

FDA FACT SHEET

FDA PROPOSED ORDER: SUNSCREEN DRUG PRODUCTS FOR OVER-THE-COUNTER-HUMAN USE; PROPOSAL TO AMEND AND REVISE THE DEEMED FINAL ORDER ESTABLISHED BY THE CARES ACT

On March 27, 2020, the Coronavirus Aid, Relief, and Economic Security Act (CARES Act) was signed into law. Through provisions in new section 505G of the Federal Food, Drug and Cosmetic Act (FD&C Act), the CARES Act established and put into effect as of that date a Deemed Final Order (DFO) that sets forth certain current requirements for OTC sunscreen products. Sunscreens that conform to these DFO requirements (and to other requirements specified by section 505G of the FD&C Act, including the general requirements for nonprescription drugs) can be legally marketed without an approved new drug application. The CARES Act also directs FDA to amend and revise the DFO for OTC sunscreens products. Accordingly, FDA issued a proposed order that, if finalized, would replace this sunscreen DFO in its entirety with new conditions under which nonprescription sunscreen drug products would be determined to be generally recognized as safe and effective (GRASE). The proposed order also sets forth certain characteristics that would establish that a sunscreen drug product is not GRASE.

This action is an important example of FDA's ongoing efforts to ensure that sunscreens are safe and effective for regular, life-long use. The agency anticipates these changes will improve the quality, safety, and efficacy of sunscreens Americans use every day. FDA will continue to work with industry and public health stakeholders to make sure that consumers have access to safe and effective sunscreens.

1. Proposed GRASE Status of Active Ingredients Listed in the Deemed Final Order

FDA has proposed the following categories for the 16 sunscreen monograph ingredients.

GRASE* for use in sunscreens	Not GRASE** for use in sunscreens because of safety concerns	***Not GRASE for use in sunscreen because additional data needed
Zinc oxide and titanium dioxide	Aminobenzoic acid (PABA) and trolamine salicylate	Cinoxate, dioxybenzone, ensulizole, homosalate, meradimate, octinoxate, octisalate, octocrylene, padimate O, sulisobenzone, oxybenzone, avobenzene

*GRASE= Generally Recognized as Safe and Effective, when also in conformity with all other applicable requirements **These ingredients are not currently marketed. ***For ingredients in this category, FDA's proposed order identifies additional data that, if provided, might establish that sunscreens with these ingredients are GRASE.

2. Proposed Requirements Related to Dosage Forms

FDA is proposing sunscreen oils, lotions, creams, gels, butters, pastes, ointments, and sticks as GRASE. FDA proposes that spray sunscreens are also GRASE, subject to proposed testing to minimize potential risks from unintended inhalation (particle size restrictions) and flammability (product flash point and drying time testing), together with related labeling requirements. We are proposing that there is insufficient data to classify sunscreen in the powder dosage form as GRASE and expect that powders would be subject to particle size restrictions if found to be GRASE for sunscreen use in a final order. Finally, we note that, by operation of section 505G(m)(2) of the FD&C Act, sunscreens in all dosage forms other than the 10 dosage forms identified above currently require an application approved under section 505 in order to be marketed. (Sunscreens in dosage forms that require an NDA in order to be marketed include, for example, wipes, towelettes, body washes, and shampoos). The proposed order does not propose to change this requirement.

3. Proposed Maximum Sun Protection Factor and Broad Spectrum Requirements

FDA had previously proposed (in 2011) that the maximum permissible labeled SPF value be SPF 50+. Because evidence shows additional meaningful clinical benefit associated with broad spectrum SPF 60 sunscreens, FDA is now proposing that the maximum labeled SPF value should be SPF 60+. While our proposed cap for SPF labeling is SPF 60+, we are proposing to permit the marketing of sunscreen products formulated with SPF values up to 80 (this formulation margin is intended to more fully account for the range of variability in SPF test results, among other things). We are proposing not to allow the marketing (without an approved NDA) of sunscreen products with SPF values above SPF 80. We are also proposing to require that sunscreens with SPF values of 15 or above be labeled with an SPF corresponding to the lowest number in a range of tested results. For example, sunscreens testing at SPF 15-19 would be labeled "SPF 15". This change would help ensure that there is a meaningful difference among labeled SPF values and better account for the range of variability in SPF test results.

In addition, the body of scientific evidence linking UVA exposure to skin cancers and other harms has grown significantly in recent years. To address this concern, FDA is proposing:

- To require that all sunscreens with SPF values of 15 and above satisfy broad spectrum requirements.
- To add a requirement to the current broad spectrum test to ensure that as SPF increases, broad spectrum protection also increases, and that broad spectrum products provide adequate protection against UVA.

FDA is seeking comment on whether SPF 2-14 sunscreens should remain on the market. They have not been demonstrated to help reduce the risk of skin cancer and early skin aging when used as directed with other sun protection measures, and we are not proposing to require that they pass the revised broad spectrum test.

4. Proposed Principal Display Panel (PDP) Labeling Requirements

To help make it easier for consumers to choose the sunscreen that best fits their needs and understand what type of skin protection each sunscreen offers, we're proposing labeling changes:

- To include an alphabetical listing of active ingredients, followed by "Sunscreen" and dosage form (such as lotion or spray).
- For sunscreens with an SPF below 15, we are proposing to require the SPF statement be followed by asterisk directing consumers to see the "Skin Cancer/Skin Aging alert" in the Drug Facts Label.
- To revise format requirements for the SPF, broad spectrum, and water resistance statements on the label to ensure they are prominent.

5. Proposed Requirements Related to Final Formulation Testing Processes and Recordkeeping

We are clarifying our expectations for testing and record keeping by entities that conduct sunscreen testing. To ensure that FDA can assess industry compliance with applicable requirements, we propose:

- To require that records of required final formulation testing of sunscreens be maintained for 1 year after the product expiration date, or, if the product is exempt from expiration dating (as most sunscreens are), for 3 years after distribution of the last lot labeled in reliance on that testing.
- To require industry to keep records of sunscreen formulation testing and clarify that required records would be subject to FDA inspection.
- Other requirements designed to clarify FDA expectations about clinical final formulation testing processes and to ensure that sunscreen testing is conducted in a way that both protects human subjects and produces reliable results.

6. Proposed Status of Sunscreen-Insect Repellent Combination Products

Sunscreen-insect repellent combination products are proposed as not GRASE because incompatibilities between instructions for use for sunscreens and insect repellents prevent these products from being labeled in a manner that sufficiently ensures safe and effective use of the sunscreen component.