Final Sunscreen Monograph Approval May Stop Social Media Misinformation

ho would have believed or predicted that we are nearing 2025 and are still without a Final Sunscreen Monograph? Instead, we have only a handful of UV filters approved by the US Food and Drug Administration (FDA). They are not the ideal ingredients to protect consumers from the ravages of sun rays, nor do they support a budding sunscreen industry responding to the health demands of burn prevention, skin damage and ultimately, reduction of skin cancer cases.

The FDA's inaction has fueled speculation of perceived inadequate protection from harmful solar radiation. Instead, the internet, social media and even the mainstream media are constantly bombarding consumers with negative and outright shocking news about sunscreens. Some recent headlines ask:

"Is your sunscreen toxic?"

"Does your sunscreen cause cancer?"

"Is your sunscreen safe?"

"Do homemade sunscreens work?"

"What is the difference between Physical vs Chemical Sunscreens?" (As if zinc oxide and titanium dioxide are not





Dr. Nadim Shaath is the president of Alpha Research & Development, Ltd. in White Plains, NY. He has over 30 years of experience in the sunscreen industry. He served as the Chairman of the chemistry department at SUNY-Purchase and the CEO of Kato Worldwide. Recently he published his new book entitled "Healing Civilizations: The Search for Therapeutic Essential Oils and Nutrients" Cameron Books, Petaluma, CA



Will this consumer see a new UV filter get approved in the US during his lifetime?

"Do sunscreens penetrate your skin?"

"Do chemical sunscreens lead to hypertension in pregnancy?"

Are sunscreens blocking the production of vitamin D?"

"Do your sunscreens hurt the environment?"

"Are sunscreens ecofriendly?"

At a minimum, these daily incendiary statements, many of them incorrect and inflammatory, have confused the public and, in some cases, have scared them from relying on sunscreens for protection. This mostly misguided public outcry must be effectively addressed to avoid a more calamitous outcome that will cost many more lives and people suffering not only painful burns but also outright higher cancer incidences that are destructive and costly to public health.

So, what is the answer? Would incentives to encourage research to create more effective and safer sunscreens help? After all, not a single new UV filter has been introduced this century in the US. Would adopting more effective UV filters that are being produced and used in Europe and the rest of the world, improve protection? The exception is, perhaps, the approval of Bemotrizinol (BEMT) in 2025/2026.

Would the finalization of the Sunscreen Monograph by the FDA put an end to the swirling controversies going viral these days? Would more effective consumer education by the major cosmetic companies dispel negative rumors and promote proper protection? Whatever it is, whether combinations of the above suggestions or new ideas and measures are taken, it must start now so that effective actions can be implemented soon.

STATE LEVEL ACTION

One interesting development moving the sunscreen industry in the right direction was the August 28 passage of Bill AJR-16 by the California State Legislature. Introduced by Assemblymember Evan Low, it urges Congress to act on allowing new sunscreen filters. The bill passed by unanimous consent (Google: "Text-AJR-16 Sunscreens: Ingredients and Filters"). "Resolved, That the Chief Clerk of the Assembly transmit copies of this resolution to the President and Vice President of the United States, to the Speaker of the House of Representatives, to the Majority Leader of the Senate, and to each Senator and Representative from California in the Congress of the United States.". Hopefully, we will hear from the US Congress soon!

Congress is in recess now and, when back in session, it will most likely be busy with the upcoming elections and other legislation more important than improving sunscreens. The last real action by Congress was bringing into law The Sunscreen Innovation Act of 2014, which President Obama signed immediately, but it was basically overturned in 2020 and a whole new mechanism was proposed by Congress during the pandemic, namely "The Final Administrative Order." Four years later an "Order" has yet to be finalized.

OTHER EFFORTS

The Personal Care Products Council, the Public Access to Sunscreen (PASS) Coalition, and other organizations constantly lobby Senators and Congressmen and Congresswomen, to no avail. We hear encouraging statements from Congress occasionally, but no real action is taken.

The FDA is the only body responsible for food and cosmetic safety in the land. It is obviously busy and effectively addressing fraud, toxic foods and noncompliant cosmetics, evaluating vaccines, and identifying and correcting safety issues. As a result, Congress

tiptoes around the FDA and is reluctant to apply excessive pressure on them to act, especially in addressing the current sunscreen policies that will provide ultimate protection that our consumers need today. Congress, will not and has not passed legislation that may be perceived as sidestepping or overruling the authority of the FDA.

FRUSTRATION & EDUCATION

If you detect a frustrated tone in my writing, it's obviously because of our feeble efforts toward reform and our inability to improve the overall issue of adequate solar protection. I have been highlighting those issues for more than 35 years, and only incomplete and inadequate stop-gap measures are taken by the FDA. In defense of the FDA, these issues are real and compli-

year-round, and apply products every two hours to provide adequate protection. This cannot happen by using UV filters designed in the middle of the last century.

Obviously, consumers need education to identify better protection techniques and how to use these products most effectively. Something better must be developed soon. More research on superior methods of protection is needed and, in the meantime, we can adopt the UV ingredients that have been used effectively and safely in the rest of the world for more than 20 years.

MORE TOPICS

I planned to address several other interesting issues here, including GenZ misinformation, debunking misinforma-



DIY Sunscreen? What could possibly go wrong?

cated. The FDA is reluctant to finalize a monograph that will not and cannot address all those controversies outlined. The US sunscreen industry has billions of dollars in sales. Consumers are encouraged to use those products not only on vacation or on the beach once a year (as it was in the 1960s) but to use these products on a daily basis,

tion in sunscreens, Over-the Counter Monograph Drug User Fee Program (OMUFA) reauthorization, approvals of European filters in the US, and efforts by several Congressional members to champion our cause of addressing our pending issues with the FDA.

Hopefully, I will address these other issues in my future columns. ■