(2) May be otherwise adulterated or misbranded.

(b) The notification made according to paragraph (a) of this section shall be made by telephone, to the Director of the appropriate Food and Drug Administration district office. After normal business hours (8 a.m. to 4:30 p.m.), FDA's emergency number, 202–857–8400, shall be used. The manufacturer shall send written confirmation of the notification to the Food and Drug Administration, Center for Food Safety and Applied Nutrition, Office of Special Nutritionals, Division of Programs and Policy Enforcement (HFS–455), Infant Formula Coordinator, 200 C St. SW., Washington, DC 20204, and to the appropriate Food and Drug Administration district office specified in § 5.115 of this chapter.

PART 107—INFANT FORMULA

7. The authority citation for 21 CFR part 107 continues to read as follows:

Authority: Secs. 201, 403, 412, 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 343, 350a, 371).

8. Section 107.1 is added to subpart A to read as follows:

§ 107.1 Status and applicability of the regulations in part 107.

(a) The criteria set forth in subpart B of this part describes the labeling requirements applicable to infant formula under section 403 of the Federal Food, Drug, and Cosmetic Act (the act). Failure to comply with any regulation in subpart B of this part will render an infant formula misbranded under that section of the act.

(b) The criteria set forth in subpart C of this part describes the terms and conditions for the exemption of an infant formula from the requirements of section 412(a), (b), and (c) of the act. Failure to comply with any regulations in subpart C of this part will result in the withdrawal of the exemption given under section 412(h)(1) of the act.

(c) Subpart D of this part sets forth the nutrient requirements for infant formula under section 412(i) of the act. Failure to comply with any regulation in subpart D of this part will render an infant formula adulterated under section 412(a)(1) of the act.

9. Section 107.10 is amended by revising the introductory text of paragraph (a)(2) to read as follows:

§ 107.10 Nutrient information.

(a) * * *

(2) A statement of the amount, supplied by 100 kilocalories, of each of the following nutrients and of any nutrient added by the manufacturer:

* * * * *

10. Section 107.240 is revised to read as follows:

§ 107.240 Notification requirements.

(a) *Telephone report.* When a determination is made that an infant formula is to be recalled, the recalling firm shall telephone within 24 hours the appropriate Food and Drug Administration district office listed in § 5.115 of this chapter and shall provide relevant information about the infant formula that is to be recalled.

(b) *Initial written report.* Within 14 days after the recall has begun, the recalling firm shall provide a written report to the appropriate Food and Drug Administration district office. The report shall contain relevant information, including the following cumulative information concerning the infant formula that is being recalled:

(1) Number of consignees notified of the recall and date and method of notification, including recalls required by § 107.200, information about the notice provided for retail display and the request for its display.

(2) Number of consignees responding to the recall communication and quantity of recalled infant formula on hand at the time it was received.

(3) Quantity of recalled infant formula returned or corrected by each consignee contacted and the quantity of recalled infant formula accounted for.

(4) Number and results of effectiveness checks that were made.

(5) Estimated timeframes for completion of the recall.

(c) *Status reports.* The recalling firm shall submit to the appropriate Food and Drug Administration district office a written status report on the recall at least every 14 days until the recall is terminated. The status report shall describe the steps taken by the recalling firm to carry out the recall since the last report and the results of these steps.

11. Section 107.250 is amended by revising the introductory text to read as follows:

§ 107.250 Termination of an infant formula recall.

The recalling firm may submit a recommendation for termination of the recall to the appropriate Food and Drug Administration district office listed in § 5.115 of this chapter for transmittal to the Division of Enforcement (HFS–605), Office of Field Programs, Center for Food Safety and Applied Nutrition, for action. Any such recommendation shall contain information supporting a conclusion that the recall strategy has been effective. The agency will respond within 15 days of receipt by the Division of Enforcement (HFS–605), Office of Field Programs, Center for Food Safety and Applied Nutrition, of the request for termination. The recalling firm shall continue to implement the recall strategy until it receives final written notification from the agency that the recall has been terminated. The agency will send such notification, unless it has information, from FDA's own audits or from other sources demonstrating the recall has not been effective. The agency may conclude that a recall has not been effective if:

* * * * *

Dated: April 19, 1996.

David A. Kessler,

Commissioner of Food and Drugs.

Donna E. Shalala,

Secretary of Health and Human Services.

[FR Doc. 96–17058 Filed 7–8–96; 8:45 am]

BILLING CODE 4160–01–P

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.

[FR Doc. 03–10334 Filed 4–25–03; 8:45 am]

BILLING CODE 4910–13–P

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.*

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

issues in the proposed rule. Comments previously submitted to the Dockets Management Branch do not need to be resubmitted because all comments submitted to the docket number will be considered in any final rule to the 1996 proposal. Since the 1996 proposal was published, several issues within the scope of that proposal have come to the agency's attention and are set forth in this document for comment.

(Issue 1) In April 2001, an outbreak of *E. sakazakii* occurred in 10 infants in the neonatal intensive care unit of a hospital in Tennessee (Ref. 1). One of these infants died. The ill infants had consumed formula that was made from sterile water and a specific batch of powdered infant formula. Samples from both opened and unopened cans of the implicated brand of powdered infant formula were cultured. *E. sakazakii* was found in all samples from one particular batch of the product. Because of its concerns with *E. sakazakii*, FDA requests comment on whether there is a need to include a microbiological requirement for *E. sakazakii* and, if so, what requirement the agency should consider to ensure the safety of powdered infant formula and prevent future outbreaks. The agency requests comment on what other changes, if any, in the proposed microbiological requirements would be appropriate to ensure the safety of powdered infant formula and to prevent outbreaks of illness. FDA also requests comment on whether powdered infant formula to be consumed by premature and newborn infants should meet stricter microbiological requirements than formula intended for older infants. The agency specifically requests comments on issues discussed at the CNTS meeting that are relevant to this rulemaking.

(Issue 2) On March 19, 2002, FDA issued a letter (Ref. 2) in response to a notice of a manufacturer's conclusion that *Bifidobacterium lactis* strain Bb12 and *Streptococcus thermophilus* strain Th4 are generally recognized as safe (GRAS) for their intended use as ingredients in milk based infant formula that is intended for consumption by infants 4 months and older, at levels not to exceed CGMP. The agency has no questions about the manufacturer's conclusion at this time. In the 1996 proposal, FDA provided controls in proposed § 106.55 for powdered infant formula to prevent adulteration from microorganisms, including a proposed limit on the maximum allowable number of microorganisms in the aerobic plate count. The agency requests comment on what changes, if any, in the proposed microbiological requirements would be appropriate to provide for powdered infant formula and to ensure its safety if microorganisms are intentionally added to infant formulas. Would infant formula containing these added microorganisms exceed the maximum allowable number in the aerobic plate count? How can manufacturers ensure that a high aerobic plate count is due to the intentional addition of microorganisms and not contamination?

(Issue 3) The agency requests comments on which provisions of the proposed rule would require manufacturers to change their current activities. What new activities would manufacturers have to undertake to comply with the proposed regulations? What activities would manufacturers have to discontinue to comply with the proposed regulations? What are the costs of these changes? For example:

(Issue 3a) Proposed § 106.20(a) requires that buildings used in the manufacture of infant formula allot space for the separation of incompatible operations, such as the handling of raw materials, the manufacture of the product, and packaging and labeling operations. FDA requests comment on the types of control systems that manufacturers use to separate raw, in-process, and finished materials and the costs of making changes.

(Issue 3b) Proposed § 106.20(d) would require manufacturers to use air filtration systems, including prefilters and particulate matter air filters, on air supplies to production areas where ingredients or infant formula are directly exposed to the atmosphere. FDA requests comment on the types and costs of air filtration systems used by infant formula manufacturers and the costs of making changes.

(Issue 4) One comment to the 1996 proposal stated that the validation section in proposed § 106.35 is so vague and the impact so enormous that implementing it would be counterproductive. In proposed § 106.35(a)(4) the agency proposed that, for purposes of the section, "validation" means establishing documented evidence that provides a high degree of assurance that a system will consistently produce a product meeting its predetermined specifications and quality characteristics. In proposed § 106.35(b)(1), FDA proposed that all automatic systems be designed, installed, tested, and maintained in a manner that will ensure that they are capable of performing their intended function. The agency proposed in proposed § 106.35(b)(4) that automatic systems be validated before their first use to manufacture commercial product. Proposed § 106.35(b)(5) states that the infant formula manufacturer shall ensure that any automatic system that is modified be validated after the modification and before use of the modified system to manufacture commercial product. FDA requests comments on the proposed validation requirements. The agency specifically requests comments on current validation activities of infant formula facilities and how often manufacturers validate their systems.

(Issue 5) Several provisions of the 1996 proposal (e.g., §§ 106.30(d)(1) and 106.35(b)(2)) would require that manufacturers calibrate instruments and controls. In these proposed provisions the agency specifies that calibration occur at routine intervals. FDA requests comments on how often and under what conditions manufacturers now calibrate instruments and controls against a known standard and the adequacy of current procedures.

(Issue 6) FDA proposed to establish two quality factor measures for infant formula, protein quality and normal physical growth. Quality factors are those factors necessary to demonstrate that the infant formula, as prepared for market, provides nutrients in a form that is bioavailable and safe as shown by evidence that demonstrates that the formula supports healthy growth when fed as a sole source of nutrition. The agency requests comments on the appropriateness of these quality factors and any information on other quality factors that could be implemented to be consistent with current scientific knowledge as required under section 412(b)(1) of the act. FDA specifically requests comments on issues relevant to this rulemaking that were discussed at the two FAC meetings and on the following quality factor issues:

(Issue 6a) What requirements should the agency establish to determine when manufacturers must conduct clinical growth studies for a new or reformulated infant formula?

(Issue 6b) In proposed § 106.97, FDA would require that manufacturers compare their clinical study growth data with the National Center for Health Statistics (NCHS) growth charts. The IFS of the FAC considered other sources of reference data in addition to the NCHS and recommended the Iowa reference data as the most appropriate reference data for comparison because they are longitudinal, collected over the time period of interest for clinical studies of infant growth, and collected in a research setting. FDA requests comments on whether the Iowa reference data should be the standard

for clinical study growth data rather than the NCHS growth charts.

(Issue 6c) In proposed § 106.97(a)(1)(i)(A), the agency would require that manufacturers conduct clinical studies that are no less than 4 months in duration, enrolling infants no more than 1 month old at time of entry into the study. The IFS of the FAC recommended that infants be enrolled by 14 days of age. FDA requests comments on the appropriate age for infants enrollment into clinical studies and on the duration of the studies.

(Issue 7) In proposed § 106.97(a)(1)(ii), the agency states provisions that it recommends manufacturers include in a clinical study protocol. Proposed § 106.97(a)(1)(ii)(C) discusses review and approval by an Institutional Review Board (IRB) in accordance with part 56 (21 CFR part 56), and the need for obtaining written informed consent from parents or legal representatives of the infants in accordance with part 50 (21 CFR part 50). Subsequent to the publication of the 1996 proposal, the agency issued an interim final rule entitled "Additional Safeguards for Children in Clinical Investigations of FDA-Regulated Products" (66 FR 20589, April 24, 2001), which amended parts 50 and 56 to include, within the scope of that rule, data and information about a clinical study of an infant formula when submitted as part of an infant formula notification under section 412(c) of the act. Thus, requirements related to IRB review and informed consent for such clinical studies are dealt with in that interim final rule, and therefore, reference to IRB review and informed consent will be removed from the 1996 proposal. With respect to the other clinical study protocol provisions in proposed § 106.97(a)(1)(ii), the agency intends to remove them from the proposed rule and develop a guidance document on what it recommends be included in a clinical study protocol for infant formula that is submitted as part of an infant formula notification under section 412(c) of the act.

III. How to Submit Comments

Interested persons may submit to the Dockets Management Branch (*see* ADDRESSES) written or electronic comments regarding this document. Submit a single copy of electronic comments to *http://www.fda.gov/dockets/ecomments* or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the Docket Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

IV. References

FDA has placed the following references on display in the Dockets Management Branch (*see* ADDRESSES) and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday.

1. Centers for Disease Control and Prevention, "*Enterobacter sakazakii* Infections Associated With the Use of Powdered Infant Formula–Tennessee, 2001," 51(14):297, *Morbidity and Mortality Weekly Report*, April 12, 2002.

2. FDA, Agency response letter to GRAS notice number GRN 00049, March 19, 2002.

Dated: April 15, 2003.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 03–10301 Filed 4–25–03; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF COMMERCE

Patent and Trademark Office

37 CFR Part 1

[Docket No.: 2003–P–001]

RIN 0651–AB57

Changes To Implement the 2002 *Inter Partes* Reexamination and Other Technical Amendments to the Patent Statute

AGENCY: Patent and Trademark Office, Commerce.

ACTION: Notice of proposed rulemaking.

SUMMARY: The 21st Century Department of Justice Appropriations Authorization Act contains a title relating to intellectual property. The patent-related provisions in the intellectual property title of the 21st Century Department of Justice Appropriations Authorization Act include provisions permitting a third party requester in an *inter partes* reexamination proceeding to appeal a final decision by the Board of Patent Appeals and Interferences (BPAI) to the U.S. Court of Appeals for the Federal Circuit (Federal Circuit), and to participate in the patent owner's appeal of a final decision by the BPAI to the Federal Circuit. Also included are technical amendments to statutory provisions directed to *inter partes* reexamination, 18-month publication of patent applications and provisional rights, and issuance of patents. The United States Patent and Trademark Office (Office) is in this notice proposing changes to the rules of practice to implement the patent-related provisions of the 21st Century Department of Justice Appropriations Authorization Act, and other miscellaneous changes related to appeals in reexamination proceedings.

DATES: To be ensured of consideration, written comments must be received on or before June 27, 2003. No public hearing will be held.

ADDRESSES: Comments should be sent by electronic mail message over the Internet addressed to *AB57Comments@uspto.gov*. Comments may also be submitted by mail addressed to: Box Comments—Patents, Commissioner for Patents, Washington, DC 20231, or by facsimile to (703) 872–9408, marked to the attention of Kenneth M. Schor, Senior Legal Advisor. Although comments may be submitted by mail or facsimile, the Office prefers to receive comments via the Internet. If comments are submitted by mail, the Office prefers that the comments be submitted on a DOS formatted 3½ inch disk accompanied by a paper copy.

The comments will be available for public inspection at the Office of the Commissioner for Patents, located in Crystal Park 2, Suite 910, 2121 Crystal Drive, Arlington, Virginia, and will be available through anonymous file transfer protocol (ftp) via the Internet (address: *http://www.uspto.gov*). Since comments will be made available for public inspection, information that is not desired to be made public, such as an address or phone number, should not be included in the comments.

FOR FURTHER INFORMATION CONTACT: Kenneth M. Schor or Gerald A. Dost, Senior Legal Advisors. Kenneth M. Schor may be contacted by telephone at (703) 308–6710; by mail addressed to: U.S. Patent and Trademark Office, Box Comments—Patents, Commissioner for Patents, Washington, DC 20231, marked to the attention of Kenneth M. Schor; by facsimile transmission to (703) 872–9408, marked to the attention of Kenneth M. Schor; or by electronic mail message over the Internet addressed to *kenneth.schor@uspto.gov*. Gerald A. Dost may be contacted by telephone at (703) 305–8610; by mail addressed to: U.S. Patent and Trademark Office, Box Comments—Patents, Commissioner for Patents, Washington, DC 20231, marked to the attention of Gerald A. Dost; by facsimile transmission to (703) 308–6916, marked to the attention of Gerald A. Dost; or by electronic mail message over the Internet addressed to *gerald.dost@uspto.gov*.

SUPPLEMENTARY INFORMATION: The American Inventors Protection Act of 1999 (AIPA), enacted on November 29,