August 31, 2011

Margaret Hamburg, MD
Commissioner
Food and Drug Administration
Division of Dockets Management (HFA–305)
5630 Fishers Lane
Room 1061
Rockville, MD 20852

Subject: FDA–1978–N–0018; Revised Effectiveness Determination; Sunscreen Drug Products for Over-the-Counter Human Use

Dear Commissioner Hamburg,

I am contacting you on behalf of the more than 16,000 members of the American Academy of Dermatology Association (Academy) to share our comments on the proposed rule on revised effectiveness determination for over-the-counter sunscreen drug products, as published in the Federal Register on June 17, 2011. The Academy appreciates the opportunity to join the Food and Drug Administration (FDA) to present the recent sunscreen testing and labeling ruling, and respectfully submits our comments for consideration as final regulations are determined on the effectiveness of sunscreen products.

Sun Protection Factor (SPF) Cap

In 2007, the FDA proposed an increase in the SPF cap of sunscreen products from SPF 30+ to SPF 50+. In our comment letter of November 2, 2007, the Academy indicated its support of this proposed change as an improvement over the original 1999 proposal citing that the increase would greatly benefit the majority of consumers who need or desire additional photoprotection due to personal or environmental risk factors. We recognized that the increase of the cap to SPF 50+ would also better allow consumers to partially compensate for underapplication of sunscreen, a widespread issue the Academy continues to address in our public education efforts. We applaud the FDA for acknowledging the clinical benefit of sunscreen and for confirming that SPF testing will permit this label information to be accurate when used as directed.

The Academy also supports the FDA’s willingness to accept data demonstrating clinical effectiveness for products with an SPF over 50 and its consideration of further raising the SPF cap. Our 2007 comments on this issue were directly related to support for raising the prior proposed cap from SPF 30+ to SPF 50+, and were based on the absence of clinical data at the time to support higher SPF sunscreen as well as the uncertainty of SPF testing accuracy. Today, as in 2007, the Academy does not have an official position regarding an overall SPF cap. However, if the FDA believes a cap is necessary, we reiterate our support for the increase from 30+ to 50+, and encourage the agency to allow for higher SPF values based upon clinical studies and validated SPF assessments.
Since 2007 several publications have highlighted the potential clinical benefit of such products. Sunscreens with higher SPF (SPF >60) have recently been shown to:

- Prevent development of actinic keratoses and invasive squamous cell carcinoma in organ-transplant recipients\(^1\),
- Reduce lesion formation in patients with polymorphic light eruption (PMLE), and cutaneous lupus erythematosus\(^2\)\(^3\), and,
- Minimize erythema and wheal development in patients with solar urticaria.\(^4\)

Likewise, a sunscreen with SPF 85 has demonstrated ability to more effectively protect against sunburn compared to an SPF 50 sunscreen in a high-UV environment.\(^5\)

Importantly, the FDA has also confirmed via this proposed ruling that SPF testing is reliable and reproducible for sunscreen with an SPF of up to 80. Therefore, the Academy is supportive of further increases in the maximum allowable SPF (i.e. greater than SPF 50+) as substantiated by clinical efficacy data and corroborated by accurate SPF testing.

The potential benefit of higher SPF sunscreen may also extend beyond these specific populations and exposure scenarios, in so far as higher SPF sunscreen will also be accompanied by an increase in UVA broad-spectrum protection, a critical feature of sunscreen in order to reduce the risk of skin cancer and early skin aging. Given this, the Academy is not supportive of a specific or different labeling for sunscreen products over SPF 50 suggesting a limitation to those with increased risk or for use in extreme conditions, as we believe this could lead to undue confusion for consumers, patients and physicians.

We thank you for the opportunity to provide comments regarding the revised effectiveness of sunscreen drug products and commend the FDA for their continued attention and dedication to these sunscreen regulations. We look forward to the completion of the entire sunscreen monograph. Please direct any questions to Barbara Greenan, Senior Director, Government Affairs, at bgreenan@aad.org or 202-842-3555.

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Sincerely,

Ronald M. Moy, MD, FAAD
President

cc:  Daniel M. Siegel, MD, MS, President-Elect
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