

## **FDA News Release**

# **FDA to require warnings on sunlamp products**

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Today, the U.S. Food and Drug Administration issued a final order reclassifying sunlamp products and ultraviolet (UV) lamps intended for use in sunlamp products from low-risk (class I) to moderate-risk (class II) devices. The order also requires that sunlamp products carry a visible black-box warning on the device that explicitly states that the sunlamp product should not be used on persons under the age of 18 years. In addition, certain marketing materials for sunlamp products and UV lamps must include additional and specific warning statements and contraindications.

Sunlamp products, which include tanning beds and tanning booths, emit UV radiation that may cause skin cancer. According to the American Academy of Dermatology, people who have been exposed to UV radiation from indoor tanning experience a 59 percent increase in the risk of melanoma, the deadliest type of skin cancer. This risk increases each time they use a sunlamp product.

“The FDA has taken an important step today to address the risk to public health from sunlamp products,” said Jeffrey Shuren, M.D., director of the FDA’s Center for Devices and Radiological Health. “Repeated UV exposure from sunlamp products poses a risk of skin cancer for all users—but the highest risk for skin cancer is in young persons under the age of 18 and people with a family history of skin cancer.”

As part of today’s action, manufacturers will now have to submit a premarket notification (also called a “510(k)”) to the FDA – and obtain FDA clearance – prior to marketing these devices, which until now were exempt from premarket review. Manufacturers also will now have to show that their products meet certain performance testing requirements and address certain product design characteristics, and will have to include certain warnings and contraindications on sunlamp products and in certain marketing materials for sunlamp products and UV lamps that present consumers with clear information on the risks of use.

In addition to a warning placed on the sunlamp product advising that the product not be used on children under 18, certain marketing materials promoting sunlamp products and UV lamps must carry additional warnings and contraindications, including “Persons repeatedly exposed to UV radiation should be regularly evaluated for skin cancer.”

The FDA’s final order for the reclassification of sunlamp products and UV lamps follows the recommendations from a panel meeting of outside experts convened in March 2010. This panel of outside experts evaluated the risks of sunlamp products, and recommended that FDA increase regulation of these devices and certain members of the panel recommended that children and teenagers not use the products.

Today's action follows a public comment period after the release of the proposed order in May 2013. The FDA received comments from industry, patient groups and professional societies, which are addressed in the final order.

The FDA, an agency within the U.S. Department of Health and Human Services, protects the public health by assuring the safety, effectiveness, and security of human and veterinary drugs, vaccines and other biological products for human use, and medical devices. The agency also is responsible for the safety and security of our nation's food supply, cosmetics, dietary supplements, products that give off electronic radiation, and for regulating tobacco products.

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