

# FDA FACT SHEET

## FDA PROPOSED RULE: SUNSCREEN DRUG PRODUCTS FOR OVER-THE-COUNTER-HUMAN USE; PROPOSAL TO AMEND AND LIFT STAY ON MONOGRAPH

On February 21, 2019, FDA [issued a proposed rule](#) describing the conditions under which FDA proposes that OTC sunscreen monograph products are generally recognized as safe and effective (GRASE) and not misbranded.

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 Stayed 1999 Final Monograph

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

| GRASE* for use in sunscreens    | Not GRASE** for use in sunscreens                 | ***Insufficient data for use in sunscreens   |
|---------------------------------|---|--|
| Zinc oxide and titanium dioxide | Aminobenzoic acid (PABA) and trolamine salicylate | Cinoxate, dioxybenzone, ensulizole, homosalate, meradimate, octinoxate, octisalate, octocrylene, padimate O, sulisobenzene, oxybenzone, avobenzone |

\*GRASE= Generally Recognized as Safe and Effective \*\*These ingredients are not currently marketed. \*\*\*For those ingredients in the “insufficient data” category, FDA proposes that it needs additional data to determine that sunscreens with these ingredients would be GRASE.

### 2. Proposed Requirements Related to Dosage Forms

After considering all available data, 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. Sunscreen powders are proposed to be eligible for inclusion in the monograph but we propose that we need additional data to support their GRASE status. We expect that powders would also be subject to particle size restrictions if found to be GRASE for sunscreen use in the final monograph. Sunscreens in all other dosage forms – including wipes, towelettes, body washes, and shampoos – are proposed to be excluded because FDA did not receive data showing that they were eligible for inclusion in the monograph.

### 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 our regulations, 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.
- To require a number of revisions to labeling and testing regulations 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. 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. There are also data suggesting that combining some sunscreen active ingredients with some insecticides may increase absorption of one or both components.

#### **7. Proposed Actions to Effectuate Lifting of Stay and Harmonize Impacted Regulations**

FDA is proposing to lift the stay on the 1999 Final Monograph and has proposed revisions to the regulations necessary to lift the stay and to harmonize any impacted regulations.