DEPARTMENT HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 896

[Docket No. 83N–0193]

RIN 0905–AD83

Performance Standard for the Infant Apnea Monitor

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is proposing a regulation to establish a mandatory performance standard for infant apnea monitors, which are a subset of breathing frequency monitors also called neonatal apnea monitors. The infant apnea monitor is a system intended for use on infants to detect cessation of breathing. FDA believes that a performance standard is necessary to ensure that infant apnea monitors accurately and reliably detect the absence of effective respiration and provide an alarm in such cases. The objective of this proposed regulation is to establish performance requirements and test methods that will provide reasonable assurance of the safety and effectiveness of the infant apnea monitor.

DATES: Submit written comments by May 22, 1995. FDA is proposing that any final rule that may issue based on this proposal become effective 1 year following its publication in the **Federal Register**.

ADDRESSES: Submit written comments to the Dockets Management Branch (HFA–305), Food and Drug Administration, rm. 1–23, 12420 Parklawn Dr., Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: James J. McCue, Center for Devices and Radiological Health (HFZ–84), Food and Drug Administration, 2098 Gaither Rd., Rockville, MD 20850, 301–594–4765.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of September 10, 1982 (47 FR 39816), FDA issued a final rule under section 513 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360c) classifying the generic type of device, the breathing (ventilatory) frequency monitor (21 CFR 868.2375), into class II (performance standards). In the **Federal Register** of July 8, 1983 (48 FR 31392), FDA initiated a proceeding to establish a performance standard for the breathing frequency monitor, pursuant to section 514(b) of the act (21 U.S.C. 360d(b)) and part 861 (21 CFR part 861). The notice provided interested persons with the opportunity to request a change in the classification of the device. In the **Federal Register** of February 26, 1986 (51 FR 6886), FDA continued the proceeding to establish a performance standard pursuant to section 514(c) of the act (21 U.S.C. 360d(c)) and part 861. The notice invited interested persons to submit an existing standard as a proposed performance standard under section 514 of the act for the device, or to submit an offer to develop such a proposed standard. In that notice, FDA limited the proceeding to those breathing frequency monitors commonly called neonatal apnea monitors, which are intended for use on infants to detect cessation of breathing.

In the **Federal Register** of July 1, 1986 (51 FR 23832), FDA announced that, in accordance with the provisions of section 514(e)(3) of the act and § 861.32, the agency might, upon application (which could be made before the acceptance of the offer), agree to contribute to an accepted offeror's cost for developing a proposed standard if FDA were to determine that its contribution would likely result in a more satisfactory standard than would be developed without such contribution. Subsequently, FDA allocated approximately $250,000 to contribute to the cost for the first year of effort in developing a proposed standard.

In the **Federal Register** of April 22, 1988 (53 FR 13296), FDA advised that a notice of grant award (cooperative agreement) had been issued to the Emergency Care Research Institute (ECRI), 5200 Butler Pike, Plymouth Meeting, PA 19462. The cooperative agreement with ECRI was completed on August 31, 1988. Because certain performance requirements for the infant apnea monitor were not addressed in ECRI's draft document, FDA proceeded to develop a proposed standard itself for the infant apnea monitor, using the information developed during the cooperative agreement with ECRI (21 U.S.C. 380d(f)).

In the **Federal Register** of January 4, 1989 (54 FR 187), FDA announced the availability of its ''First Draft Proposed Standard for the Infant Apnea Monitor—October 1988,'' and requested public comments on the draft standard. In accordance with § 861.30, in the same notice, FDA also announced an open public meeting to discuss the draft standard. The meeting was held on January 25, 1989, in conjunction with the Seventh Annual Conference on Apnea of Infancy held in Rancho Mirage, CA.

In the **Federal Register** of July 25, 1989 (54 FR 30951), FDA announced an open public meeting that was held on September 11 and 12, 1989, at the Crowne Plaza Holiday Inn, Rockville, MD, to discuss current sensor modalities and devices used to measure infant apnea, combinations of sensors used to detect apnea and the pathophysiological result of apnea, and currently used test methods.

In the **Federal Register** of December 6, 1989 (54 FR 50437), FDA announced the availability of its ''Second Draft Proposed Standard for the Infant Apnea Monitor—October 1989'' and again requested public comments on the draft. In the same notice FDA also announced an open public meeting to discuss the draft standard. The meeting was held on January 24, 1990, in conjunction with the Eighth Annual Conference on Apnea of Infancy held in Rancho Mirage, CA.

A summary of the proceedings of the public meetings and all data and information submitted to FDA during these meetings are part of the administrative record of this rulemaking and are available to the public under 21 CFR 20.111 from the Dockets Management Branch (address above).

II. The Proposed Regulation

The second draft proposed standard was based on 22 written comments received in response to the **Federal Register** request for comments on the first draft proposed standard and on the information received at the public meetings. This proposed mandatory standard is based on 22 written comments received in response to the **Federal Register** request for comments on the second draft proposed standard, on information received at the public meeting, and on other information available to FDA.

The proposed standard includes specific requirements for infant apnea monitors in four areas: Patient monitoring, electrical characteristics, mechanical and environmental characteristics, and labeling. FDA has prepared several ancillary documents intended to assist the manufacturer and other interested persons in understanding both the reasons for specific requirements and the recommended means of testing specific devices against the requirements. A document entitled: ''Recommended Test Methods—Infant Apnea Monitor Standard'' (Ref. 1) recommends test methods and groups them in a similar manner to those in the proposed standard. Another document entitled: