4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 106

[Docket No. FDA-2014-D-0033]

Guidance for Industry: Demonstration of the Quality Factor Requirements for "Eligible" Infant Formulas; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notification of availability.

SUMMARY: The Food and Drug Administration (FDA or we) is announcing the availability of a final guidance which describes our current thinking on the quality factor requirements for eligible infant formulas, the record requirements for eligible infant formulas, and the submission of citizen petitions for eligible infant formulas.

DATES: Submit either electronic or written comments on FDA guidances at any time.

ADDRESSES: Submit written requests for single copies of the guidance to the Office of Nutrition, Labeling, and Dietary Supplements, Center for Food Safety and Applied Nutrition (HFS-850), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740. Send two self-addressed adhesive labels to assist that office in processing your request. See the SUPPLEMENTARY INFORMATION section for electronic access to the guidance.

Submit electronic comments on the guidance 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.

FOR FURTHER INFORMATION CONTACT: Benson M. Silverman, Center for Food Safety and Applied Nutrition (HFS-850), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 240-402-1451.

SUPPLEMENTARY INFORMATION:

I. Background

We are announcing the availability of a guidance for industry entitled "Guidance for Industry: Demonstration of the Quality Factor Requirements Under 21 CFR 106.96(i) for 'Eligible' Infant Formulas." This guidance is being issued consistent with our good guidance practices regulation (21 CFR 10.115). The guidance represents our current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternate approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

The guidance is intended to address questions regarding new requirements for eligible infant formulas in 21 CFR 106.96(i). A final rule amending part 106, and establishing the requirements under § 106.96(i), is published elsewhere in this issue of the Federal Register.

In the Federal Register of February 10, 2014 (79 FR 7609), we made available a draft guidance entitled "Draft Guidance for Industry: Demonstration of the Quality Factor Requirements for 'Eligible' Infant Formulas" and gave interested parties an opportunity to submit comments by March 27, 2014, for us to consider before beginning work on the final version of the guidance. We received no comments on the draft guidance but have modified the final guidance where appropriate to correspond to requirements set forth in the final rule, "Current Good Manufacturing Practices, Quality Control Procedures, Quality Factors, Notification Requirements, and Records and Reports, for Infant Formula," published elsewhere

in this issue of the Federal Register. For example, because the final rule revised the definition of an "eligible infant formula" from what was originally published in an interim final rule on February 10, 2014 (79 FR 7934), we revised the guidance to reflect that change. In addition, we revised the guidance to provide more detailed recommendations if a manufacturer includes proprietary information in its citizen petition submitted in accordance with § 106.96(i)(3). Furthermore, we made other edits so that the language in the guidance corresponds more closely to that used in the final rule. The guidance announced in this document finalizes the draft guidance dated February 2014.

II. Paperwork Reduction Act of 1995

This guidance refers to existing regulations in part 10 (21 CFR part 10) as well as the final rule, "Current Good Manufacturing Practices, Quality Control Procedures, Quality Factors, Notification Requirements, and Records and Reports, for Infant Formula," published elsewhere in this issue of the Federal Register, which amends parts 106 and 107 (21 CFR parts 106 and 107). The collection of information in part 10 has been approved under OMB control number 0910-0183. The collections of information in parts 106 and 107 have been approved under OMB control number 0910-0256. These collections of information amended by the final rule are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501-3520). The Information Collection Request for the final rule is currently under review.

III. Comments

Interested persons may submit either electronic comments regarding the guidance to http://www.regulations.gov or written comments to the Division of Dockets Management (see ADDRESSES). It is only necessary to send one set of comments. Identify comments with the

docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at http://www.regulations.gov.

IV. Electronic Access

Persons with access to the Internet may obtain the guidance at http://www.fda.gov/FoodGuidances or http://www.regulations.gov. Use the FDA Web site listed in the previous sentence to find the most current version of the guidance.

Dated: June 4, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

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