ANNUAL BURDEN FOR RECORDKEEPING

CFR section	Total annual responses	Hours per response	Total hours
896.59	30	12	360

Organizations and individuals desiring to submit comments regarding this burden or any aspects of these information collection requirements including suggestions for reducing the burden, should direct them to FDA's Dockets Management Branch (address above) and to the Office of Information and Regulatory Affairs, OMB, rm. 3208, New Executive Office Bldg., Washington, DC 20503, Attn: Desk Officer for FDA.

VI. Comments

Interested persons may, on or before May 22, 1995, submit to the Dockets Management Branch (HFA–305), Food and Drug Administration, rm. 1–23, 12420 Parklawn Dr., Rockville, MD 20857, written comments regarding this proposal. Two copies of any comments are to be submitted, except that individuals may submit one 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 office above between 9 a.m. and 4 p.m., Monday through Friday.

VII. References

The following information has been placed on display in the Dockets Management Branch (address above) and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday.

1. Center for Devices and Radiological Health (CDRH), ''Recommended Test Methods—Infant Apnea Monitor Standard,'' September 1993.

2. CDRH, ''Additional Guidance for Testing Immunity to Radiated Electromagnetic Fields—Infant Apnea Monitor Standard,'' September 1993.

3. CDRH, ''Rationale for Requirements—Infant Apnea Monitor Standard,'' September 1993.

List of Subjects in 21 CFR Part 896

Administrative practice and procedure, Incorporation by reference, Medical devices, Reporting and recordkeeping requirements.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, it is proposed that new part 896 be added to read as follows:

PART 896—PERFORMANCE STANDARD FOR INFANT APNEA MONITORS

Subpart A—General Provisions

Sec.

Subpart B—Patient Monitoring Requirements

Subpart C—Electrical Performance Requirements

Subpart D—Mechanical and Environmental Performance Requirements

Subpart E—Labeling Requirements

Authority: Secs. 501, 502, 513, 514, 530–542, 701, 704 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 351, 352, 360c, 360d, 360gg–360ss, 371, 374); secs. 351, 361 of the Public Health Service Act (42 U.S.C. 262, 264).

Subpart A—General Provisions

§ 896.10 Scope.

The standard set forth herein describes basic performance features and labeling requirements that infant apnea monitors, intended for hospital and/or home use, are required to meet. The monitor shall be a complete system, suitable for its intended purpose of accurately and reliably providing alarms as needed to the care giver.

§ 896.11 Applicability.

(a) *General.* The provisions of this standard are applicable to all infant apnea monitors manufactured, imported, or offered for import in any State or territory of the United States, the District of Columbia, or the Commonwealth of Puerto Rico after (insert date 1 year after date of publication of the final rule in the **Federal Register**).

(b) *Applicable documents.* Compliance with certain requirements of this section shall be determined by the standards described in the following references, to the extent specified herein, which are incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Except as otherwise indicated, copies of these publications may be purchased from the American National Standards Institute, 11 West 42d St., New York, NY 10036, and may be examined at the Office of Science and Technology, Center for Devices and Radiological Health (HFZ–100), 5600 Fishers Lane, Rockville, MD; or at the Office of the Federal Register, 800 North Capitol St. NW., suite 700, Washington, DC:

(1) ''IEC 601–1 (1988): Medical electrical equipment, part 1: General requirements for safety,'' 2d edition.

(2) ''IEC 529 (1989): Classification of degrees of protection provided by enclosures.''

(3) ''IEC 801–1 (1984): Electromagnetic compatibility for industrial process control equipment.''

(4) ''IEC 801–2 (1991): Electrostatic discharge requirements.''

(5) ''IEC 801–3 (1984): Radiated electromagnetic field requirements.''

(6) ''IEC 801–4 (1988): Electrical fast transient/burst requirements.''

(7) ''CISPR 11 (1990): Limits and methods of measurement of radio-interference characteristics of industrial,