Issued in Washington, D.C. on August 19, 1996, by the Commission.

Jean A. Webb,

Secretary of the Commission.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 730

[Docket No. 96N–0174]

RIN 0910–AA69

Food and Cosmetic Labeling; Revocation of Certain Regulations; Opportunity for Public Comment; Extension of the Comment Period

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule; extension of comment period.

SUMMARY: The Food and Drug Administration (FDA) is extending to October 10, 1996, the comment period on the proposal to revoke certain cosmetic regulations that appear to be obsolete. The proposed rule was published in the Federal Register of June 12, 1996 (61 FR 29708). The agency is taking this action in response to a request from a trade association. This extension of the comment period is intended to allow interested persons additional time to submit comments to FDA on the proposed revocation of certain cosmetic regulations.

DATES: Written comments by October 10, 1996.

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

FOR FURTHER INFORMATION CONTACT: Corinne L. Howley, Center for Food Safety and Applied Nutrition (HFS–24), 200 C St. SW., Washington, DC 20204, 202–205–4272.

SUPPLEMENTARY INFORMATION: In the Federal Register of June 12, 1996 (61 FR 29708), FDA issued a proposed rule to revoke certain regulations that appear to be obsolete. These regulations were identified by FDA as candidates for revocation following a page-by-page review of its regulations that the agency conducted in response to the Administration's ''Reinventing Government'' initiative. Interested person were given until August 26, 1996, to comment on the proposed rule.

FDA received a request from a trade association for an extension of the comment period on the agency's June 12, 1996, proposed revocation of part 730 of FDA's regulations (21 CFR part 730), on voluntary reporting of cosmetic product experiences. The trade association requested more time so that the proposed action could be considered by the association's board of directors. After careful consideration, FDA has decided to extend the comment period to October 10, 1996, to allow additional time for the submission of comments on whether it should revoke part 730. The extension is only for comments on this aspect of the proposed rulemaking.

Interested persons may, on or before October 10, 1996, submit to Dockets Management Branch (address above) written comments regarding whether part 730 should be revoked. 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.

Dated: August 21, 1996.

William B. Schultz,

Deputy Commissioner for Policy.

[FR Doc. 96–21818 Filed 8–26–96; 8:45 am]

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21 CFR Part 880

[Docket No. 85N–0285]

Medical Devices; Reclassification of the Infant Radiant Warmer

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is proposing to reclassify the infant radiant warmer from class III (premarket approval) into class II (special controls) based on new information regarding the device. The infant radiant warmer is a device consisting of an infrared heating element intended to maintain the infant's body temperature by means of radiant heat. This document summarizes the basis for the agency's findings that sufficient valid scientific evidence is available to support reclassification of the infant radiant warmer and to establish special controls to provide reasonable assurance of the safety and effectiveness of the device. This action implements the Medical Device Amendments of 1976 (the amendments) as amended by the Safe Medical Devices Act of 1990 (the SMDA).

DATES: Written comments by November 25, 1996. FDA proposes that any final rule based on this proposal become final 30 days after publication in the Federal Register.

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

FOR FURTHER INFORMATION CONTACT: Janet L. Scudiero, Center for Devices and Radiological Health (HFZ–410), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–594–1287.

SUPPLEMENTARY INFORMATION:

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I. Classification and Reclassification of Devices Under the Medical Device Amendments of 1976

Under section 513 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360c), as established by the amendments (Pub. L. 94–295) and amended by the SMDA (Pub. L. 101–629), FDA must classify devices into one of three regulatory classes: Class I, class II, or class III. FDA's classification of a device is determined by the amount of regulation necessary to provide reasonable assurance of safety and effectiveness of a device. Except as provided in section 520(c) of the act (21 U.S.C. 360j(c)), FDA may not use confidential information concerning a device's safety and effectiveness as a basis for reclassification of the device from class III into class II or class I.

Under the original 1976 act, devices were to be classified into class I (general controls) if there was information showing that the general controls of the act were sufficient to assure safety and effectiveness; into class II (performance