

New FDA requirements for over-the-counter (OTC) sunscreen products marketed in the U.S.

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On June 14, 2011 the U.S. Food and Drug Administration (FDA) announced new requirements for sunscreens currently sold over-the-counter (OTC) (i.e. non-prescription). These requirements support the Agency's ongoing efforts to ensure that sunscreens meet modern-day standards for safety and effectiveness. The new requirements, as well as several proposed changes for future rules, are outlined in four regulatory documents that include a Final Rule, a Proposed Rule, an Advance Notice of Proposed Rulemaking, and a Draft Guidance for Industry.

The following questions and answers provide a brief overview of the recent regulatory actions and highlight the most important information for consumers to know when buying and using sunscreen products.

Q1. Why is FDA making changes to how sunscreens are marketed in the United States?

A. FDA is making changes to how sunscreens are marketed in the United States as part of the Agency's ongoing efforts to ensure that sunscreens meet modern-day standards for safety and effectiveness and to help consumers have the information they need so they can choose the right sun protection for themselves and their families. Prior rules on sunscreens dealt almost exclusively with protection against sunburn, which is primarily caused by ultraviolet B (UVB) radiation from the sun, and did not address ultraviolet A (UVA) radiation, which contributes to skin cancer and early skin aging. After reviewing the latest science, FDA determined that sufficient data are available to establish a "broad spectrum" test for determining a sunscreen product's UVA protection. Passing the broad spectrum test shows that the product provides UVA protection that is proportional to its UVB protection.

Sunscreen products that pass the broad spectrum test are allowed to be labeled as "Broad Spectrum." These "Broad Spectrum" sunscreens protect against both UVA and UVB rays. Scientific data demonstrated that products that are "Broad Spectrum SPF 15 [or higher]" have been shown to reduce the risk of skin cancer and early skin aging when used

with other sun protection measures, in addition to helping prevent sunburn. Other sun protection measures include limiting time in the sun and wearing protective clothing.

These testing and labeling requirements are necessary to provide consumers with the information they need to make informed choices when selecting sunscreens.

Q2. When will these changes take effect?

A. The Final Rule will take effect by the summer of 2012, but consumers may begin to see changes to sunscreen labels before the effective date.

Q3. What does the SPF value on sunscreen labels indicate?

A. The SPF value indicates the level of sunburn protection provided by the sunscreen product. All sunscreens must be tested according to an SPF test procedure. The test measures the amount of ultraviolet (UV) radiation exposure it takes to cause sunburn when a person is using a sunscreen in comparison to how much UV exposure it takes to cause a sunburn when they do not use a sunscreen. The product is then labeled with the appropriate SPF value indicating the amount of sunburn protection provided by the product. Higher SPF values (up to 50) provide greater sunburn

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protection. Because SPF values are determined from a test that measures protection against sunburn caused by ultraviolet B (UVB) radiation, SPF values only indicate a sunscreen's UVB protection.

However, sunscreens that pass the new broad spectrum test will have demonstrated that they also provide ultraviolet A (UVA) protection that is proportional to their UVB protection. To pass the broad spectrum test, sunscreens with higher SPF values will provide higher levels of UVA protection as well. Therefore, under the new label requirements, a higher SPF value for sunscreens labeled "Broad Spectrum SPF [value]" will indicate a higher level of protection from both UVA and UVB radiation.

Q4. Does FDA believe sunscreens are still safe and effective? Do consumers need to throw away the sunscreens they are currently using?

A. The ingredients in FDA-approved sunscreens marketed today have been used for many years, and FDA has no reason to believe these products are not safe and effective when used as directed. Therefore, FDA is not advising consumers to throw away their current sunscreen products.

Sunscreens on the shelf today may have varying levels of ultraviolet A (UVA) radiation protection, but by next year, sunscreens that claim to provide UVA protection, otherwise known as broad spectrum protection, will be required to pass FDA's standardized test. This broad spectrum test will enable consumers to determine the level of UVA protection a sunscreen provides in addition to its ultraviolet B (UVB) radiation protection. This information will allow them to better manage their skin cancer and early skin aging risks. FDA does not want consumers to stop using currently marketed sunscreens in the meantime, as these products still offer sun protection.

It is also important to note that FDA is not questioning the safety of any ingredients used in marketed sunscreens. FDA believes the risk of not using sunscreen is much greater than any potential risk posed by sunscreen ingredients.

Q5. What do consumers most need to know when buying and using sunscreens?

A. Spending time in the sun increases a person's risk of skin cancer and early skin aging. To reduce these risks, consumers should regularly use a Broad Spectrum sunscreen with an SPF value of 15 or higher in combination with other protective measures such as:

- Limiting time in the sun, especially between the hours of 10 AM and 2 PM when the sun's rays are the strongest.
- Wearing clothing to cover skin exposed to the sun (long-sleeved shirts, pants, sunglasses, and broad-brimmed hats) when possible.

- Using a water resistant sunscreen if swimming or sweating.
- Reapplying sunscreen, even if it is labeled as water resistant, at least every 2 hours. (Water resistant sunscreens should be reapplied more often after swimming or sweating, according to the directions on the label.)

Consumers should also be aware that no sunscreens are "waterproof" because all sunscreens eventually wash off. Sunscreens can only be labeled as "water resistant" if they are tested according to the required SPF test procedure. Sunscreens labeled "water resistant" sunscreens will also be required to state whether the sunscreen remains effective for 40 minutes or 80 minutes when swimming or sweating, and all sunscreens will be required to provide directions on when to reapply.

Q6. What are the main points of the new Final Rule?

A. The new final rule includes the following requirements:

- **Broad Spectrum designation.** Sunscreens that pass FDA's broad spectrum test procedure, which measures a product's ultraviolet A (UVA) protection relative to its ultraviolet B (UVB) protection, may be labeled as "Broad Spectrum SPF [value]" on the front label. For Broad Spectrum sunscreens, SPF values also indicate the amount or magnitude of overall protection. Broad Spectrum SPF products with SPF values higher than 15 provide greater protection and may claim additional uses, as described in the next bullet.
- **Use claims.** Only Broad Spectrum sunscreens with an SPF value of 15 or higher can claim to reduce the risk of skin cancer and early skin aging if used as directed with other sun protection measures. Non-Broad Spectrum sunscreens and Broad Spectrum sunscreens with an SPF value between 2 and 14 can only claim to help prevent sunburn.
- **"Waterproof," "sweatproof" or "sunblock" claims.** Manufacturers cannot label sunscreens as "waterproof" or "sweatproof," or identify their products as "sunblocks," because these claims overstate their effectiveness. Sunscreens also cannot claim to provide sun protection for more than 2 hours without reapplication or to provide protection immediately after application (for example – "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 remains effective for 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.

Q7. Does the Final Rule apply to cosmetics and moisturizers containing sunscreen?

A. Yes. All products that claim to provide Broad Spectrum SPF protection are regulated as sunscreen drug products. Therefore, the regulations FDA has developed for OTC sunscreen drug products apply to cosmetics and moisturizers labeled with SPF values.

Q8. What does the Proposed Rule address?

A. The proposed rule, if finalized, would limit the maximum SPF value on sunscreen labels to “50 +” because there is not sufficient data to show that products with SPF values higher than 50 provide greater protection for users than products with SPF values of 50.

The proposed regulation is available for public comment at regulations.gov¹ until September 15, 2011.

Q9. What is the purpose of the Advance Notice of Proposed Rulemaking (ANPR)?

A. The Advance Notice of Proposed Rulemaking (ANPR) allows the public a period of time to comment on regulations FDA may pursue as part of future rulemaking. In developing regulations for over-the-counter (OTC) sunscreens, FDA has not previously specified to which dosage forms the regulations would apply. Therefore, FDA is requesting additional data relating to sunscreen products in specific dosage forms to further our understanding of how dosage forms affect the safety and effectiveness of sunscreen products. For example, the ANPR invites public comment on possible directions for use of and warnings for sunscreen sprays, as well as supporting data or information for sprays and other sunscreen dosage forms including lotions, oils, sticks, gels, butters, ointments, creams, and pastes. The ANPR also explains how interested parties can supply information for FDA to consider other dosage forms, including powders, towelettes, body washes, and shampoos.

Q10. Why is the Advance Notice of Proposed Rulemaking (ANPR) requesting additional data on sunscreen products in the form of sprays?

A. Currently, the record (data and information) about sunscreens in spray dosage forms is not comparable to that for sunscreens in other dosage forms such as oils, creams, and lotions. The manner of application differs significantly between sprays and these other dosage forms. Therefore, we are requesting additional data to address questions of effectiveness and safety that arise from differences in the manner of application.

Q11. What is included in the Draft Guidance for Industry?

A. The Draft Guidance for Industry, entitled “Enforcement Policy – OTC Sunscreen Drug Products Marketed Without an Approved Application (PDF-83KB)²,” is an enforcement guidance that includes information to help sunscreen product manufacturers understand how to label and test their products in light of the new Final Rule, the Proposed Rule, and the Advance Notice of Proposed Rulemaking (ANPR).

Q12. Why isn’t FDA finalizing all the proposed sunscreen changes under one rule?

A. FDA is finalizing those changes that are based on proposals it made in earlier stages of rulemaking, including a 2007 proposed rule, on which it already received public comment. Those comments also helped to inform the Agency’s thinking about additional aspects of sunscreen regulation, which in turn gave rise to the Proposed Rule and Advance Notice of Proposed Rulemaking (ANPR). The regulatory process requires FDA to give public notice and opportunity for comment before finalizing additional changes, which also gives the public and FDA an opportunity to further develop the record (data and information) on safety and effectiveness.

Q13. Where can I find more information on these various regulatory actions?

A. On June 17, 2011, FDA published the new sunscreen Final Rule (PDF-485KB)³, the Proposed Rule (PDF-197KB)⁴, the Advance Notice of Proposed Rulemaking (ANPR) (PDF-187KB)⁵ and the notice of availability of the Draft Guidance for Industry (PDF-217KB)⁶ in the Federal Register. The draft guidance entitled “Enforcement Policy – OTC Sunscreen Drug Products Marketed Without an Approved Application” (PDF-83KB)⁷, is also available.

Q14. Where can I find more information on sunscreen use?

A. Additional information about FDA’s changes to sunscreen regulations can be found at www.fda.gov/sunscreen⁸. At this link, consumers can see what new sunscreen labels will look like, what types of sun protection various sunscreens will provide, and how to use sunscreens safely and effectively.

In addition, FDA responded to common questions about the new sunscreen regulations submitted by the WebMD community via Twitter and Facebook. These questions and FDA’s responses can be found at WebMD Newsroom: FDA’s New Sunscreen Rules – FAQ⁹.

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