Personal Care Products Council
Committed to Safety, Quality & Innovation

CHPA CONSUMER HEALTHCARE PRODUCTS ASSOCIATION

January 19, 2016

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

Docket No. FDA-2015-D-3990

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on "Guidance for Industry; Sunscreen Innovation Act: Section 586C(c) Advisory Committee Process", published as *Draft Guidance*[3]. PCPC, CHPA and their member companies 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

Lines 48-52

We recommend that content in this paragraph be reconciled with that contained in the 'black box' (lines 7-12). In order to avoid confusion, FDA should address the non-binding nature of guidance documents and their intent to provide recommendations in one section. The phrase "in general" in line 65 is confusing and should be eliminated.

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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 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. 2015-29635, November 23, 2015, pp 72972-72973.

Lines 81-82

The complex nature of sunscreen science and regulation calls for the presence of many disciplines not always seated on the standing Nonprescription Drug Advisory Committee panel. CHPA recommends that FDA state its intention to supplement these panels not only with dermatologists but also additional subject matter experts in the fields of toxicology, biology, and other relevant subject matter experts. Some of these experts may be active primarily outside the clinical medicine and pharmaceutical sectors or academic institutions, thus the Agency should look broadly for expertise that is specific to the questions at hand.

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

Date 1/19/16

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

Date 1/19/16