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**Statement from the Personal Care Products Council
On FDA's Tentative Final Monograph for Sunscreens**

Washington, D.C. – “Sunscreens are central in the fight against skin cancer. The Centers for Disease Control and Prevention (CDC), the American Academy of Dermatology (AAD), the Skin Cancer Foundation and health care professionals worldwide all emphasize the importance of sunscreen use as part of a safe sun regimen. The dangers of sun exposure are clear and universally recognized by public health professionals and dermatologists. As part of their regulation of sunscreens, the FDA recently published a proposed rule, the long-anticipated Sunscreen Tentative Final Monograph (TFM).

“In the U.S., sunscreens are regulated by FDA as over-the-counter (OTC) drugs. OTC drugs are currently regulated under a monograph system, which establishes various requirements for approval. Among other items, the proposed rule addresses the effectiveness and safety of the active ingredients that sunscreens are permitted to include in their formulation. In this proposed rule, FDA identified two ingredients, zinc oxide and titanium dioxide, that meet FDA’s established conditions for safety and effectiveness.

“FDA requested the industry conduct additional testing on twelve ingredients currently used in sunscreens around the world. These twelve ingredients have been confirmed as both safe and effective in Europe and other countries around the world. While FDA proposed certain methodologies for this testing, our industry has consistently offered viable, state-of-the-art toxicological safety methods as alternatives to the historical methods proposed by FDA. We remain firm in our belief that the precise studies proposed by FDA are not the only ways to obtain the data they need.

“Importantly, sunscreens made with these ingredients will remain on the market. FDA noted in its press release, ‘Given the recognized public health benefits of sunscreen use, Americans should continue to use sunscreen with other sun protective measures as this important rulemaking effort moves forward.’ We are proud of the sunscreens our industry provides to protect families from the harmful effects of the sun. We look forward to working with FDA to best address their questions.

“Skin cancer is a significant, and largely preventable, public health concern. Our industry’s goal is and continues to be to help consumers make informed decisions and use sunscreen as an important part of an overall safe sun program. We are proud that our industry offers innovative sunscreen products that help protect consumers from the harmful effects of the sun’s ultraviolet (UV) rays. We

believe it is important to note that the TFM reflects sunscreen innovation in dosage forms and recognizes the importance of sunscreens at various SPF values, including those above SPF 50.

“Ultimately, having an array of safe and effective sunscreen active 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. Ensuring that consumers have access to products containing a broad variety of sunscreen active ingredients is critical and an important contribution to FDA’s public health mission.”

For more information about cosmetics and personal care products and their ingredients, please visit www.cosmeticsinfo.org.

Based in Washington, D.C., the Personal Care Products Council (PCPC) is the leading national trade association representing the global cosmetic and personal care products industry. Founded in 1894, PCPC represents approximately 600 member companies who manufacture, distribute, and supply the vast majority of finished personal care products marketed in the U.S. As the makers of a diverse range of products millions of consumers rely on every day, from sunscreens, toothpaste and shampoo to moisturizer, lipstick and fragrance, personal care products companies are global leaders committed to product safety, quality and innovation.

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