FDA Regulation of Sunlamp Products – an update

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Objectives

• Explain FDA’s role (and limitations) in the regulation of sunlamp products/ indoor tanning under
  – Electronic Product Radiation Control Authority
  – Medical Device Authority
• Current and proposed FDA regulations
• Role of States
What prompted FDA to begin regulating sunlamp products?

- In the mid 1970s, skin burns and eye injuries reported to the Consumer Product Safety Commission @ ~10,000 per year.

- Known hazards of exposure to UV: acute burns, skin cancer, cataracts, etc.
FDA Regulation – Two Authorities

FDA has the authority to regulate tanning beds under two different statutes:

- Electronic Product Radiation Control Act (formerly Radiation Control for Health & Safety Act)
- Medical Device authority
Regulatory History

Under Radiation Control for Health and Safety Authority:

• 1979 – publication of Sunlamp Products Performance Standard in 21 CFR 1040.20

• 1985 - 21 CFR 1040.20 amended to accommodate UVA lamps
FDA Regulation of Tanning Lamps under Medical Device Authority

UV lamps meet definition of "device" at FDCA 201(h)
A medical device is defined as an “instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article” which is:

- Intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment or prevention of disease in man or other animals, or
- Intended to affect the structure or any function of the body of man or other animals, and
- Does not achieve its primary intended purposes through chemical action within or on the body and which is not dependent upon being metabolized for the achievement of its primary intended purpose
Medical Device Regulation

• Currently, tanning beds are Class I Medical Devices

• Exempt from pre-market notification

• This issue is under review at the FDA, more later!
FDA Sunlamp Products Performance Standard

Includes requirements for:

- Labeling
- User instructions
- Timer
- Replacement lamps
- Radiation emissions
- Protective eyewear
Performance Standard

• Limits ratio of ‘UVC’/ ‘UVB’ to 0.003
• Limits maximum exposure time based on maximum allowable erythemal-effective dose
• Timers must have +/- 10% accuracy
• ‘Panic Button’ to allow user to manually terminate radiation
Performance Standard

• Protective Eyewear
  – Spectral transmittance:
    • < 0.001 for 200nm - 320nm
    • < 0.01 for 320nm - 400 nm

• Requires labeling and user instructions
• Requires specification of compatible replacement lamps
Recent Activities
2007 TAN* Act

FDAAA 2007 Sec. 230; Required FDA to determine:

- If labeling for tanning devices provides sufficient information about risk
- If revised warning label better conveys risks, OR, if
- No warning label can adequately communicate risks

*Tanning Accountability and Notification
Current Warning Label

“DANGER - Ultraviolet radiation. Follow instructions. Avoid overexposure. As with natural sunlight, overexposure can cause eye and skin injury and allergic reactions. Repeated exposure may cause premature aging of the skin and skin cancer.

WEAR PROTECTIVE EYEWEAR; FAILURE TO MAY RESULT IN SEVERE BURNS OR LONG-TERM INJURY TO THE EYES.

Medications or cosmetics may increase your sensitivity to the ultraviolet radiation. Consult physician before using sunlamp if you are using medications or have a history of skin problems or believe yourself especially sensitive to sunlight. If you do not tan in the sun, you are unlikely to tan from the use of this product.”
Alternate Warning Label used in Focus Groups

DANGER – Ultraviolet Radiation

Avoid overexposure- It may cause severe burns

Read instructions carefully

Ultraviolet Radiation causes:
• Skin Cancer
• Injury to the Eyes and Skin
• Skin Aging

WEAR PROTECTIVE EYEWEAR TO PREVENT EYE INJURY

Certain medicines or cosmetics can increase your sensitivity to ultraviolet radiation – Consult your physician before tanning
Conclusions from Focus Groups

• Modifying label could communicate the risks of indoor tanning more effectively

• Positioning could be improved by specifying the warning label be separated from other labels to highlight its importance.
Proposed Amendments to Sunlamp Product Performance Standard

- Revise content & format of warning label
- Ensure label is visible prior to use
- Revise Exposure Schedules based on current science
- Require uniform lamp code to facilitate correct replacement, reduce burns
- Add requirements on visible transmittance for protective eyewear - to protect retina
States Authority

- 30 States currently have regulations in place; some include restrictions on minors’ access to tanning facilities.
  - The age restriction varies among States, i.e. 14 to 18 years of age. 11 states prohibit use by minors.
- State inspectors can check for:
  - Presence of proper labeling
  - Accuracy of timer
  - Compatibility of lamps
  - Other, non-radiation issues, e.g. hygiene, training
- FDA provides input into Suggested State Regs
General & Plastic Surgery Devices Panel of the FDA/CDRH Medical Devices Advisory Committee Meeting

March 25, 2010
Purpose of meeting

• To review and discuss recent literature re: potential risks from UV exposure from tanning beds/lamps

• Review current regulatory controls in the FDA Sunlamp Performance Standard

• Discuss whether changes in the classification of tanning beds or other regulatory controls are needed
Panel Meeting Agenda

• Presentations by FDA staff
  – Regulatory History under Medical Device Authority
  – Regulatory History under Electronic Product Radiation Control Authority
  – Risks of UV radiation
  – Analysis of IARC recent up-classification to ‘Class I Carcinogen’
  – Discussion of claimed benefits of UV radiation
  – Questions for Panel to address
Presentations by General Public

- Total of 51 presentations
- Most from professional societies or private dermatologists
- Several from tanning industry
- Several melanoma survivors or family members of those who succumbed
- Representative of Congresswoman Maloney
Summary of Panel Meeting

- There was a general consensus that Tanning Beds/Lamps should be up-classified from their Class I Medical Device Status.

- Most of the panel members felt that minors should not be allowed to use tanning beds/lamps or that parental consent should be required.

- Most of the panel members felt that the information on risks of tanning should be required at the front desk area of tanning salons, or that some type of ‘informed consent’ document should be used.
Next Steps

• FDA personnel are developing a Concept Paper to outline future plans regarding additional controls that can be taken using FDA’s Medical Device Authority

• Amendments to the FDA Performance Standard for Sunlamp Products are in progress
Any Questions?