Guidance for Industry

Exempt Infant Formula Production:

Current Good Manufacturing Practices (CGMPs), Quality Control Procedures, Conduct of Audits, and Records and Reports

Additional copies are available from:
Office of Nutrition and Food Labeling, HFS-800
Center for Food Safety and Applied Nutrition
Food and Drug Administration
5001 Campus Drive
College Park, MD 20740
(Tel) 240-402-2373
http://www.fda.gov/FoodGuidances

You may submit electronic or written comments regarding this guidance at any time. Submit electronic comments to http://www.regulations.gov. Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number listed in the notice of availability that publishes in the Federal Register.

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Food Safety and Applied Nutrition

April 2016

Table of Contents

Guidance for Industry[1]

Exempt Infant Formula Production:

Current Good Manufacturing Practices (CGMPs), Quality Control Procedures, Conduct of Audits, and Records and Reports

This guidance represents the current thinking of the Food and Drug Administration (FDA or we) on this topic. It does not establish any rights for any person and is not binding on FDA or the public. You may 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 as listed on the title page.

I. Introduction

This guidance is intended to convey to industry the current thinking of the Food and Drug Administration (FDA or we) about the manufacturing of exempt infant formulas in relation to the requirements for current good manufacturing practices (CGMPs), quality control procedures, conduct of audits, and records and reports for nonexempt infant formulas in 21 CFR part 106.[2]

FDA's guidance documents, including this guidance, 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 our guidances means that something is suggested or recommended, but not required.

[1] This guidance has been prepared by the Infant Formula and Medical Foods Staff, Office of Nutrition and Food Labeling, in the Center for Food Safety and Applied Nutrition at the U.S. Food and Drug Administration.

[2] For general information about infant formula regulations see "FDA's Infant Formula webpage." For general information about food ingredient and packaging approval and notification programs see "FDA's Food Ingredients & Packaging webpage."
http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/InfantFormula/default.htm and http://www.fda.gov/Food/IngredientsPackagingLabeling/default.htm

II. Background

In a final rule published on June 10, 2014 (79 FR 33057), FDA established requirements for current good manufacturing practices (21 CFR part 106, subpart B), the conduct of audits (21 CFR part 106, subpart D), and quality factors (21 CFR part 106, subpart E); and amended requirements for quality control procedures (21 CFR part 106, subpart C (formerly subpart B)), records and reports (21 CFR part 106, subpart F (formerly subpart C), and notifications for infant formula (21 CFR part 106, subpart G (formerly subpart D)), as mandated by section 412 of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 350a). The regulations apply, with one narrow exception, requirements for non-exempt infant formulas (i.e., formulas intended for use by healthy, term infants). (Two provisions of § 106.150 in the final rule (21 CFR 106.150) ("Notification of an adulterated or misbranded infant formula"), § 106.150(a)(2) and (b), apply both to exempt and non-exempt infant formulas. *See* section 412(h)(1) of the FD&C Act.)

Section 412(h)(1) of the FD&C Act exempts an infant formula which is represented and labeled for use by an infant with an inborn error of metabolism, low birth weight, or who otherwise has an unusual medical or dietary problem from the requirements of sections 412(a), (b), and (c) of the FD&C Act. These formulas are customarily referred to as "exempt infant formulas." Section 412(h)(2) of the FD&C Act authorizes us to establish terms and conditions for the exemption of an infant formula from the requirements of sections 412(a), (b), and (c) of the FD&C Act. FDA has previously established terms and conditions for exemption in 21 CFR 107.50. We intend to promulgate regulations to address any new terms and conditions for exempt infant formulas in a future rulemaking. In the interim, this guidance provides our current thinking about the significance of the regulations in part 106, as amended, for exempt infant formulas.

As of March 2016, five infant formula manufacturers produce exempt formulas that are marketed in the United States. Of these, four manufacturers produce both non-exempt and exempt products in the same facilities, using the same production lines and equipment. The remaining manufacturer produces only exempt infant formulas.

III. Discussion

Section 412 of the FD&C Act is intended to ensure the "safety and nutrition" of infant formulas. *See* Pub. L. No. 96-395, 94 Stat 1190, 1190 (1980). For many infants, formula is the sole source of nutrition during the earliest months of life, a critical period of growth and development. Our infant formula regulations have an essential role in helping to ensure the integrity and nutritional adequacy of infant formulas. We issued the regulations in part 106, with the narrow exception noted previously in this guidance, to help ensure the consistent production of safe and nutritionally adequate infant formulas for healthy, term infants (i.e., for non-exempt infant formulas). More stringent controls are necessary for the production of infant formulas than for processing food generally because of the vulnerable nature of the infant population and the status of infant formula as the sole source of nutrition for a segment of this population.

Healthy, term infants are particularly vulnerable to the effects of a nutritional insufficiency or deficiency in the diet because of their rapid rate of growth and development during early infancy. The infants that consume exempt infant formulas are at even greater risk of adverse outcomes due to a nutritional insufficiency or deficiency in the diet due to their relative immaturity or their medical condition.

IV. Recommendations

Given the vital role infant formula serves for those infants who consume it, and pending our promulgation of a regulation setting forth any new terms and conditions for exempt infant formulas, sound public health policy dictates that products for infants who need to consume exempt formulas should be produced using manufacturing practices, quality control procedures, audit procedures, and records and reporting protocols that are at least equivalent to those used for products consumed by healthy, term infants. However, we recognize that exempt infant formulas may need to differ from non-exempt infant formulas, e.g., in nutrient content due to the specific medical condition for which the exempt infant formula is used. Accordingly, we recommend that manufacturers of exempt infant formulas follow, to the extent practicable, subparts A, B, C, D, and F of 21 CFR part 106, as amended or established by the final rule published on June 10, 2014, in the production of their formula products.