July 23, 2018

Honorable Scott Gottlieb, MD
Commissioner
Food and Drug Administration
U.S. Department of Health and Human Services
10903 New Hampshire Avenue
Silver Spring, MD 20993


Dear Commissioner Gottlieb,

On behalf of the more than 13,800 United States-based members of the American Academy of Dermatology Association (AADA), I am writing to provide comments to the Food and Drug Administration (FDA) on the Draft Guidance for Industry titled Maximal Usage Trials for Topical Active Ingredients Being Considered for Inclusion in an Over-the-Counter Monograph: Study Elements and Considerations. The AADA is committed to excellence in the medical and surgical treatment of skin disease; advocating high standards in clinical practice, education, and research in dermatology; and supporting and enhancing patient care to reduce the burden of disease.

Given the importance of sunscreen in the prevention of skin cancer and premature aging, the AADA is increasingly interested in the introduction of new safe and effective sunscreen active ingredients to benefit our patients and the public.

Earlier this month, Hawaii Governor David Ige signed into law a prohibition on the sale and distribution of sunscreens containing oxybenzone and octinoxate, citing environmental concerns, which will take effect in 2021. Last month, the Center for Biological Diversity petitioned the FDA to ban these ingredients in sunscreens as well as personal care products stating concern about adverse effects on listed endangered or threatened species. This activity implicates broad-spectrum chemical ingredients currently included on the FDA sunscreen over-the-counter (OTC) monograph available to be used in sunscreen formulations marketed in the United States. As these events further limit access to a broad range of sunscreen ingredients, we strongly encourage the FDA and industry stakeholders to expedite collaboration on study elements and considerations for human dermal absorption studies in order for new safe (and effective) sunscreen active ingredients to become available in the United States.

In May 2016, Theresa (Teri) Michele, MD, Director, Division of Nonprescription Drug Products, Office of New Drugs, FDA’s Center for Drug Evaluation and Research (CDER) and others at the FDA met with Henry W. Lim, MD, FAAD, our immediate past president and AADA staff to discuss safety testing requirements including the maximal usage trial (MUST) required for new and pending sunscreen ingredient time-and-extent applications (TEAs). The AADA has and continues to engage with both the FDA and industry stakeholders separately. We remain hopeful that we can facilitate discussion between the FDA and industry
with a desired goal that the FDA will set forth study elements and considerations that industry is willing to perform. Industry would ideally then provide the results to the FDA so that the FDA can make Generally Recognized as Safe and Effective (GRASE) determinations. This long-lasting impasse is only to the detriment of the American public and must be addressed now so that consumers have meaningful access to this major type of photoprotection.

In addition, FDA proposes that MUST be conducted for all topical active ingredients being considered for inclusion in an OTC monograph, not only sunscreen active ingredients, and sets forth draft requirements. In your statement on this draft guidance that was issued on May 22, you said that the FDA “hope[s] to encourage more product innovation.” We encourage the FDA and industry to work together and mutually agree upon protocol for safety studies appropriately tailored for each monograph so that absorption characteristics can be properly evaluated.

We appreciate the opportunity to provide comments to the FDA on the safety of topical active ingredients to be considered for inclusion in an OTC monograph, namely sunscreen, and look forward to continued engagement on this issue. If you have any questions, please contact Natasha Pattanshetti, manager of regulatory policy at (202)712-2618 or npattanshetti@aad.org.

Sincerely,

Suzanne Olbricht, MD, FAAD  
President  
American Academy of Dermatology Association

cc:  Elaine Weiss, JD, Executive Director & CEO  
     Barbara Greenan, Senior Director, Advocacy & Policy  
     Leslie Stein Lloyd, JD, Director, Regulatory and Payment Policy