

## New rules to cut confusion on sunscreen claims

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Alivia Parker, 21 months, runs through circles of spraying water on a 100-degree day in Montgomery, Ala., Tuesday, June 14, 2011. Parker is wearing sunscreen with an SPF of 100. Federal regulators will require sunscreen manufacturers to test their products' effectiveness against sun rays that pose the greatest risk of skin cancer. Under new rules, manufacturers also will have to follow stricter guidelines when describing how well their products block ultraviolet B rays. (AP Photo/Dave Martin)

(AP) -- Help is on the way to consumers confused by the jumble of sun protection numbers and other claims on sunscreens.

Currently, standards of protection apply only to one part of the sun's spectrum, ultraviolet B rays, which cause sunburn. Under new rules published Tuesday, they will also have to protect against the more penetrating ultraviolet A rays associated with skin cancer.

The guidelines, which spent more than 30 years in bureaucratic limbo, are designed to enhance the effectiveness of sunscreens and make them easier to use.

The key takeaway for consumers: Look for a sun protection factor, or SPF, of 15 and above that also says "broad spectrum." That's the new buzzword from the Food and Drug Administration to describe a product that does an acceptable job blocking both types of damaging rays.

Starting next summer, sunscreens with less than an SPF of 15 or that aren't "broad spectrum" will have to carry a warning label: "This product has been shown only to help prevent sunburn, not skin cancer or early skin aging."

"These changes to sunscreen labels are an important part of helping consumers have the information they need so they can choose the right sun protection for themselves and their families," said Dr. Janet Woodcock, director of FDA's drug division.

The new regulations require testing for the more dangerous ultraviolet A rays, which can penetrate glass and pose the greatest risk of skin cancer and premature aging. Now, the FDA only requires testing for ultraviolet B rays that cause sunburn. That's what the familiar SPF measure is based on.

"For the first time, the FDA has clearly defined the testing required to make a broad-spectrum protection claim in a sunscreen and indicate which type of sunscreen can reduce skin cancer risk," said Dr. Ronald L. Moy, president of The American Academy of Dermatology Association.

Under the new rules:

- The FDA will prohibit sunscreen marketing claims like "waterproof"

and "sweatproof," which the agency said "are exaggerations of performance."

- The FDA also proposes capping the highest SPF value at 50, unless companies can provide results of further testing that support a higher number.
- FDA says manufacturers must phase out a four-star system currently used by some companies to rate UVA protection.

In reviewing more than 3,000 comments submitted to the agency, the FDA decided the star system was too confusing. Instead, protection against UVA should be proportional to protection against UVB, which is already measured using SPF.

The SPF figure indicates the amount of sun exposure needed to cause sunburn on sunscreen-protected skin compared with unprotected skin. For example, an SPF rating of 30 means it would take the person 30 times longer to burn wearing sunscreen than with exposed skin.

The rules were decades in the making.

FDA announced its intent to draft sunscreen rules in 1978 and published them in 1999. The agency then put the plan on indefinite hold until it could address issues concerning both UVA and UVB protection.

Several companies have already adopted the some of the language. For example, all Coppertone products from Merck & Co.'s Schering-Plough unit and Neutrogena Sunblock from Johnson & Johnson already boast "broad spectrum UVA and UVB protection."

Most dermatologists recommend a broad spectrum, water-resistant sunscreen of SPF 30 or higher every two hours while outside.

Last year an estimated 68,130 people in the U.S. were diagnosed with melanoma - the most dangerous form of skin cancer - and an estimated 8,700 died, according to the National Cancer Institute. Nearly \$2 billion is spent treating the disease each year.

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