December 20, 2024

Robert M. Califf, MD
FDA Commissioner
Dockets Management Staff (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Rm. 1061
Rockville, MD 20852

Submitted electronically via https://www.regulations.gov/

RE: Reauthorization of the Over-The-Counter Monograph Drug User Fee Program; Public Meeting; Request for Comments [Docket No. FDA-2023-N-3575]

Dear Commissioner Califf,

The American Academy of Dermatology Association (Academy) appreciates the opportunity to provide comments on the Food and Drug Administration's (FDA) request for comments titled, "Reauthorization of The Over-The-Counter (OTC) Monograph Drug User Fee Program (OMUFA); Public Meeting; Request for Comments." Reauthorizing OMUFA is necessary for modernizing sunscreen regulations, streamlining ingredient evaluations, and ensuring public access to innovative and safe sunscreen products. **The Academy urges the FDA to ensure broad access to safe and effective sunscreen products by prioritizing timely updates to the OTC sunscreen monograph while collaborating with stakeholders to support these efforts.**

As the leading society in dermatological care, representing nearly 17,500 dermatologists nationwide, the Academy is committed to excellence in the medical and surgical treatment of skin disease, advocating for high standards in clinical practice, education, and research in dermatology and dermatopathology; and driving continuous improvement in patient care and outcomes while reducing the burden of disease.

Timely Updates to the OTC Sunscreen Monograph
The Academy urges the FDA to prioritize timely updates to the OTC sunscreen monograph to

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ensure that the general public has broad access to sunscreen products that are safe and effective. Skin cancer is the most common cancer in the United States, with one in five Americans expected to develop it during their lifetime.[1] Research has shown that regular sunscreen use can reduce melanoma incidence by up to 50%, making access to OTC sunscreen a proven tool for preventing skin cancer.[2-5]

The Academy appreciates the FDA's efforts to update sunscreen regulation as part of the agency's reforms in modernizing the OTC drug review process. Delays in updating the sunscreen monograph could hinder access to innovative products and limit public health protections related to skin cancer. Updating the sunscreen monograph in a timely manner is necessary not only to reflect advancements in science and technology but also to meet the needs of the public and provide access to high-quality, safe sun protection products.

Stakeholder Collaboration

To support updates to the OTC sunscreen monograph and advance the goals of OMUFA reauthorization, the Academy urges the FDA to convene a scientific symposium to bring together subject matter experts and other stakeholders to share data on sunscreen safety and effectiveness. The reauthorization of OMUFA provides an opportunity for the FDA to address regulatory challenges in sunscreen safety and access through collaboration with stakeholders, including dermatologists, researchers, and industry leaders. It also supports the evaluation and timely implementation of updates to the OTC sunscreen monograph.

Stakeholder engagement and dialogue are particularly important as the FDA considers the proposed administrative order issued in September 2021, titled "Amending Over-the-Counter (OTC) Monograph M020: Sunscreen Drug Products for OTC Human Use." The proposed order includes revisions to active ingredient requirements, labeling, dosage forms, and testing procedures to ensure nonprescription sunscreen products meet modern safety and efficacy standards. The Academy appreciates FDA's commitment to safety and believes non-governmental stakeholders can help facilitate the collection of safety and effectiveness information. The Academy strongly encourages the FDA to consider hosting a scientific symposium as it would provide valuable insights to inform the agency's decision-making for the

[1] Stern RS. Prevalence of a history of skin cancer in 2007: results of an incidence-based model. Arch Dermatol. 2010;146(3):279-282. doi:10.1001/archdermatol.2010.4
[2] Arnold M, de Vries E, Whiteman DC, et al. Global burden of cutaneous melanoma attributable to ultraviolet radiation in 2012. Int J Cancer. Sep 15 2018;143(6):1305-1314. doi:10.1002/ijc.31527
[3] Islami F, Sauer AG, Miller KD, et al. Cutaneous melanomas attributable to ultraviolet radiation exposure by state. Int J Cancer. Sep 1 2020;147(5):1385-1390. doi:10.1002/ijc.32921
[4] Sander M, Sander M, Burbidge T, Beecker J. The efficacy and safety of sunscreen use for the prevention of skin cancer. CMAJ. Dec 14 2020;192(50):E1802-E1808. doi:10.1503/cmaj.201085
[5] Green AC, Williams GM, Logan V, Strutton GM. Reduced melanoma after regular sunscreen use: randomized trial follow-up. J Clin Oncol. Jan 20 2011;29(3):257-63. doi:10.1200/JCO.2010.28.7078

proposed order. Bringing together experts and stakeholders to share data on sunscreen safety and effectiveness could help ensure that updates to the OTC sunscreen monograph reflect the latest research and align with the goals of OMUFA reauthorization. Without these efforts, it risks consumer confidence and reduces access to sunscreens that meet their needs and preferences, potentially discouraging regular use and hindering efforts to prevent skin cancer.

Thank you again for the opportunity to comment on the reauthorization of OMUFA. The Academy remains a resource in FDA's efforts in evaluating access and ensuring the safety and effectiveness of sunscreen OTC products. Please do not hesitate to reach out to Nija Chappel, JD, MPH, Manager, Regulatory Policy, at nchappel@aad.org if you have any questions or need additional information. Thank you for your attention to this matter.

Sincerely,

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