

Introduction and Executive Summary

The Personal Care Products Council (Council)¹ and the Consumer Healthcare Products Association (CHPA)² collectively play a major role in advancing the science of sunscreen safety and efficacy. We are pleased to submit the following Comments in response to the Food and Drug Administration's ("FDA") Tentative Final Monograph for Sunscreen Drug Products for Over-the-Counter Human Use ("TFM"), published at 84 Fed. Reg. 6204 on February 26, 2019.

Sunscreens are among the most important OTC drug categories because they provide a vital public health benefit -- protecting consumers against the harmful effects of ultra-violet radiation and, most importantly, playing a critical role in the fight against skin cancer. The Centers for Disease Control and Prevention, the American Academy of Dermatology, the Skin Cancer Foundation, and health care professionals worldwide all emphasize the importance of sunscreen use as part of a safe sun regimen. The dangers of sun exposure are clear and universally recognized by public health professionals and dermatologists, hence the benefits of sunscreens are clear. Of particular concern, skin cancer is on the rise in the United States. In 2019, the American Cancer Society estimates there will be 96,480 new cases of malignant melanoma, the most serious form of skin cancer, and more than two million new cases of basal cell and squamous cell skin cancers in the United States.³

Because of their well-established role in protecting public health, the significant benefits provided by sunscreens need to be appropriately weighed against any potential risks.⁴ We support FDA's commitment to ensuring that sunscreens are safe and effective for their intended use. We are confident that currently marketed sunscreens are both safe and effective. This is

¹Based in Washington, D.C., the **Personal Care Products Council** is the leading national trade association representing the global cosmetic and personal care products industry. Founded in 1894, the Council's more than 600 member companies manufacture, distribute, and supply the vast majority of finished personal care products marketed in the United States. As the makers of a diverse range of products that millions of consumers rely on every day, from sunscreens, toothpaste, and shampoo to moisturizer, lipstick, and fragrance, member companies are global leaders committed to product safety, quality, and innovation. Visit www.personalcarecouncil.org

² The **Consumer Healthcare Products Association** (CHPA) is the 138-year-old national trade association representing the leading manufacturers and marketers of over-the-counter (OTC) medicines and dietary supplements. Every dollar spent by consumers on OTC medicines saves the U.S. healthcare system more than \$7, contributing a total of \$146 billion in savings each year. CHPA is committed to empowering self-care by preserving and expanding choice and availability of consumer healthcare products. www.chpa.org

³ See Key Statistics for Melanoma Skin Cancer, <https://www.cancer.org/cancer/melanoma-skin-cancer/about/key-statistics.html>, accessed June 21, 2019.

⁴ In the Tentative Final Monograph, FDA did not address the benefits of the active ingredients that the Agency proposed to re-classify as category III. Under FDA's regulations implementing the OTC Drug Review, FDA stated that the advisory review panels must consider the benefits of a drug in determining GRASE status. 21 C.F.R. § 330.10(a)(4)(iii); see also 37 Fed. Reg. at 9469 (May 11, 1972) ("In every instance the panel must evaluate whether, balancing the benefits against the risks, the target population will experience a beneficial rather than a detrimental effect."). The Agency also has a long history of considering benefits in the safety and effectiveness determination for various active ingredients. 65 Fed. Reg., at 24704 (Apr. 27, 2000). Given the important and well-established benefits that sunscreens provide, FDA should consider the substantial benefits of these active ingredients in the Agency's GRASE evaluation.

based on the long history of safe use of these products in the United States and around the world, the breadth of existing safety data, as discussed in more detail in this and prior submissions, and the established benefits that sunscreens provide. We strongly believe that sunscreens play a critical role in protecting the public health and their continued use must be encouraged, as FDA noted in its press release accompanying the February 23, 2019 Tentative Final Monograph (TFM).

In examining FDA's discussion of its proposals, however, we are concerned that the actions taken by the agency may be causing undue worry and confusing consumers about the exact purpose of FDA's actions. The TFM and associated messaging may result in unintended negative health effects by deterring consumers from using sunscreens. It also significantly departs from how the agency has handled other OTC rulemakings where it has requested additional information to establish GRASE status of certain active ingredients.

For these reasons, we are concerned by some of the key themes that run throughout the Tentative Final Monograph. Namely, the: proposed reclassification of twelve sunscreen active ingredients as Category III; failure to leverage existing safety data; lack of consideration of newer toxicological methods for certain endpoints; the underestimated test costs and economic impacts to industry; the potential for unintended consequences such as consumers not utilizing sunscreens during the critical "sun season" due to the perception that ingredients are unsafe; and that much of this TFM seems counter to the express aims of the Sunscreen Innovation Act.

First, as stated above, we are concerned that the proposed reclassification of twelve ingredients as Category III is creating consumer confusion about whether consumers should continue to use sunscreens and whether sunscreens are safe. While the agency explained in the TFM that "this proposed rule does not represent a conclusion by FDA that the sunscreen active ingredients included in the Stayed 1999 Final Monograph but proposed here as Category III are unsafe for use in sunscreens," the TFM itself entirely fails to expressly acknowledge the critical public health benefits of continued sunscreen use. We urge FDA in the final rulemaking to strongly reinforce its key message shared in its press release accompanying the February 26, 2019 Tentative Final Monograph ("TFM"): "Given the recognized public health benefits of sunscreen use, Americans should continue to use sunscreen with other sun protective measures as this important rulemaking effort moves forward."⁵ It is therefore imperative that FDA take more direct action to make clear to consumers that the agency still considers sunscreens to be safe, still recommends that the public uses sunscreen regularly, and is *not* proposing to remove sunscreens containing the active ingredients that FDA has proposed to re-classify as Category III from the market.

⁵ See "FDA advances new proposed regulation to make sure that sunscreens are safe and effective," Feb. 23, 2019, available at: <https://www.fda.gov/news-events/press-announcements/fda-advances-new-proposed-regulation-make-sure-sunscreens-are-safe-and-effective>.

To this point, immediately following the release of the TFM, the American Academy of Dermatology created a new webpage titled “Is Sunscreen Safe?” to address the “confusing regulatory language.”⁶ Headlines in the month following FDA’s publication of the TFM included the following:

- *FDA Admits Most Sunscreens Are Probably Unsafe*⁷
- *Parents Beware: FDA Report Claims Popular Sunscreens Might Not Be Safe or Effective*⁸
- *FDA crackdown: Most sunscreens “bamboozle” consumers*⁹
- *FDA Issues Updated Regulations on Sunscreen Products After Warning Many Contain Chemicals Not Proven Safe*¹⁰
- *Majority of sunscreens could flunk proposed FDA standards for safety and efficacy, report to say*¹¹

FDA has attempted to clarify this confusion in certain statements that the agency has subsequently made. This includes an online “Sunscreen Message for Consumers” in which the Director of the Center for Drug Evaluation and Research (“CDER”), Dr. Janet Woodcock, stated that the TFM

“does not mean that sunscreens are unsafe. It also does not mean that FDA is taking sunscreens off the market. . . We recognize the benefits of using sunscreens . . . I urge you and your family to use them.”¹²

However, we do not think these efforts are sufficient. As one example, the Environmental Working Group very recently issued a report stating that sunscreen should be a “last resort” in sun protection.¹³ We are very concerned about the levels of consumer confusion and fear that

⁶ “Is Sunscreen Safe?” The American Academy of Dermatology, February 21, 2019.

<https://www.aad.org/public/spot-skin-cancer/learn-about-skin-cancer/prevent/is-sunscreen-safe>, accessed May 29, 2019.

⁷ <https://articles.mercola.com/sites/articles/archive/2019/03/13/sunscreen-safety-regulations.aspx>, accessed June 26, 2019.

⁸ <https://mom.me/news/273621-parents-beware-fda-report-claims-popular-sunscreens-might-not-be-safe-or-effective/>, accessed June 26, 2019.

⁹ https://article.wn.com/view/2019/02/21/fda_crackdown_most_sunscreens_8216bamboozle_8217_consumers/, accessed June 26, 2019.

¹⁰ <https://philadelphia.cbslocal.com/2019/02/22/fda-issues-updated-regulations-on-sunscreen-products-after-warning-many-contain-chemicals-not-proven-safe/>, accessed June 26, 2019.

¹¹ “Majority of Sunscreens Could Flunk FDA Proposed FDA standards for safety and efficacy, report to say.” CNN. May 21, 2019. <https://www.cnn.com/2019/05/15/health/sunscreen-fda-safety-standards-study/index.html>, accessed May 29, 2019.

¹² See “A Sunscreen Message for Consumers,” May 6, 2019, *available at*: <https://www.youtube.com/watch?reload=9&v=MtV0519rVU8>, accessed June 25, 2019.

¹³ <https://www.ewg.org/sunscreen/>, accessed June 21, 2019.

remain regarding the safety of sunscreens, particularly as we are in the summer months. In addition to consumers, there is the strong potential for retailer confusion such that retailers may question or institute “commercial bans” of products containing Category III ingredients.

Given the additional information that we discuss below relating to plans for additional safety testing, existing real-world safety data and post-market surveillance data, we do not think that the agency’s proposal to re-classify the twelve active ingredients as Category III is the most appropriate approach under the existing legal framework. If the agency moves forward in issuing a final monograph in the short term, we urge the agency to include in the final monograph only the two filters for which the agency has not requested additional data: titanium dioxide and zinc oxide, and to grant Category I status for those ingredients for which new information is submitted during the comment period that supports a positive GRASE determination. Separately, we urge the agency to withdraw its proposal to classify the remaining filters as Category III and to, instead, reissue a TFM proposing to classify these remaining filters as Category I. The existing and anticipated data supports such a proposal. Further, a proposal to classify these twelve active ingredients as Category I would clarify FDA’s message regarding the use of sunscreens containing these ingredients – i.e., that consumers should continue to use sunscreens and that FDA does not anticipate removing such sunscreens from the market.

Regarding the determination of ingredient safety, we know that this is a vital aspect of FDA’s mission. We submit that in order to achieve FDA’s goals, the determination of safety should use a holistic approach taking into account all information currently available and various approaches for generating additional information. In previous Comments pertaining to the FDA Guidance ‘Nonprescription Sunscreen Drug Products - Safety and Effectiveness Data’¹⁴, we recommended FDA include alternative approaches as part of the toxicological risk assessment and determination of an acceptable margin of safety (MOS). We also recommend that FDA consider information submitted utilizing such MoS assessments in the determination of GRASE for those ingredients. We advocated for the FDA to consider the input from experts and utilize more modern toxicological approaches when assessing the risk of an ingredient, noting that *in silico* and *in vitro* techniques together with traditional *in vivo* testing can provide a robust and quantitative risk assessment for ingredients and products. It is in the interest of public health for industry to work with FDA to reasonably bridge any data gaps that will allow for determination of an acceptable MOS for sunscreen ingredients under product intended use conditions.

To that end, industry remains very willing to work together with FDA to develop a work-plan for providing data to support the safety of sunscreen active ingredients. As explained in more detail below, we do not think the safety testing requirements that the agency set forth in the

¹⁴ Comment from the Personal Care Products Council and the Consumer Healthcare Products Association on Over-the-Counter Sunscreens: Safety and Effectiveness Data; Draft Guidance for Industry, Docket No. FDA-2015-D-4021, submitted Feb. 23, 2016.

TFM are the only mechanisms by which the safety of these ingredients can be affirmed, nor are these requirements necessarily consistent with current science and the recent approach that FDA has taken in evaluating the safety of other categories of medical products. As CDER purports to encourage,¹⁵ FDA should consider other potential categories of valid scientific evidence, including real world evidence and post-market surveillance data. This would meaningfully reduce the time that it will take for the agency to issue a final rule on the sunscreen ingredients for which deferral is requested and provide more certainty to the public around safe sun practices.

Regarding the other important elements of the TFM, we are grateful for the opportunity to provide comments on the spray and powder dosage forms for sunscreens and are confident that the recommendations and data provided in each section meaningfully address the points raised by FDA. Likewise, the TFM proposes several changes with respect to the sun protection factor (“SPF”) and broad spectrum claims. Our comments reflect the diversity of the sunscreen industry and the shared goals in providing consumers access to sunscreens that will protect them from the harmful effects of the sun. Additionally, the TFM includes provisions to revise the requirements for information on the Principal Display Panel (PDP) and modifications to the drug facts label. Our labeling comments will encompass the daily-use, beach-use and combination products--sunscreens/skin protectants. More specifically, these comments will cover the FDA proposed modifications to the PDP labeling, and the Drug Facts Box, as well as the lack of small package considerations.

We are also cognizant of the economic implications of the Tentative Final Monograph. Indeed, the TFM contemplates significant changes to the current framework under which sunscreen products are manufactured. The Agency’s Economic Impact Analysis acknowledges that this rule has significant economic impact on industry. Changes to the SPF test method and enhanced clinical laboratory controls will require sponsors and contract research laboratories to make changes to internal procedures and contractual agreements, which cannot be initiated until the rule is finalized at the end of November 2019. Some sunscreens may need to be reformulated to achieve the broad spectrum requirements proposed by FDA, and then will need to be re-tested following the modified method. Products affected by the proposed new requirements would need to undergo labeling changes and be relabeled to meet any new applicable labeling requirements. Like the February 2019 TFM, the June 2011 Final Rule on Sunscreen Labeling and Effectiveness Testing required a 12-month compliance period. In May 2012, FDA extended the Final Rule by six (6) months, due to “information received ...that indicates that full implementation of the 2011 final rule's requirements for all affected products will require an additional 6 months.” However, unlike the 2011 Final Rule, the 2019 proposal could require many products to be reformulated. The TFM estimates there are more than 4,000 sunscreen products currently

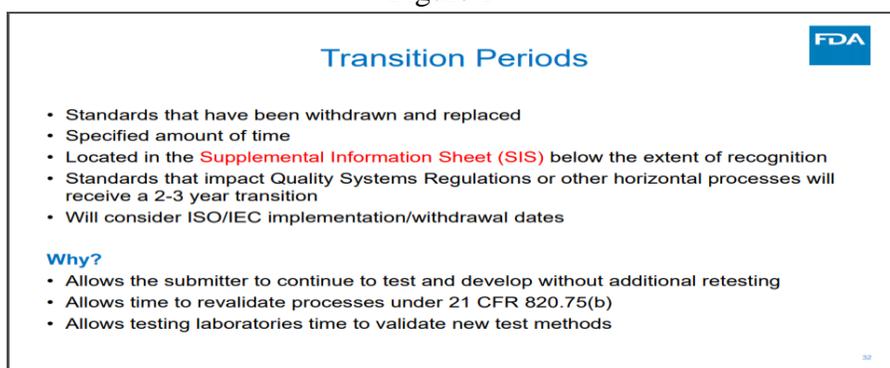
¹⁵See “Real-World Evidence”, available at <https://www.fda.gov/science-research/science-and-research-special-topics/real-world-evidence>, last accessed June 25, 2019.

on the U.S. market, and a significant percentage of these will therefore also require re-testing, further stretching laboratory capacity.

In the TFM, the agency acknowledged that “industry will need time after publication of any final regulations to comply with their provisions,” and proposed a compliance period of one year after the effective date of any final rule. Given the scope of changes in the TFM, one year is not sufficient time for industry to make the changes mandated by FDA. We strongly urge FDA to allow for at least a two-year compliance period. Two years is the minimum time needed to conduct newly required finished product testing with validated methods, reformulate products, and print new labels.

This timeframe is also consistent with the period of time FDA typically allows for compliance with new requirements that include labeling changes across product categories and will ensure that there is no disruption in the supply chain, which is particularly critical for this category of products. In its recent webinar on how to use voluntary standards, FDA states they allow 2-3 years to come into compliance with new standards based on the following reasons.¹⁶

Figure 1



In addition, while the 2-year implementation period is the minimum needed to ensure a steady flow of products into the market, it is also important that industry have express authorization to sell-through inventories that are already in the market as of the compliance date to ensure continuous supply to consumers and reasonable supply chain flexibility for industry. For example, artwork for the 2020 summer sun season will be completed and in production prior to the finalization of the sunscreen monograph. Those 2020 products should be allowed by FDA to be sold through until they reach the end of their shelf life.

Finally, we understand that the TFM was published under the auspices and timelines dictated by the Sunscreen Innovation Act (the “Act”). While finalizing the sunscreen monograph

¹⁶ CDRH webinar, "Appropriate Use of Voluntary Consensus Standards in Premarket Submissions for Medical Devices." October 25, 2018. <https://www.fda.gov/media/117223/download>, accessed June 4, 2019.

is an important aspect of the Act, perhaps as critical are the stated goals of the Act: expediting the approval of new sunscreen active ingredients in the U.S. and greater consumer access to sunscreens. This is supported by a recent letter that United States Senators Johnny Isakson, Lamar Alexander, and Richard Burr wrote to the Secretary of Health and Human Services and the Acting FDA Commissioner on May 30th, 2019.¹⁷ As noted in the letter, the Sunscreen Innovation Act was intended to provide the American consumer with “new and innovative sunscreen products that are already available in many other countries.”¹⁸ We share the concerns of the Senators that, while it was likely not the intent of the FDA, the practical result of the Tentative Final Monograph is that the American consumer will likely have less access to sunscreen products if the TFM is made final in its current form.

In summary, we appreciate the opportunity to provide the FDA with our viewpoints and comments on the Tentative Final Monograph. We share in the agency’s goal of ensuring public health and, as an industry, we are committed to providing safe and effective products for our consumers. These comments reflect the time, experience, and resources of a diverse range of companies who are equally keen to see the U.S. sunscreen market aid the American consumer in protecting their skin from the damaging effects of sun. We thank the FDA for their consideration and look forward to continued work in this area.

¹⁷ https://www.isakson.senate.gov/public/_cache/files/5a2ee884-0f07-4b96-b00d-9906e36de768/05-30-19%20FDA%20sunscreen%20letter%20May%202019.pdf.

¹⁸ *Id.*