from the utility, purchases and sales of investments, gains and losses from investment activity, disbursements from the Fund for decommissioning activity and payment of Fund expenses, including taxes; and

(3) Fund assets and liabilities at the end of the period. The report should not include the liability for decommissioning.

(e) The utility must also mail a copy of the financial report provided to the Commission pursuant to paragraph (d) of this section to anyone who requests it.

(f) If an independent public accountant has expressed an opinion on the report or on any portion of the report, then that opinion must accompany the report.

[FR Doc. 97–16043 Filed 6–18–97; 8:45 am]
BILLING CODE 6717–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 5

Delegations of Authority and Organization; Office of the Commissioner

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the regulations for delegations of authority by adding a new authority from the Assistant Secretary for Health (ASH), Office of Public Health and Science (OPHS), Office of the Secretary (OS), to the Commissioner of Food and Drugs (the Commissioner), delegating all the authorities vested in the Secretary under section 601 of Effective Medication Guides of the Agriculture, Rural Development, Food and Drug Administration, and Related Agencies Appropriations Act of 1997, as amended hereafter. The delegation excludes the authority to issue reports to Congress.

EFFECTIVE DATE: June 19, 1997.

FOR FURTHER INFORMATION CONTACT: Loretta W. Davis, Division of Management Systems and Policy (HFA–340), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–4809.

SUPPLEMENTARY INFORMATION: On October 7, 1996, the Secretary of Health and Human Services delegated to the ASH, OPHS, with authority to redelegate as appropriate, the authorities vested in the Secretary under section 601 of Effective Medication Guides of the Agriculture, Rural Development, Food and Drug Administration, and Related Agencies Appropriations Act of 1997 (Pub. L. 104–180), as amended hereafter. In a memorandum dated January 27, 1997, the ASH delegated to the Commissioner all of the authorities delegated to the ASH under section 601 of Effective Medication Guides of the Agriculture, Rural Development, Food and Drug Administration, and Related Agencies Appropriations Act of 1997 (Pub. L. 104–180), as amended hereafter.

Further redelegation of the authority delegated may only be authorized with the Commissioner's approval. Authority delegated to a position by title may be exercised by a person officially designated to serve in such position in an acting capacity or on a temporary basis.

List of Subjects in 21 CFR Part 5

Authority delegations (Government agencies), Imports, Organization and functions (Government agencies).

Therefore, under the Federal Food, Drug, and Cosmetic Act and the Public Health Service Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 5 is amended as follows:

PART 5—DELEGATIONS OF AUTHORITY AND ORGANIZATION

1. The authority citation for 21 CFR part 5 continues to read as follows:

Authority: 5 U.S.C. 504, 552, App. 2; 7 U.S.C. 138a, 2271; 15 U.S.C. 638, 1261–1282, 3701–3711a; secs. 2–12 of the Fair Packaging and Labeling Act (15 U.S.C. 1451–1461); 21 U.S.C. 41–50, 61–63, 141–149, 467f, 679(b), 801–886, 1031–1309; secs. 201–903 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321–394); 35 U.S.C. 156; secs. 301, 302, 303, 307, 310, 311, 351, 352, 361, 362, 1701–1706, 2101 of the Public Health Service Act (42 U.S.C. 241, 242, 242a, 242l, 242n, 243, 262, 263, 264, 265, 300u–300u–5, 300aa–1); 42 U.S.C. 1395y, 3246b, 4332, 4831(a), 10007–10008; E.O. 11490, 11921, and 12591.

2. Section 5.10 is amended by adding a new paragraph (a)(39) to read as follows:

(a) * * *

(39) Functions vested in the Secretary under section 601 of Effective Medication Guides of the Agriculture, Rural Development, Food and Drug Administration, and Related Agencies Appropriations Act of 1997 (Pub. L. 104–180), as amended hereafter. The delegation excludes the authority to issue reports to Congress.

* * * * *

Dated: June 12, 1997.

Michael A. Friedman,

Lead Deputy Commissioner for the Food and Drug Administration.

[FR Doc. 97–16065 Filed 6–18–97; 8:45 am]
BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 880

[Docket No. 85N–0285]

Medical Devices; Reclassification of the Infant Radiant Warmer

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing a final rule to reclassify the infant radiant warmer from class III (premarket approval) into class II (special controls). The infant radiant warmer is a device intended to maintain the infant's body temperature by means of radiant heat. The special controls are the Association for the Advancement of Medical Instrumentation (AAMI) Voluntary Standard for the Infant Radiant Warmer, a prescription statement, and labeling. This reclassification is based on new information regarding the device contained in a reclassification petition submitted by the Health Industries Manufacturers Association (HIMA). This action is taken under the Medical Device Amendments of 1976 as amended by the Safe Medical Devices Act of 1990.

EFFECTIVE DATE: July 21, 1997.

FOR FURTHER INFORMATION CONTACT: Patricia M. Cricenti, Center for Devices and Radiological Health (HFZ–480), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–443–8913.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of August 24, 1979 (44 FR 49873), FDA published a proposed rule to classify the infant radiant warmer into class III. The preamble included the classification recommendation of the General Hospital and Personal Use Devices Panel (the Panel). The Panel's recommendation included a summary of the reasons why the device should be subject to premarket approval and identified certain risks to health presented by the device, including electric shock, possible eye damage due to long-term exposure to infrared radiation, patient

injury, hospital staff burns, insensible water loss, and hyperthermia or hypothermia. The Panel also recommended a high priority for initiating a proceeding to require premarket approval applications (PMA's) under section 515(b) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360e(b)).

In the **Federal Register** of October 21, 1980 (45 FR 69694), FDA published a final rule classifying the infant radiant warmer into class III (§ 880.5130 (21 CFR 880.5130)). The sole reason for classifying the device into class III was FDA's concern for possible long-term effects of infrared radiation on the skin and eyes of infants. FDA believed the other risks to health identified in the proposed rule could be addressed by labeling or by a standard.

In the **Federal Register** of September 6, 1983 (48 FR 40272), FDA published a notice of intent to initiate proceedings to require premarket approval of 13 preamendments class III devices, including the infant radiant warmer which was assigned a high priority by FDA for the application of premarket approval requirements.

In the **Federal Register** of January 15, 1986 (51 FR 1910), FDA published a proposed rule to require filing of a PMA or notice of completion of a product development protocol for the infant radiant warmer. In accordance with section 515(b) of the act and 21 CFR 860.132, FDA announced an opportunity for interested persons to request a change in classification of the device based on new information. FDA also identified the potential risks to health associated with the use of the device.

On January 30, 1986, HIMA submitted a petition to reclassify the infant radiant warmer from class III into class II. The petition was referred to the Panel for its recommendation on the requested change. After two Panel meetings (May 21, 1986, and May 11, 1994), the Panel unanimously recommended that the infant radiant warmer be reclassified from class III into class II, identifying the AAMI voluntary standard for infant radiant warmers as the special control. They further recommended labeling restricting the device to use only upon the order of a physician, only in health care facilities, and only by persons with specific training and experience in the use of the device. Accordingly, in the **Federal Register** on August 27, 1996 (61 FR 44013), FDA issued a proposed rule to reclassify the infant radiant warmer from class III to class II based on information in the form of publicly available, valid scientific evidence respecting the device. Interested persons were given until November 25, 1996, to comment on the proposed rule. During the comment period, FDA received one comment from a manufacturer who supported the proposed reclassification and stated that the previous risks to health associated with the use of the device have been addressed through improvements in technology, education, and medical practice.

I. FDA's Conclusion

FDA agrees with the recommendation of the Panel that the generic infant radiant warmer intended for maintaining an infant's body temperature by means of radiant heat should be classified into class II. The agency also concludes that sufficient ''new information'' in the form of publicly available, valid scientific evidence exists for establishing special controls to provide reasonable assurance of the safety and effectiveness of the device for its intended use. The agency further identifies the AAMI voluntary standard for infant radiant warmers and labeling identified above as the special controls. Moreover, the agency believes that because existing devices within this generic type have established a reasonable record of safe and effective use, the regulatory controls of class II will provide the necessary regulation to reasonably assure that current and future infant warmers are safe and effective. The agency's decision is based on the Panel's recommendation and a review of the data and information contained in the administrative records referenced in the August 27, 1996, proposed rule.

Therefore, under section 513(e) of the act (21 U.S.C. 360c(e)), FDA is issuing a final rule that revises § 880.5130(b), thereby reclassifying the generic type device, the infant radiant warmer, from class III into class II.

II. Environmental Impact

The agency has determined under 21 CFR 25.24(e)(2) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

III. Analysis of Impacts

FDA has examined the impacts of the final rule under Executive Order 12866 and the Regulatory Flexibility Act (5 U.S.C. 601–612). Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). The agency believes that this final rule is consistent with the regulatory philosophy and principles identified in the Executive Order. In addition, the final rule is not a significant regulatory action as defined by the Executive Order and so is not subject to review under the Executive Order.

The Regulatory Flexibility Act requires agencies to analyze regulatory options that would minimize any significant impact of a rule on small entities. Because the regulatory burden for all manufacturers of infant radiant warmers covered by this rule would be reduced, the agency certifies that this final rule will not have a significant economic impact on a substantial number of small entities. Therefore, under the Regulatory Flexibility Act, no further analysis is required.

IV. Paperwork Reduction Act of 1995

FDA concludes that the labeling requirements in this final rule are not subject to review by the Office of Management and Budget because they do not constitute a ''collection of information'' under the Paperwork Reduction Act of 1995 (Pub. L. 104–13). Rather, the labeling statements are ''public disclosure of information originally supplied by the Federal Government to the recipient for the purpose of disclosure to the public'' (5 CFR 1320.3(c)(2)).

List of Subjects in 21 CFR Part 880

Medical devices.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs and redelegated to the Director, Center for Devices and Radiological Health, 21 CFR part 880 is amended as follows:

PART 880—GENERAL HOSPITAL AND PERSONAL USE DEVICES

1. The authority citation for 21 CFR part 880 continues to read as follows:

Authority: Secs. 501, 510, 513, 515, 520, 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 351, 360, 360c, 360e, 360j, 371).

2. Section 880.5130 is revised to read as follows:

§ 880.5130 Infant radiant warmer.

(a) *Identification*. The infant radiant warmer is a device consisting of an infrared heating element intended to be placed over an infant to maintain the infant's body temperature by means of

radiant heat. The device may also contain a temperature monitoring sensor, a heat output control mechanism, and an alarm system (infant temperature, manual mode if present, and failure alarms) to alert operators of a temperature condition over or under the set temperature, manual mode time limits, and device component failure, respectively. The device may be placed over a pediatric hospital bed or it may be built into the bed as a complete unit.

(b) *Classification*. Class II (Special Controls):

(1) The Association for the Advancement of Medical Instrumentation (AAMI) Voluntary Standard for the Infant Radiant Warmer;

(2) A prescription statement in accordance with § 801.109 of this chapter (restricted to use by or upon the order of qualified practitioners as determined by the States); and

(3) Labeling for use only in health care facilities and only by persons with specific training and experience in the use of the device.

Dated: June 10, 1997.

Joseph A. Levitt,

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

[FR Doc. 97–16123 Filed 6–18–97; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF TRANSPORTATION

Federal Highway Administration

23 CFR Part 470

[Docket No. FHWA 97–2394]

RIN 2125–AD74

Federal-Aid Highway Systems

AGENCY: Federal Highway Administration (FHWA), DOT.

ACTION: Interim final rule; request for comments.

SUMMARY: The FHWA is amending its regulation on Federal-aid highway systems to incorporate changes made by the Intermodal Surface Transportation Efficiency Act of 1991 (ISTEA) and the National Highway System Designation Act of 1995. The ISTEA, among other things, added provisions defining the Federal-aid highway systems as the Interstate System and the National Highway System (NHS) which replaced the provisions defining the Federal-aid highway systems as the Interstate, Primary, Secondary, and Urban Systems. The purpose of this document is to reflect the statutory changes in defining the Federal-aid highway systems, reduce regulatory requirements and simplify recordkeeping requirements imposed on States, and consolidate (in appendices to the regulation) all nonregulatory guidance material issued previously by the FHWA on this subject.

DATES: This interim final rule is effective July 21, 1997. Comments must be received by August 18, 1997.

ADDRESSES: Submit written, signed comments to the docket number that appears in the heading of this document to the Docket Clerk, U.S. DOT Dockets, Room PL–401, 400 Seventh Street SW., Washington, DC 20590–0001. All comments received will be available for examination at the above address between 10 a.m. and 5 p.m., e.t., Monday through Friday, except Federal holidays. Those desiring notification of receipt of comments must include a self-addressed, stamped envelope or postcard.

FOR FURTHER INFORMATION CONTACT: Thomas R. Weeks, Intermodal and Statewide Programs Division (202) 366–5002, or Grace Reidy, Office of the Chief Counsel, HCC–32, (202) 366–6226, Federal Highway Administration, 400 Seventh Street SW., Washington, DC 20590. Office hours are from 7:45 a.m. to 4:15 p.m., e.t., Monday through Friday, except Federal holidays.

SUPPLEMENTARY INFORMATION: The FHWA is amending its regulation at 23 CFR Part 470, subpart A, on Federal-aid highway systems to: (1) Reflect recent statutory changes made by sections 1006, 1024, 1025, and 1105 of the ISTEA, Pub. L. 102–240, 105 Stat. 1914, and sections 101 and 332 of the NHS Act, Pub. L. 104–59, 109 Stat. 568; (2) reduce regulatory requirements and simplify recordkeeping requirements imposed on States; and (3) consolidate, in appendices to the regulation, all relevant nonregulatory guidance previously issued in the FHWA's policy memoranda and the ''Federal-Aid Policy Guide.'' The amended regulation, including its appendices, now combines all policies and guidance on the Federal-aid highway systems in a single document for easy reference.

For a number of years prior to the ISTEA, the Federal-aid highway systems consisted of four components—the Primary System (which also included the Interstate System), the Urban System, and the Secondary System. These four highway systems established basic eligibility of qualifying roads and streets for construction or improvement with certain categories of Federal-aid highway funds, i.e., the Interstate, Primary, Secondary, and Urban System apportionments. The ISTEA restructured the Federal-aid highway systems by rescinding the Federal-aid Primary, Secondary, and Urban Systems and requiring the establishment of a new NHS. Certain components of the NHS were specified by statute, including the Interstate System and 21 high priority corridors. The ISTEA also required a functional reclassification of all public roads and streets to determine eligibility for inclusion on the NHS and eligibility for funding under the Surface Transportation Program. Pending enactment of legislation approving the NHS, the ISTEA established an interim NHS that was eligible for funding under the NHS program and consisted of all rural and urban routes which were functionally classified as principal arterials.

During December 1993, a proposed NHS was submitted by the Department of Transportation (DOT) to Congress for approval, and the NHS was subsequently designated by the NHS Act. The NHS Act, within 180 days of enactment, required the Secretary of Transportation (Secretary) to submit to Congress for approval proposed additions to the NHS, consisting of connections to major intermodal terminal facilities. The NHS Act also authorized the Secretary to approve modifications to the NHS, including, once the initial designations were enacted by law, the connections to intermodal terminals. Finally, the NHS Act designated eight additional high priority corridors on the NHS and designated all, or part of, four high priority corridors as future Interstate routes.

The proposed NHS connections to major intermodal terminals were submitted to Congress in May 1996. To date, Congress has not enacted legislation regarding these additional routes.

The FHWA issued interim guidance in February 1996 establishing procedures for use by the States in proposing modifications to the NHS. Guidance for use by the States in proposing modifications to the Interstate System under 23 U.S.C. 139 was issued in 1986. Guidance for use by the States in proposing additions to the Interstate System under Section 332 of the NHS Act was issued in February 1996. Guidance for signing and numbering routes identified as future parts of the Interstate System was issued in August 1996 and later modified in December 1996. All guidance material contained in the documents noted above is incorporated in the regulation at 23 CFR part 470 as nonregulatory appendices. The documents were initially issued as FHWA Headquarters memoranda that