General and Plastic Surgery Devices Panel Meeting - March 25, 2010

The General and Plastic Surgery Devices Panel of the FDA/CDRH Medical Devices Advisory Committee met on Thursday, March 25, 2010 to review and discuss recent information, including recent literature regarding the possible risks to the general public from intentional exposure to ultraviolet radiation (UV) from use of tanning lamps. The committee discussed the growing body of information related to the association of UV light and permanent skin changes including skin cancer. The Panel was asked to recommend whether changes to current classification or current regulatory controls of UV emitting devices (lamps) used for tanning are needed.

The FDA presentation began with the history and current regulatory status of medical device classification of tanning lamps for tanning beds (CFR 878.4635) and for medical usage (21 CFR 878.4630), followed by a brief outline of medical device classification and related concepts and processes. The next portion of the FDA presentation focused on FDA's role in the regulation of sunlamp products under the Electronic Product Radiation Control authority; current and proposed FDA regulations in that area; the role of States and the Federal Trade Commission; and on actions by regulatory bodies outside the United States. The FDA presentation continued with a clinical review of the potential benefits and risks of tanning beds, and a review of the IARC meta-analysis of sunbed use and skin cancer, and concluded with a risk-based assessment of indoor tanning.

Approximately four hours of public testimony followed, with an additional hour of questions from the Panel to the public speakers. The Panel then took up the questions posed by FDA.

The Panel discussed a variety of measures that would provide a reasonable assurance of safety and effectiveness for ultraviolet (UV) lamps for tanning. Regarding the user's age, the majority of the Panel favored an age restriction for tanning; however, a minority suggested other measures, e.g. parental consent, for minors.[1] For users with Fitzpatrick skin type 1, the Panel agreed that tanning is not safe or effective. However, for other skin types, the Panel concluded that insufficient data exists regarding the safety or effectiveness of tanning. The Panel further decided that individuals with a genetic or family history of skin cancer should be subject to special restrictions and education requirements prior to using tanning beds. In terms of UV wavelengths, the Panel stated that there is not sufficient data to address the wavelength issue (with the exception of UV-C), but upcoming research may elucidate more guidelines in that regard. In terms of other risks or measures, the Panel felt that insufficient data exists to allow for a determination of what specific measures should be taken; however, there was some discussion of restrictions for pregnant users and users who take certain drugs or use

[1] The major media is reporting that the Panel called for a ban; however, the term used in the majority of the discussion by the Panel, and by the FDA, was consideration of an age restriction. It should be noted that at least one member did use the word "ban".

certain cosmetics that interact with UV that could result in photosensitization reactions in the individual.

On the subject of tanning bed classification, the Panel's unanimous conclusion was that tanning lamps/beds should not be Class I devices. The Panel was split on a proposed reclassification of tanning beds, with some Panel members stating that tanning beds should be Class III, with the acknowledgement that such classification would be difficult to put into practice due to the impracticality of creating PMA submissions for tanning beds. Other Panel members recommended that tanning beds be classified as Class II, with age, skin type etc. (as already discussed) as special controls. The Panel also recommended that the special controls could include a registry program for users of tanning beds, possibly to include a user fee that would support such a registry. Other special controls proposed by the Panel included strengthened requirements for education, training, testing and recertification of tanning bed operators, and a mechanism by which the tanning bed user would be required to read and accept a series of warnings about the risks of indoor tanning before the tanning bed would activate. The Panel also endorsed the FDA's proposed use of focus groups to best determine which type of warning labels, educational materials etc. would be most effective in educating users about the risks associated with indoor tanning.

Regarding devices that are UV-A only, UV-B only, or a mixture of both, the Panel's consensus was that such devices do not need to be regulated or classified separately; however, they do need to be understood separately and the same controls would apply to all. Regarding proposed changes to the current FDA performance standard, the Panel was in favor of a review and changes or improvements to the current performance standard. Particular attention was paid to strengthening requirements for protective eyewear. There was some discussion the fact that these products are currently categorized based upon the irradiance emitted when the lamp is new. In actuality, the irradiance decreases as the lamp ages. The Panel recommended that irradiance be measured on a schedule as the device is in use. The Panel also supported the collection of data on spectral output from tanning beds (similar to the data that is used in the IEC classification system of tanning beds). Such data could be collected in the registry system that was discussed earlier. This would mean that FDA would need to require that the "type" of tanning lamp would need to be noted on the tanning bed.

Regarding labeling and additional restrictions, the Panel was in favor of patient disclosure and/or patient brochures. The Panel also supported more prominent posting of user disclosures or warnings; it was noted that this might be one way of approaching the issue of tanning for users under age 18. The Panel concluded that such regulations would also need to apply to tanning beds sold for in-home use, and that home-use devices might even need to have stronger regulations than those sold for salon use. Again, the Panel endorsed FDA's proposed use of focus groups to best determine which type of warning labels, educational materials etc. would be most effective in educating users about the risks associated with indoor tanning. The Panel also reiterated its

support of a system in which a tanning bed would not be switched on until the user had reviewed and accepted a series of warnings about the risks of indoor tanning.

The meeting adjourned at 6:15 PM.
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