DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Silver Spring, MD 20993

The Honorable Carolyn B. Maloney
House of Representatives
Washington, D.C. 20515-3212

NOV 17 2014

Dear Ms. Maloney:

Thank you for your letter of June 27, 2014, regarding the Food and Drug Administration's (FDA or the Agency) recent reclassification order for sunlamp products. FDA recognizes that indoor tanning can damage skin and increase the risk of developing skin cancer. To that end, FDA's recent reclassification order requires, among other things, that sunlamp products carry a visible black-box warning on the device stating that sunlamp products should not be used on persons under the age of 18 years.

In your letter, you urge FDA to consider whether "additional controls are necessary to protect the health of young Americans." In particular, you urge FDA to impose an age restriction for use of tanning beds. As you are aware, during the March 2010 General and Plastic Surgery Devices Advisory Panel, some members of the panel favored an age restriction for indoor tanning (i.e., individuals under a certain age would not be permitted to use sunlamp products) and spoke in favor of a cutoff age of 18. As provided under section 520(e) of the Federal Food, Drug, and Cosmetic Act (FD&C Act), such restrictions would require notice and comment rulemaking. As such, the Agency has developed proposed rulemaking establishing device restrictions for sunlamp products. In September 2014, this proposed rule, "*General and Plastic Surgery Devices: Restriction of Sunlamp Products,*" was submitted to the Office of Management and Budget for review[1] and it is pending acceptance.

Thank you, again, for your support of this important public health issue.

Sincerely,

Ruth Watson
Acting Supervisory Congressional
Affairs Specialist

[1] See "General and Plastic Surgery Devices: Restriction of Sunlamp Products" (RIN 0910-AH14), available at *http://www.reginfo.gov/public/do/eAgendaViewRule?pubId=201404&RIN=0910-AH14.*