

ANOTHER FDA DELAY IS COMING OUR WAY

WHAT ARE the odds that the US Food and Drug Administration will issue the Final Monograph on November 26, 2019? The Sunscreen Innovations Act (SIA) of November 26, 2014 mandates its release within five years from that date. Additionally, the FDA released its Proposed Final Sunscreen Regulations on February 26, 2019 and promised to finalize the monograph by this very date. My simple answer is “No way!” Why do I say that? Well, one reason is the fact that the FDA has never met a deadline for the past 40 years or so since issuing the 1978 Advanced Notice for Proposed Rulemaking (ANPR). Other indications that allow me to liberally use the phrase “No way!” include the following recent developments:

- On April 18, the FDA published a notice in the Federal Register to extend the deadline for comments on the Proposed Rule to June 27, 2019.¹ Here we go: the first 30-day official extension.

- Also on April 18, the FDA published Technical Corrections regarding formulas.² This is an indication that changes and corrections to their proposed final regulations



If you were a teenager when FDA first proposed its sunscreen monograph, you're middle-aged by now!

are imminent. It is still a work-in-progress.

- The Feb. 26, 2019 Proposed Rule has created a major crisis in the sunscreen industry. It designated only two ingredients (zinc oxide and titanium dioxide) as GRASE Category I approved ingredients, banished two others (PABA and trolamine salicylate) to Category II (not allowed) status, and relegated the remaining 12 ingredients to Category III; i.e., unsafe until extensive data is submitted to approve them as GRASE Category I. Unless this action is rectified, or new ingredients such as the Time and Extent Application (TEA) filters are approved, it makes it impossible to have meaningful sunscreen protection in a cream, lotion, gel or a spray in the future.

All concerned organizations are scrambling to make sense of those Proposed Final Sunscreen Regulations. This includes many sun care manufacturers, suppliers of ultraviolet filters, the Personal Care Product Council, the Public Access to SunScreens (PASS) Coalition and others. The PCPC has set up several subcommittees to gather data from ultraviolet filter manufacturers in order to convince the FDA to reverse its recent course of action.

In the meantime, taking Hawaii's lead and that of the other municipalities in Florida and California, the call to ban oxybenzone and octinoxate for harming the coral reefs gets louder and more controversial. A few state senators in Florida are protesting Key West's action to ban those two

ingredients³ and some dermatologists are starting to worry about the lack of protection that banning those two ingredients and others will have an impact on the incidence of skin cancer. Meanwhile, the Environmental Working Group (EWG) and others, as well as the authors of more recent studies, are hailing their action of calling for the ban of oxybenzone and octinoxate.⁴

Senator Jeff Merkley (D-OR) and others have proposed new legislation in Congress authorizing the Environmental Protection Agency (EPA) to perform studies to test the environmental impact of oxybenzone and octinoxate. The PASS Coalition has also expressed an interest in studies that would not only look at the environmental impact of those sunscreen ingredients but also assess the potential negative public health impact of reducing or eliminating access to sunscreen ingredients. The PASS Coalition feels that the National Academy of Science (NAS) is better equipped to form ad hoc committees to look at scientific issues that span multiple agencies (in this case the EPA and FDA). This proposed approach represents a more comprehensive alternative to an EPA-only study on these issues. The time involved in completing this study will surely impact the date of issuing the Final Sunscreen Monograph and introduce meaningful legislation that insures the protection of consumers from the ravishing rays of the sun.

It is my belief that the impact those new FDA Proposed Regulations and the many actions taken by state municipalities banning sunscreen ingredients have not yet been fully realized or assessed. This, along with the fact that the FDA and government bureaucracy are unbelievably slow and cumbersome, insures that my stated predictions for a Final Monograph to be issued by November 26, 2019 is impossible, impractical and unfortunately will not happen!

The FDA released a bombshell report published in JAMA on May 6, 2019.⁵ The



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study evaluated four UV filters, avobenzone, oxybenzone, octocrylene and ecamsule in three vehicles (two spray products, a lotion and a cream). Twenty-four subjects were randomized to the four sunscreen products.

Spray 1 had 3% avobenzone, 6% oxybenzone, 2.35% octocrylene and 0% ecamsule.

Spray 2 had 3% avobenzone, 5% oxybenzone, 10% octocrylene and 0% ecamsule.

Lotion had 3% avobenzone, 4% oxybenzone, 6% octocrylene and 0% ecamsule.

Cream had 2% avobenzone, 0% oxybenzone, 10% octocrylene and 2% ecamsule.

The results of the MUSt test revealed the following:

- Avobenzone—All formulations had exposures exceeding 0.5 ng/mL on day 1, with the majority of participants reaching that threshold within six hours after the first application

- Oxybenzone—All three products had plasma concentrations exceeding 0.5ng/mL within two hours after a single application on day 1.

- Octocrylene—All four products resulted in exposures with plasma concentrations exceeding 0.5ng/mL within six hours of the first administration.

- Ecamsule—Five of the six participants in the cream study had plasma concentrations exceeding 0.5ng/mL on day 1.

The FDA acknowledges that the clinical effect of plasma concentrations exceeding 0.5ng/mL is unknown, necessitating further research. Regardless, this study has hit the air waves and will have a major impact on the medical community, the consumer and the whole sunscreen industry.

I will devote my next column to elaborate on this report and to address the impact it will have on sun protection and the industry. ●

References:

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