March 21, 2016

Dr. Robert Califf, MD, MACC
Commissioner
Food and Drug Administration
5630 Fishers Lane, Rm. 1061
Rockville, MD 20852

Re: Docket No. FDA-1998-N-0880, RIN 0910-AG30, Sunlamp Products; Proposed Amendment to Performance Standard

Dear Commissioner Califf:

The American Cancer Society Cancer Action Network (ACS CAN) appreciates the opportunity to provide comments on the proposed rule amending the technical and labeling requirements for sunlamp manufacturers and tanning facilities. ACS CAN is the nonprofit, nonpartisan advocacy affiliate organization of the American Cancer Society (ACS). We are dedicated to eliminating cancer as a major health problem by supporting legislative, regulatory, and policy efforts that will make cancer a top national priority.

ACS CAN urges the Food and Drug Administration (FDA) to finalize the proposed rule that would put consumer safety first by requiring sunlamp manufacturers and tanning facility operators to improve device warning labels, eye safety requirements, and sunlamp technical requirements, as well as require emergency panic buttons on the devices.

Background and Health Risks of Tanning Devices

Skin cancer is the most commonly diagnosed cancer in the United States, and rates have been rising for the past 30 years.[1] Nearly 84,000 *invasive* skin cancers (not including basal and squamous cancers) will be diagnosed in the United States this year, and more than 76,000 of these cases will be melanoma, the most serious form of skin cancer.[1] ACS estimates there will be over 68,000 cases of *non-invasive* melanomas diagnosed in the United States in 2016.[1] In total, nearly 14,000 men and women are expected to die of skin cancer this year, and over 10,000 of those deaths will be from melanoma.[1]

In addition to melanomas, there are millions of cases of basal and squamous cell skin cancers. For 2012 – the latest data available – there were an estimated 5.4 million cases of basal and squamous cancers.[1]

The desire for a tanned appearance causes many people, especially young adults and teenagers, to ignore the risks and warnings and put themselves at risk by using indoor tanning devices. Each year, an estimated 11.3 million Americans engage in indoor tanning.[2,3] A 2014 systematic review and meta-

analysis estimated that over 400,000 cases of skin cancer may be attributable to indoor tanning in the U.S.[4] Of the 400,000 cases, approximately 6,200 cases of melanoma have been attributed to indoor tanning.[4] Additionally, over 3,200 indoor tanning-related injuries are treated in U.S. hospital emergency departments each year.[5]

ACS CAN commends the FDA for updating the technical requirements of sunlamp products to reflect the most current scientific knowledge, and adopting the International Electrotechnical Commission's (IEC) safety performance standards, to improve consumer and facility operator awareness of the risks of using tanning devices. We believe that facilitating compliance with these standards will help improve the public's health and prevent many of the injuries attributed to the use of tanning devices.

Annual Exposure Limit, UVC Absolute Limit, and Maximum Timer Interval

ACS CAN appreciates the FDA addressing the annual exposure limit, UVC absolute limit, and maximum timer interval standards to improve patient safety. We believe these are necessary steps toward the safety of the public's health. However, ACS CAN believes that there is no such thing as a truly safe tan, as a tan indicates damage to the skin.

A suntan is the skin's protective response to injury from ultraviolet radiation (UVR). Exposure to UVR, in any form, can lead to DNA damage to skin, resulting in short-term adverse effects such as sunburn, eye damage (i.e., keratitis and corneal burns), syncope (or fainting), and suppression of the immune system.[1,5,6] The damage of UVR is cumulative over an individual's lifetime.[1] This can result in long-term effects such as premature aging of the skin, wrinkles, solar keratosis, permanent eye damage, and skin and ocular cancers.[1,5] Reducing exposure to UVR by seeking shade and wearing sunscreen is critical, but avoiding the use of indoor tanning devices is the most easily avoidable known risk factor for skin cancer.

Panic Button Requirement

ACS CAN commends the FDA for requiring that the panic button or "stop button" be easily accessible and readily identifiable to the user. We agree that this is needed to help protect consumers, by giving users the option to turn the tanning device off for any reason.

Labeling and Warning Statement Requirements

ACS CAN strongly agrees with the FDA that the current warning statement on tanning devices is too long, not user-friendly, and that the content and format should be improved to more effectively communicate the risks associated with sunlamps. We commend the FDA for the changes they made to the warning statement on labels for sunlamp products, as well as the location and spacing requirements for these labels.

We recommend making the warning statement stronger. We are concerned that the required minimum 10-millimeter height font for the word "DANGER" and the 5-millimeter height font for the warning statement cannot be easily read. We urge the FDA to consider a larger minimum font size for both "DANGER – Ultraviolet Radiation (UV)" and the warning statement to improve readability. Additionally, we recommend that "**DANGER – Ultraviolet Radiation (UV)**" be bolded, along with the red font color FDA is requiring, to make it more conspicuous, as research shows that bold type can enhance the saliency of warnings.[7] We also recommend that the sentence: "UV can cause…" be simplified to "UV causes…." This is more succinct, clearer, and shows a direct cause and effect relationship of the risks of

sunlamp products than the language "can cause." The science is strong to show the relationship between UV radiation and skin cancer, skin burns, premature skin aging, and eye damage, so we believe it is more appropriate to use "causes."[1,5,6,8] Finally, we recommend that the protective eyewear language be strengthened to say "Users must wear FDA-compliant eyewear to prevent eye damage, such as burns or cataracts," as we believe the current language does not effectually stress the importance of wearing eyewear while using sunlamp products.

Additionally, ACS CAN strongly encourages the FDA to require a universal or pictorial image be added to the warning statement for the readability of individuals whose native language may not be English or for those who are unable to read. This would ensure that all Americans are properly informed of the dangers to their health from UVR and tanning devices. We urge the FDA to also consider language directing individuals to a website that contains the warning statement in other languages to ensure transparency.

Record and Reporting Requirements for UV Lamp Manufacturers

ACS CAN commends the FDA for the provision requiring UV lamp manufacturers be subject to the same record and reporting requirements as sunlamp product manufacturers. We believe it is important for UV lamps intended to be used in sunlamp products be compliant with these requirements to ensure the safety of consumers. Requiring UV lamps to be subject to these requirements will help to prevent unnecessary burns caused by lamps used in sunlamp products that are not compatible with that product.

Protective Eyewear Requirements

ACS CAN supports the proposal to extend the testing and performance requirements to all protective eyewear manufacturers. We believe compliance with these testing and performance requirements, particularly the UV and visible transmittance requirements, are essential to prevent consumer eye damage (i.e., keratitis and corneal burns) and ocular cancers. Approximately 2,800 new cases of ocular cancer are expected to be diagnosed this year, with intraocular melanoma (or melanoma of the eye) being the most common ocular cancer in adults.[1,9] Although rare, exposure to natural and artificial sunlight (such as tanning devices) over long periods of time has been found to be a risk factor for ocular cancers.[10,11,12] Therefore, this provision could help prevent eye exposure to artificial light from tanning devices.

Recertification of Modified Sunlamp Products

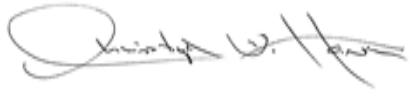
ACS CAN commends the FDA for requiring manufacturers who modify a sunlamp product to be recertified and re-identified in accordance with requirements for manufacturers of new products. This requirement will help to prevent manufacturers from making dangerous device modifications, such as installing stronger bulbs in their tanning devices to achieve greater biological effects. This provision will ensure that all sunlamp product manufacturers, whether they are creating or refurbishing products, must follow the same identification and certification requirements to ensure the safety of the public's health.

Conclusion

ACS CAN appreciates the opportunity to comment on the proposed rule. We believe that finalizing this proposed rule, with the above recommended changes, will put consumer safety first and help protect the public's health. We stand ready to assist the FDA in implementing these changes.

If you have any questions, please feel free to contact me or have your staff contact Rosalie Abbott at Rosalie.Abbott@cancer.org of our federal team or Michelle DelFavero of our policy team at Michelle.DelFavero@cancer.org.

Sincerely,



Christopher W. Hansen
President
American Cancer Society Cancer Action Network

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