

FDA Set to Slather Us With New Sunscreen Regulations, But Will They Stick?

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By Brian Donnelly



While soaking up those glorious rays of sunshine this summer, Americans should be mindful about what types of rays their sunscreen bottles claim to protect against, because the manufacturers won't.

The sun emits two types of ultraviolet (UV) radiation that penetrates the ozone layer. Most sunscreen products protect against just one kind — ultraviolet B rays — which can cause sunburns. But most products do not protect against ultraviolet A rays, which are responsible for wrinkles — and skin cancer. The truth is, sunscreen manufacturers aren't going to tell you what their product *won't* protect against, only what it will — and even that isn't a guarantee, according to some doctors.

But this isn't a new problem.

This October, the Food and Drug Administration (FDA) plans to issue the first new regulations for sunscreen in more than 30 years. The proposed changes, which would be the final rule to the FDA's 2007 proposed guide,

may implement new testing and labeling practices to clear up the confusion over the reliability of the sun protection factor (SPF), and whether products actually do what they advertise, such as lasting all day, being waterproof or qualifying as sunblock — meaning they protect against both UVA and UVB rays.

The guidelines currently in place, adopted in 1978, give sunscreen manufacturers room to fudge the facts about their products. The biggest offense many commit is advertising their product as sunblock, said Dr. Ariel Ostad, assistant professor of dermatology at NYU Medical Center.

"A lot of companies now come out with SPF 60, or 80 or 100, and that's misleading. But that's only half the equation because that only protects against UVB... They don't really block UVA that well. And that's why there's this whole controversy over regulation," said Ostad, who added that sunscreen manufacturers likely don't include ingredients that would better protect against UVA rays because it would cost them more, therefore driving up the cost to the consumer.

There is no such thing as a waterproof sunscreen, according to Ostad. He said he advises his patients to apply sunscreen every two hours while exposed to the sun, and that they do so liberally — using about one shot glass worth.

In the 2007 proposed rule, the FDA introduced a new four-star grading system for UVA protection, 1 being the lowest and 4 the highest degree of protection.

"Hopefully, by October, new regulations will force these manufacturers to grade on a scale of 1 to 4 of how well their products block both UVA and UVB," Ostad said.

While he is hopeful, Ostad noted that the FDA proposed these most current changes three years ago and never implemented them. The last time the FDA tried to implement new guidelines, the turnover from proposal to finalization took twice as long. In 1993, the agency proposed regulation that wasn't finalized until 1999, only to "stay" the final rule — meaning it never went into effect.

"We stayed the final rule because it did not address UVA testing and labeling; SPF reflects primarily UVB radiation," Shelly Burgess, Public Affairs Specialist for the FDA, said in a statement via e-mail. "Therefore, we published the 2007 proposed rule to, for the first time, propose UVA testing and labeling. This final rule will include SPF and UVA testing and labeling."

The FDA cites an abundance of research that needs to be evaluated, especially regarding UVA testing, as one reason why regulations haven't been finalized. Another reason is the large amount of feedback they have received on the 2007 proposed rule.

"In order to issue a final rule, we have to evaluate all of the information included in the public submissions," Burgess said. "Some of these submissions included new data which require scientific evaluation. Therefore, developing the sunscreen final rule has required more FDA resources than originally anticipated."

Ostad, in addition to elected officials and consumer watchdog groups, isn't buying it.

"The reason why the FDA hasn't done that yet, I'm not sure ... Ten years ago, five years ago, maybe they didn't have the research. But now they do," said Ostad, who added that the FDA may not have passed regulation in the last few years because of pressure from sunscreen manufacturers.

Pressure also has begun to mount from the other side. Various senators have made calls to the FDA asking for sweeping changes to sunscreen labels, and some have claimed false advertising in class-action lawsuits filed against the manufacturers.

Asked if the final rule would look any different from the proposed rule, Burgess declined further comment.

"We cannot state the specific content of the sunscreen final rule other than stating that the rule will address the proposals that we issued in the 2007 sunscreen rule," she said.

Looking further into the 2007 proposed rule, slight changes may be made to the procedure that determine a product's SPF, and a maximum SPF may be set at 50-plus. Additionally, the FDA may require manufacturers to display a rating for UVA rays, which may use the proposed four-star system, next to the SPF rating on sunscreen bottles.

The FDA also is considering Tinosorb M, which protects against a broad spectrum of UVA rays, for approval. Tinosorb M falls under a category of ingredients that currently cannot be used in sunscreen because of the United States' standards for safety and effectiveness.

Similar ingredients are more readily available in sunscreen from other countries, like those in Europe, because they regulate sunscreen as a cosmetic, whereas the U.S. regulates it as a drug.

This drives many consumers to seek out sunscreen from overseas, either online or through a dermatologist. But Ostad says more doesn't necessarily mean better.

"The U.S. outpaces, by far, any other country in terms of sunscreen production. There is no other country ahead of us," Ostad said.

Until new regulations are finalized and enacted, Ostad recommends that people look for particular ingredients in their sunscreen that provide the broad spectrum of protection he deems necessary.

- Micronized Zinc Oxide - for broad-spectrum UV protection (including UVA), soothing effects for skin irritations, antimicrobial properties
- Titanium Dioxide - absorbs both UVA and UVB rays, provides long-term UV protection.
- Niacin - clinically shown to improve skin tone, texture and [hyper pigmentation](#)
- Vitamin E - helps heal and protect your skin

"The main thing is that you do need to use a broad-spectrum [sunscreen]. There's a big difference," Ostad said.