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-4012

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on "Guidance for Industry; Sunscreen Innovation Act: Withdrawal of a 586A Request or Pending Request", published as *Draft Guidance*[3].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

Lines 41-45

We recommend that content in this section be reconciled with that contained in the 'black box' (lines 10-14). 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 41 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. 2015-29634, November 23, 2015, pp 72970-72971.

Lines 187-189 and 302-305

It is not clear how FDA can rely on data and information that has been withdrawn, since no entity would be left to support the data. We request that FDA delete mention of continuing to rely on withdrawn data and information.

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