

# Infant Formula Transition Plan for Exercise of Enforcement Discretion: Guidance for Industry

*Additional copies are available from:  
Office of Nutrition and Food Labeling  
Center for Food Safety and Applied Nutrition  
Food and Drug Administration  
5001 Campus Drive  
College Park, MD 20740  
(Tel) 240-402-4487*

<http://www.fda.gov/FoodGuidances>

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For questions regarding this guidance document, contact the Center for Food Safety and Applied Nutrition, Office of Nutrition and Food Labeling, at 240-402-4487.

**U.S. Department of Health and Human Services  
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# Infant Formula Transition Plan for Exercise of Enforcement Discretion: Guidance for Industry<sup>1</sup>

This guidance represents the current thinking of the Food and Drug Administration (FDA, the Agency, 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

FDA plays a critical role in ensuring the safety and nutritional adequacy of infant formula in the United States. We work to ensure that infant formula sold in the United States meets the required safety and nutritional standards specified in section 412 of the Federal Food, Drug, and Cosmetic Act (FD&C Act) and in FDA's implementing regulations at 21 CFR parts 106 and 107. Given recent events precipitating a critical shortage of infant formula in the United States, FDA is issuing this guidance document to protect public health by helping to stabilize the supply of infant formula in the United States and to maintain a consistent supply of a variety of infant formula products.<sup>1</sup> Continued product availability is an issue of particular significance for infants who started on a specific formula during the shortage and have come to rely on such formula as an essential source of nutrition.<sup>2</sup>

The current period of supply shortage and disruption caused by, among other things, the temporary shutdown of a major infant formula manufacturing facility, has demonstrated the need for FDA to support the availability of an adequate supply of safe and nutritionally adequate infant formula, create a more resilient U.S. supply for infant formula products, and help avoid the future risk of lack of access to a sole source of nutrition for a vulnerable population. To help meet these goals, FDA intends to temporarily exercise enforcement discretion for certain manufacturers of infant formula that continue to introduce into interstate commerce (including through importation) infant formula products that may not comply with certain statutory and regulatory requirements if: (1) such manufacturers market these products consistent with a letter of enforcement discretion relating to information provided under our "Infant Formula Enforcement Discretion Policy: Guidance for Industry" issued May 2022 (May 2022 Enforcement Discretion Guidance),<sup>3</sup> which remains in effect until November 14, 2022; and (2) such manufacturers take specific actions to achieve compliance

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<sup>1</sup> This guidance has been prepared by the Office of Nutrition and Food Labeling and the Office of Regulations and Policy in the Center for Food Safety and Applied Nutrition at the U.S. Food and Drug Administration.

<sup>2</sup> See, e.g., 79 FR 7933 at 8026 (Feb. 10, 2014).

<sup>3</sup> Consistent with the policies described in the May 2022 Enforcement Discretion Guidance, available at <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/guidance-industry-infant-formula-enforcement-discretion-policy>, certain manufacturers have submitted information to FDA to substantiate the safety and nutritional adequacy of specific infant formula products and have been marketing such products under FDA's exercise of enforcement discretion.

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with the statutory and regulatory requirements applicable to their products. This guidance document will help infant formula manufacturers meet the regulatory requirements applicable to these products while ensuring continued access to formulas that are currently fulfilling the needs of infants consuming such products. This guidance is intended to advise infant formula manufacturers marketing products in accordance with letters of enforcement discretion issued under the May 2022 Enforcement Discretion Guidance about: (1) the type of information to provide to FDA; and (2) our timing expectations related to such information, if they would like us to consider the exercise of enforcement discretion with respect to infant formula products that are safe and nutritionally adequate, but that may not comply with all statutory and regulatory requirements, during the period described below. FDA expects that all infant formula products will comply with all applicable U.S. requirements by the end of the enforcement discretion period.

This guidance also allows FDA to refocus resources on reviewing product and manufacturer information submitted in accordance with FDA regulations prior to the May 2022 Enforcement Discretion Guidance. Infant formula manufacturers that submitted packages to FDA pursuant to the May 2022 Enforcement Discretion Guidance but that did not receive enforcement discretion letters may continue to seek FDA review in accordance with FDA regulations.

This guidance document will remain in effect until October 18, 2025, and we will evaluate whether any extension is necessary before that date. We will give public notice if we determine that an extension is warranted.

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

This guidance is being issued to protect public health by helping to stabilize the supply of infant formula in the United States and to maintain a consistent supply of a variety of infant formula products. This guidance is being implemented without prior public comment because FDA has determined that prior public participation for this guidance is not appropriate (see section 701(h)(1)(C) of the FD&C Act (21 U.S.C. 371(h)(1)(C)) and 21 CFR 10.115(g)(2)). This guidance is being implemented immediately, but it remains subject to comment in accordance with our good guidance practices.

## **II. Background**

The FD&C Act 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" (section 201(z) of the FD&C Act (21 U.S.C. 321(z)). Our regulations define infants as persons not more than 12 months old (21 CFR 105.3(e)).

Infant formula is often used as the sole source of nutrition for a vulnerable population during a critical period of growth and development. In general, the laws and regulations that apply to food also apply to infant formula, but additional requirements specific to infant formula appear in section 412 of the FD&C Act and in our regulations at 21 CFR parts 106 and 107. For example,

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under section 412(i) of the FD&C Act and 21 CFR 107.100, an infant formula must meet specific requirements for the levels of protein, fat, essential fatty acids, 15 vitamins, and 12 minerals.

A “new infant formula” means: (1) an infant formula manufactured by a person that has not previously manufactured an infant formula; and (2) an infant formula manufactured by a person that has manufactured an infant formula and in which there is a major change in processing or formulation from a current or any previous formulation produced by such manufacturer, or which has not previously been the subject of a submission under section 412(c) of the FD&C Act (21 U.S.C. 350a(c)) for the U.S. market (21 CFR 106.3). A “major change” in an infant formula is any new formulation, or any change of ingredients or processes where experience or theory would predict a possible significant adverse impact on levels of nutrients or bioavailability of nutrients, or any change that causes an infant formula to differ fundamentally in processing or in composition from any previous formulation produced by the manufacturer (21 CFR 106.3).

Among other requirements applicable to new infant formula products, section 412(c)(1)(B) of the FD&C Act (21 U.S.C. 350a(c)(1)(B)) and FDA regulations (21 CFR 106.120) require the manufacturer of a new infant formula to submit notice (i.e., a new infant formula submission) to FDA at least 90 days before the new infant formula is introduced or delivered for introduction into interstate commerce.<sup>4</sup>

FDA is aware that a voluntary recall and facility shutdown conducted by Abbott Nutrition in 2022 contributed to a supply disruption with respect to certain types of infant formula, which has been exacerbated by the overall strains on supply chains during the COVID-19 pandemic. As part of the Federal government’s response to the infant formula shortage, on May 16, 2022, FDA issued the May 2022 Enforcement Discretion Guidance discussing our intent to consider, on a case-by-case basis, the temporary exercise of enforcement discretion for the introduction into interstate commerce of infant formula that may not meet certain statutory and regulatory requirements. The May 2022 Enforcement Discretion Guidance describes the information that an infant formula manufacturer should provide to FDA if the manufacturer wishes to have FDA consider the exercise of enforcement discretion relating to the introduction into interstate commerce (including importation) of infant formula that is safe and nutritionally adequate but that may not comply with all FDA statutory and regulatory requirements.

Since the issuance of the May 2022 Enforcement Discretion Guidance, several manufacturers of infant formula have provided information to FDA as recommended in the guidance and, following FDA’s thorough review of the information provided, are marketing infant formula products under our exercise of enforcement discretion.<sup>5</sup>

FDA’s review of information received in response to the May 2022 Enforcement Discretion Guidance is one of several efforts that have enabled FDA to increase infant formula supplies to address the shortage, while also protecting the health of infants. Many companies marketing infant formula products under the enforcement discretion policy have expressed interest in continuing to

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<sup>4</sup> We do not consider the introduction or delivery for introduction into interstate commerce of products under the exercise of enforcement discretion to alter the status of such products as “new infant formula” under 21 CFR 106.3 for purposes of the applicability of the new infant formula registration and submission requirements under section 412(c) and (d) of the FD&C Act (21 U.S.C. 350a(c) and (d)) and 21 CFR 106.110 and 106.120.

<sup>5</sup> See FDA’s website for a list of companies receiving enforcement discretion for regular infant formulas and specialty formulas for infants with special medical needs (<https://www.fda.gov/food/infant-formula-guidance-documents-regulatory-information/enforcement-discretion-manufacturers-increase-infant-formula-supplies>).

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serve the U.S. market, which could help protect the public health by creating more resiliency in the U.S. infant formula supply and reducing the risk of reliance on too few production facilities.

On July 6, 2022, FDA announced that we were developing a strategy for continued and expanded access to infant formula for U.S. consumers (see [FDA Developing New Framework for Continued, Expanded Access to Infant Formula Options for U.S. Parents and Caregivers](#)). We determined that a more streamlined pathway that leverages information we have received and thoroughly reviewed for the infant formula products for which we are temporarily exercising enforcement discretion would help provide for the long-term availability of many of these products. Therefore, we stated that we intended to, among other things, provide a pathway for companies that import, sell, and/or distribute infant formula under our temporary enforcement discretion policy to continue to supply infant formula to the United States past November 14, 2022. This “Infant Formula Transition Plan for Exercise of Enforcement Discretion: Guidance for Industry” (Infant Formula Transition Plan Guidance) provides information about FDA’s current thinking on circumstances under which FDA intends to continue exercising temporary enforcement discretion for certain infant formula products beyond November 14, 2022.

### **III. Guiding Principles**

In developing this guidance, we followed several guiding principles:

- Infant formula is an essential food product that is the sole source of nutrition for many infants in the United States. Ensuring that the youngest and most vulnerable individuals have access to safe and nutritionally adequate formula products is a top priority for FDA. It is important to diversify and strengthen the U.S. infant formula supply in case of unanticipated disruptions. Minimizing disruption in the supply of infant formula products is also important because health care providers have recognized the importance of consistency in feeding an infant a certain formula once feeding is begun, as variations in infant formula products might not be equally tolerated by every infant. Therefore, continued access to certain formulas currently in the U.S. market is important for infants who started on a specific formula during the shortage and have come to rely on such products as an essential source of nutrition.
- This guidance sets forth a transparent pathway that leverages information we have already received and thoroughly reviewed for the products for which we are temporarily exercising enforcement discretion under our May 2022 Enforcement Discretion Guidance. This pathway is intended to help mitigate the short-term product shortage and provide for the long-term availability and marketing of infant formulas that fall within the scope of this guidance and to help create a more resilient U.S. infant formula supply.
- Infant formula manufacturers and their manufacturing facilities must meet rigorous requirements to demonstrate that the infant formulas meet the minimum requirements for quality factors (see, e.g., 21 CFR 106.96, “Requirements for quality factors for infant formulas”). Thus, the policies and recommendations in this guidance are consistent with our statutory mandate to both protect and promote the public health while responding to the need to take action to help alleviate current challenges with the supply of infant formula products and create a more resilient infant formula supply.<sup>6</sup>
- As in other situations, if FDA deems appropriate, we may, at any time, take action regarding a specific infant formula. FDA may choose to take action if, for example, the infant formula

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<sup>6</sup> See section 1003(b) of the FD&C Act (21 U.S.C. 393).

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manufacturer that is receiving enforcement discretion fails to make meaningful progress on the timeline detailed in this document or if we otherwise become aware of information that raises a concern about the safety or nutritional adequacy of the product.

### **IV. Discussion**

This guidance document describes the actions a covered infant formula manufacturer should take if it wishes to have FDA consider the continued exercise of enforcement discretion relating to the introduction into interstate commerce of its infant formula product while this guidance remains in effect. A “covered infant formula manufacturer” is a manufacturer to which FDA has issued a letter of enforcement discretion relating to information provided in response to the May 2022 Enforcement Discretion Guidance, which remains in effect until November 14, 2022. A “covered infant formula product” is an infant formula product that is specifically identified in the letter of enforcement discretion issued to the manufacturer in response to information provided under the May 2022 Enforcement Discretion Guidance.

To facilitate the opportunity for covered infant formula manufacturers to submit a letter of intent to pursue completion of all regulatory requirements, FDA is, through this document, announcing our intent to extend the period of enforcement discretion for covered infant formula manufacturers to January 6, 2023. FDA’s continued exercise of enforcement discretion after January 6, 2023, will be made on a case-by-case basis for covered infant formula products that are specifically identified in a letter of intent submitted to FDA and that FDA has acknowledged, consistent with the policies described below.

What is a “covered infant formula manufacturer” under this Infant Formula Transition Plan Guidance?	A manufacturer to which FDA has issued a letter of enforcement discretion relating to information provided in response to the May 2022 Enforcement Discretion Guidance.
What is a “covered infant formula product” under this Infant Formula Transition Plan Guidance?	An infant formula product that is specifically identified in the letter of enforcement discretion issued to the manufacturer in response to information provided under the May 2022 Enforcement Discretion Guidance.
How should a covered infant formula manufacturer request that FDA continue to exercise enforcement discretion with respect to covered infant formula products on the U.S. market under this Infant Formula Transition Plan Guidance?	By submitting a letter of intent to pursue completion of all regulatory requirements for one or more covered infant formula products. FDA will respond with a letter of acknowledgement. (See Phase 1 of this Transition Plan below.)
Does FDA intend to continue exercising enforcement discretion for covered infant formula products between issuance of this Infant Formula Transition Plan Guidance and FDA’s issuance of a letter of acknowledgment?	Yes, unless the manufacturer receives written notification to the contrary from FDA.

This guidance aims to balance the need to ensure that manufacturers of infant formulas sold in the United States demonstrate that their products meet the minimum requirements for specified quality factors with the need to help ensure the existence of a more resilient infant formula supply and to minimize disruptions in the availability of formulas that have become an essential source of infant nutrition during recent periods of supply disruption. We expect all infant formula sold in the United

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States to comply with all applicable requirements under the FD&C Act and FDA regulations, and we intend to continue exercising enforcement discretion for those covered infant formula products for which the manufacturer provides information and takes other actions to achieve compliance in accordance with the timelines set forth in this guidance. Any manufacturer of a new infant formula product, including a manufacturer not currently marketing an infant formula product in accordance with a letter of enforcement discretion issued under the May 2022 Enforcement Discretion Guidance, also may seek to market the product in the United States by taking actions in accordance with FDA’s regulatory requirements for infant formula, including by submitting a new infant formula submission under 21 CFR 106.120.

Because different regulatory requirements apply to: (1) infant formulas that are subject to the requirements of section 412(a), (b), and (c) of the FD&C Act (21 U.S.C. 350a(a), (b), and (c)) (“non-exempt infant formulas”) and related FDA regulations, and (2) exempt infant formulas as described in section 412(h)(1) of the FD&C Act (21 U.S.C. 350a(h)(1)) (“exempt infant formulas”),<sup>7</sup> which are subject to the terms and conditions in 21 CFR 107.50 and other applicable regulations, this guidance describes those different requirements and considerations related to the continued marketing of these types of infant formula under FDA’s exercise of enforcement discretion.

What is a “non-exempt infant formula”?	A non-exempt infant formula is an infant formula subject to—among other requirements—the requirements of section 412(a), (b), and (c) of the FD&C Act and related FDA regulations in 21 CFR parts 106 and 107. Non-exempt infant formulas typically are intended for consumption by healthy, full-term infants.
What is an “exempt infant formula”?	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. An exempt infant formula is subject to the provisions of 21 CFR 107.50 and other FDA regulations.

General expectations relating to the type of information manufacturers should submit and the timeframes in which it should be provided to demonstrate meaningful progress toward full compliance are set forth below. However, upon the request of a firm making a good-faith effort to work within recommended timelines, we will consider whether firms need additional time to take actions specified in the guidance on an individual basis. We believe some manufacturers may have already started to collect the information outlined in this guidance and may complete the process in a shorter time frame than outlined in this guidance. All materials submitted to FDA in accordance with this guidance should be in English or translated into English. In response to materials manufacturers submit in accordance with this guidance, we may provide feedback and request additional information needed to advise firms on how they can meet the requirements pertaining to their infant formula products.

<sup>7</sup> Section 412(h)(1) of the FD&C Act (21 U.S.C. 350a(h)(1)) states that any infant formula which is represented and labeled for use by an infant (A) who has an inborn error of metabolism or a low birth weight, or (B) who otherwise has an unusual medical or dietary problem, is exempt from section 412(a)-(c) of the FD&C Act (21 U.S.C. 350a(a)-(c)). Section 412(h)(2) of the FD&C Act (21 U.S.C. 350a(h)(2)) states that FDA may by regulation establish terms and conditions for the exemption of an infant formula from the requirements of section 412(a)-(c); requirements applicable to exempt infant formulas are set forth in 21 CFR 107.50.

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### A. Transition Plan for Covered Non-Exempt Infant Formula Products

Covered infant formula manufacturers that wish to continue to market covered non-exempt infant formula products under FDA enforcement discretion should provide information to FDA and take other actions in accordance with the phased approach set forth below.

We recognize that covered infant formula manufacturers are at varying stages of providing FDA with information that would be required as part of a new infant formula submission in accordance with 21 CFR 106.120. To the extent that manufacturers have already provided information recommended under the phases set forth below, the manufacturers do not need to resubmit this information unless updated information is available.

The following table provides an overview of the phases and timing expectations for information related to non-exempt infant formulas. FDA may choose to take action if the infant formula manufacturer that is receiving enforcement discretion fails to make meaningful progress on the timeline detailed in this document or if we otherwise become aware of information that raises a concern about the safety or nutritional adequacy of the product. Additional detail regarding each phase appears below the table.

<b>Phase</b>	<b>Manufacturer Action Item(s)</b>	<b>Timing Expectation</b>
1	Letter of Intent	By December 5, 2022
2	Plan for Meeting New Infant Formula Requirements	By February 28, 2023
3	Data Demonstrating Sufficient Biological Quality of Protein and Plan to Develop Data Supporting Normal Physical Growth	By June 16, 2023
4	Data Demonstrating Support of Normal Physical Growth	By January 5, 2024 (if seeking exemption from 21 CFR 106.96(b) under 21 CFR 106.96(c)(1), (c)(2)(ii), or (c)(2)(iii))  By September 6, 2024 (if intending to comply with 21 CFR 106.96(b) or (c)(2)(i))
5	New Infant Formula Submission	By February 16, 2024 (if seeking exemption from 21 CFR 106.96(b) under 21 CFR 106.96(c)(1), (c)(2)(ii), or (c)(2)(iii))  By October 18, 2024 (if intending to comply with 21 CFR 106.96(b) or (c)(2)(i))

#### 1. Phase 1: Letter of Intent (by December 5, 2022)

By December 5, 2022, covered manufacturers wishing to continue to market covered non-exempt infant formula products under FDA's exercise of enforcement discretion after January 6, 2023, should submit to FDA (using the mailbox at [Infant\\_formula\\_flexibility@fda.hhs.gov](mailto:Infant_formula_flexibility@fda.hhs.gov)) a letter of intent identifying the specific covered infant formula products for which the firm intends to comply with all applicable regulatory requirements in accordance with this guidance. Manufacturers may include all or a subset of their covered infant formula products in their letter of intent to seek continued enforcement discretion with respect to such products.

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In mid- to late November 2022, FDA intends to provide an optional “orientation” to infant formula manufacturers to explain the phased approach of the Infant Formula Transition Plan Guidance, the applicable timelines associated with the information to be provided by the firm and achievement of other milestones, and steps we intend to take under the guidance. FDA also intends to provide a webinar on the requirements for quality factors for infant formulas, specifically normal physical growth (21 CFR 106.96(a)) and sufficient biological quality of protein (21 CFR 106.96(e)).

FDA will review all letters of intent submitted by covered non-exempt infant formula manufacturers and communicate with manufacturers, as needed, to clarify any information. We intend to issue a letter of acknowledgement to each manufacturer that has submitted a letter of intent.<sup>8</sup> If appropriate, the letter of acknowledgement will state that FDA intends to exercise enforcement discretion by not objecting to the importation, sale, or distribution of the specified covered infant formula products, provided that: (1) the manufacturer continues to adhere to the steps identified in our letter announcing the exercise of enforcement discretion relating to information provided under the May 2022 Enforcement Discretion Guidance; and (2) the manufacturer continues to make meaningful progress toward compliance with applicable regulatory requirements in accordance with the Infant Formula Transition Plan Guidance.

### 2. Phase 2: Manufacturer’s Plan for Meeting New Infant Formula Requirements (by February 28, 2023)

By February 28, 2023, covered non-exempt infant formula manufacturers should submit the following to FDA:

- A copy of product labeling conforming to the requirements of 21 CFR 107.10-107.30 (or a proposed time by which the product labeling would be provided);
- To demonstrate meaningful progress toward establishing that the quality factor of sufficient biological quality of protein (21 CFR 106.96(e)) is met, one of the following should be submitted:
  - A draft protocol for an appropriate modification of a Protein Efficiency Ratio (PER) rat bioassay in accordance with 21 CFR 106.96(f),
  - A draft protocol for a proposed alternative method of demonstrating that a formula supports the quality factor of sufficient biological quality of protein in accordance with 21 CFR 106.96(g)(3), or
  - An outline of the firm’s rationale for an exemption from the requirement of conducting an appropriate modification of a PER rat bioassay under 21 CFR 106.96(f) and information supporting the request for exemption in accordance with 21 CFR 106.96(g)(1) or (g)(2).
- To demonstrate progress toward establishing that the quality factor of normal physical growth (21 CFR 106.96(a)) is met, one of the following should be submitted:
  - A statement of intent to conduct a growth monitoring study (GMS) under 21 CFR 106.96(b),
  - A statement of intent to demonstrate that a formula supports normal physical growth when the formula is fed as the sole source of nutrition using an alternative method or study design that is based on sound scientific principles under 21 CFR 106.96(c)(2)(i), or

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<sup>8</sup> As stated above, covered infant formula manufacturers may continue to market specific infant formula products under FDA’s exercise of enforcement discretion between November 15, 2022, and January 6, 2023.

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- A statement that the manufacturer otherwise intends to request an exemption from the requirements of 21 CFR 106.96(b) under 21 CFR 106.96(c)(1), (c)(2)(ii), or (c)(2)(iii).
- Other information<sup>9</sup> relevant to the non-exempt infant formula product (e.g., stability testing of nutrient levels, regulatory status of ingredients, testing of nutrient pre-mixes, product packaging information) not previously provided to FDA (or a proposed time by which this information would be provided).

To help manufacturers prepare this information, FDA intends to begin meeting with covered infant formula manufacturers to discuss the actions each manufacturer should take under this guidance to ensure that its covered non-exempt infant formula products meet regulatory requirements, in particular for quality factors under 21 CFR 106.96, as well as when the manufacturer should take such actions, consistent with this guidance. In these consultation sessions, FDA intends to identify remaining gaps in information required in a new infant formula submission for the manufacturer's non-exempt infant formula product(s) following our review of information submitted in response to the May 2022 Enforcement Discretion Guidance, and to discuss a projected schedule for the manufacturer's provision of this information. The manufacturer and FDA will also discuss whether the manufacturer intends to comply with the requirements of 21 CFR 106.96(b) and (f) to demonstrate that the covered infant formula meets applicable quality factors, or whether the firm intends to request an exemption from these requirements under 21 CFR 106.96(c) and (g). Manufacturers may use these consultation sessions to present any other questions they might have concerning the information set forth in this guidance and the requirements for new infant formula submissions.

#### 3. Phase 3: Demonstration of Sufficient Biological Quality of Protein and Plan to Develop Data Supporting Normal Physical Growth (by June 16, 2023)

FDA will review the manufacturer's draft protocol for an appropriate modification of the PER rat bioassay (21 CFR 106.96(f)), draft protocol for an alternative method to demonstrate that the formula supports the quality factor of sufficient biological quality of protein (21 CFR 106.96(g)(3)), or draft rationale under 21 CFR 106.96(g)(1) or (g)(2) for an exemption from the requirement in 21 CFR 106.96(f). We intend to communicate our feedback with the manufacturer in writing and/or in a meeting.

By June 16, 2023, each manufacturer of a covered non-exempt infant formula product should submit either: (1) a draft report of the appropriate modification of the PER rat bioassay (see 21 CFR 106.96(f) or alternative method to the PER it has conducted (or has had conducted on its behalf) (see 21 CFR 106.96(g)(3)); or (2) a draft narrative explanation of why data and information demonstrate that the quality factor of sufficient biological quality of protein is met (see 21 CFR 106.96(g)(1) and (g)(2)), along with the data relied on and copies of additional studies cited in support.

In addition, each manufacturer should begin developing its plan for meeting the requirements for the quality factor of normal physical growth (21 CFR 106.96(a)) for its non-exempt infant formula products as soon as possible after submitting a statement of intent to conduct a GMS or to seek an exemption from this requirement. (We note that manufacturers may begin work on meeting these requirements while their efforts to demonstrate sufficient biological quality of protein for their product(s) are underway.) The manufacturer's plan for meeting the normal physical growth quality factor requirements should include either of the following:

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<sup>9</sup> FDA intends to clarify the type of additional information to be provided, if any, during consultation sessions.

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- The design of the GMS or clinical study it will conduct (or will have conducted on its behalf) (either under 21 CFR 106.96(b) or (c)(2)(i)) and a draft protocol for the study with a statistical analysis plan; or
- A written explanation of the firm's rationale for the requested exemption under 21 CFR 106.96(c)(1), (c)(2)(ii), or (c)(2)(iii).

By June 16, 2023, manufacturers of a covered non-exempt infant formula product should either submit a draft protocol for their planned GMS or their written explanation of the rationale for requesting an exemption from the GMS requirement in 21 CFR 106.96(b).

4. Phase 4: Demonstration of Support of Normal Physical Growth (by January 5, 2024, or September 6, 2024)
  - a. Narrative Explanation for Reliance on an Exemption from the GMS Requirements in 21 CFR 106.96(b) Based on 21 CFR 106.96(c)(1), (c)(2)(ii), or (c)(2)(iii)

By January 5, 2024, each manufacturer of a covered non-exempt infant formula product that seeks an exemption from the requirement to conduct a GMS as specified in 21 CFR 106.96(b) that does not involve an alternative method or study design (see 21 CFR 106.96(c)(2)(i)) should submit a draft narrative explanation of why data and information demonstrate that the formula supports normal physical growth, along with supporting information and citations (see 21 CFR 106.96(c)(1), (c)(2)(ii), and (c)(2)(iii)).

- b. Draft Report Documenting Compliance with GMS Requirements in 21 CFR 106.96(b) or the Exemption from GMS Requirements in 21 CFR 106.96(b) for an Alternative Method or Study Design (see 21 CFR 106.96(c)(2)(i))

By September 6, 2024, each manufacturer of a covered non-exempt infant formula product that conducts a GMS or alternative study to meet the requirement to demonstrate support of normal physical growth should submit a draft report on its GMS or alternative study.

5. Phase 5: New Infant Formula Submission (by February 16, 2024, or October 18, 2024)
  - a. Submission That Includes a Request for Exemption from the GMS Requirements in 21 CFR 106.96(b) Based on 21 CFR 106.96(c)(1), (c)(2)(ii), or (c)(2)(iii)

By February 16, 2024, each manufacturer of a covered non-exempt infant formula product that seeks an exemption from the requirement to conduct a GMS (not involving an alternative method or study design) should submit a new infant formula submission for each such product containing the information required under 21 CFR 106.120.<sup>10</sup> Once the new infant formula submission is submitted to FDA, we will review the submission, reach out with questions as necessary, and respond to the manufacturer in accordance with 21 CFR 106.120(e). The date that FDA receives a new infant formula submission that is complete is the filing date for such submission. For infant formulas marketed under this Infant Formula Transition Plan Guidance, FDA will not object to the manufacturer's continued marketing of the new infant formula before the date that is 90 days after the

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<sup>10</sup> For information on submitting a new infant formula submission, see our website at <https://www.fda.gov/food/guidance-documents-regulatory-information-topic-food-and-dietary-supplements/infant-formula-guidance-documents-regulatory-information>.

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date of the filing date for the submission.

- b. Submission That Includes a GMS Compliant with 21 CFR 106.96(b) or an Alternative Method or Study Design (see 21 CFR 106.96(c)(2)(i))

By October 18, 2024, each manufacturer of a covered non-exempt formula that conducts a GMS or alternative study to meet the requirement to demonstrate support of normal physical growth should submit a new infant formula submission for each such product containing the information required under 21 CFR 106.120. Once the new infant formula submission is submitted to FDA, we will review the submission, reach out with questions as necessary, and respond to the manufacturer in accordance with 21 CFR 106.120(e). The date that FDA receives a new infant formula submission that is complete is the filing date for such submission. For infant formulas marketed under this Infant Formula Transition Plan Guidance, FDA does not intend to object to the manufacturer's continued marketing of the new infant formula before the date that is 90 days after the date of the filing date for the submission.

#### B. Transition Plan for Covered Exempt Infant Formula Products

Covered manufacturers that wish to continue to market covered exempt infant formula products under FDA enforcement discretion should provide information to FDA and take other actions in accordance with the phases set forth below. The approach in Phases 1 and 2 is similar to the approach for non-exempt infant formulas in those phases, while Phases 3, 4, and 5 reflect the different requirements applicable to exempt infant formulas as compared to those for non-exempt infant formulas.

We recognize that covered manufacturers are at varying stages of providing FDA with information that would be required as part of a new infant formula submission in accordance with 21 CFR 107.50. To the extent that manufacturers have already provided information recommended under the phases set forth below, the manufacturers do not need to resubmit this information unless updated information is available.

The following table provides an overview of the phases and timing expectations for information related to exempt infant formulas. FDA may choose to take action if the infant formula manufacturer that is receiving enforcement discretion fails to make meaningful progress on the timeline detailed in this document or if we otherwise become aware of information that raises a concern about the safety or nutritional adequacy of the product. Additional detail regarding each phase appears below the table.

<b>Phase</b>	<b>Manufacturer Action Item(s)</b>	<b>Timing Expectation</b>
1	Letter of Intent	By December 5, 2022
2	Plan for Meeting Applicable Infant Formula Requirements	By February 28, 2023
3	Additional Information Pertaining to Covered Exempt Infant Formula	By August 1, 2023
4	Data Related to Exempt Status and Clinical Evidence	By January 5, 2024 (if a clinical study to support use for the intended medical condition is not required), or June 6, 2025 (if a clinical study to support use of product for the intended medical condition is conducted).

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5	New Infant Formula Submission	By February 16, 2024 (if a clinical study to support use for the intended medical condition is not required), or July 18, 2025 (if a clinical study to support use of product for the intended medical condition is conducted).
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### 1. Phase 1: Letter of Intent (by December 5, 2022)

By December 5, 2022, covered manufacturers wishing to continue to market covered exempt infant formula products under FDA’s exercise of enforcement discretion after January 6, 2023, should submit to FDA (using the mailbox at [Infant\\_formula\\_flexibility@fda.hhs.gov](mailto:Infant_formula_flexibility@fda.hhs.gov)) a letter of intent identifying the specific infant formula products for which the firm intends to comply with all applicable regulatory requirements in accordance with this guidance. Manufacturers may include all or a subset of their covered exempt infant formula products in their letter of intent to seek continued enforcement discretion with respect to such products.

In mid- to late November 2022, FDA intends to provide an optional “orientation” to infant formula manufacturers to explain the phased approach of the Infant Formula Transition Plan, the applicable timelines associated with the information to be provided by the firm and achievement of other milestones, and steps we intend to take under the guidance.

FDA will review all letters of intent submitted by covered exempt infant formula manufacturers and communicate with manufacturers, as needed, to clarify any information. We intend to issue a letter of acknowledgement to each manufacturer that has submitted a letter of intent. If appropriate, the letter of acknowledgement will state that FDA intends to exercise enforcement discretion by not objecting to the importation, sale, or distribution of the specified covered infant formula products provided that: (1) the manufacturer continues to adhere to the steps identified in our letter announcing the exercise of enforcement discretion under the May 2022 Enforcement Discretion Guidance; and (2) the manufacturer continues to make meaningful progress toward compliance with applicable regulatory requirements in accordance with the Infant Formula Transition Plan Guidance.

### 2. Phase 2: FDA Review of Manufacturer’s Plan for Meeting New Infant Formula Requirements (by February 28, 2023)

Covered exempt infant formula manufacturers should submit to FDA, by February 28, 2023, the following:

- A copy of the product label and other labeling conforming to the labeling provisions in 21 CFR 107.10-107.30 (or a proposed time by which the product labeling would be provided), unless the firm provides a rationale for deviating from the requirements (as provided in 21 CFR 107.50(b)(5) and (c)(5));
- A statement describing how the manufacturer intends to develop the information required under 21 CFR 107.50(b)(3)<sup>11</sup> or (c)(4),<sup>12</sup> as applicable.

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<sup>11</sup> Under 21 CFR 107.50(b)(3), to retain the exempt status of an infant formula product generally available at the retail level, the manufacturer must submit the label and other labeling of the infant formula, a complete quantitative formulation for the infant formula, and a detailed description of the medical conditions for which the infant formula is represented.

<sup>12</sup> Under 21 CFR 107.50(c)(4), to retain the exempt status of an infant formula product not generally available at the retail level, the manufacturer shall submit the information required by 21 CFR 107.50(b)(3) and (b)(4).

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- Other information<sup>13</sup> relevant to the exempt infant formula product (e.g., regulatory status of ingredients, testing of nutrient pre-mixes, product packaging information) not previously provided to FDA (or a proposed time by which this information would be provided).

To help manufacturers prepare this information, FDA intends to begin meeting with covered infant formula manufacturers to discuss the actions each manufacturer should take under this guidance to ensure that its covered exempt infant formula products meet regulatory requirements, as well as when the firm should take specific actions, consistent with this guidance. In these consultation sessions, FDA intends to identify remaining gaps in information required in a new infant formula submission for the manufacturer's exempt infant formula product(s) following our review of information submitted in response to the May 2022 Enforcement Discretion Guidance, and to discuss a projected schedule for the manufacturer's provision of this information. Manufacturers may use these consultation sessions to present any other questions they might have concerning the information set forth in this guidance and the requirements for new infant formula submissions.

### 3. Phase 3: FDA Review of Additional Information Pertaining to Covered Exempt Infant Formula (by August 1, 2023)

By August 1, 2023, each manufacturer of a covered exempt infant formula product should submit documentation addressing issues specified in 21 CFR 107.50(b)(3) and (c)(4) regarding a detailed description of the medical condition(s) for which the infant formula is represented and a detailed discussion of the medical condition(s) for which the product provides dietary management, to support that the proposed product is appropriate for the intended population. In most cases, if the manufacturer has not already done so, the manufacturer will need to conduct a clinical study using the infant formula product to support its use for the intended medical condition (see 21 CFR 107.50(b)(5) and (c)(5)).

Additionally, manufacturers should submit by August 1, 2023, the basis for any deviations from the nutrient requirements in section 412(i) of the FD&C Act (21 U.S.C. 350a(i)) and 21 CFR 107.100. Under 21 CFR 107.50(b)(5) and (c)(5), an infant formula manufacturer may deviate from nutrient requirements only with respect to specific requirements for which it submits to FDA the medical, nutritional, scientific, or technological rationale (including any appropriate animal or human clinical studies) in support of the deviation. This includes information on the medical rationale for the covered exempt infant formula product and the evidence for its use in the dietary management of the disorder.

Manufacturers of covered exempt infant formulas should also submit by August 1, 2023, information on compliance with labeling requirements in accordance with 21 CFR 107.50(b)(3) and, if applicable, quality control procedure requirements under 21 CFR 107.50(b)(5). Quality control procedure information includes processing (process flow diagrams with equipment, times, and temperatures) and stability information that provides the assurance that the product is not adulterated and will meet nutrient content levels up to the use-by date.

FDA will review the documentation provided in Phase 3 and will notify the manufacturer as to whether the information appears to provide a sufficient basis for a new infant formula submission—including whether clinical studies are required to support the use of the product for the intended medical condition—or we may ask for clarification.

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<sup>13</sup> FDA intends to clarify the type of additional information to be provided, if any, during consultation sessions.

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4. Phase 4: Data Related to Exempt Status and Clinical Evidence (by January 5, 2024, or June 6, 2025)
  - a. Covered Exempt Infant Formula for Which Clinical Studies Are Not Required (by January 5, 2024)

By January 5, 2024, each manufacturer of a covered exempt infant formula product for which a clinical study is not required to support use of the product for the intended medical condition should submit to FDA documentation specified under 21 CFR 107.50 to support the use of the product for the intended medical condition.

- b. Covered Exempt Infant Formula for Which Clinical Studies Are Required (by June 6, 2025)

By June 6, 2025, each manufacturer of a covered exempt infant formula product for which a clinical study is required to support use of the product for the intended medical condition should submit to FDA a draft study report(s) and, if applicable, published literature relevant to the medical condition for which the product is represented for use and the dietary management of such medical condition. Given that these studies may be conducted in populations with limited numbers of infants (e.g., infants with inborn errors of metabolism), we have factored in additional time to conduct the study since subject recruitment may be more challenging.

5. Phase 5: New Infant Formula Submission (by February 16, 2024, or July 18, 2025)
  - a. Submission for Which Clinical Studies Are Not Required (by February 16, 2024)

By February 16, 2024, each manufacturer of a covered exempt infant formula product for which a clinical study is not required to support use of the product for the intended medical condition should submit to FDA a new infant formula submission for its product containing the information required under 21 CFR 107.50(b)(3) or (c)(4).<sup>14</sup> Once the new infant formula submission is received, we will review the submission, reach out with questions as necessary, and respond to the manufacturer upon completion of our review. While FDA conducts its reviews of new infant formula submissions for covered exempt infant formulas, FDA does not intend to object to the manufacturer's continued marketing of such covered exempt infant formula.

- b. Submission for Which Clinical Studies Are Required (by July 18, 2025)

By July 18, 2025, each manufacturer of a covered exempt infant formula product that conducts a clinical study to support use of the product for the intended medical condition should submit to FDA a new infant formula submission for its product containing the information required under 21 CFR 107.50(b)(3) or (c)(4). Once the new infant formula submission is received, we will review the submission, reach out with questions as necessary, and respond to the manufacturer upon completion of our review. While FDA conducts its reviews of new infant formula submissions for covered

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<sup>14</sup> For information on submitting a new infant formula submission, see our website at <https://www.fda.gov/food/guidance-documents-regulatory-information-topic-food-and-dietary-supplements/infant-formula-guidance-documents-regulatory-information>.

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exempt infant formulas, FDA does not intend to object to the manufacturer's continued marketing of such covered exempt infant formula.