

# SUNSCREEN LEGISLATION SHOWS NO SIGNS OF HEATING UP

**T**HE SOCIETY of Cosmetic Chemists' 71st Annual Scientific Meeting and Technology Showcase was held for the first time at the Times Square Westin Hotel in New York City on Dec. 11-12, 2017. The proceedings were slightly delayed on the first day due to a terrorist incident in the subway station in the nearby Port Authority Bus Terminal (see Happi, January, p. 59).

The set-up, in my opinion, was more confusing than in previous years when it was held at the Hilton Hotel but, nevertheless, the meeting was well attended. The meeting featured 120 podium and poster presentations on cosmetic science, a supplier exhibit and several keynote speakers.

The Sunscreen Review (Session A) was a bit disappointing as the speakers did not adequately address the major issues that sunscreens confront in today's environment including issues related to the Final Sunscreen Monograph, especially the lack of one, and the topics concerning ultraviolet filters and regulations were not well covered. Audience



Hear, ye! Hear, ye? Will industry's sunscreen concerns be answered in Senate hearing rooms like this one?

participation reflected some of the frustrations that we all feel with the lack of adequate regulations and with the US Food and Drug Administration's intransigence in adopting new UVA filters and in addressing the vital issues relating to sprays, SPF limits, and, most importantly, on the safety and effectiveness of our current dismal number of approved ultraviolet filters.

The lack of adequate regulations still festers in the land and is not being adequately addressed by the FDA nor the recently approved Sunscreen Innovation Act (SIA). More than three years after it was signed into law by President Barack Obama, SIA was supposed to amend the Federal Food, Drug and Cosmetic Act to establish an expedited process for the review and approval of over-the-counter (OTC) sunscreens. Since 1999, the FDA has not approved a single new active ingredient in sunscreens despite the fact that at least a half dozen other UV filters exist in Europe and the rest of the world that adequately protect

against UVA radiation. The SIA created a process through which sunscreen manufacturers could get the so-called eight pending TEA (Time and Extent Applications) approved through an administrative order, and that order would then be added to the Final Monograph. When the FDA was finally forced by SIA to approve the ingredients that were introduced over a dozen years through the TEA process, they summarily rejected all eight! Further, FDA proposed additional complicated and controversial testing for adopting new ingredients into the US market.

## Let the Debate Begin

Now, Congress is debating an amended over-the-counter (OTC) bill that will presumably incorporate the SIA and the eight pending filters and be merged with the OTC Reform Act. On January 17, Senator Johnny Isakson (R-Ga.) introduced the Senate's OTC legislation as S. 2315. However, the House has not yet completed its deliberations.



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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 formed a consulting company serving the cosmetic industry called ShaathMeadows Corporation (SMC) with laboratories in New York, New Jersey, Texas, Florida and Egypt.

PASS (Public Access to SunScreens) coalition members are talking to staffers on both the House and Senate committees and to members on both sides of the aisle ensuring that the original priority goals met by the SIA are still preserved in the final bill.

Three issues apparently remain for debate in the House's version of the bill. The first is the "Cosmetic Consumer User Fee" legislation that was proposed by Representative Frank Pallone (D-NJ), the ranking member within the Energy and Commerce Committee, which is debating OTC reform and cosmetic regulations. The Personal Care Product Council (PCPC) seems to be involved in those negotiations.

The second is the "exclusivity language," with some members pushing back the exclusivity terms from two years to a period less than that.

Finally, the "confidentiality" of the meetings with the FDA is delaying the implementation of the bill. The FDA had recently implemented a program that would deem all meetings with sponsors of cosmetic and sunscreen products non-confidential and has also limited the number of meetings with the sponsors for each application.

### Is a Final Bill on the Way?

All indications are that the Republican sponsors in the House will soon submit their final version of the bill to the Health subcommittee. Presumably, as the House completes its deliberations of the bill, the Senate version seems to be complete, which will lead to the ensuing negotiations between the House's and the Senate's versions, and the final bill submitted for President Trump's signature soon. It should be mentioned that the Republicans have no appetite in marrying the OTC Reform bill with the Cosmetics Act while the Democrats seem to favor such action.

I hope and trust that I did not lose you in describing legislative actions in Congress! It takes a genius to understand the inner workings of how regulations are implemented in the US. If you are currently unaware that major legislation impacting cosmetics, drugs and sunscreens is being implemented in Congress today, make sure you contact your representative to better understand the implications of this legislation. The bottom line, however, is regardless of what version of the final bill being currently debated in Congress is passed and the ultimately signed by the President, it

seems to me that it will not speed up the process of approvals of the pending TEA ingredients, nor will it result in the imminent issuing of the long-awaited Final Sunscreen Monograph.

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Due to the seriousness of the pending legislation in Congress today, I have decided not to address any other sunscreen developments, as I usually do in my columns. Hopefully, this will give us all time to allow for reflection on the state of regulations in America today. ●



Whether in the surf or on the slopes, US consumers deserve better sunscreens!