FDA Proposes Sunscreen Regulation Changes

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The U.S. Food and Drug Administration (FDA) regulates sunscreens to ensure they meet safety and effectiveness standards. To improve the quality, safety, and effectiveness of sunscreens, FDA issued a proposed rule that describes updated proposed requirements for sunscreens. Given the recognized public health benefits of sunscreen use, Americans should continue to use broad spectrum sunscreen with SPF 15 or higher with other sun protective measures as this important rulemaking effort moves forward.

Highlights of FDA's Proposals

1 Sunscreen active ingredient safety and effectiveness

Two ingredients (zinc oxide and titanium dioxide) are proposed to be safe and effective for sunscreen use and two (aminobenzoic acid (PABA) and trolamine salicylate) are proposed as not safe and effective for sunscreen use. FDA proposes that it needs more safety information for the remaining 12 sunscreen ingredients (cinoxate, dioxybenzone, ensulizole, homosalate, meradimate, octinoxate, octisalate, octocrylene, padimate O, sulisobenzone, oxybenzone, avobenzone).

2 Sunscreen dosage forms

Sunscreen sprays, oils, lotions, creams, gels, butters, pastes, ointments, and sticks are proposed as safe and effective. FDA proposes that it needs more data for sunscreen powders.

3 New proposed sun protection factor (SPF) and broad spectrum requirements

- Raise the maximum proposed labeled SPF from SPF 50+ to SPF 60+
- Require any sunscreen SPF 15 or higher to be broad spectrum
- Require for all broad spectrum products SPF 15 and above, as SPF increases, broad spectrum protection increases

4 New proposed label requirements

- Include alphabetical listing of active ingredients on the front panel
- Require sunscreens with SPF below 15 to include "See Skin Cancer/Skin Aging alert" on the front panel
- Require font and placement changes to ensure SPF, broad spectrum, and water resistance statements stand out

5 Sunscreen-insect repellent combination products proposed not safe and effective