Wednesday, May 18, 2022

In recognition of the infant formula crisis facing the United States supply chain, the Food and Drug Administration (“FDA”) issued guidance on May 16, 2022 providing for enforcement discretion with respect to certain requirements for infant formulas that may not comply with certain statutory and regulatory requirements. The guidance remains in effect until November 14, 2022. Under this guidance, three categories of manufacturers may submit information to FDA:

- Infant formula manufacturers who manufacture infant formula for export in domestic facilities;
- Infant formula manufacturers who presently do not export infant formula manufactured in foreign facilities to the United States; and
- Infant formula manufacturers who may be able to provide infant formula to help address shortages by changing production site(s), changing production
practice(s), or making other changes to an existing infant formula.

Submissions should contain all the required information in Section III. D of the guidance and be submitted to Infant_formula_flexibility@fda.hhs.gov. FDA requests information including product specifications and labeling, current markets, inventory, manufacturing facilities, distribution plans to the retail level, full quantitative formulations, test results, and certifications for the manufacturing facility, as applicable. Upon receipt of the request, FDA will then consider “whether to exercise enforcement discretion and the extent of that enforcement discretion.”

Generally, FDA requires persons responsible for infant formula manufacture or distribution to register with FDA and provide submissions for any new formulations or changes to existing formulations. There is a built-in timing delay, as manufactures may not market the new infant formula until 90 days after the filing date provided by FDA upon receipt of the submission. The submission package requires details including a description of the formula, quantitative formulation, compliance assurances, and quality assurance data, among other requirements.

Regulated as a food, infant formula has its own statutory and regulatory requirements located in 21 CFR Parts 106 and 107 that manufacturers need to follow. This includes minimum amounts for thirty nutrients and maximum amounts for ten of them. See 21 CFR § 107.100. FDA has explained in guidance that infant formula not meeting these designated levels are considered adulterated. The guidance provides an important pathway for manufacturers who may presently meet FDA requirements to assist in alleviating the domestic shortage of infant formula.

© Copyright 2022 Squire Patton Boggs (US) LLP

National Law Review, Volume XII, Number 138

Source URL: https://www.natlawreview.com/article/fda-issued-enforcement-discretion-measures-infant-formula