

PART 878--GENERAL AND PLASTIC SURGERY DEVICES

1. The authority citation for 21 CFR part 878 continues to read as follows:

Authority: 21 U.S.C. 351,360, 360c, 360e, 360j, 3601,371.

2. Section 878.4635 is revised to read as follows:

§ 878.4635 Sunlamp product.

(a) Identification. An electronic product that includes one or more ultraviolet (UV) lamps and a fixture intended for irradiation of any part of the living human body, by UV radiation with wavelengths in air between 200 and 400 nanometers, to induce skin tanning. This definition includes tanning beds, tanning booths, and UV lamps (bulbs) sold separately.

(b) Classification. Class II (special controls). The special controls for this device are:

(1) Conduct performance testing that demonstrates the following:

(i) Sunlamp products meet appropriate output performance specifications such as wavelengths, energy density, and lamp life; and

(ii) Safety features, such as timers to limit UV exposure and alarms, function properly.

(2) Demonstrate that sunlamp products are mechanically safe to prevent user injury.

(3) Demonstrate software verification, validation, and hazard analysis.

(4) Demonstrate that sunlamp products are biocompatible.

(5) Demonstrate that sunlamp products are electrically safe and electromagnetically compatible in their intended use environment.

(6) Labeling must bear all information required for the reasonable assurance of safe and effective use of the device.

(i) The warning statement below must appear on all sunlamp product fixtures. This statement must be permanently affixed or inscribed on the product when fully assembled for use so as to be legible and readily accessible to view by the person who will be exposed to UV radiation immediately before the use of the product. It shall be of sufficient durability to remain legible throughout the expected lifetime of the product. It shall appear on a part or panel displayed prominently under normal conditions of use so that it is readily accessible to view whether the tanning bed canopy (or tanning booth door) is open or closed when the person who will be exposed approaches the equipment and the text shall be at least 10 millimeters (height).

Labeling on the device must include the following statement:

"Attention: This sunlamp product should not be used on persons under the age of 18 years."

(ii) Manufacturers of sunlamp products shall provide or cause to be provided in the user instructions for a sunlamp product as well as all catalogs, specification sheets, and descriptive brochures intended for consumers in which sunlamp products are offered for sale, and on all consumer-directed webpages on which sunlamp products are offered for sale, the following contraindication and warning statements:

(A) "Contraindication: This sunlamp product is contraindicated for use on persons under the age of 18 years."

(B) "Contraindication: This sunlamp product must not be used if skin lesions or open wounds are present."

(C) "Warning: This sunlamp product should not be used on individuals who have had skin cancer or have a family history of skin cancer."

(D) "Warning: Persons repeatedly exposed to ultraviolet sunlamp products should be regularly evaluated for skin cancer."

(iii) Manufacturers of sunlamp products shall provide validated instructions on cleaning and disinfection of sunlamp products between uses in the user instructions.

(c) Sunlamp products are subject to the electronic product performance standard at § 1040.20 of this chapter.

"Attention: This sunlamp product should not be used on persons under the age of 18 years."