Update on FDA Activities related to Sunlamp Products

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Regulatory History
Electronic Product Radiation Control authority

- 1979 – publication of Sunlamp Products Performance Standard in 21 CFR 1040.20
- 1985 - FDA amended 21 CFR 1040.20 to accommodate UVA lamps
- 1986 – FDA published 3 policy letters to provide guidance on:
  - Warning label
  - Maximum Recommended Exposure Time calculations
  - Lamp Compatibility
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
Proposed Amendments from 2003 – ct’d

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 UV code approach (from IEC) for measuring and labeling replacement lamps
Proposed Amendments from 2003 – ct’d

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)

2016 – TEPRSSC reconvened – summary provided of activities in regulation of Sunlamp Products
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
Regulatory History - continued

12/22/15: 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;

Future

Publish Final Rule for both the Restriction and the Amendments to the Performance Standard for Sunlamp Products
State Indoor Tanning Restrictions for Minors, 2017

Prohibits all minors from UV tanning
Prohibits some minors from UV tanning
Requires parent or guardian permission or accompaniment
No Restrictions
* Allows for use with doctor’s prescription