(k) Credit for Previous Actions

This paragraph provides credit for the actions required by paragraph (h) of this AD, if those actions were performed before the effective date of this AD using the service information specified in paragraph (k)(1) or (k)(2) of this AD.

(1) B/E AEROSPACE Service Bulletin 1XCXX–0100–35–005, dated March 14, 2011.

(2) B/E AEROSPACE Service Bulletin 22CXX–0100–35–003, dated March 17, 2011.

(l) Other FAA AD Provisions

The following provisions also apply to this AD:

(1) *Alternative Methods of Compliance (AMOCs):* The Manager, International Branch, ANM–116, Transport Airplane Directorate, FAA, has the authority to approve AMOCs for this AD, if requested using the procedures found in 14 CFR 39.19. In accordance with 14 CFR 39.19, send your request to your principal inspector or local Flight Standards District Office, as appropriate. If sending information directly to the International Branch, send it to ATTN: Sanjay Ralhan, Aerospace Engineer, International Branch, ANM–116, Transport Airplane Directorate, FAA, 1601 Lind Avenue SW., Renton, Washington 98057–3356; telephone (425) 227–1405; fax (425) 227–1149. Information may be emailed to: *9-ANM-116-AMOC-REQUESTS@faa.gov.* Before using any approved AMOC, notify your appropriate principal inspector, or lacking a principal inspector, the manager of the local flight standards district office/certificate holding district office. The AMOC approval letter must specifically reference this AD.

(2) *Airworthy Product:* For any requirement in this AD to obtain corrective actions from a manufacturer, use these actions if they are FAA-approved. Corrective actions are considered FAA-approved if they were approved by the State of Design Authority (or its delegated agent, or the Design Approval Holder with a State of Design Authority's design organization approval, as applicable). For a repair method to be approved, the repair approval must specifically refer to this AD. You are required to ensure the product is airworthy before it is returned to service.

(m) Related Information

(1) Refer to Mandatory Continuing Airworthiness Information European Aviation Safety Agency Airworthiness Directive 2012–0083, dated May 16, 2012, for related information. This may be found in the AD docket on the Internet at *http://www.regulations.gov* by searching for and locating it in Docket No. FAA–2012–0807.

(2) For service information identified in this AD, contact Airbus, Airworthiness Office—EIAS, 1 Rond Point Maurice Bellonte, 31707 Blagnac Cedex, France; telephone +33 5 61 93 36 96; fax +33 5 61 93 44 51; email *account.airworth-eas@airbus.com;* Internet *http://www.airbus.com.* For B/E service information identified in this proposed AD, contact B/E Aerospace Systems GmbH, Revalstrasse 1, 23560 Lubeck, Germany; telephone (49) 451 4093–2976; fax (49) 451 4093–4488. You may view this referenced service information at the FAA, Transport Airplane Directorate, 1601 Lind Avenue SW., Renton, WA. For information on the availability of this material at the FAA, call 425–227–1221.

Issued in Renton, Washington, on January 21, 2014.

Jeffrey E. Duven,

Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 2014–02722 Filed 2–7–14; 8:45 am]

BILLING CODE 4910–13–C

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 March 27, 2014.

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.

[FR Doc. 2014–02731 Filed 2–6–14; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 106

[Docket No. FDA–2014–D–0044]

Draft Guidance for Industry; Exempt Infant Formula Production: Current Good Manufacturing Practices, Quality Control Procedures, Conduct of Audits, and Records and Reports; 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 the draft guidance entitled ''Guidance for Industry; Exempt Infant Formula Production: Current Good Manufacturing Practices (CGMPs), Quality Control Procedures, Conduct of Audits, and Records and Reports.'' The draft guidance, when finalized, will describe our current thinking on the manufacturing of exempt infant formula in relation to the requirements for CGMPs, quality control procedures, conduct of audits, and records and reports that apply to nonexempt infant formulas.

DATES: Although you may comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the Agency considers your comment on the draft guidance before we begin work on the final version of the guidance, submit either electronic or written comments on the draft guidance by May 12, 2014.

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 on the draft guidance 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 the draft guidance entitled ''Guidance for Industry; Exempt Infant Formula Production: Current Good Manufacturing Practices (CGMPs), Quality Control Procedures, Audit Procedures, and Records and Reports.'' Section 412(h)(1) (21 U.S.C. 350a(h)(1) of the Federal Food, Drug, and Cosmetic Act (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 sections 412(a), (b), and (c) of the FD&C Act. These formulas are customarily referred to as ''exempt infant formulas.'' The draft guidance is intended to describe the significance of the regulations in 21 CFR part 106 for production of exempt infant formulas. Amendments to part 106, in the form of an interim final rule, are published elsewhere in this issue of the **Federal Register**.

We are issuing this draft guidance as Level 1 draft guidance consistent with our good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent our current thinking on the manufacturing of exempt infant formulas in relation to the requirements for CGMPs, quality control procedures, conduct of audits, and records and reports for nonexempt infant formulas in part 106. 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.

II. Paperwork Reduction Act of 1995

Under the Paperwork Reduction Act of 1995 (the PRA) (44 U.S.C. 3501–3520), Federal Agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. ''Collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal Agencies to publish notice in the **Federal Register** soliciting public comment on each proposed collection of information before submitting the collection to OMB for approval. To comply with this requirement, FDA will publish a 60-day notice on the proposed collection of information in a future issue of the **Federal Register**.

III. Comments

Interested persons may submit either electronic comments regarding the draft guidance and proposed collection of information 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.

[FR Doc. 2014–02732 Filed 2–6–14; 8:45 am]

BILLING CODE 4160–01–P