THE FINAL MONOGRAPH IS UPON US!

These are difficult times for the sunscreen industry. First, we were faced with the prospects of no Final Monograph in sight and no Time and Extent Application (TEA) filters to improve the protection of US consumers especially from the UVA solar radiation. Next, Category I filters came under fire from environmental groups, when action was taken in Hawaii, Palau, Key West, the US Virgin Islands and other locations that banned oxybenzone, octinoxate and octocrylene. Two other back-breaking decisions included the FDA's Final Proposal that found only two filters as Generally Recognized as Safe and Effective (GRASE) and approved as Category I filters, banned two filters (PABA and trolamine salicylate) and designated the remaining 12 filters as Category III requiring extensive data (MUsT, DART, etc.) before they can be reclassified as Category I. Finally, the FDA's report published in JAMA in May of this year found four filters (avobenzone, oxybenzone, octocrylene and ecamsule) exceeding the safety threshold limits of 0.5 ng/ml in the MUsT test.

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However, the sunscreen industry and its advocates sprung to action. The PASS Coalition requested a meeting with the Surgeon General, Vice Admiral Dr. Jerome Adams, who in turn invited representatives from the FDA, the EPA, the CDC, the ACS and the AAD to attend the October meeting. All promised to help. PASS held productive meetings with members of the House and the Senate. The Personal Care Product Council (PCPC) sent a letter to Dr. Theresa Michele of the FDA on Sept. 17, 2019 providing a draft of Work Plan for the generation and compilation of sunscreen safety data on behalf of its members. The PCPC requested a deferral to 2023 to decide the fate of eight UV filters deemed non-GRASE Category III ingredients by the FDA. The FDA conditionally agreed to a one-year deferral pending the publication of the detailed Work Plan. The eight filters that the PCPC plans to support, with the data that the FDA is requesting to include as GRASE Category I filters are avobenzone (CAS# 70356-09-1), homosalate (CAS#118-56-9), octinoxate (CAS# 5466-77-3), octisalate (CAS# 118-60-5), octocrylene (CAS# 6197-30-4), oxybenzone (CAS# 131-57-7), ensulizole (CAS# 27503-81-7) and meradimate (CAS# 134-09-8).

I hate being the bearer of bad news, but most of the above ingredients will require a miracle to pass the current MUsT test and be reapproved as Category I ingredients. Three of them (avobenzone, octocrylene and oxybenzone) failed the MUsT test with thresholds above the minimal safety levels. PCPC may have to present data justifying a modified MUsT test with differing safety levels. Oxybenzone, octinoxate and octocrylene are already banned in Hawaii, Key West and the US Virgin Islands, and considerable negative publicity has all but killed them as effective UV filters. The remaining four ingredients, homosalate, octinoxate, meradimate and ensulizole, are small molecules with molecular weights well below 500, which is the minimum requirement for non-penetration into the skin. Even though the MUsT test has not been applied to those four ingredients, my guess is that it would take a miracle to expect them to pass the current MUsT test with the 0.5ng/ml safety threshold.

So, where does that leave us? The FDA is mandated by the Sunscreen Innovation Act (SIA) to issue a Final Monograph by Nov. 26, 2019 (before you received this issue) and it will. FDA may defer a decision on at least 8 out of the 12 filters deemed as non-GRASE for at least one year and, perhaps, all the way to 2023. In the meantime, FDA will emphasize to the consumers that it is safe to use sunscreen products with filters currently labeled as non-GRASE until a final decision is reached in the future. My questions are: Will the FDA accept any of the thousands of petitions and comments they received to amend any of their February 26 proposals? Or will some of them, or all of them, be postponed?

These proposals that may or may not be adopted in the Final Monograph are:

1. GRASE status- Discussed above
2. Dosage Forms – My guess is that the FDA will proceed with classifying
   a. Oils, lotions, creams, gels, butters, pastes, ointments and sticks as Category I.
   b. Powders, wipes, towelettes, body wash and shampoos as Category II
   c. Will the FDA make a final decision on sprays?
3. Maximum SPF: I believe the FDA will adopt its Proposed Rules of SPF 60+
4. UVA and Broad Spectrum labeling I believe the FDA will adopt its Proposed Rules requiring the new calculation of: UVAI/UV = 0.7 minimum
5. PDP labeling Requirements: I believe the FDA will adopt their Proposed Rules on the changes to the Statement of Identity (SOI) suggested in February 2019.
6. Insect Repellent/ Sunscreen Combination Products: Here, I hope

FDA heard the many voices at the Florida Sunscreen Symposium requesting that the FDA allow the marketing of those combinations. Petitions allowing the marketing of these combinations were submitted too. I submitted a proposal to allow Category I GRASE zinc oxide as a sunscreen ingredient in combination with proven essential oils as insect repellents. All those ingredients are allowed by both the FDA and EPA. The petition highlighted the need for combination products, that the main objection by the FDA was the use of DEET and other harsh chemicals that may or may not interact with the UV absorbing filters (most notably oxybenzone), and that the use of the milder zinc oxide and effective essential oils would be advantageous. The FDA's main objection of contradictory EPA vs FDA label requirements was clearly addressed in the petition. Re-application by consumers every two hours is perfectly acceptable and recommended for those products, thereby addressing both FDA and EPA concerns. After all, anyone using an insect repellent while being exposed to the sun will also use sunscreen. Whether they use them in combination or in tandem, safe products as suggested in the petition, would make little difference of any possible interactions on the skin. Using combination products in one convenient bottle would encourage compliance for sun care and insect repellent protection and the use of the milder ZnO and essential oils would be safe and effective. I hope FDA will allow the proposed safe and effective repellent-sunscreen combination of zinc oxide and essential oils.

A recent study from the University of Washington School of Medicine in Seattle published in JAMA Dermatology,[1] demonstrated that skin cancer rates have been dropping since 2005 among teens and millennials who use sunscreens. That report, and a 2018 Australian study,[2] showed the risk of melanoma was reduced by 40% when sunscreens were used effectively since childhood. Such positive outcomes due to consumer compliance are extremely encouraging.

The sunscreen industry and the consumers have suffered greatly from the uncertainty of consistent final regulations; hopefully, the FDA's Final Monograph is reasonable and also approves the sorely needed, broad spectrum TEA filters from Europe.

Keep your eyes and ears open! ●

References:

1. Age-Specific Incidence of Melanoma in the United States", Jennifer M. Gardner, MD. et al. JAMA Dermatology, doi.org/10.1001/jamadermatol.2019.3353

2. "Sunscreen Use and Melanoma Risk Among Young Australian Adults", Caroline G. Watts, et al. JAMA Dermatology, 2018; doi:10.1001/jamadermatol.2018.1774