

January 19, 2016

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

Re: Docket No. FDA-2015-D-4033

Dear Sir or Madam,

On behalf of the joint Personal Care Products Council (Council) (formerly the Cosmetic, Toiletry, and Fragrance Association)¹ - Consumer Healthcare Products Association (CHPA)² Sunscreen Task Force (SSTF), enclosed herein are comments on “Guidance for Industry; Nonprescription Sunscreen Drug Products – Content and Format of Data Submissions to Support a GRASE determination Under the Sunscreen Innovation Act”, published as *Draft Guidance*³.

PCPC, CHPA and member companies of the SSTF have an interest and expertise in over-the-counter (OTC) sunscreen products and support FDA’s efforts to develop guidance for industry on this important topic.

General Comments

The general structure and table of contents described in the Common Technical Document serves as a good starting point for organizing a GRASE data submission. There are several additional categories of data/information that could be relevant to a GRASE determination, and it is not clear where these should be included. Specifically, we recommend FDA provide guidance on the following:

1. Ex-U.S. regulatory experience, including data or other evidence to support a history of safe use and regulatory actions associated with the ingredient
2. Ex-U.S. adverse event information, including any evaluations by regulators or other authoritative bodies
3. Safety or efficacy data reviewed and accepted by governmental, scientific and nonscientific bodies
4. Periodic Safety Update Reports filed with ex-U.S. regulators

We believe that the guidance must clearly recognize the practical differences between GRAS/E determinations and approval of new chemical entities under the NDA process. It should be made clear

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 135-year-old national trade association representing the leading manufacturers and marketers of over-the-counter (OTC) medicines and dietary supplements. CHPA is committed to empowering consumer self-care by preserving and expanding choice and availability of consumer healthcare products.

³ **Federal Register**, Vol 80, Doc. No. 2015-29637, November 23, 2015, pp 72973-72975.

that data on a variety of formulations with varying levels of active ingredients can contribute towards the demonstration of safety and effectiveness and that this data may be derived from actual experience in use, especially a long history of extensive use by consumers. Further, during the original OTC Drug Review, the determination of general recognition of safety and effectiveness depended in large part on publicly available scientific literature.⁴ Indeed, FDA stated that the “panel’s evaluation of a drug should be based on the best scientific evidence available. In most cases, this consists of published studies which are available for peer review and criticism.”

Data supporting GRAS/E determinations will often be contained in published reports from the scientific literature, which will seldom if ever contain the level of detail expected for reports of nonclinical tests and clinical trials submitted in support of NDAs. FDA should thus not disregard data from the published literature simply because case level detail is not included nor should data from other ‘older’ studies be excluded due to their being performed according to standards of quality which have since been revised.

Specific Comments

Lines 65-69: We recommend the content in this section be reconciled with that in the black box of lines 8-14. There should be one place in the document that states how FDA guidance documents should be used. The phrase “in general” in line 65 is confusing and should be eliminated.


Lines 387-389 and 427-429: In both places, FDA states that they generally do not consider study data provided only in summary form to be sufficient evidence that an active ingredient is GRASE. Data published in the peer-reviewed literature has always been considered acceptable for supporting determination of GRASE status. One could consider these data as in summary form, since case level data (by animal or by human subject) may never be available to FDA. FDA should consider many types and forms of data as they make a GRASE determination.

Members of the joint PCPC-CHPA Sunscreen Task Force look forward to working with FDA to further develop this guidance.

Respectfully submitted,



Farah K. Ahmed, Esq.
Chair, Sunscreen Task Force



Barbara A. Kochanowski, Ph.D.
Vice President, Regulatory & Scientific
Affairs

Date

1/19/16

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1/19/16

⁴ **Federal Register**, Vol 37, May 11, 1972, pp 9467-9469.