FDA Advances New Rule to Ensure Sunscreens Are Safe and Effective

The proposal addresses active ingredient safety, dosage forms, and SPF and broad-spectrum requirements for over-the-counter sunscreens.

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FDA advances new proposed regulation to make sure that sunscreens are safe and effective

The U.S. Food and Drug Administration today issued a proposed rule that would update regulatory requirements for most sunscreen products in the United States.

This significant action is aimed at bringing non-prescription, over-the-counter (OTC) sunscreens that are marketed without FDA-approved applications up to date with the latest science to better ensure consumers have access to safe and effective preventative sun care options. Among its provisions, the proposal addresses sunscreen active ingredient safety, dosage forms, and sun protection factor (SPF) and broad-spectrum requirements. It also proposes updates to how products are labeled to make it easier for consumers to identify key product information.

“Broad spectrum sunscreens with SPF values of at least 15 are critical to the arsenal of tools for preventing skin cancer and protecting the skin from damage caused by the sun’s rays, yet some of the essential requirements for these preventive tools haven’t been updated in decades. Since the initial evaluation of these products, we know much more about the effects of the sun and about sunscreen’s absorption through the skin. Sunscreen usage has changed, with more people using these products more frequently and in larger amounts. At the same time, sunscreen formulations have evolved as companies innovated. Today’s action is an important step in the FDA’s ongoing efforts to take into account modern science to ensure the safety and effectiveness of sunscreens,” said FDA Commissioner Scott Gottlieb, MD. “The proposal we’ve put forward would improve quality, safety and efficacy of the sunscreens Americans use every day. We will continue to work with industry, consumers and public health stakeholders to ensure that we’re striking the right balance. To further advance these goals, we’re also working toward comprehensive OTC reform, which will help foster OTC product innovation as well as facilitate changes necessary for the FDA to keep pace with evolving science and new safety data.”

The agency is issuing this proposed rule to put into effect final monograph regulations for OTC sunscreen drug products as required by the Sunscreen Innovation Act. OTC monographs establish conditions under which the FDA permits certain OTC drugs to be marketed without approved new

drug applications because they are generally recognized as safe and effective (GRASE) and not misbranded. Over the last twenty years, new scientific evidence has helped to shape the FDA's perspective on the conditions, including active ingredients and dosage forms, under which sunscreens could be considered GRASE.

In the proposed rule, the FDA makes the following proposals for sunscreens marketed without FDA-approved applications:

- Proposes that, of the 16 currently marketed active ingredients, two ingredients — zinc oxide and titanium dioxide — are GRASE for use in sunscreens; two ingredients — PABA and trolamine salicylate — are not GRASE for use in sunscreens due to safety issues. There are 12 ingredients for which there are insufficient safety data to make a positive GRASE determination at this time. To address these 12 ingredients, the FDA is asking industry and other interested parties for additional data. The FDA is working closely with industry and has published several guidances to make sure companies understand what data the agency believes is necessary for the FDA to evaluate safety and effectiveness for sunscreen active ingredients, including the 12 ingredients for which the FDA is seeking more data.

- Proposes that dosage forms that are GRASE for use as sunscreens include sprays, oils, lotions, creams, gels, butters, pastes, ointments and sticks. Powders are proposed to be eligible for inclusion in the monograph, but additional data are requested before powders can be included in the monograph. Wipes, towelettes, body washes, shampoos and other dosage forms are proposed to be categorized as new drugs because the FDA has not received data showing they are eligible for inclusion in the monograph.

- Proposes to raise the maximum proposed SPF value on sunscreen labels from SPF 50+ to SPF 60+.

- Proposes to require sunscreens with an SPF value of 15 or higher to also provide broad spectrum protection and that, for broad-spectrum products, as SPF increases, the magnitude of protection against UVA radiation also increases. These proposals are designed to ensure that

these products provide consumers with the protections that they expect.

- Proposes new sunscreen product label requirements to assist consumers in more easily identifying key information, including the addition of the active ingredients on the front of the package to bring sunscreen in line with other OTC drugs; a notification on the front label for consumers to read the skin cancer/skin aging alert for sunscreens that have not been shown to help prevent skin cancer; and revised formats for SPF, broad spectrum and water resistance statements.

- Proposes to clarify FDA's expectations for testing and record keeping by entities that conduct sunscreen testing to ensure that the FDA can assess industry compliance with regulations.

- Proposes that products that combine sunscreens with insect repellents are not GRASE.

"It is important that, as this rulemaking effort moves forward and the FDA gathers additional scientific information, given the recognized public health benefits of sunscreen use, consumers continue to use sunscreen in conjunction with other sun-protection measures," said Janet Woodcock, M.D., director of the FDA's Center for Drug Evaluation and Research. "To help make sure this effort is successful, the FDA is looking to industry to gather the data needed to help ensure that products marketed to offer protection from the sun's effects are safe and deliver on these promises."

As this rulemaking process proceeds, OTC sunscreen products will continue to be available on the market for consumer use. Sunscreens are only one element of a skin-cancer prevention strategy. Other sun protective behaviors include: wearing protective clothing that adequately covers the arms, torso and legs; wearing sunglasses and a hat that provides adequate shade to the whole head; and seeking shade whenever possible during periods of peak sunlight.

The FDA is seeking public comment on the proposed rule and will consider comments provided as the agency works towards developing a final rule.

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