

Main points of the new FDA regulations for sunscreen

Broad Spectrum labeling:

The final regulation allows sunscreen products that pass the FDA's test for protection against both ultraviolet A (UVA) and ultraviolet B (UVB) rays to be labeled as "Broad Spectrum" on the front label. This is a Pass/Fail test based on the amount of UVA & UVB wavelength blocked.

Use claims:

Under the new labeling, sunscreens labeled as **both** Broad Spectrum and SPF 15 or higher, can claim to help prevent sunburn, reduce the risk of skin cancer, and reduce the risk of early skin aging if used regularly, as directed, and in combination with other sun protection measures.

Products that have SPF values between 2 and 14 may be labeled as Broad Spectrum if they pass the required test, but may **NOT** state that they reduce the risk of skin cancer and early skin aging, when used as directed.

Any product that is not Broad Spectrum, **OR** that is Broad Spectrum but has an SPF between 2 to 14, will be required to have a warning stating that the product has not been shown to help prevent skin cancer or early skin aging.

"Waterproof, "sweatproof" or "sunblock" claims:

Sunscreens may not be labeled as "waterproof" or "sweatproof," or as "sunblocks". These claims overstate their effectiveness. Sunscreens also cannot claim to provide sun protection for more than 2 hours without reapplication or to offer instant protection without submitting data to support these claims and obtaining FDA approval.

Water resistance claims:

Water resistance claims on the front label must indicate whether the sunscreen works for either 40 minutes or 80 minutes while swimming or sweating, based on standard testing. Sunscreens that are not water resistant must include a direction instructing consumers to use a water resistant sunscreen if swimming or sweating.

Drug Facts:

All sunscreens must include standard "Drug Facts" information on the back and/or side of the container.

Proposed Rule: NOT YET FINALIZED

The proposed rule would limit the maximum SPF value on sunscreen labels to "50 +". The proposed rule is available for public comment.