STATE OF NEW YORK
OFFICE OF THE ATTORNEY GENERAL
120 BROADWAY, NEW YORK, NEW YORK 10271

ERIC T. SCHNEIDERMAN
Attorney General

August 6, 2013

Via Electronic Submission:
http://www.regulations.gov
Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Re: 21 C.F.R. Part 878 - Docket No. FDA-2013-N-0461

To Whom It May Concern:

The New York State Office of the Attorney General submits these comments on the United Stated Federal Drug Administration's (FDA) proposed order for Reclassification of Ultraviolet Lamps for Tanning, 21 C.F.R. Part 878, published at 78 Fed. Reg. 27117 (May 9, 2013).

Our State is concerned with the nationwide increase in skin melanomas and the contribution that indoor tanning makes to this public health problem. Many states, including New York, have age restrictions in place to limit indoor tanning to older individuals, and view the FDA's recent proposal as an important parallel effort to highlight the known risks of sunlamp products. Notwithstanding these federal and state efforts, we also would like to raise our serious concerns that indoor tanning companies minimize the known risks of indoor tanning by marketing sunlamp services as a way to improve health, a purpose for which sunlamps have not been approved.

Background

On May 6, 2013, the FDA issued a proposed order ("Proposed Order") that would reclassify sunlamp products from a low-risk device (class I) to a moderate-risk device (class II) and require pre-market certification, whereby manufacturers would have to demonstrate that their products meet certain performance testing requirements. In addition, the Proposed Order would demand that manufacturers place a label directly on sunlamps warning persons under 18 not to use them. Sales and promotional materials accompanying sunlamps would be required to contain certain warnings and

contraindications, including, for example, a warning that frequent users should be regularly screened for cancers.

The Proposed Order Strengthens Sunlamp Product Protections.

We commend the FDA for strengthening the regulation of sunlamps for the reasons set forth in the FDA's discussion.

The FDA's original classification panels advised in 1977 that indoor tanning posed risks to humans, including "Burns to skin and eyes...Aging of skin...Skin cancer...and Photosensitivity." 78 Fed. Reg. at 27118. Notwithstanding these health risks, in 1994 the FDA classified UV lamps for tanning (now called "sunlamp products") as class I devices with no requirement of premarket notification.

The Proposed Order acknowledges the overwhelming evidence that UV radiation exposure can lead to permanent damage to DNA in the skin, which has been shown to lead to an increased risk of skin cancer, and that "tanning in childhood to early adult life increases the rate of melanoma." *Id.* at 27119.

Esteemed public health institutions and leading medical societies are in agreement that indoor tanning poses serious risks of skin cancer and eye damage. The Centers for Disease Control and Prevention (CDC), as well as the American Cancer Society and the American Academy of Dermatologists, confirm that indoor tanning has been linked with skin cancers, including melanoma (the deadliest type of skin cancer), squamous cell carcinoma, and cancers of the eye (ocular melanoma), and warn that indoor tanning exposes users to both UV-A and UV-B rays, which damage the skin and can lead to cancer.[1] Using sunlamp products is particularly dangerous for younger individuals; those who begin indoor tanning before they are 35 years old have a 75% higher risk of melanoma than those who have not.[2] Sunlamp use also increases the risk of wrinkles and eye damage, and changes skin texture.[3] The CDC's position, as well as that of the established medical societies, reflects the scientific literature linking indoor tanning bed use to melanoma.

Given the serious risks posed by sunlamps, the FDA's change in sunlamp classification and additional warnings are a welcome step forward to protect the public from harm.

---

[1] *Indoor Tanning*, Centers for Disease Control and Prevention (May 8, 2013), *available at* http://www.cdc.gov/cancer/skin/basic_info/indoor_tanning.htm; Rebecca V. Snowden, *Study Links Tanning Bed Use to Increased Risk of Melanoma*, American Cancer Society (May 27, 2010), *available at* http://www.cancer.org/cancer/news/news/study-links-tanning-bed-use-to-increased-risk-of-melanoma; *The Dangers of Indoor Tanning*, American Academy of Dermatology, *available at* http://www.aad.org/spot-skin-cancer/understanding-skin-cancer/dangers-of-indoor-tanning#.Ud2bNqwZ-q0 (last visited July 10, 2013).

[2] *Indoor Tanning*, *supra* n.1.

[3] *Id.*

FDA Should Emphasize that Sunlamp Products Have Been Approved for Cosmetic Purposes, Not Health Purposes.

Sunlamp products have been approved by the FDA as devices to be used for cosmetic purposes, "to tan the skin." 21 C.F.R. Part 878.4635. In light of this, we urge the FDA to make explicit that its approval is limited to the use of sunlamp products for cosmetic purposes only. We see increasing evidence that tanning salons are marketing sunlamp products as "safe" and having no "adverse effect". Even worse, they are promoting indoor tanning for alleged health benefits, including Vitamin D-creation and cancer prevention, which are supported neither by the scientific literature nor by the FDA. The FDA has approved sunlamps for one purpose only: to "tan the skin." There is no safe threshold of exposure from tanning devices that allows for vitamin D synthesis without increasing skin cancer risk. Given the FDA's very specific findings and authorization for continued sunlamp usage, and given the clear evidence of harm from sunlamp product use, we urge the FDA to underscore that the only basis on which sunlamp products have been approved is for the narrow purpose set out in the regulation (skin tanning), and not as a treatment or cure for disease or health ailment.

* * *

We commend the FDA's Proposed Order, which adds a number of important protections for consumers, including a shift in classification of sunlamps from class I to class II, as well as new warnings on sunlamps. These efforts present important steps forward. Given the well-documented risks of tanning beds already acknowledged by the FDA and evidenced in the announcement of new protections, we urge the FDA to further clarify that its approval of sunlamp products is for cosmetic purposes only, and that advertising sunlamp products as devices that provide health benefits is not permissible in light of the carcinogenic consequences from sunlamp exposure and the significant nationwide increases in melanoma. The FDA's clarification is needed to counter current marketing efforts that send the very opposite and very dangerous message to consumers.

Sincerely,

Lisa Landau
Bureau Chief
Health Care Bureau

Jane M. Azia
Bureau Chief
Consumer Frauds and
Protection Bureau