CPG Sec. 396.300 Defective Suntanning Booths and Bed

BACKGROUND:

Sunlamp products, suntanning booths and beds manufactured prior to May 7, 1980, are not subject to the sunlamp performance standard; however, these electronic products are subject to the defect regulations under 21 CFR 1003 and the Chapter V, Subchapter C of the Federal Food, Drug, and Cosmetic Act (FFDCA), formerly known as the Radiation Control for Health and Safety Act of 1968 (RCHSA). Suntanning products, booths, and beds are also medical devices subject to the other provisions of the FFDCA.

FDA field surveillance activities have located a number of suntanning booths operating in health spas which lack protective eyewear and/or timers. The lack of protective eyewear or timer is considered to be a serious defect and health hazard, and correction is required by the manufacturer under Subchapter C of the FFDCA.

The health spa owner/operator is not required to correct or discontinue the use of defective suntanning booths/beds under the authority of Subchapter C of the FFDCA. Therefore, in cases where the manufacturer is unknown, the authority of Section 304 of the FFDCA will be used when necessary to gain control of the defective product until it is corrected. The owner/operator will be advised of the defect and requested to voluntarily withdraw hazardous units from use until corrections are made by the manufacturer.

POLICY:

Enforcement under the defect provisions of Subchapter C of the FFDCA rather than Section 304 of FFDCA is the action of choice, when possible. In those cases where the manufacturer fails to perform required corrections, or the owner/operator refuses to withdraw the hazardous unit(s) from service, or to make corrections on a voluntary basis, or the unit(s) is returned to use before corrections can be made by the manufacturer, initiate detention and/or seizure under Section 304 of the FFDCA to remove the device from use, if the following criteria are met:

1. The product has a Class A health hazard as defined in CP *7386.002.* (A suntanning device which lacks protective eyewear or timer is misbranded within the meaning of 502(f)(1) and 502(j) of the FFDCA;

and

2. The most responsible owner/operator has been notified in writing to discontinue use;

and

3. The owner/operator fails or refuses to discontinue use until the product is corrected.

Contact HFZ-300 to discuss details before administrative detention is ordered.

Material between asterisks is new or revised

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