

Update on Sunlamp Products

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What is a Sunlamp Product?

- Electronic product with UV lamps (200-400 nm) for irradiation of human skin to induce tanning
- Tanning beds/booths, facial units, feet tanners

Tanning Bed/Booth (most common)



Regulatory History

- 1979: publication of Sunlamp Products Performance Standard in 21 CFR 1040.20
- 1985: 21 CFR 1040.20 amended to accommodate UVA lamps
- 1986: 3 policy letters published to provide guidance on:
 - Warning label
 - Maximum Recommended Exposure Time calculations
 - Lamp Compatibility

TEPRSSC - 2003

Several proposed amendments to the Performance Standard for Sunlamp Products were presented at the 2003 TEPRSSC meeting. All proposals were accepted:

1. Strengthen language in the Warning Label and make it easier to read
2. Require a Warning Label to be included in sales material targeted to consumers
3. Specify that modification of a sunlamp product that results in a change to safety constitutes manufacturing

2003 Proposed Amendments

4. Change requirements for protective eyewear to include cap on transmittance in visible region and a quantitative floor on luminous transmittance (from IEC) and extend requirements to *ALL* eyewear intended to be used with sunlamp products
5. Replace current erythema action spectrum with universally-recognized CIE Reference Action Spectrum for Erythema *AND* change maximum dose limit accordingly (from IEC, modified)
6. Adopt the IEC's UV code approach for measuring and labeling replacement lamps

2003 Proposed Amendments

7. Change approach for limiting UVC radiation exposure from current 'ratio' to an 'absolute' limit (from IEC)
8. Update guidelines for Recommended Exposure Schedule to reduce cumulative UV burden (from IEC)



Medical Device Authority

- In May, 2014, FDA published a Final Order to re-classify tanning beds (sunlamp products) as Class II Medical Devices and require 510(k) submissions
- In addition, all sunlamp products must bear a Black Box warning label –

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

Recent EPRC Regulatory History

December 22, 2015: FDA published two Proposed Rules:

1. A **Restriction** that would prevent tanning facilities from allowing anyone < 18 yrs of age to use indoor tanning devices *AND* require that all users ≥ 18 yrs of age sign an 'Acknowledgement of Risks' form prior to their first tanning session and every 6 months, thereafter
2. Proposed amendments to the FDA Performance Standard for Sunlamp Products (last updated in 1985), which adopt some elements of the IEC standard by reference

Future

- Publish Final Rule for the age restriction
- Publish Amendments to the Performance Standard for Sunlamp Products

