

# UV Filter Concerns Addressed At Florida Sunscreen Symposium

The Florida Sunscreen Symposium this year was a major success. The attendance record was smashed with over 700 registrants and a host of speakers and exhibitors who captured the attention and interest of attendees. The first day featured a course entitled “Sunscreen Claims and Regulatory Overview,” a poster session, a golf outing and a lively cocktail reception. The presentations were held during the second and third day of the conference.

There were two speakers from the Personal Care Products Council (PCPC). As reported last month in HAPPI, Kimberly Norman of PCPC detailed the results of a nationwide survey on the application habits of sunscreen users in the US. The second PCPC representative, Alexandra Kowcz, spoke on the Sunscreen Consortium that the PCPC established in support of seven sunscreen active ingredients to be marketed as GRASE (Generally Regarded As Safe and Effective). The panel has worked diligently in the past four years and has compiled an impressive portfolio addressing the clinical, non-clinical concerns along with the for-



US Representative Alexandria Ocasio-Cortez (D-NY) and Senator Mike Lee (R-UT) have called for better sunscreens in the US.

mulation of the seven UV filters, namely Avobenzene, Ensulizole, Homosalate, Octisalate, Octinoxate, Octocrylene and Oxybenzone. This will be a monumental task to have those ingredients reclassified from their current status as Category III ingredients to Category I.

Kowcz was asked about the challenges and impediments of receiving approvals from the FDA on all seven ingredients—despite the fact that a JAMA study deemed most of those ingredients as skin penetrable with levels above the 0.5 ng level set in the MUsT studies. Her answer was that the consortium developed several unique, single active formulations in four different product forms as recommended by the FDA to be “market image” products. Hopefully, this will work as we are all counting on PCPC’s efforts to stop the carnage caused by dramatically diminishing the UV filters allowed in the US.

One very interesting and encouraging development was announced by DSM that it has submitted all the studies required to approve this European ingredient, Bemotrizinol (BEMT), as a GRASE Category I UV filter in the US. Approval of a new filter would be a wel-

come change after more than 25 years of no new discoveries or approvals in UV filters.

## FDA WEIGHS IN

Hearing presentations from two FDA representatives is always a welcome development, as they rarely address the sunscreen industry directly. Unfortunately, no announcements on issuing the Final Monograph were made. We heard Dr. Linda Katz discussing the Modernization of Cosmetic Regulation Act (MoCRA) for cosmetic regulations and then Dr. Chinmay Shukla spoke on clinical pharmacological assessments for topical sunscreens. Even though he spoke about the MUsT testing, which we heard about a few years back, he was at least engaging with the audience and attempted to address their concerns. Dr. Shukla was asked about comments made by Representative Alexandria Ocasio Cortez (D-NY) and Senator Mike Lee (R-UT). Both have publicly blamed the lack of new innovations in sunscreens and UV filters because sunscreens are classified as drugs and not cosmetics as most of the rest of the world classifies them. This fact, according to Ocasio-

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Cortez, is an impediment for approving new ingredients and has basically stifled innovation due to the high cost and time delays. Not surprisingly, Dr. Shukla recommended that we write to his superiors in the FDA.

### PASS EFFORTS

The PASS Coalition sent a thank you letter to Representative Ocasio-Cortez for addressing the issue of inadequate regulations in the US, and requested a meeting with her to coordinate our efforts in addressing those FDA regulatory issues and issuing the Final Monograph.

The PASS Coalition requested a meeting with the FDA a month ago with no response. A second request was sent to the Commissioner in the hopes that we finally get an audience to discuss all issues relevant to the publication of the



Further ecological risk assessment is required to determine whether UV filters are the culprit in coral bleaching, according to a study by the National Academy of Sciences.

Final Rule, addressing new UV filters, and all other issues related to the use and availability of effective sunscreens for the protection of consumers from the ravishing rays of the sun. The US

Congress has also decided to debate sunscreen regulations with the FDA in its upcoming session and calls to request more information were sent to coalitions established to ensure the proper protection of individuals and the lowering of the skin cancer rates in the US.

As expected, research and development of mineral sunscreens and testing methods commanded the lion's share of presentations and discussions. The final speaker was Dr. Cary Mitchelmore from the National Academy of Sciences, who presented Academy findings which basically concluded that a further ecological risk assessment was required to decide whether UV filters were the culprit in coral bleaching. Until these studies are completed, it is difficult to conclude that sunscreens should be implicated in environmental damage. ■