

that have been previously inspected using Dowty Aerospace Propellers MSB No. 61-1119, Revision 3, dated March 8, 2002, or earlier issue, are considered to be in compliance with paragraph (a) of this AD.

#### Repetitive Ultrasonic Inspections

(d) Thereafter, within 1,000 flight hours TIS after each ultrasonic inspection, perform an ultrasonic inspection of the rear wall of the rear half of the propeller hub for cracks in accordance with Appendix A of the applicable Dowty Aerospace Propellers MSB listed in Table 1 of this AD.

#### Inspection Reporting Requirements

(e) For each inspection, record the inspection data on a copy of Appendix B of the applicable MSB listed in Table 1 of this AD, and report the findings to the Manager, Boston Aircraft Certification Office, FAA, Engine and Propeller Directorate, 12 New England Executive Park, Burlington, MA 01803-5299 within 10 days after the inspection. Reporting requirements have been approved by the Office of Management and Budget (OMB) and assigned OMB control number 2120-0056.

#### Alternative Methods of Compliance

(f) An alternative method of compliance or adjustment of the compliance time that provides an acceptable level of safety may be used if approved by the Manager, Boston Aircraft Certification Office. Operators must submit their request through an appropriate FAA principal Maintenance Inspector, who may add comments and then send it to the Manager, Boston Aircraft Certification Office.

**Note 2:** Information concerning the existence of approved alternative methods of compliance with this airworthiness directive, if any, may be obtained from the Boston Aircraft Certification Office.

#### Special Flight Permits

(g) Special flight permits may be issued in accordance with §§ 21.197 and 21.199 of the Federal Aviation Regulations (14 CFR 21.197 and 21.199) to operate the airplane to a location where the requirements of this AD can be done.

**Note 3:** The subject of this AD is addressed in CAA UK AD 003-11-2001, dated November 30, 2001.

Issued in Burlington, Massachusetts, on April 22, 2003.

Robert Guyotte,

Acting Manager, Engine and Propeller Directorate, Aircraft Certification Service.  
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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

#### 21 CFR Parts 106 and 107

[Docket No. 95N-0309]

RIN 0910-AA04

#### Current Good Manufacturing Practice, Quality Control Procedures, Quality Factors, Notification Requirements, and Records and Reports for the Production of Infant Formula; Reopening of the Comment Period

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Proposed rule; reopening of the comment period.

**SUMMARY:** The Food and Drug Administration (FDA) is reopening until June 27, 2003, the comment period for the proposed rule, published in the **Federal Register** of July 9, 1996 (61 FR 36154), revising its infant formula regulations in 21 CFR parts 106 and 107. The proposed rule would establish requirements for current good manufacturing practice (CGMP) and audits, establish requirements for quality factors, and amend its quality control procedures, notification, and records and reports requirements for infant formula. FDA is reopening the comment period to update comments and to receive any new information.

**DATES:** Submit written or electronic comments by June 27, 2003.

**ADDRESSES:** Submit written comments to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to <http://www.fda.gov/dockets/ecomments>.

**FOR FURTHER INFORMATION CONTACT:** Shellee Anderson, Center for Food Safety and Applied Nutrition (HFS-800), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 301-436-1491, or e-mail: [Shellee.Anderson@cfsan.fda.gov](mailto:Shellee.Anderson@cfsan.fda.gov).

#### SUPPLEMENTARY INFORMATION:

##### I. Reopening of Comment Period

In the **Federal Register** of July 9, 1996 (61 FR 36154), FDA proposed regulations (the 1996 proposal) to revise its infant formula regulations to establish requirements for quality factors and CGMP; to amend its quality control procedure, notification, and records and report requirements for infant formulas; to require that infant formulas contain, and be tested for,

required nutrients and for any nutrient added by the manufacturer throughout their shelf life, and that they be produced under strict microbiological controls; and to require that manufacturers implement the CGMP and quality control procedure requirements by establishing a production and in-process control system of their own design. The agency proposed these requirements to implement provisions of the Drug Enforcement, Education and Control Act of 1986 (Public Law 99-570) that amended section 412 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 350a).

Interested persons were originally given until October 7, 1996, to comment on the 1996 proposal. However, at the request of a trade organization, the comment period was extended to December 6, 1996 (61 FR 49714, September 23, 1996).

FDA's Food Advisory Committee (FAC) met on April 4 and 5, 2002, to discuss general scientific principles related to quality factors for infant formula. The committee was also asked to discuss the scientific issues related to the generalization of findings from a clinical study using preterm infant formula consumed by preterm infants to a term infant formula intended for use by term infants. On November 18 and 19, 2002, the Infant Formula Subcommittee (IFS) of the FAC met to discuss the scientific issues and principles involved in assessing and evaluating whether a "new" infant formula supports normal physical growth in infants when consumed as a sole source of nutrition. The Contaminants and Natural Toxicants Subcommittee (CNTS) of the FAC met on March 18 and 19, 2003, to discuss the scientific issues and principles involved in assessing and evaluating *Enterobacter sakazakii* contamination in powdered infant formula, risk reduction strategies based on available data, and research questions and priorities. Information on these three meetings, including the agenda, questions asked, guest speakers, committee roster, briefing information, and transcripts of the meetings can be found at <http://www.fda.gov/ohrms/dockets/ac/cfsan02.htm>.

##### II. Request for Comments

Because of the length of time that has elapsed since publication of the 1996 proposal and the occurrence of the FAC, IFS, and CNTS meetings, FDA is interested in updating comments and receiving any new information before issuing a final rule. Accordingly, the agency is requesting comments on all