DEPARTMENT OF HEALTH & HUMAN SERVICES

Memorandum

Date December 21, 2011

From Director, CDRH Office of Compliance

Subject Replacement of Tanning Lamps with Red Light Therapy Lamps in Tanning Salons

To Conference of Radiation Control Program Directors (CRCPD)

The Food and Drug Administration is aware that some tanning salon owners are removing the original ultraviolet (UV)-emitting tanning lamps from their tanning beds/booths and replacing them with lamps that emit red light. These salon owners are then selling sessions in the red light units with a range of indications and promotional claims, including ones pertaining to:

- Reversal of sun or UV damage to skin,
- wound healing,
- increased blood flow/circulation,
- reduced pain and/or inflammation,
- treatment of acne,
- reduction of appearance of wrinkles, pigmentation spots, stretch marks, and/or scarring,
- skin rejuvenation, restoration, oxygenation, and/or hydration,
- collagen/elastin production/reorganization, and
- skin structure, elasticity, and/or metabolism.

Ultraviolet tanning beds/booths/lamps meet FDA's definition of "device" and "electronic product" at sections 201(h) and 531 of the Federal Food, Drug, and Cosmetic Act (FD&C Act). Tanning lamps are subject to an electronic product performance standard, and are generally 510(k)-exempt. See 21 CFR 878.4635, part 1010, and 1040.20.

Replacing the original ultraviolet lamps with lamps that emit red light and are intended for uses such as those listed above creates a new type of product that is also a "device" and an "electronic product" under the FD&C Act. Exposure to red light has been scientifically shown and is understood by consumers to affect skin structure, for example by reducing wrinkles for months after treatment, which may be the result of new collagen formation or reorganization, or repair of elastin damage. Claims such as those listed above would cause the product to meet one or both of the "device" definitions at sections 201(h)(2) and (3) of the FD&C Act.

Red lights intended for uses such as those listed above would not fall under 21 CFR 878.4635, and would not be 510(k)-exempt (they also would not fall under 21 CFR 1040.20, but would be subject to the regulations generally applicable to electronic products at parts 1000 - 1005). Unless and until such device receives 510(k) clearance or premarket approval from FDA, it would be an adulterated and misbranded device that may not be marketed for sale. Red light therapy systems intended for uses such as those described above may fall under 21 CFR 878.4810, 878.5400, or 890.5500, depending on the technology and the claims made. For devices that fall within one of these classification regulations, the proper application to file is the 510(k) or "Premarket Notification."

Some states have expressed concern about this practice to FDA and have already taken action on their own. FDA would like to see a consistent message and coordinated approach, and requests CRCPD's assistance in sharing this communication with state radiation control programs.

The FDA is also communicating with the Indoor Tanning Association and asking it to advise manufacturers and salon owners of its concern about this practice.

Some useful links to the FDA website relevant to this issue are shown below:

The instructions on how to submit a Premarket Notification application can be found at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/PremarketNotification510k/default.htm.

The sunlamp regulations and other resources can be found at http://www.fda.gov/Radiation-EmittingProducts/RadiationEmittingProductsandProcedures/HomeBusinessandEntertainment/ucm116447.htm#Laws.

Contacting FDA

Questions about the premarket requirements for red light devices may be directed to Richard Felten in the Office of Device Evaluation, CDRH, 10903 New Hampshire Avenue, WO-66, Silver Spring, Maryland 20993 or by email at Richard.Felten@fda.hhs.gov.

Questions about FDA radiation control requirements for electronic products may be directed to Sharon Miller in the Electronic Products Branch, Office of Communication, Education, and Radiation Programs, CDRH, 10903 New Hampshire Avenue, WO-66, Silver Spring, Maryland 20993 or by email at Sharon.Miller@fda.hhs.gov.