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New FDA Guidance Allows Companies to Continue Marketing Infant Formula Under an Enforcement Discretion Letter Beyond November 14, 2022

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- After the publication of its May 2022 Enforcement Discretion Guidance (discussed here), FDA issued letters of enforcement discretion to various companies for marketing specific infant formula products in the United States without having submitted a mandatory new infant formula notice and perhaps not meeting all regulatory and statutory requirements for infant formula. FDA's policy is meant to increase the supply of infant formula in the U.S while ensuring that any non-compliant infant formula that it allows to be introduced into interstate commerce under this policy will be safe and nutritionally adequate. As we have previously reported, FDA announced plans in June to facilitate the continued use of infant formula marketed under the enforcement discretion policy past its November 14, 2022 expiration date.

- On September 30, 2022, FDA announced a new guidance, Infant Formula Transition Plan for Exercise of Enforcement Discretion, whereby manufacturers of infant formula marketed subject to enforcement discretion may submit information related to exempt infant formulas while continuing to market such products beyond November 14, 2022 while they work toward meeting all FDA requirements. Specifically, FDA's Infant Formula Transition Plan Guidance identifies phases and timing expectations as follows:

Phase 1: 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 a letter of intent identifying which specific infant formula products that the firm intends to bring into full compliance with all applicable regulatory requirements;

Phase 2: By February 28, 2023, covered exempt infant formula manufacturers should submit to FDA a detailed plan for meeting applicable infant formula requirements;

Phase 3: By August 1, 2023 covered exempt infant formula product manufacturers should submit information and documentation;

Phase 4: Data related to exempt status and clinical evidence should be submitted by January 5, 2024

(if a clinical study is not required), or June 6, 2025 (if a clinical study to support use of product for the intended medical condition is conducted); and

Phase 5: A New Infant Formula Submission must be made 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).

- FDA's Infant Formula Transition Plan Guidance will remain in effect until October 18, 2025, or later if FDA deems an extension necessary. Any manufacturer of a new infant formula product, including a manufacturer that is not currently marketing an infant formula product under FDA's May 2022 enforcement discretion policy, may submit a New Infant Formula Submission at any time.

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