

Looking for Answers To Sunscreen Issues

Well, the highly anticipated Sept. 27, 2021 FDA deadline of an Administrative Order (AO) on sunscreen regulations as mandated by Congress's CARES Act of 2020, has come and gone. And, as predicted, nothing substantial was announced. We now have a Deemed Final Order (DFO) for sunscreens which set the current requirements for marketing sunscreen OTC products.

Nothing new has been proposed in the Proposed Order (PO), and no new regulations have been introduced, except for a few changes related to the testing protocol (prompted by the new International (ISO) standard) and in requesting an environmental impact analysis on the UV filters be conducted. We are still left with having to navigate the uncertainty caused earlier by the February 2019 ruling and the March 2020 CARES Act. They proposed that only ZnO and TiO₂ remain as the only two Category I GRASE UV Filters in the land. The other previously approved Category I UV Filters have been either totally banned (two filters) or relegated to Category III status (eight filters) requiring further safety tests before being classified as Category I GRASE status.

The Public Access to SunScreens (PASS) coalition and the Personal Care Products



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Council (PCPC) have been requesting meetings with the FDA for the past 18 months, but no such meeting was held. The PCPC submitted safety data to the FDA on the eight filters currently designated as Category III with no response yet. These eight filters are Avobenzene, Octocrylene, Octisalate, Homosalate, Oxybenzone, Octinoxate, Meradimate and Ensulizole. The data submitted by the PCPC Sunscreen Consortium included IVPT studies and human clinical data as well as non-clinical animal studies. The FDA has not responded to any of the overtures made by the PCPC and the PASS Coalition.

Undoubtedly, sunscreens today are used in a "chronic fashion" that was never envisioned in 1978 when regulations were first proposed. Caution in issuing Final Regulations is certainly important, but *four decades* is a tad too long! This fact and the recent Journal of American Medical Association (JAMA) studies revealing that UV filters permeate the bloodstream at potentially unsafe levels, have caused the confusion and the uncertainty in the minds of sunscreen users as to the effectiveness

and safety of sunscreens in the US today.

In my opinion, the lack of definitive final regulations in the US and the barriers set by the FDA to approve new UV filters have contributed significantly to the stalling of the research and development of new and improved UV filters. While research in UV filters elsewhere in the world, most notably in Europe, is robust and has resulted in several new UV filters that are safer and properly designed to avoid substantial skin permeation into the bloodstream, the current lack of scientific motivation in conducting research leading to safer and more effective UV filters in the US is disturbing. It also does not help that sunscreen companies, suppliers of UV filters and the organizations dealing with skin cancer, cosmetics, and sunscreens do not focus greater efforts in highlighting the shortcomings of the present regulations in sunscreens and the lack of adequate UV filters that afford better protection and prevent damage from the emission of the total solar radiation of the sun (UVB, UVA, HEV and IR rays). Take, for example, the 75th SCC Annual Scientific Meeting taking

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It's always a good time to wear sunscreen.

aerosol propellant problem.

Finally, a new bill (No 135) in Maui received a unanimous vote on November 20 to ban all non-mineral filters from being sold in Hawaii. A hearing was held on November 5 and both sides on that issue stated their opposing views. Sunscreen products are not only a multibillion-dollar

industry but, more importantly, these sunscreen products presumably have been designed to protect consumers from the ravaging rays of the sun. Sunscreen products are a proven method for reducing the discomfort of a burn and minimize the skin aging process and, most importantly, reduce the incidences of skin cancers. ■

place in New York City this month. Traditionally, this meeting has been a forum to discuss all the important issues confronting the industry. Out of the 35 podium lectures scheduled, none are on UV filters, and only one peripherally addresses the topic of sunscreens (a presentation entitled “Minimize Your Environmental and VOC Footprint in Suncare Products”). I am not being critical of the SCC as it has set the theme in this year’s meeting to be about Diversity in Beauty and CBD and microbiomes, but it is reflective of the priority UV filter development plays in today’s uncertain market. Other than the Sunscreen Symposium in Florida, few other meetings and presentations are addressing the real issues confronting ultraviolet filters and sunscreens.

IN OTHER NEWS

The nomination of Commissioner of the FDA, Dr. Robert Califf, is awaiting confirmation by the Senate. Despite some opposition, we expect the nomination to go through soon. Dr. Califf was the FDA Commissioner during the Obama Administration in 2016. As for the Appropriation Bill in Congress, sunscreens were included in the bill, and we believe it will pass in early December. The FDA in its September 2019 Proposed Rule set up a public docket for comments with a deadline of Nov. 12 to receive any last-minute comments.

Sunscreen companies are still reeling from the news that some sunscreen products contain benzene. Recently it was reported that benzene was also found in underarm sprays, possibly suggesting an