recommendations in FDA's final guidance document.

Because of the above factors, FDA believes apnea monitor manufacturers will incur no costs other than those associated with the submission of 510(k) premarket notifications for ''new'' monitors. FDA has estimated this cost to be $6,000 per submission on the basis that it takes device firms approximately 80 hours to complete a 510(k) package (exclusive of preparing clinical data, research, etc.) and costs an average of $75.00 per hour to perform this type of work. Thus, FDA estimates the cost to industry of this classification proposal to be approximately $12,000 per year ($6,000 per 510(k) submission x 2 submissions per year). Therefore, the agency certifies that this proposal, if finalized, will not have a significant economic impact on a substantial number of small businesses.

Section 202(a) of the Unfunded Mandates Reform Act of 1995 (Public Law 104–4) requires that agencies prepare a written statement of anticipated costs and benefits before proposing any rule that may result in an expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $100 million in any one year (adjusted annually for inflation). The Unfunded Mandates Reform Act of 1995 does not require FDA to prepare a statement of costs and benefits for the proposed rule, because the proposed rule is not expected to result in any 1-year expenditure that would exceed $100 million adjusted for inflation.

V. Paperwork Reduction Act of 1995

This proposed rule contains information collection provisions that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The burden hours required for proposed § 868.2377 are reported and approved under OMB Control No. 0910–0120.

VI. Federalism

FDA has analyzed this proposed rule in accordance with the principles set forth in Executive Order 13132. FDA has determined that the rule does not contain policies that have substantial direct effects on the States, on the relationship between the National Government and the States, or on the distribution of power and responsibilities among the various levels of government. Accordingly, the agency has concluded that the rule does not contain policies that have federalism implications as defined in the order and, consequently, a federalism summary impact statement is not required.

VII. Submission of Comments

Interested persons may submit to the Dockets Management Branch (address above) written comments regarding this proposal by December 21, 2000. 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 Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

List of Subjects in 21 CFR Part 868

Medical devices.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, it is proposed that 21 CFR part 868 be amended as follows:

PART 868—ANESTHESIOLOGY DEVICES

1. The authority citation for 21 CFR part 868 continues to read as follows:

Authority: 21 U.S.C. 351, 360, 360c, 360e, 360j, 371.

2. Section 868.2375(a) is revised to read as follows:

§ 868.2375 Breathing frequency monitor.

(a) *Identification.* A breathing (ventilatory) frequency monitor is a device intended to measure or monitor a patient's respiratory rate. The device may provide an audible or visible alarm when the respiratory rate, averaged over time, is outside operator settable limits. This device does not include the apnea monitor classified in § 868.2377.

* * * * *

3. Section 868.2377 is added to subpart C to read as follows:

§ 868.2377 Apnea monitor.

(a) *Identification.* An apnea monitor is a complete system intended to alarm primarily upon the cessation of breathing timed from the last detected breath. The apnea monitor includes a secondary modality, such as heart rate monitoring, that will alarm in response to the physiological consequences of apnea.

(b) *Classification.* Class II (special controls) (Guidance document: ''Guidance for Apnea Monitor 510(k) Submissions'').

Dated: September 1, 2000.

Linda S. Kahan,

Deputy Director for Regulations Policy, Center for Devices and Radiological Health.

[FR Doc. 00–24334 Filed 9–21–00; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 896

[Docket No. 83N–0193]

Medical Devices; Performance Standard for the Infant Apnea Monitor; Withdrawal Notice

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule; withdrawal.

SUMMARY: The Food and Drug Administration (FDA) is withdrawing the proposed rule it issued on February 21, 1995 (60 FR 9762). The document set out proposed requirements for a mandatory performance standard for the infant apnea monitor. In light of declining births and reduced mortality rates for infants at risk for death due to apparent life-threatening events (ALTE's), including certain apneas, and after considering other factors, FDA no longer believes that a mandatory performance standard is needed for this class II device. The agency believes that FDA guidance to industry that identifies minimum performance, testing, and labeling recommendations will provide reasonable assurance of the safety and effectiveness of the apnea monitor, including infant/child monitors. FDA is making this draft guidance available for comment through a notice published elsewhere in this issue of the **Federal Register**. Also, elsewhere in this issue of the **Federal Register**, FDA is proposing to create a separate classification for the apnea monitor, with the FDA guidance document as the special control.

FOR FURTHER INFORMATION CONTACT: James J. McCue, Center for Devices and Radiological Health (HFZ–84), Food and Drug Administration, 2094 Gaither Rd., Rockville, MD 20850, 301–594–4766, ext. 101.

SUPPLEMENTARY INFORMATION:

I. Background

On September 10, 1982 (47 FR 39816), FDA classified devices intended to measure or monitor a patient's respiratory rate into class II (performance standards) as part of the generic group of devices known as breathing (ventilatory) frequency

monitors (21 CFR 868.2375). Under the classification scheme set forth in section 513 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360c), as amended by the Medical Device Amendments of 1976 (the 1976 amendments) (Public Law 94–295), the agency determined that performance standards were necessary to provide reasonable assurance of the safety and effectiveness of these devices.

In subsequent years, FDA initiated a series of actions to provide for the development of a mandatory performance standard for the subset of breathing frequency monitors, commonly called neonatal apnea monitors, that are intended to be used on infants to detect the cessation of respiratory air flow. Early actions included the initiation of a proceeding under section 514(b) of the act (21 U.S.C. 360d(b)) (48 FR 31392, July 8, 1983), and the issuance of an invitation for interested persons to submit an existing standard as a proposed standard or to submit an offer to develop a proposed standard (51 FR 6886, February 26, 1986).

Thereafter, FDA issued a grant award to the Emergency Care Research Institute (ECRI) to develop a proposed standard for the neonatal apnea monitor (53 FR 13296, April 22, 1988). However, the proposed standard ECRI developed did not cover certain performance requirements for the device. As a consequence, FDA initiated notice and comment rulemaking to develop a performance standard for the infant apnea monitor, which would include the neonatal apnea monitor. FDA intended that the standard would encompass monitors used in hospitals and in patients' homes to detect and alarm upon the cessation of respiratory air flow (i.e., apnea) in children under 3 years old.

In the **Federal Register** of January 4, 1989 (54 FR 187), FDA made available for public comment its ''First Draft Proposed Standard for the Infant Apnea Monitor, October 1988.'' In the **Federal Register** of December 6, 1989 (54 FR 50437), FDA announced the public availability of its ''Second Draft Proposed Standard for the Infant Apnea Monitor October, 1989.'' After considering comments received on these drafts, and comments made at public meetings, including the Seventh and Eighth Conference(s) on Apnea of Infancy, FDA issued a proposed rule setting forth requirements for a mandatory performance standard for the infant apnea monitor (60 FR 9762, February 21, 1995).

II. Summary of Requirements in the Proposed Standard

The mandatory performance standard proposed by FDA on February 21, 1995, specified requirements for infant apnea monitors in four areas: Patient monitoring, electrical characteristics, mechanical and environmental characteristics, and labeling. Certain provisions required conformance, to the extent specified, with identified international standards.

Proposed patient monitoring provisions included: Requirements for primary and secondary monitoring modalities, visual and audible alarms (status indicators), a remote alarm unit for monitors intended for home use, and a self-test mechanism. Proposed electrical requirements included: Provisions for battery backup, operation from ungrounded power sources, limitation of leakage current, and operational specifications and test procedures ensuring electromagnetic compatibility. Proposed mechanical and environmental requirements mandated: Tamper proof controls, protection against misconnections, and resistance to normal shock, vibration, temperature extremes, and fluid spills. Proposed labeling provisions specified: Information that manufacturers would be required to provide to operators and health care practitioners, including specific product labels.

III. Summary of Comments Received on the Proposed Standard

FDA received more than 100 comments from manufacturers, hospitals, physicians, medical societies, and national trade associations. A number of comments objected to the 1-year effective date of the standard. One comment claimed that the cost of compliance would exceed $100 million. Another maintained that the need for the standard was based on outdated data and that FDA had not established that the standard was necessary to provide reasonable assurance of the device's safety and effectiveness.

Most comments addressed terms, definitions, specifications, and/or technical requirements proposed in the standard. Many commented on the terms ''breath,'' ''breathing,'' ''cessation of breathing,'' and ''breathing effort;'' others on the definitions of infant apnea monitor, operator, primary monitoring modality, and secondary monitoring modality. Comments concerning primary and secondary monitoring modalities focused on proposed requirements for apnea duration settings, activation times for warning indicators, and sensor fault alarms.

Some comments questioned the adequacy of requirements for visual and audible warning indicators. Others objected to requirements for resetting silenced alarms, low battery warning indicators, and minimum battery capacity. Comments on proposed electromagnetic compatibility requirements included objections to three levels of radiated electromagnetic testing and three voltage levels of fast transient burst testing. Comments also suggested that alarming or degradation of the monitor during immunity testing should be considered an acceptable response and testing endpoint.

Some comments wanted temperature ranges raised for monitor operations and surfaces contacting patients. Comments about labeling objected generally that some of the proposed requirements were duplicative, or unnecessary, or were not a manufacturer responsibility.

IV. Withdrawal of the Proposed Standard

FDA is withdrawing the proposed rule issued on February 21, 1995 (60 FR 9762), and terminating the proceeding for the development of a mandatory performance standard for the infant apnea monitor, in accordance with section 514(b)(3)(A) of the act. FDA no longer believes that the special control of a mandatory standard is necessary, at this time, to provide reasonable assurance of the safety and effectiveness of this device (i.e., an apnea monitor used on an infant/child under 3 years old). The agency considered the following factors in reaching this conclusion: (1) Reductions in at-risk infant populations, (2) few deaths and serious injuries reported to FDA for infant/child apnea monitors attributed to monitor design problems or malfunctions, (3) improved technology, (4) alternative development of consensus standards, and (5) compliance costs versus risks and benefits.

A. Declining Death Rates Within At-Risk Infant Populations

Current U.S. medical opinion continues to support the consensus statement and report issued on the subject of infantile apnea and home monitoring, in accordance with the National Institutes of Health (NIH) Consensus Development Conference, held on September 29 to October 1, 1986. There was consensus agreement, at that conference, with respect to the relationship of neonatal and infant apnea to each other and to infant morbidity, especially from sudden infant death syndrome (SIDS). The conferees agreed that apnea of

prematurity is not a risk factor for SIDS. The conferees also agreed that an ALTE would encompass any episode experienced by infants characterized by some combination of apnea (central or occasionally obstructive), color change, marked change in muscle tone, choking, or gagging. The conferees agreed that such an episode is considered a risk factor for sudden death (including SIDS).[1] Thus, while the conferees generally agreed that there was no evidence of a direct relationship between apnea experienced by infants and SIDS deaths, certain pathophysiological consequences of apnea were not excluded as possible contributors to sudden infant death.

Regarding home monitoring, the consensus conference concluded that there were no reports of scientifically designed studies of the effectiveness of electronic home monitoring of premature infants for ALTE's, or for other pathologic conditions. However, there was agreement that cardiorespiratory monitoring was effective in preventing death due to apnea for certain infants, such as those with a history of recurrent or severe apnea. It was also agreed that cardiorespiratory monitoring, or an alternative therapy, was medically indicated for certain groups of infants at high risk for sudden death, such as infants with one or more ALTE's, symptomatic preterm infants, siblings of multiple SIDS victims, and others.[2]

FDA also notes the dramatic drop that has occurred in SIDS deaths as increased numbers of healthy infants have been placed on their backs to sleep, as a method of reducing the risk of SIDS, under the 1992[3] and 1996 recommendations of the American Academy of Pediatrics and the national ''Back to Sleep'' campaign launched in 1994 under the coordination of the National Institute of Child Health and Human Development. The number of SIDS deaths has declined by over 48 percent from 4,891 deaths in 1992[4] to 2,529 deaths in 1998.[5]

FDA is also aware of the general reductions over the past 7 years in infant mortality rates. The infant (under 1 year) mortality rate has dropped from 8.5 infant deaths per 1,000 live births in 1992[6] to a 7.2 rate in 1998.[7] FDA believes that these reductions in infant mortality rates, in conjunction with reduced numbers of SIDS deaths, serve to reduce the population, and attendant risks, of infants subject to apnea of infancy (i.e., ''pathological'' apnea of 20 seconds or longer associated with bradycardia, cyanosis, pallor, and/or marked hypotonia), and infants subject to ALTE's, including prone sleeping, and other risk factors for SIDS.

B. Deaths, and Serious Injuries Attributable to Infant/Child Apnea Monitors

Under the Medical Device Reporting (21 CFR part 803) and Medical Device Distributor Reporting (21 CFR part 804) regulations, FDA has received manufacturer MDR reports, user facility reports, distributor MDR reports (until February 1998), and voluntary reports and complaints of alleged adverse events associated with the use of apnea detectors, breathing frequency monitors, respiratory monitors, and related devices. From 1986 through 1991, FDA received approximately 150 reports of deaths, and 31 reports of serious injuries allegedly associated with these devices.

In MDR reports received by FDA during the past 8 years, few deaths or serious injuries of children have been reported for apnea monitor usage that could be attributed to monitor problems as the cause of the adverse events. From July 1992 to October 1997, the MDR data base lists receipt of reports alleging 20 deaths and 16 serious injuries that might be associated with apnea monitors. Sixteen deaths and 5 serious injury incidents could be identified as involving infants and children under 3 years old. For 1998 and 1999, data base reports identify six of six alleged deaths and three of four serious injuries as involving patients under 3 years of age. Since 1992, 22 deaths and 8 serious injuries have allegedly occurred during the use of infant/child apnea monitors.

In two of those deaths reported since July 1992 were device problems considered to have caused or contributed directly to the reported event. In a February 1993 incident (User Report No. 3200010000–1993–0008), the audible alarm of a respiration rate monitor reportedly did not sound at the decrease in respiration during the seizure of a 3-month-old infant who subsequently could not be resuscitated. In an August 1993 incident (User Report No. 1402080000–1993–0002), the electrical power source of an apnea monitor allegedly changed from the battery mode to the alternating current mode, resulting in the electrocution of the infant.

Similarly, in three of the serious injury events reported after July 1992 were monitor problems thought to be causal factors. In 1992 (User Report No. 3300270000–1992–002) and 1998 (Voluntary Report No. MW1014260) incidents, electrode connections reportedly caused red skin irritations, with skin breakdowns or burns. Multiple false bradycardia alarming resulted in unnecessary hospitalization of an infant in one October 1997 incident (Voluntary Report No. MW1012327).

FDA considers the continuing low number of reported deaths and serious injuries in which a monitor problem is the possible cause of the adverse event to be a factor that lessens the need for a mandatory performance standard for the infant/child apnea monitor at this time. Moreover, as discussed below, the agency believes that newer technologies will reduce these small numbers even further.

C. Improved Technology

Monitors to detect apnea in infants have been used in hospitals and patients' homes since the early 1970's. Methods to detect respiration have included mattress motion sensors, capnometry, impedance pneumography, inductive plethysmography, and others. Impedance pneumography, utilizing electrodes, leads, and patient cables, remains the most prevalent method, but other methods have been developed, including those that utilize nonelectrical or pneumatic sensors and telemetric respiratory detection.

Various detection modalities and features have been added to improve apnea monitor designs, including: Heart rate; oxygen saturation and airway carbon dioxide monitoring; noise suppression; automatic sensitivity adjustments; signal processing algorithms; and the capacity to record, display, print, and retain in memory, both patient and equipment data. The use of heart rate monitoring modalities in impedance pneumography units and the inclusion of recording and memory capabilities have improved the general performance of home-use infant/child apnea monitors. For example, the introduction in the late 1980's of home-use monitors with internal memory has aided in determining monitor activity

[1] ''Infantile Apnea and Home Monitoring,'' NIH Consensus Statement Online 1986, September 29 to October 1; 6(6): 1–10, pp. 1–3.

[2] ID. at pp. 6–7.

[3] American Academy of Pediatrics, Task Force on Infant Positioning and SIDS, ''Positioning and SIDS,'' *Pediatrics* 89 (6): 1120–1126, June 1992.

[4] U.S. Department of Health and Human Services, ''Reduction in SIDS Deaths Helps Bring Low Infant Mortality,'' Washington, DC, Press Release, October 9, 1996.

[5] National Center for Health Statistics, ''Births and Deaths: Preliminary Data for 1998,'' National Vital Statistics Reports; vol. 47, No. 25, table 15, p. 32. Hyattsville, MD, National Center for Health Statistics, 1999.

[6] National Center for Health Statistics, ''Deaths: Final Data for 1997,'' National Vital Statistics Reports; vol. 47, No. 19, table 27, p. 86. Hyattsville, MD, National Center for Health Statistics, 1999.

[7] See National Center for Health Statistics, note 5, supra.

during adverse events. These newer technologies are in most hospital units, in configurable modules that include programmable apnea detection modalities. Approximately 90 percent of hospital monitoring systems in current use already comply with the February 21, 1995, proposed standard for infant/child apnea monitors (now withdrawn).

Moreover, apnea monitors for home use that were introduced into commercial distribution after November 1993 were cleared for marketing under evaluation criteria described in a guidance document[8] used by reviewers in the Center for Devices and Radiological Health's (CDRH's) Office of Device Evaluation (ODE). This ''Reviewer Guidance'' was made available to industry through the Center's Division of Small Manufacturers' Assistance and is still used by ODE reviewers in evaluating 510(k) submissions for home-use respiratory devices. Many performance, labeling, and testing recommendations included in the guidance document correspond to requirements in the proposed standard. Thus, CDRH believes that most home-use apnea monitors that received 510(k) clearance after November 1993 already meet most of the provisions of the proposed standard. Some apnea monitors distributed before this time, however, may not conform to certain requirements of the proposed standard.

D. Alternative Development of Consensus Standards

In 1995 (60 FR 9762), FDA proposed to make compliance with certain requirements of the infant apnea monitor standard contingent upon meeting specified provisions of 13 standards developed by other organizations. Since then, global efforts to harmonize standards and domestic efforts to develop consensus standards have increased. FDA's historical support of these efforts has also been strengthened by the FDA Modernization Act of 1997, which added new section 514(c) to the act, allowing FDA to recognize consensus standards that may be used to satisfy device review requirements identified by the agency. In the **Federal Register** of February 25, 1998 (63 FR 9561), FDA provided public notice of its policy on this use of standards and published its first list of FDA-recognized consensus standards related to medical devices.

[8] ''Reviewer Guidance For Premarket Notification Submissions November 1993, Anesthesiology and Respiratory Devices Branch, Division of Cardiovascular, Respiratory, and Neurological Devices.''

FDA believes global harmonization and domestic standardization are producing widely accepted consensus standards embodying the latest scientific developments. In a draft guidance to industry, providing recommended criteria for infant/child apnea monitors, FDA will identify the latest versions of 17 international and domestic consensus standards that have some applicability to performance and testing criteria, particularly electromagnetic compatibility test methods, which the agency considers appropriate for these devices. The agency believes these consensus standards are applicable as well to apnea monitors used on patients of any age. After considering comments on the draft guidance and further evaluating clinical study criteria, FDA will modify the draft document and issue final guidance setting out minimum performance, testing, labeling, and clinical criteria that it considers necessary to assure the safety and effectiveness of any apnea monitor type of device.

Manufacturers will have the flexibility to follow the consensus standards, and other recommendations, set out in the agency's apnea monitor guidance or to use alternative approaches of equal or better merit (e.g., in the use of test procedures). As standards referenced in the agency's guidance become FDA-recognized consensus standards, industry will be able to obtain expedited marketing clearance by certifying conformance to them. FDA believes this process will provide reasonable assurance of the safety and effectiveness of the apnea monitor type of device used on patient populations of any age, including the infant/child apnea monitor.

E. Compliance Costs versus Risks and Benefits

Following its review of comments on the proposed standard, FDA assessed the cost and analyzed the economic impact of various modified versions of the proposed standard. FDA concluded that, if the standard were issued as a final regulation with a 1-year effective date, the one-time cost of complying with the modified standard would be approximately $146.8 million. Annual compliance costs would be about $2.7 million. Extending the effective date to 3 years would reduce the one-time compliance cost to an estimated $89.7 million, while annual costs would remain at $2.7 million.

The largest portion of estimated one-time costs were costs that would be associated with the market removal and correction of infant apnea monitors that did not meet the requirements of the standard. CDRH made the assessment that certain home-use infant apnea monitors marketed before November 1993 would not meet some recommendations set forth in the guidance made available on that date. CDRH also believed that some of these monitors would not meet certain requirements of the February 21, 1995, proposed standard. After a final standard based on the proposed one went into effect, noncompliant monitors would have to be removed from the market and corrected, for example, to provide visual indication of a change in apnea duration from a setting of 20 seconds, to change the color of some visual indicators, to change the volume level for audible alarms, and/or to add shielding and/or filtering to provide additional electromagnetic compatibility.

In light of reductions in at-risk infant populations, few recent deaths or serious injuries attributable to malfunctions, improvements in post-1993 monitor technology, and standardization developments, FDA has concluded that a mandatory performance standard is not necessary to provide reasonable assurance of the safety and effectiveness of the infant(/child) apnea monitor, and that the benefit to the public health would not justify the costs to industry to comply with the standard.

V. Alternative Actions—Classification, Industry Guidance, and Education Program

A. Classification

Elsewhere in this issue of the **Federal Register**, FDA is proposing to create a separate classification for the generic type of device known as the apnea monitor. The generic apnea monitor would include the infant/child apnea monitor intended for use on infants less than 12 months old and children less than 3 years old to detect and alarm upon apnea and its pathophysiological consequences. The apnea monitor device will remain classified in class II, but will be subject to a special control. The special control is a FDA guidance to industry. FDA believes that this special control will provide reasonable assurance of the safety and effectiveness of the apnea monitor device, including the infant/child apnea monitor.

B. FDA Guidance to Industry (Special Controls)

Elsewhere in this issue of the **Federal Register**, FDA is announcing the availability for comment of a draft guidance document for industry

concerning infant/child apnea monitors. This draft guidance sets forth the agency's current position regarding minimum performance characteristics, test procedures and criteria, labeling, and, as appropriate, clinical testing that will provide reasonable assurance of the safety and effectiveness of this kind of apnea monitor device. This guidance includes basic concepts that were included in the proposed standard for infant apnea monitors, but updates, consolidates, or eliminates certain elements of the proposed standard on the basis of comments received in response to the proposal and the continuing development and FDA recognition of appropriate consensus standards. Although the proposed standard did not require clinical testing, the guidance document addresses this subject.

As noted above, FDA believes the performance, testing, labeling, and clinical parameters in the draft industry guidance for infant/child apnea monitors are applicable as well to apnea monitors used on patients in every age group. After considering comments on this guidance and further evaluating clinical criteria, FDA will issue final industry guidance identifying minimum performance, testing, labeling, and clinical criteria as the special control for the entire apnea monitor group of devices. Once this special control is established, new products seeking to enter the market will be required to conform with the special control. The final guidance document will describe a means by which an apnea monitor device may comply with the requirements of special controls for class II devices.

Designation of the agency's guidance document as a special control means that manufacturers attempting to establish that their device is substantially equivalent to a predicate apnea monitor, including one used to monitor apnea in children under 3 years of age, should demonstrate that the proposed device complies with either the specific recommendations of this guidance or some alternative control that provides equivalent assurances of safety and effectiveness. FDA recognizes that older products already on the market will not be required to meet this special control. The agency expects, however, that labeling on the newer devices and other market forces will encourage manufacturers of these older devices to comply with the guidance. FDA also expects the education program, described below, to accelerate the improvement of these older products.

FDA is participating with the Association for the Advancement of Medical Instrumentation in a separate effort to develop clinically-based test methods and clinically-derived bench tests for measuring the effectiveness of monitoring modalities in detecting apnea. At the conclusion of this effort, the agency may consider these tests to be referee test methods.

C. Education Program

FDA intends to develop an education program targeted to reach manufacturers of the infant/child apnea monitor, manufacturers of accessories marketed for use with this device, distributors and rental companies handling the devices, users, including hospitals and other health care services, and other consumers. This particular audience is targeted initially because infants and children under 3 years of age are particularly subject to the pathophysiological consequences of prolonged apneas lasting over 20 seconds in duration.

The purpose of this program will be to inform the target audience of FDA's current position regarding performance characteristics and specifications, test methods and results, and labeling information the agency believes are appropriate for the infant/child apnea monitor. The program also will advise the target audience that some monitors previously cleared for marketing prior to November 1993 may not meet the agency's current recommendations and, although they may adequately detect and alarm upon prolonged episodes of central apnea, they may not be adequate for detection of episodes of obstructive apnea or mixed apnea.

As circumstances warrant, FDA may direct additional educational efforts at parties involved with apnea monitors used on patient populations of other ages.

Dated: September 12, 2000.

William K. Hubbard,

Senior Associate Commissioner for Policy, Planning, and Legislation.

[FR Doc. 00–24335 Filed 9–21–00; 8:45 am]

BILLING CODE 4160–01–F

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 271

[FRL–6874–5]

Tennessee: Final Authorization of State Hazardous Waste Management Program Revisions

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: Tennessee has applied to EPA for Final authorization of the changes to its hazardous waste program under the Resource Conservation and Recovery Act (RCRA). EPA proposes to grant final authorization to Tennessee. In the ''Rules and Regulations'' section of this **Federal Register**, EPA is authorizing the changes by an immediate final rule. EPA did not make a proposal prior to the immediate final rule because we believe this action is not controversial and do not expect comments that oppose it. We have explained the reasons for this authorization in the preamble to the immediate final rule. Unless we get written comments which oppose this authorization during the comment period, the immediate final rule will become effective on the date it establishes, and we will not take further action on this proposal. If we get comments that oppose this action, we will withdraw the immediate final rule and it will not take effect. We will then respond to public comments in a later final rule based on this proposal. You may not have another opportunity for comment. If you want to comment on this action, you must do so at this time.

DATES: Send your written comments by October 23, 2000.

ADDRESSES: Send written comments to Narindar Kumar, Chief, RCRA Programs Branch, Waste Management Division, U.S. Environmental Protection Agency, The Sam Nunn Atlanta Federal Center, 61 Forsyth Street, SW, Atlanta, Georgia 30303–3104. You can examine copies of the materials submitted by Tennessee during normal business hours at the following locations: EPA Region 4 Library, The Sam Nunn Atlanta Federal Center, 61 Forsyth Street, SW, Atlanta, Georgia 30303–3104, Phone number: (404)562–8190; or Tennessee Department of Environment and Conservation, Division of Solid Waste Management, 5th Floor, L & C Tower, 401 Church Street, Nashville, Tennessee 37243–1535, Phone number: (615) 532–0850.

FOR FURTHER INFORMATION CONTACT: Narindar Kumar, Chief, RCRA Programs