

FDA Proposed Order: Reclassification of Ultraviolet Lamps for Tanning

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FDA Proposed Order: Reclassification of Ultraviolet Lamps for Tanning, Henceforth to Be Known as Sunlamp Products. (DEPARTMENT OF HEALTH AND HUMAN SERVICES, Food and Drug Administration, 21 CFR Part 878, [Docket No. FDA-2013-N-0461]). [The full document can be found here.](#)

A press conference was held Monday May 6th to publicly introduce a new proposed FDA order “to increase consumer awareness of tanning bed risks”. The reclassification of tanning devices based on new information that impacts current regulations designed to protect the public safety. It took about 20 minutes including a question and answer session. A replay is available until June 6, 2013. To listen to the replay, call 866-470-8786. The conference included Dr. Jeff Shuren, director of the Center for Devices and Radiological Health and Dr. Mary Maloney, the regulatory policy committee chairwoman of the American Academy of Dermatology. If finalized, the order would reclassify sunlamp products from a low risk device (class I) to a moderate risk device (class II). Examples of low risk devices that, when used as designed, present “little to no risk to the user”

- tongue depressors
- adhesive bandages

Examples of moderate risk devices” that require special controls to ensure reasonable safety for the user”

- Surgical mesh
- Tissue adhesive- topical
- Surgical lamp
- Low level laser system for aesthetic use
- Ultraviolet lamp for dermatologic disorders

Previous regulations were based on a 1977 report of the General and Plastic Surgery Device Classification Panel and the Physical Medicine Device Classification Panel that recommended that dermatologic UV lamps; devices that provide UV radiation intended primarily for the treatment of dermatologic disorders or for tanning, be classified into class II (see 47 FR 2810 at 2835; January 19, 1982). However, in its final rule, published on June 24, 1988 (53 FR 23856 at 23868), FDA separated UV lamps for dermatological disorders and UV lamps for tanning. The FDA eventually finalized UV Lamps for the purpose of tanning as class 1 on November 20, 1990 (55 FR 48436 at 48440).

For the first time, the FDA is taking a stand on the use of tanning devices by minors. “A warning label, clearly visible on the device, is stating that minors should not use the device”. In addition, manufacturers would:

1. Have to submit a pre-market notification (510(k)) to the FDA for these devices. They are currently exempt from any pre-market review.
2. Show that their products have met certain performance testing requirements, address certain product design characteristics and provide comprehensive labeling that presents consumers with clear information on the risks of use.
3. Labeling would have to include a warning that frequent users of sunlamp products should be regularly screened for skin cancer.

“The FDA is not trying to burden salons but rather to educate consumers,” Jeff Shuren, director of the Center for Devices and Radiological Health said Monday on a call with reporters. He said the responsibility for the new warnings falls on the companies that make the products, not salons. Dr. Shuren was asked why the FDA proposal just included a “strong warning” rather than an outright ban on use of tanning beds by children. He replied that “Nothing is off the table” and “they will take in to consideration any changes to the proposal after they sift through the public commentary”.

DNA will be preparing comments to submit to the FDA within the 90 day comment period. All members are encouraged to submit their own comments. If you need help with this please contact me at kmaster@tctc.com.