FDA takes new action to improve quality and efficacy of sunscreens

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As part of its ongoing implementation of new authorities for certain over-

the-counter (OTC) drugs, the U.S. Food and Drug Administration has taken actions aimed at improving the quality, safety, and efficacy of sunscreens.

The provisions in the Sept. 24 proposed order closely follow a 2019 proposed rule on sunscreens and aim to bring sunscreens that are marketed without FDA-approved applications up to date with the latest science to better ensure safety and efficacy for consumers. There is a 45-day public comment period before a revised final order will be released. Comments are being accepted through Nov. 12, 2021.

The FDA is proposing updates to the generally recognized as safe and effective (GRASE) status for 16 active ingredients. For instance, sunscreens containing zinc oxide and titanium dioxide would meet GRASE status, but sunscreens with aminobenzoic acid and trolamine salicylate would not. Other changes include limiting the maximum labeled sun protection factor to 60+ and other product labeling requirements.

"We applaud the efforts by the FDA and industry to prioritize patient health," Kenneth J. Tomecki, M.D., president of the American Academy of Dermatology Association (AADA), said in a statement. "We look forward to the completion of the required testing and analysis to help eliminate public confusion about sunscreen ingredients."

More information: Update on Sunscreen Requirements
More Information from the FDA
Notice of Proposed Order
AADA Statement