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TITLE 21--FOOD AND DRUGS

CHAPTER I--FOOD AND DRUG ADMINISTRATION, DEPARTMENT OF HEALTH AND HUMAN SERVICES (CONTINUED)

PART 1040 PERFORMANCE STANDARDS FOR LIGHT-EMITTING PRODUCTS

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Sec. 1040.20 **Sunlamp** products and ultraviolet lamps intended for use in **sunlamp** products.

(a) Applicability. (1) The provisions of this section, as amended, are applicable as specified herein to the following products manufactured on or after September 8, 1986.

(i) Any **sunlamp** product.

(ii) Any ultraviolet lamp intended for use in any **sunlamp** product.

(2) **Sunlamp** products and ultraviolet lamps manufactured on or after May 7, 1980, but before September 8, 1986, are subject to the provisions of this section as published in the Federal Register of November 9, 1979 (44 FR 65357).

(b) Definitions. As used in this section the following definitions apply:

(1) Exposure position means any position, distance, orientation, or location relative to the radiating surfaces of the **sunlamp** product at which the user is intended to be exposed to ultraviolet radiation from the product, as recommended by the manufacturer.

(2) Intended means the same as "intended uses" in Sec. 801.4.

(3) Irradiance means the radiant power incident on a surface at a specified location and orientation relative to the radiating surface divided by the area of the surface, as the area becomes vanishingly small, expressed in units of watts per square centimeter (W/cm²).

(4) Maximum exposure time means the greatest continuous exposure time interval recommended by the manufacturer of the product.

(5) Maximum timer interval means the greatest time interval setting on the timer of a product.

(6) Protective eyewear means any device designed to be worn by users of a product to reduce exposure of the eyes to radiation emitted by the product.

(7) Spectral irradiance means the irradiance resulting from radiation within a wavelength range divided by the wavelength range as

the range becomes vanishingly small, expressed in units of watts per square centimeter per nanometer ($W/(cm^2/nm)$).

(8) Spectral transmittance means the spectral irradiance transmitted through protective eyewear divided by the spectral irradiance incident on the protective eyewear.

(9) **Sunlamp** product means any electronic product designed to incorporate one or more ultraviolet lamps and intended for irradiation of any part of the living human body, by ultraviolet radiation with wavelengths in air between 200 and 400 nanometers, to induce skin tanning.

(10) Timer means any device incorporated into a product that terminates radiation emission after a preset time interval.

(11) Ultraviolet lamp means any lamp that produces ultraviolet radiation in the wavelength interval of 200 to 400 nanometers in air and that is intended for use in any **sunlamp** product.

(c) Performance requirements--(1) Irradiance ratio limits. For each **sunlamp** product and ultraviolet lamp, the ratio of the irradiance within the wavelength range of greater than 200 nanometers through 260 nanometers to the irradiance within the wavelength range of greater than 260 nanometers through 320 nanometers may not exceed 0.003 at any distance and direction from the product or lamp.

(2) Timer system. (i) Each **sunlamp** product shall incorporate a timer system with multiple timer settings adequate for the recommended exposure time intervals for different exposure positions and expected results of the products as specified in the label required by paragraph (d) of this section.

(ii) The maximum timer interval(s) may not exceed the manufacturer's

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recommended maximum exposure time(s) that is indicated on the label required by paragraph (d)(1)(iv) of this section.

(iii) No timer interval may have an error greater than 10 percent of the maximum timer interval of the product.

(iv) The timer may not automatically reset and cause radiation emission to resume for a period greater than the unused portion of the timer cycle, when emission from the **sunlamp** product has been terminated.

(v) The timer requirements do not preclude a product from allowing a user to reset the timer before the end of the preset time interval.

(3) Control for termination of radiation emission. Each **sunlamp** product shall incorporate a control on the product to enable the person being exposed to terminate manually radiation emission from the product at any time without disconnecting the electrical plug or removing the ultraviolet lamp.

(4) Protective eyewear. (i) Each **sunlamp** product shall be accompanied by the number of sets of protective eyewear that is equal to the maximum number of persons that the instructions provided under paragraph (e)(1)(ii) of this section recommend to be exposed simultaneously to radiation from such product.

(ii) The spectral transmittance to the eye of the protective eyewear required by paragraph (c)(4)(i) of this section shall not exceed a value

of 0.001 over the wavelength range of greater than 200 nanometers 320 nanometers and an value of 0.01 over the wavelength range of greater than 320 nanometers through 400 nanometers, and shall be sufficient over the wavelength greater than 400 nanometers to enable the user to see clearly enough to reset the timer.

(5) Compatibility of lamps. An ultraviolet lamp may not be capable of insertion and operation in either the "single-contact medium screw" or the "double-contact medium screw" lampholders described in American National Standard C81.10-1976, Specifications for Electric Lamp Bases and Holders--Screw-Shell Types, which is incorporated by reference. Copies are available from the American National Standards Institute, 1430 Broadway, New York, NY 10018, or available for inspection at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202-741-6030, or go to: <http://www.archives.gov/federal-register/code-of-federal-regulations/ibr-locations.html>.

(d) Label requirements. In addition to the labeling requirements in part 801 and the certification and identification requirements of Sec. Sec. 1010.2 and 1010.3, each **sunlamp** product and ultraviolet lamp shall be subject to the labeling requirements prescribed in this paragraph and paragraph (e) of this section.

(1) Labels for **sunlamp** products. Each **sunlamp** product shall have a label(s) which contains:

(i) A warning statement with the words "DANGER--Ultraviolet radiation. Follow instructions. Avoid overexposure. As with natural sunlight, overexposure can cause eye and skin injury and allergic reactions. Repeated exposure may cause premature aging of the skin and skin cancer. WEAR PROTECTIVE EYEWEAR; FAILURE TO MAY RESULT IN SEVERE BURNS OR LONG-TERM INJURY TO THE EYES. Medications or cosmetics may increase your sensitivity to the ultraviolet radiation. Consult physician before using **sunlamp** if you are using medications or have a history of skin problems or believe yourself especially sensitive to sunlight. If you do not tan in the sun, you are unlikely to tan from the use of this product."

(ii) Recommended exposure position(s). Any exposure position may be expressed either in terms of a distance specified both in meters and in feet (or in inches) or through the use of markings or other means to indicate clearly the recommended exposure position.

(iii) Directions for achieving the recommended exposure position(s) and a warning that the use of other positions may result in overexposure.

(iv) A recommended exposure schedule including duration and spacing of sequential exposures and maximum exposure time(s) in minutes.

(v) A statement of the time it may take before the expected results appear.

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(vi) Designation of the ultraviolet lamp type to be used in the product.

(2) Labels for ultraviolet lamps. Each ultraviolet lamp shall have a

label which contains:

(i) The words ``**Sunlamp**--DANGER--Ultraviolet radiation. Follow instructions."

(ii) The model identification.

(iii) The words ``Use ONLY in fixture equipped with a timer."

(3) Label specifications. (i) Any label prescribed in this paragraph for **sunlamp** products shall be permanently affixed or inscribed on an exterior surface of the product when fully assembled for use so as to be legible and readily accessible to view by the person being exposed immediately before the use of the product.

(ii) Any label prescribed in this paragraph for ultraviolet lamps shall be permanently affixed or inscribed on the product so as to be legible and readily accessible to view.

(iii) If the size, configuration, design, or function of the **sunlamp** product or ultraviolet lamp would preclude compliance with the requirements for any required label or would render the required wording of such label inappropriate or ineffective, or would render the required label unnecessary, the Director, Office of Compliance (HFZ-300), Center for Devices and Radiological Health, on the Center's own initiative or upon written application by the manufacturer, may approve alternate means of providing such label(s), alternate wording for such label(s), or deletion, as applicable.

(iv) In lieu of permanently affixing or inscribing tags or labels on the ultraviolet lamp as required by Sec. Sec. 1010.2(b) and 1010.3(a), the manufacturer of the ultraviolet lamp may permanently affix or inscribe such required tags or labels on the lamp packaging uniquely associated with the lamp, if the name of the manufacturer and month and year of manufacture are permanently affixed or inscribed on the exterior surface of the ultraviolet lamp so as to be legible and readily accessible to view. The name of the manufacturer and month and year of manufacture affixed or inscribed on the exterior surface of the lamp may be expressed in code or symbols, if the manufacturer has previously supplied the Director, Office of Compliance (HFZ-300), Center for Devices and Radiological Health, with the key to such code or symbols and the location of the coded information or symbols on the ultraviolet lamp. The label or tag affixed or inscribed on the lamp packaging may provide either the month and year of manufacture without abbreviation, or information to allow the date to be readily decoded.

(v) A label may contain statements or illustrations in addition to those required by this paragraph if the additional statements are not false or misleading in any particular; e.g., if they do not diminish the impact of the required statements; and are not prohibited by this chapter.

(e) Instructions to be provided to users. Each manufacturer of a **sunlamp** product and ultraviolet lamp shall provide or cause to be provided to purchasers and, upon request, to others at a cost not to exceed the cost of publication and distribution, adequate instructions for use to avoid or to minimize potential injury to the user, including the following technical and safety information as applicable:

(1) **Sunlamp** products. The users' instructions for a **sunlamp** product shall contain:

(i) A reproduction of the label(s) required in paragraph (d)(1) of this section prominently displayed at the beginning of the instructions.

(ii) A statement of the maximum number of people who may be exposed to the product at the same time and a warning that only that number of protective eyewear has been provided.

(iii) Instructions for the proper operation of the product including the function, use, and setting of the timer and other controls, and the use of protective eyewear.

(iv) Instructions for determining the correct exposure time and schedule for persons according to skin type.

(v) Instructions for obtaining repairs and recommended replacement components and accessories which are compatible with the product, including compatible protective eyewear, ultraviolet lamps, timers, reflectors, and filters, and which will, if installed or used as instructed, result in continued compliance with the standard.

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(2) Ultraviolet lamps. The users' instructions for an ultraviolet lamp not accompanying a **sunlamp** product shall contain:

(i) A reproduction of the label(s) required in paragraphs (d)(1)(i) and (2) of this section, prominently displayed at the beginning of the instructions.

(ii) A warning that the instructions accompanying the **sunlamp** product should always be followed to avoid or to minimize potential injury.

(iii) A clear identification by brand and model designation of all lamp models for which replacement lamps are promoted, if applicable.

(f) Test for determination of compliance. Tests on which certification pursuant to Sec. 1010.2 is based shall account for all errors and statistical uncertainties in the process and, wherever applicable, for changes in radiation emission or degradation in radiation safety with age of the product. Measurements for certification purposes shall be made under those operational conditions, lamp voltage, current, and position as recommended by the manufacturer. For these measurements, the measuring instrument shall be positioned at the recommended exposure position and so oriented as to result in the maximum detection of the radiation by the instrument.

[50 FR 36550, Sept. 6, 1985, as amended at 67 FR 9587, Mar. 4, 2002; 69 FR 18803, Apr. 9, 2004]