United States Senate
WASHINGTON, DC 20510

July 29, 2013

The Honorable Margaret Hamburg
Commissioner
U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

Dear Commissioner Hamburg:

We write to urge the Food and Drug Administration (FDA) to finalize its proposed order to reclassify sunlamp products to Class II medical devices promptly, update the warning labels on sunlamps, and restrict minors under the age of 18 from the use and purchase of sunlamps.

We commend the FDA for taking an important first step in protecting individuals from the dangers of sunlamp products with its proposed order. Indeed, indoor tanning is a growing health issue. One million Americans, approximately 70 percent of whom are girls and women, visit a tanning salon each day.

Currently, sunlamp products are classified as Class I medical devices, an indication that there is a reasonable assurance of its safety, much like that of other Class I medical devices like elastic bandages and examination gloves. However, there is documented risk of exposure to ultraviolet light stemming from sunlamp products. Moreover, in a review of 19 international studies, the World Health Organization (WHO) found that the use of sunlamp products increases the risk of skin cancer. Reclassifying sunlamp products to Class II medical devices would ensure a comprehensive pre-market review and that certain performance standards are met, consistent with riskier devices.

The proposed order would also update the warning labels on sunlamp products, which will help ensure consumers are aware that there is a risk of using these devices. Warning labels on sunlamp products have not been updated since 1979. The current out-of-date labels are printed in small typeface and often placed out of direct sight of the consumer. This has been area of longstanding concern. As such, we urge the FDA to require that the text and placement of sunlamp warning labels be revised, consistent with the "Alternative Warning Statement" outlined in the 2011 Report to Congress pursuant to Section 230 of the Food and Drug Administration Amendments Act of 2007.

We also strongly urge the FDA to implement a special control on sunlamp products with respect to the use and purchase of the devices by minors under the age of 18. The WHO also reported that the risk of melanoma increases by 75 percent when use of sunlamps start before 35 years of age. As you know, age restrictions exist for the use and purchase of other known carcinogens, like cigarettes. To be sure, prohibiting minors under the age of 18 from using or purchasing sunlamp products would be consistent with existing rules and regulations.

Thank you for taking action to address the dangers posed by sunlamp products, and we look forward to working with you as you finalize this proposed order.

Sincerely,

Jack Reed

Tom Harkin

Patrick Leahy

Robert F. Menendez

Sheldon Whitehouse

Richard Blumenthal

Dianne Feinstein

Elizabeth Warren

Jay Rockefeller