FDA TANNING DEVICE RECLASSIFICATION
FREQUENTLY ASKED QUESTIONS

What actions have the U.S. Food and Drug Administration (FDA) taken on indoor tanning devices?

- The FDA is strengthening regulations of tanning beds, including a strong recommendation against the use of tanning beds by minors under the age of 18.
- The FDA is recommending that people do not use indoor tanning devices if they have skin lesions and/or open wounds/sores.
- The FDA is warning that people do not use indoor tanning devices if they have been diagnosed with skin cancer or if they have a family history of skin cancer.
- The FDA has recommended that indoor tanning device users be regularly checked for skin cancer.

Why is the FDA doing this?

- The FDA has changed its regulation of sunlamp products to help consumers better understand the risks of using tanning beds and protect the public from some — but not all — of the risks associated with tanning beds.
- Using indoor tanning beds can damage your skin and cause cancer.
- Indoor tanning equipment, which includes all artificial light sources, including beds, lamps, bulbs, booths, etc., emits UVA and UVB radiation. The amount of the radiation produced during indoor tanning is similar to the sun, and in some cases might be stronger.
- Indoor tanners have a 59 percent increased risk of developing melanoma, and the risk increases with each use.
- According to the American Cancer Society, melanoma will account for 76,100 cases of skin cancer in 2014.

What is a “reclassification”?

- The FDA classifies devices in three categories depending on the health risk associated with using that device. The regulatory classes are based on the level of controls needed to ensure the safety and effectiveness of the devices.
- The FDA has raised the classification for sunlamps and tanning beds to a Class II level which institutes stricter regulations to protect public health. Previously, indoor tanning devices were Class I, the category for items that have minimal potential to cause harm to individuals, such as adhesive bandages and tongue depressors.
What will reclassifying tanning devices require of tanning bed and lamp manufacturers?

- With a reclassification, tanning bed and lamp manufacturers will be required to show that their products have met certain performance testing requirements.

- Tanning bed and lamp manufacturers will also be required to label the devices so that they:
  - clearly inform consumers about the risks of using tanning beds;
  - warn frequent users of sunlamps to be regularly screened for skin cancer; and
  - alert users that tanning lamps are not recommended for people under 18 years old.

- Under the final changes, manufacturers will be required to provide updated labeling for all products on the market within 450 days of June 2, 2014.

Why is the FDA advising that minors under the age of 18 do not use tanning devices?

- The risk of developing melanoma increases by 59 percent for individuals who have been exposed to UV radiation from indoor tanning, and the risk increases with each use. Since 2.3 million teens tan indoors in the United States annually, restricting teens’ access to indoor tanning is critical to preventing skin cancer.

- Melanoma is the most common form of cancer for young adults 25-29 years old and the second most common form of cancer for adolescents and young adults 15-29 years old.

- In a study conducted by the Washington University School of Medicine in St. Louis and published in Pediatrics found that many indoor tanning facilities in Missouri provide incorrect information to patrons about the dangers of indoor tanning – indicating that 43 percent of tanning facilities denied any risks to indoor tanning. Additionally, researchers found that two-thirds of 243 facilities in Missouri would allow minors ages 10 to 12 to use tanning devices, sometimes without obtaining parental consent.

- According to the New England Journal of Medicine, frequent, intentional exposure to UV light - found in tanning beds - may lead to an addiction to tanning.

- California, Connecticut, Illinois, Nevada, Oregon, Texas, Vermont and Washington have passed laws prohibiting the use of indoor tanning devices by minors under 18, in an effort to protect minors from the dangers of indoor tanning.

Is this a final rule?

- Yes. Under the final changes, manufacturers will be required to provide updated labeling for all products on the market within 450 days of June 2, 2014.
What is the American Academy of Dermatology Association’s (AADA) position?

- The AADA supports the reclassification of indoor tanning devices and placing additional restrictions on indoor tanning, and we applaud the FDA for taking this important step.

- We recognize that there is still more work to be done to protect the public from these dangerous devices. The AADA will continue to urge the FDA to restrict the use and sale of indoor tanning devices for minors under the age of 18.

How was the American Academy of Dermatology Association (AADA) involved in the FDA’s actions?

- The AADA has been working closely with the FDA, and both state and federal legislatures to protect minors from the dangers of indoor tanning.

- In 2010, representatives from the AADA and leading dermatologists and researchers testified before an FDA panel in support of changes to the current classification of indoor tanning devices.

- As medical doctors who diagnose and treat skin cancer, dermatologists are committed to reducing its incidence and saving lives. The AADA will continue to partner with the FDA and other stakeholders to educate the public about the importance of UV protection.