

Recent Developments In Sunscreens

A recent US Supreme Court ruling against the US Food and Drug Administration was in response to a Texas judge's suspension of the FDA's approval of the abortion pill, Mifepristone. I was surprised at biopharma's overwhelming response to that ruling and the potential consequences of the Supreme Court overruling the FDA on its presumably exclusive authority to approve drugs in the US. But the biopharma industry never raised those same concerns and spoke of dire consequences when Hawaii overruled the FDA and banned two UV filters, Oxybenzone and Octinoxate, and preempted FDA's authority of being the only body that can authorize issuing of prescriptions of drugs in the US!

I concluded that perhaps the lack of furor by the biopharma industry to Hawaii's ban is due to a perception that ultraviolet filters are either not drugs or are not worthy to be pursued economically to approve as drugs in the US. That debate must be elevated by all those concerned. First and foremost, consumers who rely on sunscreens for



Will justice finally prevail in US sunscreen rulings?

protection from skin cancer must be included. More importantly, the FDA needs to assert its authority as the final arbitrator of approving drugs in the US. Finally, this discussion should bring the US in line with the rest of the world that considers sunscreens as cosmetics—and not as drugs. This decision will have major consequences in determining the future of sunscreens in America.

The FDA, as expected, is busy approving drugs and exerting its authority to keep consumers safe from food poisoning or misbranded and unsafe drugs in consumer products. I tip my hat for their efforts, but I cannot help but conclude that their work in finalizing the sunscreen monograph is both inadequate and disheartening.

Many years have passed since the 1978 ANPR (Advanced Notice of Proposed Rulemaking) for sunscreens was issued—45 years in fact, this year—and we are still struggling with the “Tentative Final Rule” and now the “Deemed Final Order” and the

“Proposed Order.” FDA's publication of the MUsT studies (Maximum Usage Trial) results revealed that six UV absorbing filters have all failed that test, and as a result classified zinc oxide and titanium dioxide as the only two approved GRASE (Generally Regarded as Safe and Effective) filters. The results cast a shadow on all those UV absorbing filters and allowed social media to go wild with accusations that US sunscreens are ineffective and, to some, considered dangerous or cancer causing!

It is my sincere hope that the FDA and consumer companies promoting sunscreen products, should mount an active campaign to dispel those rumors and to get on with FDA's mission of finalizing the safety and efficacy of ultraviolet filters and issue a Final Monograph soon!

HAWAII 2.0

Hawaii is facing some opposition but is still proceeding with legislation to ban all UV absorbing filters (Avobenzone,

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Homosalate, Octisalate, Octocrylene, Oxybenzone, Octinoxate, Ensulizole and Methyl Anthranilate) from use in sunscreens sold in Hawaii. Regulators would like to see zinc oxide and titanium dioxide as the only approved filters in sunscreens. Without these UV absorbing filters and, more importantly, the other so-called TEA (Time and Extent Application) European filters, we would not be able to sustain the sunscreen industry in the US.

In other news, the Florida Sunscreen Symposium will be held on September 13-15 at Disney World in Orlando. This has traditionally been an important gathering of scientists and marketers of sunscreens allowing for the free dissemination of the latest advancements and information in sunscreens and ultraviolet filters.



Sunscreen bans make Hawaii less than idyllic for marketers and their suppliers.

MELANOMA MONTH

May was Melanoma Month and many organizations, including UV filter and sunscreen companies, promoted this event with mobile cancer screening centers and distributed helpful information

on cancer prevention. Finally, Suppliers' Day organized by the New York Chapter of the Society of Cosmetic Chemists was held in the Jacob Javits Convention Center in New York City. It was well attended and a major success. This event was the largest ever in the history of NYSCC Suppliers' Day, attended by more than 10,000 people with 546 Global Exhibitors from 73 countries.

In my next column, I will review the newest ingredients in sun care. Since no new UV filters are on the horizon for approval in the US, except for potentially Bemotrizinol in a year or so, the ingredients that I will highlight will be SPF boosters and specialty antioxidants. These ingredients help fight off free radicals that may be responsible for causing damage to the skin.

See you in Florida! ■