Personal Care Products Council
Committed to Safety, Quality & Innovation

CHPA. CONSUMER HEALTHCARE PRODUCTS ASSOCIATION

February 23, 2015

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Center for Drug Evaluation and Research
Food and Drug Administration
10903 New Hampshire Ave., Bldg. 22, Rm. 5491
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Re: Sunscreen Feedback Letters; Notice of Availability Under the Sunscreen Innovation Act: Docket: FDA–2005–N–0453, FDA–2003–N–0196, and FDA–2006–O–0314

On behalf of the Personal Care Products Council (Council) (formerly the Cosmetic, Toiletry, and Fragrance Association)[1] and the Consumer Healthcare Products Association (CHPA)[2] (collectively, we) thank the Food and Drug Administration (FDA) for the opportunity to file these comments.

The Sunscreen Innovation Act (SIA) prescribes new procedures for establishing the conditions under which sunscreens containing active ingredients that have been reviewed through the SIA process and found in a final sunscreen order to be generally recognized as safe and effective (GRASE) and not misbranded may be marketed in the United States.

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1 Founded in 1894, the Council is the national trade association representing the personal care products industry. Our membership includes approximately 300 active member companies that manufacture or distribute personal care products, including OTC sunscreens. We also represent approximately 300 additional associate members who provide goods and services to manufacturers and distributors of personal care products.

2 The Consumer Healthcare Products Association (CHPA) is the 133-year-old trade association representing the leading manufacturers and marketers of over-the-counter (OTC) medicines and dietary supplements. CHPA is committed to promoting the increasingly vital role of over-the-counter medicines and dietary supplements in America's healthcare system through science, education, and advocacy.

Section 586C(b)(3) of the FD&C Act, as added by the SIA, provides that sunscreen feedback letters (Feedback Letters) issued before the SIA was enacted are deemed to be proposed sunscreen orders (Proposed Orders). Of the six Proposed Orders addressed, all have been tentatively classified under category (C) – insufficient data to determine GRASE, as described in the previous sentence.

It is important to note that FDA issued Feedback Letters (now sunscreen orders) *prior* to the September 4-5, 2014 Sunscreen Nonprescription Drug Advisory Committee meeting – a meeting where we provided information focused on the appropriate framework for determining the safety of sunscreen Time and Extent Application (TEA) ingredients.[3] **Therefore, we ask that in its review of the Proposed Orders, FDA take our framework into consideration when making its GRASE determinations.**

We believe that as FDA evaluates the safety of OTC sunscreen active ingredients, the framework the Agency employs should be science-based – incorporating current approaches and understandings – and flexible given advances in toxicological and medical science. In brief, our recommendation is to incorporate convergent toxicological approaches including data from *in vitro-* , *in vivo* preclinical-, and clinical studies, along with computational analyses, data from chemically-related molecules, and relevant market experience from other geographies in a weight-of-evidence approach, intended to evaluate and limit human risk. In addition, we agree with FDA that ingredients should be evaluated on a case by case basis versus a prescribed list of requirements. Further, we encourage FDA to refer to the existing data available from sources like the European Union Scientific Committee on Consumer Safety (SCCS) Opinions (*i.e.,* valid data from other scientifically recognized and credible sources) or other recognized toxicological and medical expert organizations to identify data requirements and to interpret ex-U.S. post-marketing data.

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[3] PCPC/CHPA Briefing Information for the September 4-5, 204 Sunscreen NDAC meeting: http://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/Drugs/NonprescriptionDrugsAdvisoryCommittee/UCM410318.pdf

We believe using the above approach is particularly important given what the Agency and industry knows about the dangers of UV exposure and the benefits that sunscreen ingredients provide. Mainly:

- UV radiation is a known carcinogen and sun exposure is linked to 65% of melanoma skin cancers in the U.S.[4]
- Melanoma, the most deadly form of skin cancer, causes nearly 9,000 deaths each year."[5]
- Every year in the United States, nearly 5 million people are treated for skin cancer, at an estimated cost of $8.1 billion.
- FDA recognizes sunscreens for their effectiveness in protecting the skin against UV exposure, their ability to prevent sunburn, in reducing the risk of skin cancer, and in mitigating premature skin aging.[6]
- Use of sunscreens is a simple procedure, inexpensive, with demonstrated health benefits and limited associated sequelae; and as such is an important measure to limit the overall healthcare burden in the U.S.

Having an array of safe and effective sunscreen ingredients allows sunscreen manufacturers to formulate safe and effective products that meet the differing needs of individuals and their families; while providing necessary protection against the damaging effects of the sun, including premature skin aging and skin cancer. Ensuring that consumers have access to a broad variety of sunscreen ingredients is critical and in furtherance of FDA's public health mission.

In addition, it is important to note that, currently, we have a very limited palette of sunscreen filters available to use in developing high protecting products. The FDA monograph lists 16 Sunscreen Active Ingredients, nine of which are most commonly used in U.S.

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4 Armstrong BK, Kricker A. (1993) How much melanoma is caused by sun exposure? *Melanoma Res.* 3(6):395-401; Pleasance et. Al (2010). A comprehensive catalogue of somatic mutations from a human cancer genome. *Nature* 463 191–196.

5 Surgeon General Report 2014: Call to Action to Prevent Skin Cancer.

6 76 Fed. Reg. 117 35620 (June 17, 2011) FDA Final Rule: Labeling and Effectiveness Testing; Sunscreen Drug Products for OTC Human Use (2011).

formulations today due to limited UV absorbance range, difficulty in formulation, or low absorbance efficiency, poor aesthetics or solubility, etc. When formulating, to develop higher SPF, broad spectrum sunscreen products it takes a combination of UV filters.

For example, when considering the number of sunscreen active ingredients that are allowed to be combined with the UVA active ingredient Avobenzone for broad spectrum protection, of the nine most used active ingredients, there are only five that can be combined in a formula with Avobenzone. This demonstrates that currently there is a limited palette of sunscreen filters available to develop high protecting products. Other combinations await approval or an Enforcement Policy from FDA. There are eight sunscreen ingredients submitted and awaiting approval for monograph status through the Time and Extent Application process (six of which are now Process Orders).

In conclusion, both FDA and industry alike recognize that skin cancer prevention is a public health priority; and that sunscreens have a demonstrated ability to reduce the risk of this often deadly disease. Thus, it is critical that manufacturers have a broad variety of available sunscreen active ingredients to formulate products that the public will use and enjoy. With this in mind, we ask that in its review of the Proposed Orders, FDA take the industry's framework into consideration when making its GRASE determinations.

For additional information, please feel free to contact Farah K. Ahmed at ahmedf@personalcarecouncil.org or 202-331-1770.

Sincerely,

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