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Division of Dockets Management (HFA-305)
U.S. Food and Drug Administration
5630 Fishers Lane
Room 1061
Rockville, MD 20852

Friday, November 12, 2021

EWG comments regarding Proposed Order ID Number OTC000008 and Docket No. FDA-1978-N-0018: “Amending Over-the-Counter (OTC) Monograph M020: Sunscreen Drug Products for OTC Human Use”

The Environmental Working Group (EWG) is a nonprofit public health and environmental research and advocacy organization based in Washington, D.C. For more than 20 years EWG has conducted research on the safety of ingredients in personal care products, including sunscreens. Annually for the past 15 years, EWG has published a guide for consumers on sunscreen products, available at <https://www.ewg.org/sunscreen/>, evaluating the efficacy of product formulations alongside the potential ingredient hazards. EWG organized a sun safety campaign focused on providing tips to consumers about how to reduce potential long-term damage from UV overexposure. These tips, which include avoiding sunburn, covering up, and using sunscreen, when appropriate, represent the best public advice supported by scientific research.¹

This year EWG published a research paper on the measured UV protection of 51 sunscreen products, finding UV and especially UVA protection significantly below what the SPF value would indicate.

EWG respectfully submits these comments to the Food and Drug Administration. As requested, we have focused our comments on information that has become available since the 2019 proposed rule. EWG previously submitted two sets of comments on the 2019 proposed rule and continues to support those comments.²

1) The FDA must act expeditiously

It is imperative that FDA move forward quickly to ensure that sunscreen users are not subject to long-term health harms from product use. The FDA should also ensure that sunscreen products are as effective as possible at reducing both UVB and UVA radiation. As it currently stands with the publication of *Final Administrative Order (OTC000006), Over-the-Counter Monograph M020: Sunscreen Drug Products for*



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Over-the-Counter Human Use, the regulation of sunscreen active ingredients and their approved concentrations represent the agency position in 1999. As the FDA has noted, the use of sunscreens and the safety data needed to determine safe use have changed considerably in the past two decades. The FDA proposed numerous changes to sunscreen regulations in February 2019, and those changes have been reintroduced in the proposed sunscreen order, which cannot be finalized until fall 2022 at the earliest. Any changes for consumers will take years to be implemented and reach store shelves, and substandard products currently on the market will likely remain for an additional three to five years.³ At least four studies linking oxybenzone exposure to health harm have been published since the 2019 proposal. In the past year, the European Commission Scientific Committee on Consumer Safety published scientific reviews and safety opinions on three sunscreen active ingredients. The European Commission opinions found two active ingredients, oxybenzone and homosalate, unsafe for use at concentrations allowed by the FDA.⁴ Based on well-established scientific evidence of harm from overexposure to UVA radiation change to product efficacy is also long overdue. Some of the more substantive changes to efficacy standards for UVA protection were first proposed by the FDA in 2011. It is an urgent health priority that FDA move as quickly as possible to ensure that sunscreens be both effective at reducing the health harm from UV exposure and safe for long-term use. Consumers have waited too long.

- 2) There is sufficient scientific data to resolve uncertainty about the GRASE status of oxybenzone and homosalate

Sunscreen ingredients that absorb through the skin at levels that could cause long-term health impacts cannot be considered GRASE. The European Commission opinions on oxybenzone and homosalate identified numerous health hazards, and the scientific evidence published after 2019 has found oxybenzone can act as an endocrine disruptor and may increase the risk of breast cancer and endometriosis.⁵ In addition, the National Toxicology Program found equivocal evidence of carcinogenicity in rats after observing increases in thyroid tumors and uterine hyperplasia in females with high exposure to oxybenzone (NTP 2020). The European Commission found current human exposure levels to oxybenzone in sunscreen to be unsafe and proposed a concentration restriction of 2.2 percent – lower than the limited amount allowed in U.S. sunscreens, which is up to 6 percent.⁶ A recent opinion from the European Commission found that homosalate was not safe to use at concentrations up to 10 percent and recommended a maximum concentration of 1.4 percent, because of concerns for potential endocrine disruption (SCCS 2020). The FDA allows U.S. sunscreen manufacturers to use it in



concentrations up to 15 percent. Currently, sufficient scientific data indicates that these compounds are not generally recognized as safe for their intended use.

- 3) Sunscreen companies are not making a good faith effort to substantiate that their ingredients are safe

More than seven years ago, in 2014, the Nonprescription Drug Advisory Committee met and established the types and extent of safety tests required for sunscreen active ingredients. The agency subsequently published guidance for the industry on safety data required for new sunscreen ingredients to enter the market. The FDA stated the “recommended studies are not novel and are consistent with our standard data requirements for NDA-approved topical drug products for chronic use.”⁷ For active ingredients in sunscreen that absorb through the skin, FDA outlined these same testing requirements as being necessary to make a GRASE determination. The agency itself tested sunscreen skin absorbance from commercial sunscreen products and found that all tested active ingredients absorbed at a concentration that would require long-term toxicity testing. The public statements and testing plans from the sunscreen industry continue to focus on repeating those tests of skin absorption, instead of initiating comprehensive toxicity testing, as required. Further, and in direct contrast to the statements made by FDA that there is insufficient data to substantiate the safe use of sunscreens, the Personal Care Products Council put out a press release touting the upcoming publication of the deemed final order as confirmation “that active ingredients currently used in sunscreens on the market today are generally recognized as safe and effective (GRASE).”⁸ Americans are being advised to apply sunscreen daily to a large portion of their body, yet there is an unwillingness to test these products for long-term toxicity.

In addition to testing the active ingredients, the FDA should take action to ensure products are free from contamination. Independent analysis of commercial sunscreen products for benzene contamination led to a citizen petition and a large recall of sunscreen products from store shelves.⁹ The current proposed order from FDA provides little assurance to the public that products on store shelves will be free from benzene, PFAS or other contaminants.

- 4) Our newly published sunscreen testing results highlight the need for greater sunscreen efficacy with respect to UVA protection



EWG published a peer-reviewed study in *Photodermatology, Photoimmunology & Photomedicine* in October 2021 that evaluated the in vitro protection provided by 51 common sunscreens on the U.S. market with SPF values that varied from 15 to 110.¹⁰ On average, the tested sunscreen products reduced UVA radiation just one-quarter of what would be expected from the SPF value. Overexposure to UVA radiation is associated with skin cancer, free radical generation, and immune harm. The currently proposed sunscreen order does not go far enough to address this deficiency in UV protection. Although the FDA proposed change to substantiate broad spectrum protection by requiring a UV/UVA1 ratio of 0.7 or higher, there remain significant shortcomings in the FDA approach, including the continued focus on SPF protection and the lack of any required correlation between in vitro and in vivo tests used to meet the proposed standards.

The problem with the focus on SPF and the lack of any correlation between in vitro and in vivo test results is illustrated clearly in our published analysis where just 35 percent of the tested products could meet the EU UVAPF/SPF 1:3 ratio standard but an estimated 67 percent would meet the proposed standard of UVA1/UV ≥ 0.7 . The products most likely to fail the EU standard but pass the proposed FDA standard were SPF values over 50 and those products with the greatest discrepancy between the labeled SPF and the in vitro measured UV-protection. All our in vitro and modeled sunscreen test results are provided in supplemental information, <https://onlinelibrary.wiley.com/doi/10.1111/phpp.12738>.

- 5) It is a problem that UV protection is only presented to the public through SPF values

Since 1976, when FDA first initiated the sunscreen monograph system, sun protection products have always been evaluated on the basis of SPF value. Over the four and half decades since, the evidence of harm from UV exposure has continued to mount, and differential exposure to tanning beds, which emitted primarily UVA light, was classified as a known human carcinogen by IARC on the basis of increased melanoma rates in young women who used them.¹¹ The inclusion of UVA protection in sunscreen products has always been secondary to the SPF value, and that secondary status continues within the new FDA proposed order. Our product testing results, along with results published by FDA researchers, confirm suboptimal UVA attenuation and a lack of correlation between SPF and UVA protection.¹² The continued emphasis on SPF values with no required correlation between SPF and UVA will continue to mislead consumers so they believe they are better protected from UV damage than they actually are, and it will enable products with substandard UVA protection to remain on the market. As we stated in our recent



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publication, the “focus [on SPF] may limit the value of UV reduction products currently sold in the United States for people of color whose naturally occurring melanin reduces their comparative risk from sunburn, even though they may still benefit from the use of sunscreen.”¹³ EWG suggests that the FDA consider moving away from SPF testing in people in favor of in vitro UV protection testing, and the agency should consider replacing the SPF value with a UV protection value that equally weights the entire UV spectra.

Submitted on behalf of the Environmental Working Group,

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References

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³ Cosmetics Europe. Re: WTO Notification Proposed Order amending Over-the-Counter Monograph 020: Sunscreen Drug Products for Over-the-Counter Human Use (Proposed Order) – G/TBT/N/USA/1443/Add.2, November 5, 2021.

⁴ European Commission Scientific Committee on Consumer Safety, Opinion on Benzophenone-3. European Union, SCCS/1625/20. 2020; European Commission Scientific Committee on Consumer Safety, Opinion on Homosalate. European Union, SCCS/1622/20. 2020.



⁵ A. Kariagina et al., Benzophenone-3 promotion of mammary tumorigenesis is diet-dependent. *Oncotarget*. 2020; 11: 4465-4478; F.M Peinado et al., Cosmetic and personal care product use, urinary levels of parabens and benzophenones, and risk of endometriosis: results from the EndEA study. *Environmental Research*, 2020. Oct 16:110342; J. Rooney et al., A Gene Expression Biomarker Identifies Chemical Modulators of Estrogen Receptor α in an MCF-7 Microarray Compendium. *Chem Res Toxicol*. 2021 Feb 15;34(2):313-329; C.G Santamaria et al., Dermal exposure to the UV filter benzophenone-3 during early pregnancy affects fetal growth and sex ratio of the progeny in mice. *Archives of Toxicology*, 2020, 94: 2847-2859.

⁶ European Commission Scientific Committee on Consumer Safety, Opinion on Benzophenone-3. European Union, SCCS/1625/20. 2020.

⁷ Food and Drug Administration. <https://www.fda.gov/drugs/news-events-human-drugs/our-perspective-helping-ensure-safety-and-effectiveness-sunscreens>

⁸ Statement from the Personal Care Products Council on Sunscreen Regulations in COVID-19 Legislation, 2020. Available: <https://www.personalcarecouncil.org/statement/statement-from-the-personal-care-products-council-on-sunscreen-regulations-in-covid-19-legislation/>

⁹ Valisure LLC. Valisure Citizen Petition on Benzene in Sunscreen and After-sun Care Products. May 24, 2021.

¹⁰ Andrews DQ, Rauhe K, Burns C, et al. Laboratory testing of sunscreens on the US market finds lower in vitro SPF values than on labels and even less UVA protection [published online ahead of print, 2021 Oct 3]. *Photodermatol Photoimmunol Photomed*. 2021;10.1111/phpp.12738. doi:10.1111/phpp.12738.

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