].
[3] Section 201(z) of the FD&C Act (21 U.S.C. 321(z)) defines "infant formula" as a food which purports to be or is represented for special dietary use solely as a food for infants by reason of its simulation of human milk or its suitability as a complete or partial substitute for human milk.

(*i.e.,* exempt infant formulas[4]). FDA intends to continue gathering data regarding the market(s) for other types of critical food to help inform guidance related to those products. Although this guidance is specific to infant formula, manufacturers of other types of critical foods are still required to comply with section 424 of the FD&C Act.

In general, FDA's guidance documents, including this guidance, do not establish legally enforceable responsibilities. Instead, guidance documents describe our 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 FDA guidance documents means that something is suggested or recommended, but not required.

II. BACKGROUND

The Food and Drug Omnibus Reform Act of 2022 (FDORA), enacted on December 29, 2022, amended the FD&C Act to help address the problem of critical food shortages in the United States, including by adding requirements related to notifying FDA about critical food manufacturing discontinuances and interruptions. While some supply disruptions and product shortages cannot be predicted or prevented, early communication and detailed notifications from manufacturers to FDA can play a significant role in decreasing the incidence, impact, and duration of supply disruptions and product shortages. Timely notifications that include specific information about the situation allow FDA to evaluate the situation and determine an appropriate course of action. When FDA does not receive timely, informative notifications, FDA's ability to respond appropriately is limited.

III. NOTIFYING FDA OF A PERMANENT DISCONTINUANCE IN OR AN INTERRUPTION OF MANUFACTURING

A. Who Must Notify FDA?

Section 424(a)(1) of the FD&C Act states that a manufacturer of a critical food must notify FDA of a permanent discontinuance in the manufacture or an interruption of the manufacture of such food that is likely to lead to a meaningful disruption in the supply of such food in the United States.

B. When Should a Manufacturer Notify FDA?

Section 424(a)(1) of the FD&C Act requires manufacturers to notify us "as soon as practicable, but not later than 5 business days" after a permanent discontinuance or an interruption of the manufacture of a critical food that is likely to lead to a meaningful disruption in the supply of such food in the United States. In FDA's experience, even if it is not possible for a manufacturer to notify us before a decision to discontinue or an interruption that is likely to lead to a meaningful disruption in supply, it generally should be possible for the manufacturer to provide notice within one or two calendar days of the decision to discontinue or the interruption.

[4] An "exempt infant formula" is an infant formula intended for commercial or charitable distribution that is represented and labeled for use by infants who have inborn errors of metabolism or low birth weight, or who otherwise have unusual medical or dietary problems. (21 CFR 107.3).

What Is a Permanent Discontinuance of an Infant Formula?

Section 424 of the FD&C Act does not define "permanent discontinuance," but, with respect to infant formula, we interpret the phrase "permanent discontinuance" in section 424 of the FD&C Act to be a decision by an infant formula manufacturer to cease manufacturing and distributing its product indefinitely, for any reason. The reason can include business reasons (such as discontinuing a product due to low sales). All permanent discontinuances must be reported according to the timeline above (see section 424(a)(1) of the FD&C Act).

What Is an Interruption of the Manufacture of an Infant Formula That Is Likely to Lead to a Meaningful Disruption in the Supply of Such Food in the United States?

Section 424(a)(4) of the FD&C Act, states that, for purposes of section 424(a) of the FD&C Act, "meaningful disruption":

- means a change in production that is reasonably likely to lead to a significant reduction in the supply of a critical food by a manufacturer that affects the ability of the manufacturer to meet expected demand for its product; and
- does not include interruptions in manufacturing due to matters such as routine maintenance, changes or discontinuance of flavors, colors, or other insignificant formulation characteristics, or insignificant changes in manufacturing so long as the manufacturer expects to resume operations in a short period of time.

In the case of interruptions in manufacturing, when assessing whether a meaningful disruption in supply is likely to occur, the relevant analysis is whether a change in production is likely to lead to a reduction in the supply of a product *by the manufacturer* that is more than negligible and would affect the *manufacturer's* ability to fill orders or meet expected demand for its product. In other words, the assessment is to be based solely on the reporting manufacturer's capacity and supply.

Additional Recommendations

Given the importance that infant formula can have in infant nutrition and health, we encourage manufacturers to voluntarily notify us at least 6 months before permanently discontinuing manufacturing an infant formula product.

If a manufacturer is unsure of whether to notify us about a possible permanent discontinuance or a meaningful disruption in the manufacture of infant formula, we encourage manufacturers to submit a notification. Timely notifications will allow us to monitor the overall market and take steps, where possible and necessary, to help prevent, mitigate, or otherwise address potential infant formula shortages.

C. What Information Should Be in a Notification?

Section 424(a)(1) of the FD&C Act states that a manufacturer of a critical food must notify FDA of a permanent discontinuance in the manufacture or an interruption of the manufacture of such food that is likely to lead to a meaningful disruption in the supply of such food in the United States, and the reasons for such discontinuance or interruption. With respect to infant formula, we interpret this to mean that the notification must state:

- The manufacturer's name;
- The name of each infant formula product impacted;
- Whether the notification relates to a permanent discontinuance in manufacturing one or more infant formula product(s) or an interruption in the manufacture of one or more infant formula product(s); and
- The reason(s) for the permanent discontinuance or interruption in manufacturing.

Additionally, we recommend that a notification voluntarily include the following information that will help FDA appropriately identify the affected product(s), determine the potential for and the criticality of a supply chain disruption, and better assess the overall state of the market:

- A point of contact for the notification;
- The UPC code(s) for each infant formula product impacted;
- Infant formula product alternatives available (or planned) from the manufacturer that consumers may consider for each infant formula product impacted;
- If the manufacturer intends to permanently discontinue manufacturing:
    - The date on which it will stop manufacturing the product;
    - The production volume of infant formula product(s) that will be or has been permanently discontinued;
    - The estimated amount of product remaining for sale/distribution when manufacturing stops;
    - The shelf life for each impacted infant formula product;
    - If known, the geographic distribution impacted by the reduction of the infant formula product(s); and
    - Whether the manufacturer intends to inform the public and/or other stakeholders regarding the discontinuance.
- If the manufacturer anticipates an interruption in manufacturing or an interruption has already occurred:
    - The projected duration of the interruption, including, if possible, the dates on which the interruption will start and end;
    - The size/amount of product reduction anticipated and estimate of amount of product remaining for sale/distribution when the interruption began or begins;
    - The shelf life for each impacted infant formula product;
    - The production volume by facility and the potential availability of alternative production sites;
    - Whether the manufacturer can increase and anticipates increasing production of the impacted product(s) when the interruption ends to replace the lost supply;
    - If known, the geographic distribution impacted by the reduced production of the infant formula product(s); and

  - Whether the manufacturer intends to inform the public and/or other stakeholders regarding the actual or potential shortage.
- Any additional information the manufacture considers helpful.

Notifications can be updated to include additional information at any time after they are submitted to FDA. Therefore, we recommend that manufacturers not delay notifying FDA until all information is available, but instead recommend that they provide an initial notification as soon as practicable and additional information as it becomes available. If manufacturers do not notify FDA within the timeline specified in the statute (as soon as practicable, but not later than 5 business days), FDA requests that manufacturers explain why notification within such timeline was not possible.

If information changes after the manufacturer has submitted a notification to us, we recommend that the manufacturer send us revised or updated information. In the case of a manufacturing interruption, we also recommend that manufacturers engage with us regarding the specifics of the disruption to determine what information should be submitted as part of updates and the frequency of those updates. These updates can help us consider what actions we may take to address the situation.

D. How Should a Manufacturer Notify FDA?

Manufacturers should submit their notifications to us by email to CriticalFoodShortage@fda.hhs.gov, which we will closely monitor, with a subject line "Infant Formula – Permanent Discontinuance" or "Infant Formula – Interruption in Manufacturing," as appropriate.

To help facilitate FDA's review of notifications, manufacturers should submit separate notifications for permanent discontinuances and interruptions in manufacturing. A single notification (*i.e.*, a notification for permanent discontinuance(s) or a notification for interruption(s) in manufacturing), however, can include more than one affected infant formula product. For example, if a manufacturer markets three different infant formula products and intends to permanently discontinue manufacturing of all three products at the same time, the manufacturer can submit a single notification covering the three products. If a manufacturer markets two different infant formula products and intends to permanently discontinue one product and temporarily stop manufacturing another, we ask that the manufacturer submit one notification for the permanent discontinuance and another notification for the interruption. After receipt of notification, FDA will work with the manufacturer to understand the full scope of the impact and determine appropriate next steps.

E. Failure to Notify FDA

If a manufacturer fails to provide information of a permanent discontinuance or an interruption in manufacturing as required by section 424(a) of the FD&C Act, we must issue a letter to that manufacturer ("noncompliance letter") informing the manufacturer of its failure to notify (see section 424(c)(1)(A) of the FD&C Act). Within 45 days of sending the noncompliance letter to the manufacturer, we will post on our website the letter, and, at the request of the manufacturer,

any response to the letter the manufacturer submitted to us, with appropriate redactions to protect trade secrets or confidential information (see section 424(c)(1)(B) of the FD&C Act). However, we will not post the noncompliance letter and response if we determine that the letter was issued in error, or, after a review of the manufacturer's response, we determine that the manufacturer had a reasonable basis for not submitting the notification (see section 424(c)(2) of the FD&C Act).