FDA PROPOSAL: PART I IS THE WAIT FINALLY OVER?

On Feb. 26, 2019, the FDA published a "proposed" rule that would put into effect a final monograph for non-prescription OTC sunscreen drug products.[1] It is being published to comply with the Federal Food, Drug and Cosmetic Act (FD&C Act) as amended by the Sunscreen Innovation Act (SIA) that we at the PASS (Public Access to SunScreen) Coalition lobbied for successfully in 2014. Written or electronic comments will be accepted by the FDA 90 days after the publication date, or by May 26, 2019.

Due to the importance of this document, I will devote two columns on the subject. Here, I will outline what the FDA is proposing. Next month, I will offer my comments and critique of the FDA's Proposed Rule.

The "Final Monograph" for non-prescription, OTC sunscreen drug products establishes conditions under which certain OTC drugs may be marketed without approved new drug applications because they are GRASE (Generally Recognized as Safe and Effective) and are not misbranded. The proposed rule classifies active ingredients as Category I (GRASE and not misbranded), Category II (not GRASE or misbranded) and Category III (additional data needed). Twenty years ago, on May 21, 1999, the FDA published the "Final Rule" and then on June 17, 2011, "stayed," i.e., invalidated the earlier issued 1999 ruling, and then required additional data regarding the safety of the individual sunscreen active ingredients. Shortly thereafter, a group of sunscreen and UV filter suppliers collaborated with some health advocates and sunscreen experts to form the PASS Coalition as a lobby group in Washington, DC.

With this latest announcement by the USFDA, are brighter days ahead for sun care raw material suppliers and their customers?

Our efforts in Congress to demonstrate the need for more effective ultraviolet filters (the pending TEA ingredients and others) culminated in the passing of the SIA bill and the signing into law by President Obama on November 26, 2014. The SIA calls for the FDA to issue a final OTC sunscreen monograph to be effective within five years of enactment (Section 586 E(a) of the FD&C Act). So, the time line for enacting a final rule is November 25, 2019, a mere seven months from now!

In Summary…

Here is a summary of the major provisions of the Proposed Rule:

1. Proposed GRASE Status of Active Ingredients listed in the stayed 1999 Final Monograph. According to the FDA only zinc oxide and titanium dioxide (at concentrations of up to 25%) would be GRASE and are Category I ingredients. Two other ingredients, namely PABA and trolamine salicylate, were classified as Category II; i.e., cannot be used anymore in sunscreen products. The FDA proposed that the remaining 12 ingredients be classified as Category III; i.e., require further testing. The FDA acknowledges that all 12 of these UV filters have limited data—or no data—characterizing their absorption. It specifically singled out oxybenzone being absorbed through the skin to a greater extent than previously understood.

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2. Proposed Requirements Related to Dosage Forms. In 2011, the FDA published an ANPR (Advanced Notice of Proposed Rule Making) identifying sunscreen dosage forms. This new proposal identifies the following dosage forms as Category I: oils, lotions, creams, gels, butters, pastes, ointments and sticks. As for "sprays" they would be considered Category I subject to further testing necessary to minimize potential risks from unintended inhalation (particle size restrictions), flammability, drying time testing and related labeling requirements. The FDA proposes to classify "powders" as Category III and that sunscreens in all other dosage forms, including "wipes, towelettes, body wash and shampoos," are new drugs because the FDA did not receive data showing that they were marketed prior to 1972, as required for inclusion in the monograph.

3. Proposed Maximum SPF and Broad Spectrum Requirements. The 1978 ANPR set SPF 15 as the maximum labeled SPF value, the 1999 Final Monograph (now stayed) established SPF 30+ as the maximum labeled SPF value and subsequently in 2011 raised the value to 50+. In this Proposed Rule (2019) the maximum allowed will be an SPF of 60+. The proposal permits the marketing of SPF values up to 80 and would allow sunscreen products with SPF values above 80 with an approved NDA. The FDA has raised concerns about the potential for inadequate UVA protection—particularly in high SPF sunscreen products. To address these concerns, FDA proposes that all sunscreen products with SPF values of 15 and above satisfy broad spectrum requirements and meet UVAI/UV ratio of 0.7 or higher. Finally, the proposal calls for testing at SPF 30 or more be labeled in increments of 10 (e.g., SPF 30, 40, 50, 60+) and sunscreen testing at SPF 15 to 29 be labeled in increments of 5 (e.g., SPF 15, 20, 25) and no ranges are required for SPFs below 15.

4. Proposed PDP Labeling Requirements. A major feature of the Principal Display Panel is the Statement of Identity (SOI). The FDA proposes that the SOI consist of alphabetical listing of the sunscreen active ingredients in the product, followed by "sunscreen" and the product's dosage form (such as lotion or spray). Other changes to the format of the PDP are also proposed.

5. Proposed Requirements Related to Final Formulation Testing Process and Record Keeping. The FDA is proposing to require records of the testing of sunscreen products to be maintained for one year after three years from the distribution of the last lot of the product. Other revisions will also be required.

FDA may finally be opening its eyes to the dangers posed by not approving UV ingredients.

6. Proposed Status of Sunscreen – Insect Repellent Combination Products. The FDA proposes to classify these products as Category II because of incompatibilities between FDA and EPA labeling requirements.

7. Proposed Actions to Effectuate Lifting of Stay and Harmonize Impacted Regulations. The FDA proposes to lift the stay on the 1999 Final Monograph subject to the revision of this proposed Final Rule.

On Feb. 27, FDA commissioner Dr. Scott Gottlieb testified before the House Agriculture-Rural Development Appropriations Subcommittee to answer questions regarding FDA's ongoing activities related to congressional funding. During the hearing, Rep. John Moolenaar (R-MI) asked the Commissioner about the proposed Sunscreen Rule issued a day earlier.

Specifically, he asked about the 90-day data submission timeline for the existing 12 ingredients to conform with the rule. Gottlieb replied that the ingredients would not be banned or come off the market and that the manufacturers of those 12 ingredients for which the FDA is requesting additional data to make a GRASE determination, can request a deferral to gain more time to collect and submit data while the proposed rule is finalized.

During this data submission period, the ingredients would remain on the market during the review process. He also predicted that the agency is expecting six to eight of those 12 ingredients to receive deferrals.

(Last month, news reports indicated that Gottlieb will soon leave his post at the government agency.)

I will comment and critique the specific proposals next month's The Sunscreen Filter column. Stay tuned! ●

References:

1. www.fda.gov/Drugs/DevelopmentApprovalProcess/