

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.

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## 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](mailto: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](mailto: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](mailto:gerald.dost@uspto.gov).

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