

## FDA Announces New Rules for OTC Sunscreen Products

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The FDA recently announced new requirements for sunscreens sold over-the-counter. The new rules came in the form of a Final Rule, a Proposed Rule, an Advance Notice of Proposed Rulemaking, and a Draft Guidance for Industry.

The Final Rule, which will be effective in the summer of 2012, addresses the labeling of sunscreens with Sun Protection Factor (SPF) ratings. Currently, SPF ratings relate only to protection against sunburn caused by ultraviolet (UV) B rays and not to protection against skin cancer and premature skin aging caused by UVA rays. The Final Rule establishes a Broad Spectrum SPF rating which covers both UVA and UVB protection. Sunscreens that pass FDA's broad spectrum test procedure may be labeled as "Broad Spectrum SPF [value]." Further, sunscreens with a Broad Spectrum SPF value of 15 or more can claim to reduce the risk of skin cancer and early skin aging when used as directed and with other skin protection measures. The other skin protection measures include wearing protective clothing and limiting exposure to the sun. Conversely, sunscreens with a Broad Spectrum SPF value of 2-14, or which do not pass the broad spectrum test, can only claim to prevent sunburn. These rules apply to all cosmetics and moisturizers that claim to provide Broad Spectrum SPF protection.

The Final Rule also prohibits manufacturers from labeling sunscreens as "waterproof" or "sweatproof" or as "sunblocks." Further, without prior FDA approval, manufacturers cannot claim that their sunscreens provide "immediate" protection or that they provide protection for more than two hours without reapplication. Claims of "water resistance" must state whether the sunscreen remains effective for 40 or 80 minutes while swimming or sweating, based on standard testing. Sunscreens that are not water resistant must include an instruction to consumers to use a water resistant sunscreen if swimming or sweating. Finally, all sunscreens must include standard "Drug Facts" information.

The Proposed Rule would limit the maximum SPF value on sunscreen labels to 50+. According to the FDA, there is insufficient evidence that products with SPF values higher than 50 provide greater protection for users.

By the Advance Notice of Proposed Rulemaking, the FDA is seeking additional data on the safety and effectiveness of sunscreen products in different dosage forms, such as lotions, oils, sticks, gels, butters, ointment, creams and pastes. Prior rules have not specified to which dosage forms the regulations apply, and the FDA is seeking evidence upon which to base such a decision.

Although the Final Rule does not become effective until the summer of 2012, consumers can already see the new labeling as manufacturers take advantage of the use claims.

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