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FDA's Proposed Order For Sunscreens, A First Under OTC Reforms, Reprises 2019 Proposed Rule

by Ryan Nelson

As anticipated, the US FDA's proposed order for sunscreens released on 24 September creates a bridge to the agency's 2019 proposed rule before the CARES Act overhauled OTC drug review in March 2020.

The US Food and Drug Administration's 24 September proposed order to amend the OTC sunscreen drug monograph provides a first look at the new administrative – versus rulemaking – process for OTC drug review under reforms achieved through COVID relief legislation last year.

Acting FDA commissioner Janet Woodcock states in a same-day release, "Today's activities represent a key milestone in our implementation of transformative new authorities related to OTC drugs that will allow us to continue ensuring that sunscreens are safe and effective for frequent, life-long use and provide consumers with the protection they expect from these products."

Woodcock adds, "We are committed to using our new authorities to help meaningfully advance innovative, safe and effective options for consumers and secure a robust OTC marketplace."

While providing a taste of the future, the FDA's *proposed order* simultaneously transports sunscreen industry stakeholders more than two years back in time, as it essentially reprises positions taken by the agency in a 2019 proposed rule on sunscreen drug products. ((Also see "*'Data Gaps' Keep 12 Ingredients Off FDA's Proposed OTC Sunscreen Monograph*" - HBW Insight, 21 Feb, 2019.)

The agency is asking those who submitted timely comments on the 2019 proposed rule not to provide them again, a request it emphasized in a same-day press briefing.

According to the FDA, the requirements it is proposing for sunscreens via administrative order are "substantively the same" as those laid out in the 2019 proposed rule, with just "minor changes".

The agency explains, "Similarly, our scientific discussions regarding sunscreens are generally the same. ... FDA is using this proposed order as a vehicle to efficiently transition its ongoing consideration of the appropriate requirements for OTC sunscreens marketed without approved applications from the previous rulemaking process to the order process created by new section 505G of the FD&C Act."

That means that UV filters zinc oxide and titanium dioxide are proposed again as generally recognized as safe and effective (GRASE), while avobenzone, homosalate, octinoxate, octisalate, octocrylene, oxybenzone, ensulizole, and meradimate, among others, are again tentatively not GRASE due to insufficient data.

Industry previously requested deferred rulemaking for the above-listed chemical UV filters in order to address data gaps identified by the FDA in its proposed rule, work that a consortium of companies has carried on to date. (Also see "*US FDA's Proposed Sunscreen Order Due With Inquiry Ongoing Re Environmental Impacts*" - HBW Insight, 21 Sep, 2021.)

The FDA remains concerned that sunscreens are being used by more people more regularly and in greater amounts, while a growing body of research suggests that sunscreen ingredients can absorb through skin to greater extents than previously understood, all of which could challenge previously held safety assumptions. (Also see "*FDA's Follow-Up Sunscreen Trial Shows More Of The Same: Absorption Of All Tested UV Filters*" - HBW Insight, 21 Jan, 2020.)

Specifically, the FDA says "the significant systemic availability of oxybenzone, coupled with a lack of data evaluating the full extent of its absorption potential, is a concern, among other reasons, because of questions raised in the published literature regarding the potential for endocrine activity in connection with systemic oxybenzone exposure."

The agency notes, "Nearly all of these sunscreen active ingredients also have insufficient or no data characterizing their absorption."

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Proposed SPF Caps Are Back

The FDA's proposed order, which meets a deadline set by the Coronavirus Aid, Relief, and Economic Security (CARES) Act enacted in late March 2020, also addresses testing and labeling issues related to SPF and broad-spectrum protection. The agency calls for an SPF 60+ labeling cap, an SPF 80 formulation cap, and requirements to ensure that UVA defense increases in proportion to SPF – again, generally in line with its 2019 proposal.

With regard to dosage forms, the FDA is inclined to deem oils, lotions, creams, gels, butters, pastes, ointments, and sticks as GRASE for use in sunscreens, in addition to spray sunscreens "subject to testing necessary to minimize potential risks from unintended inhalation (particle size restrictions) and flammability (flammability and drying time testing), together with related labeling requirements."

According to the agency, data are insufficient to support a GRASE proposal for powder sunscreens. The FDA maintains that new drug approvals are required for all other sunscreen dosage forms, including wipes, towelettes, body washes, and shampoos. (Also see "*FDA Scorches Sunscreen Wipe Marketers With October Warning Letters*" - HBW Insight, 25 Oct, 2016.)

Among other provisions, the proposed order also seeks to revise current requirements for information that must appear on the principal display panel of sunscreen products "to make it easier for consumers to identify key product information."

The FDA will consider public comments on the proposed order submitted during a 45-day period before issuing a revised final order. The agency is asking those who submitted timely comments on the 2019 proposed rule not to provide them again, a request it emphasized in a same-day press briefing, assuring stakeholders that their previous comments will be considered constructively submitted to the proposed order.

Should industry submit new data that resolves uncertainty as to the GRASE status of a sunscreen ingredient currently deemed under-supported, the FDA will proceed to a revised final order that reflects its changed conclusion, according to the proposed order.

On the other hand, if the comment period closes without the missing data having been provided, but the FDA has received adequate indication of timely and diligent progress on needed studies, the agency says it is prepared to defer issuance of a revised final order for up to one year, with a possibility for extension if progress is still being made to its satisfaction.

"However, if, in FDA's judgment, studies for any active ingredient do not appear to be proceeding in a timely manner or otherwise do not appear to be productive, the Agency expects that it will proceed to a revised final order on sunscreens containing this ingredient after this initial deferral," the agency says.

The FDA notes that the effective date for a revised final order cannot be earlier than one year after its issuance, per the CARES Act.

Industry should be pleased that the FDA continues to recognize the important public health benefits of sunscreen use.

“Americans can reduce risks from sun exposure with continued use of sun protection measures including broad spectrum sunscreen with SPF values of at least 15,” Woodcock says in the release.