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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:

Table of Contents

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

standards) if there was insufficient information showing that general controls themselves would ensure safety and effectiveness, but there was sufficient information to establish a performance standard that would provide such assurance; and into class III (premarket approval) if there was insufficient information to support classifying a device into class I or class II and the device was a life-sustaining or life-supporting device or was for a use that is of substantial importance in preventing impairment of human health.

Most generic types of devices that were on the market before the date of the original 1976 amendments (May 28, 1976) (generally referred to as preamendments devices) have been classified by FDA under the procedures set forth in section 513(c) and (d) of the act through the issuance of classification regulations into one of these three regulatory classes. Under sections 513(c) and (d) of the act, FDA secures expert panel recommendations on the appropriate device classifications for generic types of devices. FDA then considers the panel's recommendations and, through notice and comment rulemaking, issues classification regulations.

For those devices introduced into interstate commerce for the first time after May 28, 1976, the device is classified through the premarket notification process under section 510(k) of the act (21 U.S.C. 360(k)). Those devices that FDA finds to be substantially equivalent to a classified preamendments generic type of device are thereby classified in the same class as the predicate preamendments device.

Reclassification of classified preamendments devices is governed by section 513(e) of the act. This section provides that FDA may, by rulemaking, reclassify a device (in a proceeding that parallels the initial classification proceeding) based on ''new information.'' The reclassification can be initiated by FDA or by the petition of an interested person.

The term ''new information,'' as used in section 513(e) of the act, includes information developed as a result of a reevaluation of the data before the agency when a device was originally classified, as well as information not presented, not available, or not developed at that time. (See, e.g., *Holland Rantos* v. *United States Department of Health, Education, and Welfare*, 587 F.2d 1173, 1174 n.1 (D.C. Cir. 1978); *Upjohn* v. *Finch*, 422 F.2d 944 (6th Cir. 1970); *Bell* v. *Goddard*, 366 F.2d 177 (7th Cir. 1966).)

Reevaluation of the data previously before the agency is an appropriate basis for subsequent regulatory action where the reevaluation is made in light of changes in ''medical science.'' (See *Upjohn* v. *Finch*, *supra*, 422 F.2d at 951.) However, regardless of whether data before the agency are past or new data, the ''new information'' on which any reclassification is based is required to consist of ''valid scientific evidence,'' as defined in section 513(a)(3) of the act and 21 CFR 860.7(c)(2). FDA relies upon ''valid scientific evidence'' in the classification process to determine the level of regulation for devices. For the purpose of reclassification, the valid scientific evidence upon which the agency relies must be publicly available. Publicly available information excludes trade secret and/or confidential commercial information, e.g., the contents of premarket approval applications (PMA's). (See section 520(c) of the act, (21 U.S.C. 360j(c).)

II. Reclassification Under the Safe Medical Devices Act of 1990

The SMDA further amended the act to change the definition of a class II device. Under the SMDA, class II devices are those devices for which there is insufficient information to show that general controls themselves will ensure safety and effectiveness, but there is sufficient information to establish special controls to provide such assurance, including the issuance of a performance standard, postmarket surveillance, patient registries, development and dissemination of guidelines, and other appropriate actions necessary to provide reasonable assurance of the safety and effectiveness of the device. Thus, the definition of a class II device was changed from ''performance standards'' to ''special controls.''

III. History of the Proceedings

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 electrical 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 that a high priority for the application of section 515(b) of the act (21 U.S.C. 360e)(premarket approval requirement) be assigned to the infant radiant warmer.

In the Federal Register of October 21, 1980 (45 FR 69694), FDA published a final rule classifying the infant radiant warmer into class III (21 CFR 880.5130). Concern for possible long-term effects of infrared radiation on the skin and eyes of infants was the sole reason for classifying the device into class III. FDA believed that 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 assigned a high priority by FDA for the application of premarket approval requirements. Among other things, the notice described the factors FDA considered in establishing priorities for initiating proceedings under section 515(b) of the act for issuing final rules requiring preamendments class III devices to have approved PMA's or product development protocols (PDP's) which have been declared completed. Using these factors, FDA concurred with the panel's recommendation that the infant radiant warmer should be subject to a high priority for initiating a proceeding to require premarket approval.

In the Federal Register of January 15, 1986 (51 FR 1910), FDA published a proposed rule to require filing of a PMA or a notice of completion of a PDP for the infant radiant warmer. In accordance with section 515(b) of the act and 21 CFR 860.132, FDA also announced an opportunity for interested persons to request a change in classification of the device based on new information. FDA identified the following potential risks to health associated with the use of infant radiant warmers: Insensible water loss, special risk group infants with very low birth weight, hypothermia and hyperthermia, damage to the eyes and skin, increased oxygen consumption, operator error, and other safety risks common to many devices (e.g., electric shock, inadequate stability, and burns to the user).

On January 30, 1986, the Health Industries Manufacturers Association submitted a petition (Ref. 1) to reclassify the infant radiant warmer from class III into class II. The petition was submitted under section 513(e) of the act. Consistent with the act and the regulations, FDA referred the petition to the panel for its recommendation on the requested change in classification.

On May 21, 1986, during a meeting by teleconference, the panel unanimously recommended that the infant radiant warmer be reclassified from class III into class II and that any change in classification not take effect until the effective date of a performance standard for the generic type of device established under section 514 of the act (21 U.S.C. 360d) (Ref. 2 at p. 75).

In the Federal Register of May 27, 1987 (52 FR 19735), FDA published a notice of intent to initiate a proceeding to reclassify the infant radiant warmer from class III into class II. Subsequent to that notice, FDA determined that the deliberations of the 1986 panel were incomplete and that another panel meeting was necessary to allow the panel to address specific recommendations and issues concerning the reclassification of the infant radiant warmer (Ref. 2 at pp. 54 and 65). This additional panel meeting was held on May 11, 1994. A summary of the panel's recommendation is set forth below.

IV. Device Description

FDA is proposing the following device description based on the panel's recommendation and the agency's review.

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.

V. Recommendation of the Panel

In the public meeting held on May 11, 1994, the panel unanimously affirmed its previous recommendation that the infant radiant warmer should be reclassified from class III into class II (Ref. 3), and that the appropriate special control is a voluntary standard. The panel identified the Association for the Advancement of Medical Instrumentation (AAMI) voluntary standard for infant radiant warmers as the special control for the infant radiant warmer (Ref. 4).

The panel further recommended the following restrictions on the use of the device: A prescription statement in the labeling of the device that restricts 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.

VI. Summary of the Reasons for the Recommendation

The panel gave the following reasons in support of its recommendation to reclassify the infant radiant warmer from class III into class II:

1. General controls by themselves are insufficient to provide reasonable assurances of the safety and effectiveness of the device.
2. There is sufficient publicly available information to establish special controls to provide reasonable assurance of the safety and effectiveness of the device for its intended use.
3. An existing voluntary standard (Ref. 4) is the special control recommended by the panel.
4. There is sufficient publicly available information to demonstrate that the device is not potentially hazardous to the life, health, or well-being of the infant. The panel identified no new risks to health associated with the use of the device and determined that some of the previously identified potential risks to health are no longer risks or are no longer serious risks (Ref. 3 at p. 225). Thus, the probable benefits to health of the device outweigh any probable risks to health.

The panel believes that the current and any subsequent manufacturers of the infant radiant warmer can comply with this voluntary standard, that FDA can ensure the safety and effectiveness of the device made by new manufacturers through the premarket notification procedures under section 510(k) of the act, and that a regulatory level of class III is unnecessary.

VII. Risks to Health

When the infant radiant warmer was proposed for classification into class III in 1979, the panel identified certain risks to health that they believed the device presented. The risks to health were identified as electrical shock, possible eye damage, patient injury, hospital staff burns, insensible water loss, and hyperthermia or hypothermia (44 FR 49873 at 49874). When the device was classified into class III in 1980, FDA identified concern for possible delayed long-term effects of infrared radiation on the skin and eyes of infants as the only risk to health presented by the device. FDA also determined that the other risks to health identified in the proposed rule could be addressed by labeling or by a standard (45 FR 69694). Subsequently, in 1986, the agency identified increased oxygen consumption as another potential risk to health associated with the use of the device (51 FR 1910).

Based on the review of the new data and information contained in the petition and the panel members' personal knowledge of and experience with the device, the panel on May 11, 1994, agreed that all the potential risks to health (insensible water loss; special risk group, very low birth weight infants; hyperthermia and hypothermia; possible eye and skin damage; and increased oxygen consumption) associated with the use of the infant radiant warmer could be controlled by special controls (Ref. 3). The panel also believed that the general risks to health (operator error, electric shock, inadequate device stability, and burns to operators) could also be addressed by special controls.

On the basis of its review and the panel's recommendation, FDA now believes that the use of the infant radiant warmer for maintaining an infant's body temperature does not present a potential unreasonable risk of illness and injury, and that special controls would provide reasonable assurance of the safety and effectiveness of the device. In addition to the AAMI standard, FDA has also incorporated the panel's labeling recommendation as special controls for this device.

VIII. Summary of the Data Upon Which the Proposed Recommendation is Based

A. Insensible Water Loss

An increased rate of insensible water loss is the principle, well-documented risk to health associated with the use of infant radiant warmers (Refs. 5 and 6). Insensible water loss is the continuous and usually imperceptible loss of water, mainly from the skin, that occurs to some extent in all newborn infants. It is a well recognized condition of prematurity, its severity being inversely related to birth weight (Ref. 7). Other factors that contribute to insensible water loss in neonates include: Illness; environmental temperature and humidity; and other therapies, especially phototherapy and respiratory support (Ref. 5). Insensible water loss is also associated with the use of incubators (Refs. 5 through 7).

Bell (Ref. 6) evaluated four studies (Refs. 8 through 11), which reported increased rates of insensible water loss of 40 to 190 percent during the use of radiant warmers compared to the use of incubators. He determined that the variations in the increased rates of insensible water loss are related to the experimental conditions of the investigations (mainly the different

weighing methods used in the studies). Bell concluded that insensible water loss in infants under infant radiant warmers without phototherapy is 40 to 100 percent higher than in infants in incubators.

Increased insensible water loss places an infant at a risk of dehydration and electrolyte imbalance and potentially interferes with the infant's thermoregulation. Because both underestimation and overestimation of fluid and electrolyte requirements can have serious consequences to infants, especially to low birth weight infants, guidance for parenteral fluid and electrolyte administration was needed. Since the infant radiant warmer was classified in 1980, several guidances which include recommendations for parenteral fluid and electrolyte administration have been developed for premature and term infants (Refs. 6, 12, and 13).

The use of plastic heat shielding with infant radiant warmers has been reported to reduce insensible water loss (Refs. 14 through 17). However, this practice is not without risks, including both underheating and overheating of infants (Refs. 2 and 18). The panel agreed that the use of heat shielding should be at the discretion of the informed physician (Ref. 2).

Although an increased rate of insensible water loss is a risk to health in the use of the infant radiant warmer, it can be managed by careful monitoring of the infant and administration of parenteral or oral electrolyte therapy when necessary. The new parenteral fluid and electrolyte therapy guidances minimize this risk to health and support the use of infant radiant warmers in the management of critically ill infants to whom continual access by health professionals is essential.

The panel believed that this risk to health is a well-understood risk associated with the use of the infant radiant warmer and that it is related to both the prematurity of the infant and the open bed design of the device (Ref. 3). The panel agreed that this risk to health is clinically manageable and that it could be controlled by special controls.

B. Special Risk Group—Very Low Birth Weight Infants

To survive, very low birth weight infants, weighing 1,500 grams or less, require aggressive diagnostic and therapeutic procedures, such as emergency resuscitation, tracheal intubation, placement of catheters and needles, and blood sampling (Ref. 1). The use of infant radiant warmers has allowed essential access to the infants for the performance of these necessary procedures while providing effective warming. This is particularly important immediately after birth, during the first days of life, and for the care of critically ill premature infants.

Very low birth weight infants are especially susceptible to increased rates of insensible water loss because of their larger surface area to mass ratio, higher body water content, and the thinner epidermal barrier of their skin (Refs. 2 (at pp. 56 and 57), 5, and 13). The advances in parenteral fluid and electrolyte therapy since 1980 provide specific guidance to minimize this risk for very low birth weight infants (Refs. 6, 12, and 13).

The panel believed that this potential risk to health is not a risk related to the device, but that it is related to the prematurity of the infants (Ref. 3). The panel stated that the use of the infant radiant warmer has made the care of these infants more manageable, and the panel commented that now even smaller premature infants than in 1986 are successfully treated in infant radiant warmers. The panel believed that this risk can be controlled through special controls.

C. Damage to the Eyes

Infant radiant warmers operate by directing invisible infrared radiation (IR) from an overhead heater to the infant's body. The magnitude and spectral characteristics of the IR are controlled by the design of the device and are important in assessing the potential risk of exposure to IR.

During its classification deliberations in 1979, the panel considered infant radiant warmer performance data developed for FDA under a contract (Ref. 19). However, that data did not sufficiently address the panel's concern about the possibility of adverse effects on the eyes of infants resulting from long-term exposure to IR. The petition reported new performance data on five radiant warmers (Ref. 1). The new data provided measurements for individual wavelength regions of the electromagnetic spectrum, including the ultraviolet (200 to 400 nanometers (nm)), visible (400 to 760 nm), and IR–A (760 to 1,400 nm) wavelength regions, and for the 1,400 to 4,500 nm wavelength region which includes the IR–B (1,400 to 3,000 nm) wavelength region and the 3,000 to 4,500 nm portion of the IR–C wavelength region (the IR–C wavelength region extends from 3,000 to 100,000 nm). The petition also reported total irradiance, including irradiance for wavelengths extending beyond 4500 nm obtained by another measurement method. The IR–A wavelength region is associated with the potential for damage to the lens and retina of the eye. The IR–B and IR–C wavelength regions are associated with the potential for thermal damage to the cornea of the eye.

All the infant radiant warmers emitted IR primarily in the IR–B and IR–C wavelength regions (Ref. 1). No ultraviolet radiation and negligible visible radiation (nondetectable to 0.026 milliwatt per square centimeter (mW/cm^2)) was detected. The range of maximum IR–A irradiance was 0.103 to 3.463 mW/cm^2, and the range of maximum total irradiance was 39.2 to 60.3 mW/cm^2. These maximum irradiances were obtained at full power and at high line voltage (130 volts). At lower heater power levels, proportionately more of the IR is from the IR–C wavelength region.

In clinical use, however, infant radiant warmers are rarely operated at full power and at high line voltage (Ref. 1). The total irradiances necessary to maintain the desired infant skin temperature typically range from 12 to 25 mW/cm^2, and typical IR–A irradiances are less than 1.0 mW/cm^2. Engel et al. reported mean total irradiances of less than 10 mW/cm^2 and 17.1 mW/cm^2 for the warming of two groups of critically ill premature infants (Refs. 20 and 21); in general, the smaller infants required higher irradiances. In addition, the necessarily more frequent handling of critically ill neonates, which may be as often as once every 10 minutes, may interrupt delivery of a portion of the radiant heat to the infant and thus increase the amount of radiant power required for heating (Ref. 2).

The petition also summarized published information that was not reviewed by the classification panel when the infant radiant warmer was classified. Both Sliney and Freasier (Ref. 22) and Sliney and Wolbarsht (Ref. 23) reported that a safe chronic ocular exposure level to IR–A was 10 mW/cm^2. The petition reported that the maximum amount of IR–A of the tested infant radiant warmers ranged from 0.24 to 3.5 mW/cm^2, and that in actual use, infant radiant warmers emit typically less than 1 mW/cm^2 of IR–A (Ref. 1). Thus, the potentials for chronic injury to the lens and the retina are low because infant radiant warmers emit significantly less IR–A radiation than the level of IR–A radiation believed to be associated with injuries of the lens and retina.

The cornea and aqueous humor absorb almost all of the IR from 1,400 to 1,900 nm; the cornea absorbs all the IR above 1,900 nm (Ref. 23). Thus, most IR emitted by infant radiant warmers is absorbed by the anterior structures of

the eye and is not transmitted to the lens and retina. Sliney and Freasier (Ref. 22) and Sliney and Wolbarsht (Ref. 23) also reported that the irradiance of 100 mW/cm² was ''well below'' the threshold irradiance level to prevent corneal injury. Thus, the potentials for injury to the cornea and aqueous humor from exposure to IR emitted by infant radiant warmers are low because the maximum irradiances of infant radiant warmers range from 36.8 to 60.3 mW/cm² and their typical total use irradiances range from 12 to 25 mW/cm² (Ref. 1). For both the total irradiance and the IR–A irradiance, the margins for safety are significant.

To put this irradiance information in perspective, it should be noted that premature infants' eyes are rarely opened and that blinking of the eyes when opened keeps the corneal epithelium from drying out (Ref. 24). Thus, there is a low probability that a significant amount of IR actually enters the eyes of premature infants.

There are two studies on the effects of IR on the eyes of neonates. Johns et al. detected no adverse eye effects in infants warmed under radiant warmers after followup times of up to 45 days (Ref. 25). This study now has increased significance since Pitts and Cullen reported that corneal damage heals rapidly (usually within 24 hours) and that lens opacities formed within 24 hours after exposure heal earlier than expected (usually within 1 month) (Ref. 26). Thus, any corneal or lens effects, if present, would have been detected by Johns et al.

In 1993, Baumgart et al. (Ref. 27) reported a retrospective study of critically ill premature infants treated under radiant warmers and incubators with longer followup times of 30 days to 6 years. The mean followup time for the radiant warmer group was 29 months, and the mean IR irradiance of the infant radiant warmer group was less than 30 mW/cm². They found no long-term or short-term corneal or lens effects in either group. The incidence of retinopathy of prematurity was higher in the radiant warmer group, but this higher incidence was attributed to prematurity and to the hospital's policy of placing the more critically ill premature infants receiving oxygen in infant radiant warmers rather than in incubators. It is noted that the incidence of retinopathy of prematurity is associated with prolonged oxygen therapy (Ref. 28).

There are few recommended IR exposure levels specifically intended for infants under infant radiant warmers. The Emergency Care Research Institute proposed that 0.3 W/cm² (300 mW/cm²) was a reasonable total irradiance limit for an infant under an infant radiant warmer in 1973 and 1984 (Refs. 24 and 18, respectively) and that the near IR range between 700 to 1,200 nm should be limited to 40 mW/cm². The 1994 International Electrotechnical Commission standard for infant radiant warmers has irradiance limits of 100 mW/cm² for total IR irradiance and 10 mW/cm² for IR–A (Ref. 29). The 1995 AAMI voluntary standard special control has irradiance limits of 60 mW/cm² for total IR irradiance and 10 mW/cm² for IR–A (Ref. 4). The maximum irradiances of currently marketed infant radiant warmers meet the AAMI voluntary standard special control irradiance limits (Ref. 3).

This new information concerning the IR irradiance characteristics of infant radiant warmers and the irradiance levels associated with acute and chronic injuries to the eyes have addressed the safety concerns previously held about the unknown potential for IR-induced long-term effects to the eyes of infants under infant radiant warmers. The panel stated that in over 20 years of clinical use, there are no reports in the literature of any adverse long-term effects to the eyes of infants attributed to the IR radiation emitted by infant radiant warmers (Ref. 3). They further commented that long-term developmental health assessments of infants cared for in infant radiant warmers do not mention any delayed eye conditions (Ref. 3, pp. 190 and 191). The panel agreed that the potential risk to health of long-term damage from overexposure of the eyes to total IR and IR–A could be controlled by special controls.

D. Damage to the Skin

The IR emitted by infant radiant warmers is designed to be below the threshold for thermal injury to the infant's skin (Ref. 24). The IR is not of sufficient energy to cause photochemical reactions in the skin. Most of the IR–A irradiance is reflected from the skin while IR–B and IR–C irradiance are absorbed by the outer 1 millimeter of the skin to accomplish the desired warming effect.

The panel commented that there are no published reports of skin damage in infants attributed to the use of radiant warmers and that long-term developmental health assessments of infants cared for in infant radiant warmers do not mention skin conditions (Ref. 3). The panel believed that the potential risk of overexposure of the skin to IR could be controlled by special controls.

E. Increased Oxygen Consumption

Bell reviewed five studies (Ref. 6) that reported conflicting results of statistically significant increased oxygen consumption rates (Refs. 30 and 31) and unchanged oxygen or slightly increased consumption rates (Refs. 11, 28, 32, and 33) in infants warmed under radiant warmers compared to infants warmed in incubators. Because increased oxygen consumption may be an indicator of a stress-related increase in metabolism, these reports caused concern that the use of infant radiant warmers stress the metabolism of infants.

Bell evaluated these studies taking into account differences in the various study parameters used, including differences in the servocontrol skin temperatures and the humidity in the neonatal nurseries (Ref. 6). He determined that only a small increase in oxygen consumption (4 kilocalories per kilogram per 24 hours additional energy expenditure) occurs in the infants under infant radiant warmers compared to infants in incubators. Bell agreed with Wheldon and Rutter (Ref. 31) that the net total heat loss of infants under radiant warmers to the environment due to evaporation, convection, radiation, and conduction does not exceed that of infants in incubators. He concluded that the increased oxygen consumption of infants in infant radiant warmers is of unknown clinical significance. Subsequently, Marks et al. reported that premature infants under infant radiant warmers experienced no short-term metabolic complications or adverse effects on growth even though they had a 10 percent higher oxygen consumption compared to infants in incubators (Ref. 34).

The panel acknowledged that although oxygen consumption may be greater in infants cared for in infant radiant warmers than in incubators, the clinical significance of this, if any, is unknown (Ref. 3). They noted that other factors unrelated to the device can also cause increased oxygen consumption. The panel agreed this potential risk could be controlled by special controls.

F. Hypothermia and Hyperthermia

The risks to health of hypothermia and hyperthermia are low during proper use of the device (Ref. 1). Infant radiant warmers are used to treat and to prevent hypothermia. Both hypothermia and hyperthermia can result from malfunctioning alarms and radiant heater components, and hyperthermia can result from detachment of the skin temperature probe from the infant. The device's temperature and failure alarm system is designed to prevent

hypothermia and hyperthermia by alerting operators of unsafe temperature conditions, skin temperature probe detachment from the skin, probe failure and device failure. The petition (Ref. 1), current device labeling (Ref. 3), the AAMI voluntary standard special control (Ref. 4), and accepted medical practice (Refs. 1 and 3) all recommend frequent monitoring of infants under infant radiant warmers. They also recommend that infant radiant warmers should be operated in the skin temperature servocontrol mode rather than the manual mode to further reduce the risks of both hypothermia and hyperthermia (Refs. 1 and 4). The panel agreed that this risk to health could be controlled by special controls.

G. Other Risks

Four other potential risks associated with the use of infant radiant warmers are electrical shock due to improper design or construction of the device, injury due to instability of the device, burns to the operator if the device is constructed of materials that absorb radiant heat, and operator error. Operator error can be minimized by appropriate training and comprehensive device labeling. The panel agreed that these are well-known risks that are generic to many neonatal devices and that they can be controlled by special controls (Ref. 3).

H. Benefits of the Device

The infant radiant warmer has the unique benefit of providing greater accessibility to the infant than do incubators during routine nursing and intensive care procedures without interrupting the delivery of heat. Infant radiant warmers can also heat an infant faster than an incubator. Ahlgren reported that only 5 to 10 minutes are required to warm the infant's skin to the preset skin temperature with the infant radiant warmer as compared to 45 to 50 minutes for the incubator (Ref. 35). Infant radiant warmers are recommended for the care of newborn infants who lose large amounts of heat through evaporation of amniotic fluid from their skin in the delivery room (Ref. 27). It is estimated that 80 percent of all infants are placed under infant radiant warmers at some time during their hospital stay (Ref. 1). Many practitioners consider infant radiant warmers to be the only way of warming some very low birth weight and critically ill infants (Refs. 3 and 6).

The panel believes, based on publicly available, valid scientific evidence, that the infant radiant warmer can be regulated as a class II device (general and special controls) to reasonably assure the device's safety and effectiveness (Ref. 3).

IX. FDA's Tentative Findings

FDA tentatively concurs with the recommendation of the panel that infant radiant warmers should be reclassified into class II. The agency believes that ''new information'' in the form of publicly available, valid scientific evidence exists to establish special controls to provide reasonable assurance of safety and effectiveness of the infant radiant warmer for its intended use. The agency further identifies the AAMI voluntary standard and labeling as the special controls. Moreover, existing devices, within the generic type, have established a reasonable record of safe and effective use. Consistent with the purpose of the act, class II controls as defined by section 513(a)(1)(B) of the SMDA would provide the least amount of regulation necessary to reasonably assure that current and future infant warmers are safe and effective.

X. 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.

XI. Analysis of Impacts

FDA has examined the impacts of the proposed rule under Executive Order 12866 and the Regulatory Flexibility Act (Pub. L. 96–354). 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 proposed rule is consistent with the regulatory philosophy and principles identified in the Executive Order. In addition, the proposed 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 of the potential costs to comply with the provisions of premarket approval (class III) by each manufacturer, the agency believes that the economic impact to comply with special controls (class II) would likely be less. Therefore, the agency certifies that the proposed 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.

XII. Paperwork Reduction Act of 1995

FDA tentatively concludes that the labeling requirements in this proposed 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 proposed 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)).

XIII. Request for Comments

Interested persons may, on or before November 25, 1996, submit to the Dockets Management Branch (address above) 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 name of the device and 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.

XIV. 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. Health Industry Manufacturers Association Petition with incorporated errata, volumes 1 to 5, Washington, DC, 1986 (submitted January 30, 1986; revised April 15, 1986).

2. Transcript, General Hospital and Personal Use Devices Panel (telephone conference call), May 21, 1986.

3. Transcript, General Hospital and Personal Use Devices Panel with the attached general device classification questionnaire and supplemental data sheet, May 11, 1994.

4. Association for the Advancement of Medical Instrumentation, Infant Radiant Warmers (draft standard), May 1995.

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8. Williams, P. R., and W. Oh, ''Effects of Radiant Warmers on Insensible Water Loss in Newborn Infants,'' *American Journal of Diseases in Childhood*, 128:511–514, 1974 (included in Ref. 1).

9. Wu, P. Y. K., and J. E. Hodgemen, ''Insensible Water Loss in Preterm Infants. Changes with Postnatal Development and Non-Ionizing Radiant Energy,'' *Pediatrics*, 54:704–711, 1974 (included in Ref. 1).

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14. Marks, K. H., Z. Freidman, and M. B. Maisels, ''A Simple Device for Reducing Insensible Water Loss in Low-Birth Weight Infants,'' *Pediatrics*, 60:223–226, 1980 (included in Ref. 1).

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16. Baumgart, S., W. W. Fox, and R. A. Polin, ''Physiologic Implications of Two Heat Shields for Infants under Infant Radiant Warmers,'' *Journal of Pediatrics*, 100:787–790, 1982 (included in Ref. 1).

17. Fitch, C. W., and S. B. Korones, ''Heat Shield Reduces Water Loss,'' *Archives Disease in Childhood*, 59:886–888, 1984 (included in Ref. 1).

18. Emergency Care Research Institute, ''Evaluation: Infant Warmers,'' *Health Devices*, 13:119–145, 1984.

19. Emergency Care Research Institute, ''The Development of a Standard for Infant Warmers and Incubators,'' final report, FDA Contract No. 223–75–5012, Plymouth Meeting, PA, 1976.

20. Engel, W. D., S. Baumgart, W. W. Fox, and R. A. Polin, ''Effect of Increased Radiant Power Output on State of Hydration in the Critically Ill Neonate,'' *Critical Care Medicine*, 10:673–676, 1982 (included in Ref. 1).

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29. International Electrotechnical Commission, ''Medical Electrical Equipment, Part 2: Particular requirements for the safety of infant radiant warmers'', 1994.

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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, it is proposed that 21 CFR part 880 be 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) Association for the Advancement of Medical Instrumentation (AAMI) Voluntary Standard for Infant Radiant Warmers; (2) prescription statement in accordance with 21 CFR 801.109 (restricted to use by or upon the order of qualified practitioners as determined by the States); (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: August 1, 1996.

D. B. Burlington,

Director, Center for Devices and Radiological Health.

[FR Doc. 96–21846 Filed 8–26–96; 8:45 am]

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DEPARTMENT OF THE INTERIOR

Bureau of Indian Affairs

25 CFR Part 215

RIN 1076–AD35

Lead and Zinc Mining Operations and Leases on Quapaw Indian Lands

AGENCY: Bureau of Indian Affairs, Interior.

ACTION: Proposed rule.

SUMMARY: We are proposing to revise our regulations for lead and zinc mining. The purpose is to update the