the FAA amends 14 CFR part 39 as follows:

PART 39—AIRWORTHINESS DIRECTIVES

■ 1. The authority citation for part 39 continues to read as follows:

Authority: 49 U.S.C. 106(g), 40113, 44701.

§ 39.13 [Amended]

■ 2. The FAA amends § 39.13 by adding the following new airworthiness directive (AD):

2014–07–52 Airbus Helicopters (previously Eurocopter France): Amendment 39–17858; Docket No. FAA–2014–0334; Directorate Identifier 2014–SW–021–AD.

(a) Applicability

This AD applies to Airbus Helicopters Model AS350B, AS350BA, AS350B1, AS350B2, AS350B3, AS350C, AS350D, AS350D1, AS355E, AS355F, AS355F1, AS355F2, AS355N, and AS355NP helicopters, certificated in any category, with:

(1) Modification (MOD) 07 3215 installed; or

(2) With a reinforcement angle, part number (P/N) 350A08.2493.21 or P/N 350A08.2493.23, installed.

(b) Unsafe Condition

This AD defines the unsafe condition as a crack in a rear structure to tailboom junction frame reinforcement angle (reinforcement angle), which if not detected could result in loss of the tailboom and subsequent loss of control of the helicopter.

(c) Effective Date

This AD becomes effective June 25, 2014 to all persons except those persons to whom it was made immediately effective by Emergency AD 2014–07–52, issued on March 28, 2014, which contained the requirements of this AD.

(d) Compliance

You are responsible for performing each action required by this AD within the specified compliance time unless it has already been accomplished prior to that time.

(e) Required Actions

(1) For helicopters with 640 or more hours time-in-service (TIS) since installation of MOD 07 3215 or since installation of an applicable reinforcement angle, within 10 hours TIS, and thereafter, at intervals not exceeding 10 hours TIS, inspect each reinforcement angle for a crack as depicted in Figure 1 of Airbus Helicopters Emergency Alert Service Bulletin No. 05.00.70 for Model AS350B, AS350BA, AS350B1, AS350B2, AS350B3, AS350C, AS350D, AS350D1 helicopters and Airbus Helicopters Emergency Alert Service Bulletin No. 05.00.62 for AS355E, AS355F, AS355F1, AS355F2, AS355N, and AS355NP helicopters, both Revision 0 and dated March 24, 2014.

(2) If there is a crack, before further flight, repair the reinforcement angle in a manner approved by the manager listed in paragraph (f)(1) of this AD.

(3) As an optional terminating action for the repetitive inspections required by paragraph (e)(1) of this AD, at intervals not exceeding 165 hours TIS, remove screw No. 5 from the reinforcement angle, thoroughly clean the area around the hole and inspect the reinforcement angle for a crack. If there is not a crack, reinstall the screw. Sequentially repeat the steps required by this paragraph for screws No. 6 through No. 12. If there is a crack, comply with paragraph (e)(2) of this AD.

(f) Alternative Methods of Compliance (AMOCs)

(1) The Manager, Safety Management Group, FAA, may approve AMOCs for this AD. Send your proposal to: Robert Grant, Aviation Safety Engineer, Safety Management Group, FAA, 2601 Meacham Blvd., Fort Worth, Texas 76137; telephone (817) 222–5110; email *robert.grant@faa.gov.*

(2) For operations conducted under a 14 CFR part 119 operating certificate or under 14 CFR part 91, subpart K, we suggest that you notify your principal inspector, or lacking a principal inspector, the manager of the local flight standards district office or certificate holding district office, before operating any aircraft complying with this AD through an AMOC.

(g) Additional Information

The subject of this AD is addressed in European Aviation Safety Agency (EASA) Emergency AD No. 2014–0076–E, dated March 25, 2014. You may view the EASA Emergency AD on the Internet at *http://www.regulations.gov* in Docket No. FAA–2014–0334.

(h) Subject

Joint Aircraft Service Component (JASC) Code: 5302: Rotorcraft Tailboom.

(i) Material Incorporated by Reference

(1) The Director of the Federal Register approved the incorporation by reference of the service information listed in this paragraph under 5 U.S.C. 552(a) and 1 CFR part 51.

(2) You must use this service information as applicable to do the actions required by this AD, unless the AD specifies otherwise.

(i) Airbus Helicopters Emergency Alert Service Bulletin No. 05.00.62, Revision 0, dated March 24, 2014.

(ii) Airbus Helicopters Emergency Alert Service Bulletin No. 05.00.70, Revision 0, dated March 24, 2014.

Note 1 to paragraph (i)(2): Airbus Helicopters Emergency Alert Service Bulletin (EASB) No. 05.00.62, Revision 0, dated March 24, 2014, and Airbus Helicopters EASB No. 05.00.70, Revision 0, dated March 24, 2014, are co-published as one document along with Airbus Helicopters EASB No. 05.00.45, Revision 0, dated March 24, 2014, and Airbus Helicopters EASB No. 05.00.41, Revision 0, dated March 24, 2014, which are not incorporated by reference in this AD.

(3) For Airbus Helicopters service information identified in this AD, contact Airbus Helicopters, Inc., 2701 N. Forum Drive, Grand Prairie, TX 75052; telephone (972) 641–0000 or (800) 232–0323; fax (972) 641–3775; or at *http://www.airbushelicopters.com/techpub.*

(4) You may view this service information at FAA, Office of the Regional Counsel, Southwest Region, 2601 Meacham Blvd., Room 663, Fort Worth, Texas 76137. For information on the availability of this material at the FAA, call (817) 222–5110.

(5) You may view this service information that is incorporated by reference at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call (202) 741–6030, or go to: *http://www.archives.gov/federal-register/cfr/ibr-locations.html.*

Issued in Fort Worth, Texas, on May 21, 2014.

Lance T. Gant,

Acting Directorate Manager, Rotorcraft Directorate, Aircraft Certification Service.

[FR Doc. 2014–12724 Filed 6–9–14; 8:45 am]

BILLING CODE 4910–13–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.

[FR Doc. 2014–13386 Filed 6–9–14; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 106 and 107

[Docket No. FDA–1995–N–0063 (formerly 95N–0309)]

RIN 0910–AF27

Current Good Manufacturing Practices, Quality Control Procedures, Quality Factors, Notification Requirements, and Records and Reports, for Infant Formula

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA or we) is issuing a final rule that adopts, with some modifications, the interim final rule (IFR) entitled ''Current Good Manufacturing Practices, Quality Control Procedures, Quality Factors, Notification Requirements, and Records and Reports, for Infant Formula'' (February 10, 2014). This final rule affirms the IFR's changes to FDA's regulations and provides additional modifications and clarifications. The final rule also responds to certain comments submitted in response to the request for comments in the IFR.

DATES: This final rule is effective July 10, 2014. The compliance date for manufacturers to meet the requirements of §§ 106.96(a), 106.96(e), 106.96(i)(5), 106.100(p)(2) and 106.100(q)(2) related to quality factors for eligible infant formulas is November 12, 2015. The compliance date for the remaining provisions of this final rule is September 8, 2014. Submit comments on information collection issues under the Paperwork Reduction Act of 1995 by July 10, 2014 (see section VII, the ''Paperwork Reduction Act of 1995'' section of this document).

ADDRESSES: To ensure that comments on the information collection are received, the Office of Management and Budget (OMB) recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, FAX: 202–395–7285, or emailed to *oira_submission@omb.eop.gov.* All comments should be identified with the OMB control number 0910–0256 and titled ''Infant Formula Requirements.'' Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Benson M. Silverman, Office of