AMERICAN ACADEMY OF FAMILY PHYSICIANS
STRONG MEDICINE FOR AMERICA

July 17, 2013

Leslie Kux
Assistant Commissioner for Policy
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

RE: Docket No. FDA–2013–N–0461, Reclassification of Ultraviolet Lamps for Tanning, Henceforth To Be Known as Sunlamp Products

Dear Assistant Commissioner Kux:

On behalf of the American Academy of Family Physicians (AAFP), which represents more than 110,600 family physicians and medical students nationwide, I write in response to the proposed order titled "Reclassification of Ultraviolet Lamps for Tanning, Henceforth to be known as Sunlamp Products" that was issued by the Food and Drug Administration (FDA) in the May 9, 2013 *Federal Register*.

In this FDA order, the agency proposes to reclassify ultraviolet (UV) lamps intended to tan the skin from class I (general controls) exempt from premarket notification to class II (special controls) and subject to premarket notification, and to rename them "sunlamp products." This reclassification would institute stricter regulations to protect the public health and include a strong recommendation against the use of these devices by minors under the age of 18.

The AAFP fully supports this reclassification and appreciates that the FDA bases this change on an assessment of new and valid scientific data related to the health benefits and risks associated with sunlamp products. AAFP policy on skin cancer is based on the United States Preventive Services Task Force (USPSTF) recommendation and we recommend counseling children, adolescents, and young adults ages 10 to 24 years who have fair skin about minimizing their exposure to ultraviolet radiation to reduce risk for skin cancer.

The AAFP also recommends that the FDA produce consumer education materials on the dangers of indoor tanning and we support the proposed inclusion of recommendations against these devices by minors.

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Since the FDA is pursuing these changes using an administrative order instead of a proposed rule, the AAFP appreciates that the FDA is limited and cannot completely restrict a specific population, such as age or skin type, from using sunlamp products. Nevertheless the AAFP supports the FDA in taking this important first step and we encourage the agency to consider additional regulations and educational materials that further address the public health risks associated with sunlamp products.

We appreciate the opportunity to provide these comments and make ourselves available for any questions you might have or clarifications you might need. Please contact Robert Bennett, Federal Regulatory Manager, at 202-232-9033 or rbennett@aafp.org.

Sincerely,

Glen Stream MD

Glen Stream, MD, MBI, FAAFP
Board Chair