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FDA Releases Guidance on Infant Formula Enforcement Discretion Policy

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- Yesterday FDA released a guidance document which lays out the Agency's plan to help increase the supply of infant formula in the U.S through the exercise of its enforcement discretion for certain non-compliant infant formula. FDA will consider exercising enforcement discretion on a case-by-case basis and will ensure that any non-compliant infant formula that it allows to be introduced into interstate commerce under this policy will be safe and nutritionally adequate.
- Infant formula manufacturers (both domestic and foreign) who would like FDA to exercise enforcement discretion should provide FDA with the following information:

Product Information

- Product name and other identifying information (e.g., batch numbers, UPCs).
- Countries in which product currently is being marketed and length of time marketed.
- Quantity of product intended to be introduced into the U.S. (in weight at least).
- Whether product is in current inventory. If yes, then provide "use by" date, and if not, provide date of import or introduction into interstate commerce.
- Name/location of facilities where the specified batches are made.
- Distribution plans (if available).
- List of all ingredients (by weight).
- Copy of product label.
- Description of all packaging.

- Test results for nutrients levels from the most recent batches produced at each facility.
- Cronbacter and salmonella spp. test results for the most recent batches produced at each facility.

Information for each Manufacturing Facility

- Certification that the manufacturer has established CGMP to prevent adulteration.
- Process flow diagram and written narrative which includes heating and processing conditions and critical control points.
- FDA food facility registration number (as applicable).
- If the facility has not received an FDA inspection, information regarding inspections by other government authorities or auditors.
- FDA states that requests for enforcement discretion relating to items that may pose a safety concern (e.g., low levels of a critical nutrient or a failure to clearly identify food allergens) will be scrutinized and may not be appropriate candidates for enforcement discretion. In contrast, FDA cites a label that provides nutrients in the wrong order as a type of deficiency that would be a good candidate for enforcement discretion.
- The guidance is in effect until November 14, 2022, but FDA will evaluate whether an extension is necessary. Requests for enforcement discretion should be sent to FDA.

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