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.