4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 106

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

Draft Guidance for Industry: Demonstration of the Quality Factor Requirements for "Eligible" Infant Formulas; Availability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SUMMARY: The Food and Drug Administration (FDA or we) is announcing the availability of a draft guidance entitled "Guidance for Industry: Demonstration of the Quality Factor Requirements for 'Eligible' Infant Formulas." The draft guidance, when finalized, will describe our current thinking on the quality factor requirements for eligible infant formulas, the record requirements for eligible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: Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that we consider your comment on this draft guidance before we begin work on the final version of the guidance, submit either electronic or written comments on the draft guidance by [INSERT DATE 45 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES: Submit written requests for single copies of the draft guidance to the Office of Nutrition, Labeling, and Dietary Supplements, Center for Food Safety and Applied Nutrition (HFS-850), Food and Drug Administration, 5100 Paint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 See the SUPPLEMENTARY INFORMATION section for electronic access to the draft guidance.

Submit electronic comments on the draft guidance to http://www.regulations.gov.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, 240-402-1459.

SUPPLEMENTARY INFORMATION:

I. Background

We are announcing the availability of a draft guidance for industry entitled "Guidance for Industry: Demonstration of the Quality Factor Requirements Under 21 CFR 106.96(i) for 'Eligible' Infant Formulas." This draft guidance is being issued consistent with our good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent our current thinking on this topic.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 draft guidance is intended to address questions regarding new requirements for eligible infant formulas in § 106.96(i). An interim final rule amending part 106, and establishing the requirements under § 106.96(i), is published elsewhere in this issue of the Federal Register.

II. Paperwork Reduction Act of 1995

This draft guidance refers to proposed collections of information described in FDA's interim final rule on current good manufacturing practices for infant formula published

elsewhere in this issue of the Federal Register, which this draft guidance is intended to interpret. The proposed collections of information in the interim final rule are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (the PRA) (44 U.S.C. 3501-3520). As required by the PRA, FDA has provided a description of these provisions with estimates of the annual reporting, recordkeeping, and third-party disclosure burden in section IV of the Regulatory Impact Analysis for the interim final rule, entitled "Paperwork Reduction Act of 1995" (Ref. 92 to the interim final rule) and has submitted them for OMB approval.

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 draft 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: February 4, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

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