

June 26, 2019

Division of Dockets Management (HFA-305)  
Food and Drug Administration  
5630 Fishers Lane, Rm. 1061  
Rockville, MD 20852  
*Attention: Dr. Theresa Michele*

Re: Sunscreen Drug Products for Over-the-Counter Human Use; Docket No. FDA-1978-N-0018  
(formerly Docket No. FDA-1978-N-0038); Regulatory Information Number 0910-AF43

Dear Dr. Michele:

The Personal Care Products Council (PCPC)<sup>1</sup> and CHPA<sup>2</sup> write in response to the February 26, 2019 proposed rule from the Food and Drug Administration (FDA) regarding Sunscreen Drug Products for Over-the-Counter Human Use (OTC sunscreen drug products).

We write to request that the following eight sunscreen active ingredients be deferred from inclusion in the final rulemaking for OTC sunscreen drug products:

- Avobenzone
- Homosalate
- Octinoxate
- Octisalate
- Octocrylene
- Oxybenzone
- Ensulizole
- Meradimate

Based on your recommendation during our meeting of June 5, 2019, we are making this request for deferral from rulemaking for these eight sunscreen active ingredients in this single letter.

PCPC and CHPA member companies intend to partner with FDA to identify existing data and generate new data to support a final determination that these ingredients are generally recognized as safe and effective.

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<sup>1</sup> Based 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](http://www.personalcarecouncil.org)

<sup>2</sup> 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](http://www.chpa.org)

We appreciate your consideration of our request for a deferral of final rulemaking for the eight aforementioned sunscreen active ingredients under the OTC sunscreen drug product monograph and look forward to working with your office in their timely designation as generally recognized as safe and effective for such use. Please contact me if you have any questions.

Sincerely,



Emily H. Manoso  
Staff Counsel  
Legal Department-PCPC



Barbara A. Kochanowski, PhD  
Senior Vice President  
Regulatory & Scientific Affairs-CHPA