

# FDA Issues New Proposed Rule on Regulatory Requirements for Sunscreen Products

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Food, Drug, and Device

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Yesterday, FDA issued a much anticipated updated [proposed rule](#) on regulatory requirements for over the counter (OTC) sunscreen products. The proposed rule, if finalized, would require significant formulation changes in a number of marketed products that contain sunscreens, including both “beach products” and “cosmetic drugs.” Most significantly, FDA proposes:

- Of the 16 marketed active ingredients for sun protection, only titanium dioxide and zinc oxide are Generally Recognized as Safe and Effective (GRASE) for use in sunscreens;
- There is insufficient safety data to make a positive GRASE determination for 12 of the currently-marketed actives; and
- PABA and trolamine salicylate (not currently marketed in the U.S.) are not GRASE for sunscreens.

FDA additionally proposes a 90-day comment period, **an effective date for a final rule of November 26, 2019**, in keeping with the [Sunscreen Innovation Act](#), and **a compliance date of November 26, 2020 for units initially introduced or delivered for introduction in interstate commerce** after that date. FDA said it would not expect full compliance for items initially introduced or initially delivered for introduction into interstate commerce before that date, but solicited comments on that approach.

The proposal, which FDA [described](#) as a “significant action,” would provide clarity regarding the key requirements for marketing sunscreen products, a regulatory framework that has been in flux for decades. The proposed rule is part of FDA’s [ongoing](#) effort to advance its framework for sun protection products in reaction to new safety data and changing sunscreen usage in recent years, as more people use sunscreen products more frequently and in larger amounts.

If finalized, the proposed rule would put into effect a final monograph for OTC sunscreen drug products that are GRASE, as required by the Sunscreen Innovation Act. Specifically, the proposal addresses sunscreen active ingredient safety, dosage forms, and sun protection factor (SPF) and broad-spectrum requirements. It also proposes updates to product labeling to make it easier for consumers to identify key product information. FDA proposes to harmonize provisions between the new monograph requirements and existing regulations, including, among others, the sunscreen labeling requirements in 21 CFR 201.327.

### Active Ingredient Safety

FDA continues to conclude that zinc oxide and titanium dioxide are GRASE for use in sunscreens at concentrations of up to 25%. But FDA raised questions about whether virtually

every other sunscreen active ingredient on the market is GRASE. FDA also tentatively concluded that aminobenzoic acid (PABA) and trolamine salicylate are not GRASE for use in sunscreens due to safety concerns.

Crucially, FDA tentatively concluded that it has insufficient information at this time to make GRASE determinations about cinoxate; dioxybenzone; ensulizole; homosalate; meradimate; octinoxate; octisalate; octocrylene; padimate O; sulisobenzene; oxybenzone; and avobezone. FDA seeks additional information from industry and third parties to address data gaps for these ingredients, such as absorption data.

### **Dosage Forms**

Under the proposed rule, dosage forms that are GRASE for use as sunscreens would include sprays, oils, lotions, creams, gels, butters, pastes, ointments, powders and sticks. For spray sunscreens, FDA's Category I determination would be subject to testing necessary to minimize potential risks from unintended inhalation (particle size restrictions) and flammability (flammability and drying time testing). For powders, eligibility for inclusion in the monograph would be subject to particle size restrictions and additional data described in the proposed rule.

FDA tentatively concluded that wipes, towelettes, body washes, shampoos, and other dosage forms are not eligible for inclusion in the monograph and are instead new drugs, because the Agency did not receive data showing that those dosage forms were marketed prior to 1972.

### **Sun Protection Factor (SPF)**

Because of evidence showing additional meaningful clinical benefits associated with broad spectrum sunscreen products with an SPF of 60, FDA proposes to raise the maximum allowed SPF value on sunscreen labels from SPF 50+ to SPF 60+.

Given the lack of data showing that sunscreens with SPF values above 60 provide additional meaningful clinical benefits, FDA proposes not to allow labeled SPF values higher than 60. However, sunscreen products *formulated* with SPF values of up to 80 could be marketed. FDA expressed hope that this "formulation flexibility" will help facilitate development of products with greater Ultraviolet A protection and will account for the range of variability in SPF test results.

### **Broad-Spectrum Requirements**

The proposed rule also includes new UVA protection requirements arising from the growing body of scientific evidence linking UVA exposure to skin cancers. Specifically, FDA is concerned that high SPF sunscreen products that do not pass the current broad spectrum test or have inadequate uniformity in their UVA protection may fail to protect consumers from accumulating excessively large doses of UVA radiation.

To address this concern, the proposed rule would require sunscreens with an SPF value of 15 or higher to provide broad spectrum protection. The rule would also add to the current broad spectrum test a requirement that broad spectrum products meet a UVA I/UV ratio of 0.7 or higher. FDA described the need to ensure that sunscreen products provide adequate UVA I protection as "critical."

The rule would also require that sunscreen products with SPF values of 15 or higher be labeled with an SPF number corresponding to the lowest number in a range of tested SPF results. For example, sunscreens testing at 15-19 would be labeled "SPF 15." This proposal arises from

FDA's examination of the inherent variability of SPF testing (which relies on visual assessments).

### **Labeling Requirements**

The proposed rule would also impose several new labeling requirements. The rule would require that the statement of identity on a product's principal display panel consist of an alphabetical listing of the sunscreen active ingredients in the product, followed by "Sunscreen" and the product's dosage form. FDA expressed hope that this information would help consumers more easily compare products.

Additionally, for sunscreen products that have not met the relevant requirements to demonstrate that they help prevent skin cancer or early skin aging caused by the sun, labeling rules would require the SPF statement to be followed by an asterisk (\*) directing consumers to see a "Skin Cancer/Skin Aging Alert" elsewhere on the label.

The new rule would also revise the format requirements for the SPF, broad spectrum and water resistance statements on the principal display panel to prevent the required information being obscured by other labeling features.

### **Testing & Record-Keeping**

If finalized, the new rule would clarify FDA's expectations for testing and record-keeping by entities that conduct sunscreen testing, to ensure that FDA can assess industry compliance. The rule would require that responsible persons maintain records of mandatory final formulation testing for 1 year after the product expiration date or for 3 years after distribution of the last lot labeled in reliance on that testing. Responsible persons would be required to keep records of sunscreen formulation testing, and the rule would clarify that those records are subject to FDA inspection.

### **Sunscreen-Insect Repellent Combination Products**

Finally, the proposed rule would classify sunscreen-insect repellent products (which are jointly regulated by FDA as sunscreen drugs and the EPA as pesticides) as Category II products. FDA has tentatively concluded that incompatibilities between FDA and EPA labeling requirements prevent these products from being labeled in a way that sufficiently ensures safe and effective use of the sunscreen component.

### **Public Comment and Acceptance of New Safety and/or Effectiveness Data**

FDA is [accepting](#) public comments from industry and other interested parties for 90 days after the proposed rule is published in the Federal Register. FDA will also review any new safety and/or effectiveness data that is submitted during the comment period and may use such information in assessing whether to extend the comment period to allow for additional time for studies to generate new data and information.

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If you would like to submit comments, or if you have any questions concerning the information discussed in this alert, please contact the following members of our Food, Drug, and Device Practice Group:

<b><u>Jessica O'Connell</u></b>	+1 202 662 5180	<a href="mailto:jpoconnell@cov.com">jpoconnell@cov.com</a>
<b><u>Jeannie Perron</u></b>	+1 202 662 5687	<a href="mailto:jperron@cov.com">jperron@cov.com</a>
<b><u>MaryJoy Ballantyne</u></b>	+1 202 662 5933	<a href="mailto:mballantyne@cov.com">mballantyne@cov.com</a>
<b><u>Claire O'Brien</u></b>	+1 202 662 5775	<a href="mailto:cobrien@cov.com">cobrien@cov.com</a>

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