FDA 2011 Sunscreen Regulations
Talking Points

Key Messages

• The FDA’s sunscreen regulations will help the public reduce their risk for skin cancer.
  ▪ The FDA’s sunscreen regulations will give consumers more descriptive label information to help them make informed decisions about products to protect their skin.

• For the first time, FDA is clearly defining the testing required to make a broad-spectrum protection claim in a sunscreen.
  ▪ “Broad-spectrum protection” means a sunscreen protects the skin from ultraviolet A (UVA) and ultraviolet B (UVB) rays, both of which can cause skin cancer.
  ▪ Under the new FDA regulations, sunscreens that have an SPF of at least 15 and pass the test required by the FDA can reduce the risk of skin cancer and early skin aging when used as directed.

• The label also will outline the simple ways people can protect their skin from UV exposure and early aging, and ultimately reduce their risk of getting skin cancer.
  ▪ It’s simple – apply and reapply sunscreen, seek shade and wear protective clothing, hats and sunglasses.
  ▪ Broad-spectrum protection sunscreen with SPF 15 or higher is just one tool to help stop skin cancer. You also need to limit UV exposure by seeking shade, wearing protective clothing, hats and sunglasses, and avoiding tanning beds.

Frequently Asked Questions

New FDA Sunscreen Regulations

1. What does the Academy think about the FDA’s Sunscreen Regulations?
The American Academy of Dermatology Association (Academy) is delighted that the Food and Drug Administration (FDA) has clearly defined the testing method required to make a broad-spectrum claim on sunscreens. This has been missing until now.

“Broad-spectrum protection” means a sunscreen protects the skin from ultraviolet A (UVA) and ultraviolet B (UVB) rays, both of which can cause skin cancer.

(Follow-up Question): How do the new regulations do this?

There are sunscreen ingredients that are known to block the different types of UV rays. For many years, the protection provided by a sunscreen against UVB rays was clearly indicated by the SPF (sun protection factor) number on the product
label. But in the absence of the new FDA rules, “broad-spectrum protection” was open to interpretation by sunscreen manufacturers. On the same shelf, one sunscreen could provide the kind of protection required by the new FDA regulations to make the broad-spectrum protection claim, while another sunscreen with the same SPF could make the broad spectrum claim with a less protective type of UVA ingredient.

The Academy strongly supports the FDA’s efforts to help educate the public about protecting themselves from the dangers of the sun. The labeling requirements introduced today are a positive step in that direction.

2. How will these regulations benefit consumers?
   The proposed rule should take the guess work out of choosing an effective sunscreen by setting standards for making broad-spectrum claims and requiring understandable label information on sunscreens. Now when you buy a sunscreen that says “broad spectrum” you will know you are getting protection from UVA and UVB rays that can cause skin cancer.

And, the new FDA sunscreen product label is consistent with the Academy’s efforts to encourage the public to take simple steps to protect their skin – apply sunscreen, wear protective clothing and seek shade.

3. What sunscreen labeling rules are currently in effect?
   Until now, none. The 1999 version of the sunscreen monograph was never finalized and put into effect, and compliance with its labeling requirements has been voluntary. The FDA’s new rules go into effect one year from today for sunscreens that sell more than $25,000 per year, and two years for sunscreens with sales of less than $25,000.

4. Until the FDA’s new regulations go into effect, how should the public choose an effective sunscreen?
   Consumers should use a sunscreen with a Sun Protection Factor (SPF) of 30 or higher that provides broad-spectrum protection from both ultraviolet A (UVA) and ultraviolet B (UVB) rays. They should re-apply the sunscreen every two hours, even on cloudy days, and after swimming or sweating. In addition to using sunscreen, they should seek shade and wear protective clothing, such as a long-sleeved shirt, pants, a wide-brimmed hat and sunglasses, where possible.

Sunscreens and Sun-Safety Information

5. Do sunscreens provide people with a false sense of security from the sun?
   While scientific evidence supports the beneficial effects of proper sunscreen usage, no sunscreen can provide 100 percent UV protection. People should limit their time in the sun even while wearing sunscreen.
This is why the Academy continues to affirm its long-standing position that the use of sunscreen is only one component of a comprehensive UV-protection program and urges people to Be Sun Smart®. Here’s how to do it:

- **Generously apply sunscreen** to all exposed skin using a Sun Protection Factor (SPF) of 30 or higher that provides broad-spectrum protection from both ultraviolet A (UVA) and ultraviolet B (UVB) rays. Re-apply every two hours, even on cloudy days, and after swimming or sweating.

- **Wear protective clothing**, such as a long-sleeved shirt, pants, a wide-brimmed hat and sunglasses, where possible.

- **Seek shade** when appropriate, remembering that the sun’s rays are strongest between 10 a.m. and 4 p.m.

- **Use extra caution near water, snow and sand** as they reflect the damaging rays of the sun which can increase your chance of sunburn.

- **Get vitamin D safely** through a healthy diet that includes vitamin supplements. Don’t seek the sun.

- **Avoid tanning beds.** Ultraviolet light from the sun and tanning beds can cause skin cancer and wrinkling. If you want to look like you’ve been in the sun, consider using a sunless self-tanning product, but continue to use sunscreen with it.

6. **We’ve seen labels that claim “broad spectrum” for a long time; how will this rule’s requirements be any different?**
   Until now, there has been no consistent definition of “broad spectrum.” This ruling specifies that only sunscreens with an SPF of 15 or higher that pass the test required by the FDA can claim to be broad spectrum.

7. **Why does the Academy recommend Broad Spectrum SPF 30 or higher and the FDA recommends Broad Spectrum SPF 15 or higher?**
   Under the FDA’s new regulations for sunscreens, Broad Spectrum SPF 15 will provide excellent UVA and UVB protection when applied and reapplied liberally. However, we know that people are not fully protecting themselves because they don’t use enough sunscreen and don’t always follow the other sun-protection steps we have been recommending for years.

   The American Academy of Dermatology recently increased its recommendation on the SPF number from 15 or higher to 30 or higher because scientific evidence confirms that people do not apply enough sunscreen to get adequate protection. By recommending a higher SPF sunscreen, we expect that the public will be better protected if they don’t use as much sunscreen as they should.
8. What is the difference between ultraviolet A (UVA) and ultraviolet B (UVB) rays?
Sunlight consists of two types of harmful rays – UVA rays and UVB rays. An easy way to remember the difference is that “A” rays are the “aging” rays and “B” rays are the “burning” rays. The UVB rays (which are blocked by window glass) are the primary cause of sunburn and skin cancer. UVA rays (which pass through window glass) penetrate deeper into the dermis, or base layer of the skin. Both types of rays can suppress the immune system, and interfere with the body’s ability to defend against the development and spread of skin cancer. Excessive UVA exposure also can age the skin and cause wrinkles and age spots.

When implemented, this proposed sunscreen rule will help consumers choose adequate broad-spectrum protection against UVA and UVB rays.

The Dangers of UV Exposure and the Risk of Developing Skin Cancer

9. Is there a safe way to tan?
There is no safe way to tan with ultraviolet radiation. A suntan is the skin’s response to injury from ultraviolet radiation. Tanning occurs when the sun’s ultraviolet rays penetrate the skin’s inner layer, causing the skin to produce more melanin, which darkens the skin, as a response to the injury. Chronic exposure to the sun changes the skin’s texture, causing wrinkles and age spots. Thus, tanning to improve appearance is ultimately self-defeating.

Every time you tan, you accumulate damage to the skin. This damage accelerates the aging process and increases your risk for all types of skin cancer, including melanoma.

Spray tans are considered the safest way to tan, but continue to use sunscreen afterwards because your skin is not protected from UV rays.

10. How many skin cancers are diagnosed in the U.S. annually?
Currently, 1 in 5 Americans will develop some form of skin cancer in their lifetime. The incidence of skin cancer continues to rise, and in 2011, more than 3.5 million cases of skin cancer will be diagnosed in more than 2 million people,..
A recent study found that basal cell carcinoma and squamous cell carcinoma are increasing in men and women under 40. In the study, basal cell carcinoma increased faster in young women than in young men. (Christensen, LJ, JAMA 2005)

It was estimated that in 2010 there would be 114,900 l cases of melanoma and melanoma in situ, the deadliest form of skin cancer. The World Health Organization estimates that as many as 65,161 people a year worldwide die from too much sun, mostly from malignant skin cancer.
11. How has the Academy been working with the FDA?
The Academy has been providing scientific data and recommendations on sunscreen regulations to the FDA for decades. Since the release of the sunscreen monograph by the FDA in 1999, the Academy has urged the FDA to include requirements for ultraviolet A (UVA) protection in sunscreens and to increase the sun protection factor (SPF) allowed to be reported for sunscreens.

The Academy is committed to reducing the incidence of skin cancer and educating the public about the importance of sun safety. The Academy looks forward to providing the public with the information necessary to effectively protect themselves from the damaging rays of the sun.

12. Why did the FDA choose the Academy to join in the announcement today?
That’s really a question for the FDA, but we’re certainly pleased that FDA recognizes the critical role dermatologists play in educating the public about using sunscreen to help prevent skin cancer and that we have been advocating for better sunscreen labels for years.

13. The Academy provided 11 pages of comments and citations. Did you get everything you wanted?
The American Academy of Dermatology Association is pleased with the FDA’s sunscreen regulations and its commitment to helping the public make informed decisions on how to protect their skin.

We thank the FDA for seriously considering the comments submitted by the Academy and nearly 2,900 other interested organizations and individuals

There are aspects of our comments that weren’t addressed, and we look forward to further guidance. For now, these regulations represent a positive step. There are now simple, consistent labeling requirements so the public can make informed decisions about buying and using sun-protection products, and other sun-protection steps, such as seeking shade, and wearing protective clothing, hats and sunglasses.

We will continue to partner with the FDA and other skin cancer stakeholders as we educate the public about UV safety.

We stand ready to provide comments on sunscreens and any other dermatology-related questions for which the FDA seeks information.

(If pressed:) There are aspects of our comments that weren’t addressed, and we look forward to further guidance. For now, we are pleased with this positive step.

14. So, what other issues were not addressed?
Our focus is on the issues that were addressed. Specifically, consistent definitions and labeling requirements that will allow people to make informed decisions about sunscreen products.

There are aspects of our comments that weren’t addressed, and that we look forward to further guidance. For now, we are pleased with this positive step.

15. What about the chemicals in sunscreen that aren’t addressed in this rule? To date, no studies have indicated there is an inherent danger with any of these ingredients, and the benefits of wearing sunscreen in the prevention of skin cancer are well documented.

16. Why do you think it has taken so long for the Food and Drug Administration (FDA) to release these regulations? That’s a question for the FDA. This is a regulation of landmark proportion. We commend the FDA for thoroughly reviewing the thousands of comments it received and taking this positive step to help make it easier for consumers to choose effective sunscreens.. This will help reduce skin cancer incidence and save lives. As with any important issue, the Academy will continue to advocate with the FDA on behalf of its members and the public.

(If pressed:) The Academy has urged the FDA to broaden the requirements in its sunscreen monograph released in 1999. We’re pleased that we now have these important regulations.

17. Isn’t it a conflict of interest for you to speak so favorably about sunscreens when your organization takes money from sunscreen companies? For more than 25 years, dermatologists and the American Academy of Dermatology have been educating the public to protect their skin in many ways – limiting UV exposure by seeking shade and wearing protective clothing, hats and sunglasses.

We recommend using sunscreens because scientific evidence shows that they work. Sunscreens are an important tool in preventing skin cancer, but you also need to wear protective clothing, hats and sunglasses, and seek shade.

Dermatologists are the experts in skin cancer prevention and some consult with companies to help create the most effective sunscreens possible. The Academy is completely transparent about the funding it receives and uses best practices when managing any conflict of interest.

(If pressed:) I can have one of our staff members contact you to provide more information.