

Not All Drugs Are Created Equal

I must be honest with my readers! I have been writing the “Sunscreen Filter” for more than 15 years. My primary theme then, and now, remains the lack of FDA sunscreen regulations. This column highlights the development in the sunscreen ultraviolet filter industry, and particularly the UV developments in the US. I’m afraid that there have been no significant developments in 2024 on both fronts lately. Period!

The two issues are intrinsically tied together. Without a Final FDA Sunscreen Monograph, no company, scientist, investor or entrepreneur would venture into introducing a new ultraviolet filter. The barriers are extremely high for the adoption of a new filter, as the FDA treats sunscreens in the same manner as a heart drug, a cholesterol drug or a cancer-curing drug. Remember that sunscreens are classified in the US, and only in the US, as drugs and not as cosmetics.

Ask anyone who has dared to introduce a new UV filter in the past 30 years. They all failed! After Avobenzone (which went through the expensive New Drug Application (NDA) route

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As Secretary of Health and Human Services, Robert F. Kennedy Jr. could play an important role in sunscreen regulations.

to be considered a Category I ingredient), only one other filter remains under consideration, and that is Bemotrizinol (BEMT), sponsored by DSM Firmenich. Even that ingredient is still months, if not years, away from being approved as a Category I filter in the US.

You would think that the Personal Care Products Council, the Public Access to Sunscreens (PASS) Coalition, cosmetic houses, UV filter suppliers, skincare scientists and the other concerned individuals impacted directly by skin cancers, would be livid by now due to the lack of progress in the field. No! Everyone is doing the same thing they have done for several decades—scheduling meetings with the FDA, lobbying Congress to act and pressure the FDA to approve the so-called TEA ingredients as well as any new UV filters. The net result is that we are exactly in the same place as we were at more than 20 years ago!

IN SEARCH OF SUPPORTERS

There are no new developments from the FDA. But we will continue with our meetings with Congress to influence the FDA to act. After all, Congress controls the purse strings and the funding. Perhaps the new administration may act more forcefully. It seems to be doing just that, based on its first days in office!

We seek new advocates and supporters for our case in Congress. The list includes Senator Bill Cassidy (R-LA), Representatives John Joyce (R-PA), William Roth (R-KS) and others. The hearings to confirm Robert F. Kennedy Jr. as Secretary of Health and Human Services (overseeing the FDA) went as expected. Votes followed party lines and he was confirmed.

MELANOMA MONTH

May is Melanoma and Skin Care Awareness Month. All the organizations working in the skin cancer field will set up



May is Melanoma and Skin Care Awareness Month. A range of organizations are getting the word out about the importance of early detection.

screenings and protocols for individuals, including members of Congress, looking for early signs of skin cancer. They will distribute pamphlets with information about sun safety and early detection of skin damage and disseminate information on superior protocols for sun damage protection. These organizations include the Skin Cancer Foundation, the Melanoma Research Alliance and the Melanoma Research Foundation.

The Melanoma Research Foundation launched an interesting campaign that encourages everyone to Get Naked! The Get Naked campaign is geared toward earlier detection of suspicious moles. They state that 137,000 new diagnoses of melanomas are made each year. In its early stages, melanoma is curable. Visit the website, melanoma.org, for more information.¹

Advances have been made on medical procedures, early detection techniques and better drug protocols to combat the symptoms of malignant melanomas and other skin cancers. The PASS Coalition has two working groups, one for sunscreen developments in Hawaii and the other for schools. The latter deals with the laws issued to regulate the use of sunscreen in schools and to review the

Department of Health websites on use of sunscreens in schools and awareness education.

MISINFORMATION AGE

Misconceptions, false claims, misinformation and partial truths are serious issues in the dissemination of reliable, proven techniques of protection, including the use of safe and effective sunscreens. The social media sites of Facebook, TikTok, X (formerly Twitter), Instagram and other outlets disseminate such information that must be evaluated by all organizations and individuals concerned with the safe use of sunscreen.

What irks me the most are well-meaning dermatologists, scientists and consumer companies, that inadvertently share information that is incomplete or not factual. A company is currently launching a sunscreen claiming that their product is the first “scattering and UV absorber free” sunscreen! When you read the ingredients, the product clearly contains TiO₂. To the best of my knowledge titanium dioxide is not only a “scatterer” of UV rays’ ingredient, but it also is an “absorber” of UV rays through its inner d-orbitals.

To the average consumer, the mineral filters TiO₂ and ZnO are perceived “to scatter” or “to reflect” the rays by a

physical process, but for the scientists or people in the know, mineral filters also exert their protection from the UV rays not only by scattering the rays but also by significantly absorbing the harmful radiation!² Read the excellent article by Curtis Cole, also citing the work of Sayre and Kollias.³

I am deeply disappointed at the lack of reliable information emanating from the FDA to combat misinformation, but I am even more devastated that the FDA has not—after nearly 50 years—finalized the Sunscreen Monograph and, more importantly, approved better UV filters that are available in Europe and the rest of the world. Despite my advanced age and my 35 years of advocacy for sunscreens, I am not planning to cede yet, my current role, of addressing and reporting all issues, positive or negative, in the sunscreen industry. ■

References:

1. Melanoma Research Foundation – Get Naked Campaign <https://melanoma.org/>
2. Sunscreens “Regulations and Commercial Development,” Third Edition, Edited by Nadim A. Shaath, pages 247-8, Taylor Francis, FL 2005.
3. Cole, Curtis, et.al. (Photodermatology, Photoimmunology and Photomedicine), Volume 32, Issue 1, Pg. 5-10, October 2015.



Zinc oxide, along with titanium dioxide, are Generally Recognized as Safe and Effective by FDA.