



New FDA Sunscreen Regulations for 2012

The Food and Drug Administration (FDA) is taking steps to help protect consumers from skin damage caused by excessive sun exposure.

The new measures include the following:

- Final regulations that establish standards for testing the effectiveness of sunscreen products and require labeling that accurately reflects test results
- A proposed regulation that would limit the maximum SPF value on sunscreen labeling to "SPF 50+"
- A data request for safety and effectiveness information for sunscreen products formulated in certain dosage forms (e.g., sprays)
- A draft guidance for sunscreen manufacturers on how to test and label their products in light of these new measures.

These measures are necessary, says Lydia Velazquez, PharmD, in FDA's Division of Nonprescription Regulation Development, because "our scientific understanding has grown. We want consumers to understand that not all sunscreens are created equal."

"This new information will help consumers know which products offer the best protection from the harmful rays of the sun," Velazquez says.

"It is important for consumers to read the entire label, both front and back, in order to choose the appropriate sunscreen for their needs."

Everyone is potentially susceptible to sunburn and the other detrimental effects of exposure to UV radiation.

FDA's Final Regulations

The final regulations, which become effective in one year, establish a standard test for over-the-counter (sold without a prescription) sunscreen products that will determine which products are allowed to be labeled as "Broad Spectrum."

Products that pass this test will provide protection against both ultraviolet B radiation (UVB) and ultraviolet A radiation (UVA). Sunburn is primarily caused by UVB. Both UVB and UVA can cause sunburn, skin cancer, and premature skin aging. A certain percentage of a broad spectrum product's total protection is against UVA.

Under the new regulations, sunscreen products that protect against all types of sun-induced skin damage will be labeled "Broad Spectrum" and "SPF 15" (or higher) on the front.

The new labeling will also tell consumers on the back of the product that sunscreens labeled as both "Broad Spectrum" and "SPF 15" (or higher) not only protect against sunburn, but, if used as directed with other sun protection measures, can reduce the risk of skin cancer and early skin aging. For these broad spectrum products, higher SPF (Sun Protection Factor) values also indicate higher levels of overall protection.

By contrast, any sunscreen not labeled as "Broad Spectrum" or that has an SPF value between 2 and 14, has only been shown to help prevent sunburn. Reynold Tan, a scientist in FDA's Division of Nonprescription Regulation Development, notes that FDA has been developing testing and labeling requirements for sunscreen products for decades. However, only recently have the data become sufficient to establish an accurate and reliable test for broad spectrum UV protection, he says.

To help consumers select and use sunscreens appropriately, the final regulations include these additional labeling provisions:

- Sunscreen products that are not broad spectrum or that are broad spectrum with SPF values from 2 to 14 will be labeled with a warning that reads: "Skin Cancer/Skin Aging Alert: Spending time in the sun increases your risk of skin cancer and early skin aging. This product has been shown only to help prevent sunburn, not skin cancer or early skin aging."
- Water resistance claims on the product's front label must tell how much time a user can expect to get the declared SPF level of protection while swimming or sweating, based on standard testing. Two times will be permitted on labels: 40 minutes or 80 minutes.
- Manufacturers cannot make claims that sunscreens are "waterproof" or "sweatproof, or identify their products as "sunblocks." Also, sunscreens cannot claim protection immediately on application (for example, "instant protection") or protection for more than two hours without reapplication, unless they submit data and get approval from FDA.

<http://www.fda.gov/ForConsumers/ConsumerUpdates/ucm258416.htm>