June 27, 2019

Norman "Ned" E. Sharpless, MD
Acting Commissioner of Food and Drugs
US Food and Drug Administration
10903 New Hampshire Ave.
Silver Spring, MD 20993

Re: Sunscreen Drug Products for Over-the-Counter Human Use [Docket No. FDA-1978-N-0018]

Dear Acting Commissioner Sharpless,

On behalf of the American Academy of Dermatology (AAD) and American Academy of Dermatology Association (AADA), which represent more than 13,800 dermatologists across the country, we appreciate this opportunity to comment on the Food and Drug Administration (FDA) proposed rule, Sunscreen Drug Products for Over-the-Counter Human Use. AADA is committed to excellence in 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. One in four Americans suffers from a skin disease. Dermatologists diagnose and treat more than 3,000 diseases, including skin cancer, psoriasis, immunologic diseases, and many genetic disorders. In 2016, the AAD studied the effects of skin disease on the United States patient population and the resulting report can be found online.\(^1\)\(^,\)\(^2\)

As dermatologists on the front lines fighting skin cancer and treating numerous skin diseases, we are advocating for our patients and the public to have access to sunscreen products, which have been proven to protect against skin cancer, skin aging, and sunburn. Sunscreen use can prevent or lessen the adverse effects of skin disease and its continued access is of utmost importance as FDA finalizes the over-the-counter (OTC) sunscreen monograph by November 26, 2019 as mandated by Congress through the Sunscreen Innovation Act.

Sunscreen is Part of a Comprehensive Photoprotection Plan

Skin cancer is the most common cancer in the United States,\(^3\)\(^,\)\(^4\) and dermatologists see, evaluate, and treat the adverse impact it has on their patients’ lives every day. Unprotected exposure to the sun’s ultraviolet (UV) rays is a known major risk factor for skin cancer. AAD encourages the public to continue to protect themselves from the sun by seeking shade; wearing protective clothing, including a lightweight, long-sleeved shirt, pants, a wide-brimmed hat and sunglasses; and generously applying a broad-spectrum,

\(^1\) https://www.aad.org/about/burden-of-skin-disease
water-resistant sunscreen with a sun protection factor (SPF) of 30 or higher to exposed skin. Because severe sunburns during childhood may increase one’s risk of melanoma, children should be especially protected from the sun.5

The public should continue to use sunscreen products as well as other photoprotective measures to limit exposure to natural and artificial UV light given that it is a risk factor for all types of skin cancer. In addition, the majority of melanoma cases are attributable to UV exposure.6,7,8 Increasing intermittent sun exposure in childhood and during one’s lifetime is associated with an increased risk of squamous cell carcinoma, basal cell carcinoma and melanoma.9 Research suggests that regular sunscreen use reduces melanoma risk.10,11 Higher melanoma rates among men may be due in part to lower rates of sun protection.12,13 Even one blistering sunburn during childhood or adolescence can nearly double a person’s chance of developing melanoma.14 Experiencing five or more blistering sunburns between ages 15 and 20 increases one’s melanoma risk by 80 percent and nonmelanoma skin cancer risk by 68 percent.15

AADA once again thanks FDA for meeting with our physician leaders and staff on April 17 to discuss public communications about sunscreen and sun protection generally. While our organizations share the sentiment that the public should continue using sunscreen products during this rulemaking process, public confusion resulted, and misconceptions have spread about the safety of sunscreen products. Public confusion and misconceptions were exacerbated with the publication of the results of a randomized clinical trial conducted by FDA to study the Effect of Sunscreen Application Under Maximal Use Conditions on Plasma Concentration of Sunscreen Active Ingredients.16 AADA is communicating with both the public and patients using online resources, such as the AAD’s Sunscreen Resource Center, located at www.aad.org/sunscreen as well as having media-trained experts contributing to media coverage on this

topic. We ask that FDA to be more proactive in explaining the importance of using sunscreen products and the rulemaking process on sunscreen access moving forward.

**Importance of Sunscreen Product Access When Generating Additional Ingredient Safety Data**

As mentioned, UV light exposure is a risk factor for all types of skin cancer and sunscreen use is one photoprotection method to protect against it. AADA is not aware of any reports of serious adverse effects of sunscreen products, specifically any related to systemic absorption. AADA is focused on access to safe and effective sunscreen products for the benefit of patients and the public (i.e., consumers) and has not formed a specific position on any specific safety testing methodology other than that we support testing that is reasonable and as close to real-world use as possible. While we have not taken a specific position, we continue to take part in conversations with all stakeholders including Congress, FDA, other medical specialty organizations as well as patient advocacy groups, focusing our discussions on the importance of access and to understand the types of testing being proposed and required. With respect to testing, we would like to further understand how FDA determined that a steady state blood level less than 0.5 nanograms (ng)/milliliter (mL) result in an adequately conducted human pharmacokinetic maximal usage trial (MUST) would alleviate the need for a systemic carcinogenicity study, specifically for sunscreen ingredients.

As we have done and continue to do with the eight pending time-and-extent applications (TEAs) for sunscreen ingredients available abroad but not in the United States at this time, we encourage FDA and industry to come together to agree upon this methodology and not only continue but to improve upon providing access to sunscreen ingredients and products. In the process of safety data generation, analysis, and ultimately FDA’s generally regarded as safe and effective (GRASE) determinations, AADA does not want consumers to be deterred from using sunscreen products to protect themselves.

It is our understanding that FDA will be granting “deferrals” for specific ingredients for which industry needs additional time for which to generate safety data. FDA should express to the general public its intention to allow the deferral ingredients to remain on the market prior to the publication of a final rule for each specific ingredient and FDA’s expected overall timeframe of approximately three to four years.

**AADA Recommendations to Consider for Dosage Form Requirements**

FDA proposes that the following dosage forms are GRASE (Category I): Oils, lotions, creams, gels, butters, pastes, ointments, and sticks. It also proposes classifying sprays as Category I provided that necessary testing of final products is performed to minimize risk from unintended inhalation (particle size restrictions) and flammability (flammability and drying time testing). AADA recognizes the risks involving unintended inhalation and flammability of spray sunscreens and supports FDA requiring additional testing to minimize these risks.

FDA expects to require labeling for sunscreen spray use. AADA asks that FDA consider AAD’s recommendations on spray sunscreen use for the dosage form requirements when finalizing the monograph, which are as follows:

1. **Hold the nozzle close to your skin and spray generously.** Most adults need at least one ounce of sunscreen — about enough to fill a shot glass — to fully cover the body. Since it can be difficult to determine how much spray sunscreen is enough, a good rule of thumb is to spray until your skin glistens. It’s also important to remember that a typical 6-ounce bottle of spray sunscreen contains six applications.
2. **Rub it in thoroughly.** To ensure that you didn’t miss any spots and that you have an even layer of coverage, rub the sunscreen in after spraying.

3. **Avoid inhaling spray sunscreen.** Current U.S. Food and Drug Administration regulations do not pertain to spray sunscreens, although the agency continues to evaluate these products to ensure safety and effectiveness. Do not inhale spray sunscreen, and never spray sunscreen around or near your face or mouth. Instead, spray the sunscreen on your hands first and then apply it to your face.

4. **Avoid using spray sunscreen on windy days.** These conditions make it more difficult to apply the sunscreen and easier to accidentally inhale it.

5. **Never apply spray sunscreen near heat or open flame, or while smoking.** Although sunscreen isn’t usually flammable, it can be when used in aerosol form. Never spray it by a grill, candles or other source of fire, and make sure it is thoroughly rubbed in and dry before approaching any open flames.

### Higher SPF Sunscreen Products Benefit Patients

FDA is proposing to address (1) variability in SPF values and (2) additional clinical benefits associated with SPF 60 sunscreens. FDA is proposing to raise the maximum labeled SPF value for sunscreen monograph products to SPF 60+ based on its data showing additional clinical benefit provided by SPF 60 sunscreens that also provide broad spectrum protection. While AADA appreciates FDA raising the maximum labeled SPF value, sunscreens labeled with SPF 100+ have additional clinical benefits that have been published in a peer reviewed scientific journal. Researchers found that SPF 100+ sunscreen was significantly more effective in protecting against sunburn than SPF 50+ sunscreen in actual use conditions. It is our understanding that SPF 50+ was used in this study based on the previously proposed maximum labeled SPF value.

Also, on a regular basis, the benefits of high SPF sunscreen have been shared by patients with their dermatologists especially those who have had organ transplants as well as diagnosed with Stage 4 metastatic melanoma, for example. These high SPF value products offer better protection and compensate for underapplication of sunscreen products by consumers. Having a maximum labeled SPF value would adversely impact patients and sunscreen product innovation.

It is AADA’s understanding that the variability in measured SPF values is attributable to lack of consistent product application as well as that the minimal erythema dose (MED) is a visual assessment. We see an opportunity to further standardize measured SPF value determinations and develop MED assessment technology for this test.

### Broad Spectrum Requirement

Currently, sunscreens with broad spectrum label must have a critical wavelength of equal or greater than 370 nanometers (nm). FDA proposes that to pass the broad-spectrum test, an additional requirement is that a sunscreen product must show that it provides a UVA I/UV ratio of 0.7 or higher. AADA recommends using in vitro critical wavelength as a measure of assessing broad-spectrum as opposed to the UVA I/UV ratio. To improve the broad spectrum properties of sunscreens, AADA asks that FDA consider increasing the critical

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wavelength requirement from 370 nm to equal or greater than 375 nm, which is in line with international standards.\textsuperscript{18}

FDA also proposes requiring that all sunscreen products with an SPF 15 or higher satisfy this revised broad-spectrum test in order to ensure that consumers have adequate UVA protection given the increasing evidence of increasing harms of exposure. If the proposed revised broad-spectrum test is not satisfied, then the product would not be GRASE. AADA supports all sunscreen products with an SPF 15 or higher being broad spectrum for consumers to be assured that they are purchasing and using an appropriate product. FDA shared in the proposed rule that it considered not allowing products with SPF less than 15. AADA agrees with FDA’s assessment that products with SPF below 15 are better than no product. But consumers must be aware that these products are not “sunscreen” and do not protect against skin cancer and skin aging. AADA appreciates that that FDA is open to suggestions for what to call these products. We recommend that these products be called “Low SPF (dosage form)” (e.g., Low SPF Lotion) and SPF 15 or higher sunscreen products include a label of “broad-spectrum sunscreen” should that requirement be finalized. In addition, for consumers to truly understand what “Low SPF” means, AADA asks that FDA require a checklist be included on the front of the product packaging as depicted. On the “low SPF” product, only sunburn is checked off on the list and skin aging and skin cancer are not. On the “broad-spectrum sunscreen” product, sunburn, skin aging, and skin cancer are all checked off.

AADA Supports FDA’s Tentative Determination that Sunscreen-Insect Repellent Combination Products Are Not GRASE

AADA supports FDA’s proposal to determine that sunscreen-insect repellent combination products are not GRASE especially given the incompatibilities between FDA and Environmental Protection Agency (EPA) labeling requirements, and data suggesting that combining certain sunscreen ingredients with diethyltoluamide (DEET) may increase ingredient absorption. In addition, the AAD has advised against using these combination products because sunscreen products should be applied liberally and often, and insect repellent should be applied sparingly and less often than sunscreen.

Compliance with the Final Monograph

FDA discusses effective and compliance dates in the proposed rule. FDA proposes that the effective date of the proposed rule is November 26, 2019 as required by the Sunscreen Innovation Act. However, the compliance date would be different. FDA proposes that the compliance date is one year after the effective date and that any products introduced into interstate commerce (where FDA has jurisdiction) prior to this date are not subject to enforcement action. AADA acknowledges that the timing should be decided between FDA and industry so long as access to sunscreen products is not adversely impacted as a result and the timelines are clearly communicated to and understood by stakeholders (including consumers).

Thank you for the opportunity to comment on this proposed rule affecting consumer access to sunscreen products. We appreciate the open doors of communication with FDA and look forward to continued collaboration. Please contact Natasha Pattanshetti, JD, MPH, manager, regulatory policy at (202) 712-2618 or npattanshetti@aad.org if you have any questions or if we can provide additional information concerning this AADA advocacy priority.

Sincerely,

George J. Hruza, MD, MBA, FAAD
President, American Academy of Dermatology

cc: Irv Bomberger, Interim Executive Director
    Barbara Greenan, Chief Advocacy and Policy Officer
    Leslie Stein Lloyd, JD, CAE, Director, Regulatory and Payment Policy