

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.

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**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