AMERICAN ACADEMY OF FAMILY PHYSICIANS
STRONG MEDICINE FOR AMERICA

March 15, 2016

Leslie Kux, Associate Commissioner for Policy
U.S. Food and Drug Administration
Division of Dockets Management (HFA–305)
5630 Fishers Lane, Rm. 1061
Rockville, MD 20852

Re: Restricted Sale, Distribution, and Use of Sunlamp Products (FDA–2015–N–1765) and Sunlamp Products; Proposed Amendment to Performance Standard (FDA–1998–N–0880)

Dear Associate Commissioner Kux:

On behalf of the American Academy of Family Physicians (AAFP), which represents 120,900 family physicians and medical students across the country, I write in response to the proposed rules titled "Restricted Sale, Distribution, and Use of Sunlamp Products" and "Sunlamp Products; Proposed Amendment to Performance Standard" that were published by the Food and Drug Administration (FDA) in the December 22, 2015 *Federal Register*.

The AAFP supports the FDA proposals to:

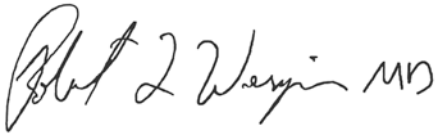
- Establish device restrictions for sunlamp products, which would restrict their use to individuals age 18 and older, require prospective users to sign a risk acknowledgement certification before use, and require the provision of user manuals.
- Amend the performance standard for sunlamp products and ultraviolet (UV) lamps to improve consumer safety by requiring more effective communication regarding the risks posed by these products.

The AAFP's policy on skin cancer is based on the United States Preventive Services Task Force (USPSTF) recommendation. 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 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.

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,



Robert L. Wergin, MD, FAAFP
Board Chair

CC:
Neil R.P. Ogden, Center for Devices and Radiological Health, FDA