

SUNSCREEN SYMPOSIUM DRAWS RECORD CROWD

I WROTE THIS COLUMN while attending the Florida Chapter of the Society of Cosmetic Chemists' Sunscreen Symposium, which was held September 12-14 in Orlando, FL. The biannual symposium, which dates back to 1986, was a huge success this year with a record 575 attendees, including the top scientists in the industry, as well as executives and marketers.



Attendees listened closely to the presentation by Dr. Theresa Michele of the US Food and Drug Administration.

Also in attendance was Dr. Theresa Michele, the director of the Division of Non-Prescription Drug Products at the US Food and Drug Administration (FDA). She spoke on Saturday and fielded a host of questions from the anxious attendees.

The sunscreen industry is facing major challenges and is truly at a crossroad these

days. The issues include legislation in Hawaii, Key West, Palau and the US Virgin Islands that banned oxybenzone, octinoxate and octocrylene due to their potential to affect coral reefs. Meanwhile, the FDA released its Proposed Final Monograph in February in time to issue the Final Monograph on Sunscreens on Nov. 26, 2019. This is the date set by the Sunscreen Innovation Act (SIA) signed by President Obama on Nov. 26, 2014 that mandated the finalization of the Monograph within five years from the date that the SIA was approved.

Finally, the industry is dealing with the explosive FDA report published in May in the Journal of the American Medical Association (JAMA) which revealed that four approved filters, namely, avobenzone, octocrylene, oxybenzone and ecamsule, penetrated the blood of volunteers at levels far above the safety level of 0.5ng per ml.

Other Presentations

The symposium featured presentations from a number of distinguished speakers on a variety of extremely interesting, vital topics. The Friday session, which was moderated by past SCC President Perry Romanowski (vice president, Element 44 Inc.) included several speakers on microbiomes and their role in protection from UV exposure. Dr. Loretta Ciraldo, a Florida dermatologist, gave a very informative talk on the medical advice she offers her patients regarding proper sun protection.

Other speakers addressed zinc oxide and sunscreen formulations and, in a very timely fashion, the emerging importance of protection from infrared (IR) and high energy visible radiation (HEV).

During the Saturday session that I moderated, we had three scientists address SPF testing technology including the promising technique of Hybrid Diffuse

Reflectance Spectroscopy (HDRS). Dennis Lott shared interesting results from his outdoor testing protocols; he highlighted the fact that the SPFs obtained outdoors from direct sun exposure are a fraction of the SPF values obtained from the traditional Solar Simulator testing protocols. Among the factors affecting those low SPF values in outdoor testing is clearly the continuum solar spectrum (which was emphasized by Dr. Nava Dayan) where the visible and infrared radiation is cut-off in the indoor testing protocols with the artificial solar simulators.

Carl D'Ruiz from DSM also revealed that his company is seeking approval of bemotrizinol (BEMT) as a new filter for use in over-the-counter (OTC) sunscreen products in the US.

Words from Washington

The highlight of the symposium was undoubtedly the interaction with Dr. Michele from the FDA. She attended all of the seminars and was available to answer all questions asked by the participants, and did so very patiently. In her presentation, she outlined the protocols for UV approvals in the Monograph, the SIA provisions, and the future actions by the FDA.

Her slide presentation can be viewed in the Florida SCC website.¹ After her presentation, she again graciously fielded the numerous questions posed by the attendees. I asked her about the Kefauver-Harris Amendment signed by President John F. Kennedy in 1962² which mandated that "consumers will not be victims of unsafe and ineffective medicine," and then I asked her "How come that the FDA, after 40 years of approving some of those controversial UV filters, only recently decided to relegate a dozen of those filters as Non-GRASE (Generally Regarded as Safe and Effective) Category III filters?"

Her lengthy response delved into how



Nadim Shaath
Alpha Research
& Development Ltd
Email: alphamd@aol.com

Dr. Nadim Shaath is the president of Alpha Research & Development, Ltd. in White Plains, NY. He has over 30 years of experience as 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.



Nearly 600 chemists and sun care executives attended the Sunscreen Symposium.

the Monograph system works in the US, and in addressing the decision to reject all eight foreign Time and Extent Application (TEA) filters for use in the US, she alluded to the “Thalidomide Syndrome” in the 1950s where foreign data was rejected, which led to the avoidance of a major medical disaster in the US. The use

of thalidomide as a sedative for pregnant mothers, unfortunately, resulted in thousands of deformed babies being delivered in that period in Europe and countries outside of the US.

Dr. Michele also fielded questions on testing protocols, compliance and on the proposed banning of sunscreen-insect repellent combination products. One participant asked about the sunscreen-insect repellent complained that it was DEET and its potential interaction with oxybenzone and other organic filters that was the culprit. He eloquently suggested the use of only zinc oxide as the GRASE UV filter, also approved on the EPA 25b list, in combination with the EPA-approved essential oil blends as the insect repellents. He emphasized that protection by those combination products would encourage consumers to use and comply with both sun protection measures and insect repellent protocols.

Dr. Michele listened intently and stated that FDA has received many similar responses and petitions in the call to comments, and the Agency is currently considering their requests.

Finally, when she was asked when will the Final Monograph be submitted to the Office of Management and Budget (OMB) in Congress, her answer was that it was not known at this stage, which was a bit disappointing.

All in all, that was a great informative weekend for the attendees and for the sunscreen industry, yet the challenges and the uncertainty that I’ve mentioned in this article still remain. ●

References:

1. www.FLSCC.org
2. [//en.wikipedia.org/wiki/Kefauver_Harris_Act_of_1962](https://en.wikipedia.org/wiki/Kefauver-Harris_Act_of_1962)