

Proposed FDA Rule on Sunscreens, Part 1: A New Label

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As most of you know, the United States, unlike many countries in the world, regulates sunscreens as over-the-counter (OTC) drugs, not as cosmetics. This designation is meaningful, as it demands much higher standards for efficacy and safety testing. In addition, as with other OTC drugs, a sunscreen manufacturer in the United States is required to adhere to specific guidelines for package labeling and marketing materials.

Sunscreen Regulation Process

The process by which the US Food and Drug Administration (FDA) arrives at the rules that regulate OTC products involves a number of complicated steps that result in the publication of a series of notices or monographs in the *Federal Register*.

For sunscreens, this process started with the publication of the “Sunscreen Drug Products for Over-the-Counter Human Use: Establishment of a Monograph; Notice of Proposed Rulemaking” in 1978.¹ This initial monograph detailed the agents and concentrations that could be used in sunscreens and, for the first time, described the testing and labeling for efficacy, which we all know as the sun protection factor (SPF). Sun protection factor is now the worldwide standard for labeling of sunscreens.¹

Since 1978, the FDA has developed a number of amendments addressing the evolution of new information about stability and toxicity of various agents. Some agents were removed; certain combinations of agents were approved and others prohibited; and an important new agent, avobenzone, was added to the list of acceptable chemicals.

Final Rule: 1999

After 21 years, the FDA issued the much awaited Final Rule in 1999.² Although long awaited, the Final

Rule was controversial. The rule mandated a cap on the SPF of 30+, did not address testing and labeling for UVA protection, and did not allow marketing of sunscreen products for anything other than “protection from sunburn.”²

Clinicians, photobiologists, and industry scientists and their representative organizations objected to the rule because they felt that its regulations would impair the future of sunscreen development, prevent clinicians from choosing the best protection for their patients, and prevent consumers from doing the same for themselves and their families.

This controversy led to the development of a conference sponsored by the American Academy of Dermatology, among others, which addressed issues raised by the new monograph and resulted in a white paper generated from the proceedings and published in 2001.³

Proposed Rule: 2007

Suggestions in the 2001 document³ and other subsequent comments were considered by the FDA, and in August 2007, the Proposed Rule was published.⁴

Although not perfect, the FDA proposal seems to have been generated from the most up-to-date scientific information. With a few changes, the Proposed Rule should result in better sunscreens and more definitive labeling, which will allow clinicians to choose the best product to suit the needs of each patient. With educational efforts made by manufacturers and physicians directed at making the new labeling system understandable, consumers also should be able to choose appropriate products for themselves and their families.

Understand that the Proposed Rule is not the final Final Rule. Once again, the FDA will accept comments from the public, including comments from the American Academy of Dermatology; pour over them; discuss within and without the FDA; and finally publish another monograph. This process will certainly take many months or even years to complete, but the end appears to be in sight.

From St. Luke's-Roosevelt Hospital Center, New York, New York, and Beth Israel Medical Center, New York.

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SPF Cap—First, and probably most importantly, the FDA has dropped its intention to limit SPF labeling to a cap of 30+. Instead, they have chosen a higher cap of 50+.⁴ While it could be argued that there should be no cap on the SPF, a cap of 50+ seems to be a reasonable and acceptable compromise.

Sunburn Protection Factor—The other 2 most substantial changes relate to testing and labeling for efficacy of sunscreens. The testing for SPF will remain essentially the same, but the words associated with the acronym will change to *sunburn protection factor* and the term *SPF* will be associated with UVB, as in UVB SPF or UVB sunburn protection factor.⁴ Sunburn protection factor is based on protection from erythema or sunburn. The change will reinforce to consumers that while the SPF gives a good approximation of the protection from sunburn afforded by the labeled product, it does not necessarily suggest the same level of protection from other effects like immune suppression or carcinogenesis.

A new system of category descriptor also has been put in place. These descriptors will now include low, medium, high, and highest (Table).⁴

More importantly, for the first time, the FDA has defined for manufacturers how to test and label for UVA protection. The required testing will consist of an in vivo and in vitro method and will be discussed in detail in the second part of this series.⁴

The New Label—The most prominent change resulting from the new rule is a requirement for each sunscreen product to bear a label on the front of the

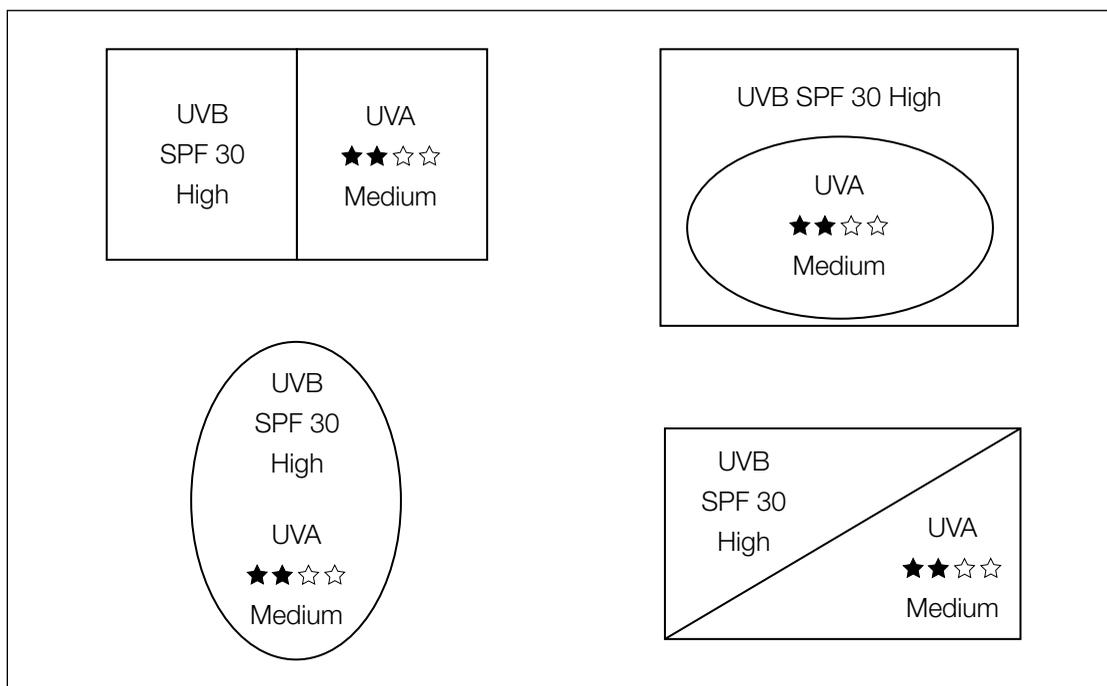
UVB Sunburn Protection Factor

UVB SPF	Category Descriptor
2 to <15	Low
15 to <30	Medium
30 to 50	High
50+	Highest

Abbreviation: SPF, sunburn protection factor.

bottle reflecting the UVB and UVA efficacy of the product. This label will include a UVB SPF number and UVB category descriptor, as well as a 1- to 4-star UVA rating indicating low to highest overall UVA protection, respectively, and a UVA category descriptor (Figure).⁴

Substantivity—In addition, the FDA has required some changes in methodology, including a change in the nomenclature for substantivity.⁴ Previously, the SPF on a product could bear 1 of 2 substantivity ratings. For a water-resistant SPF, the SPF determination was conducted on individuals who experienced two 20-minute whirlpool exposures, and for a waterproof SPF, the SPF determination was conducted on individuals who experienced four



Examples of UVA/UVB protection designators for product labeling. SPF indicates sunburn protection factor.

20-minute whirlpool exposures. Water-resistant, therefore, suggested that the SPF of a product was valid after 40 minutes of water immersion, while the waterproof product would maintain protection after 80 minutes in water, at least under research conditions. According to the Proposed Rule, in addition to performing the SPF testing under the conditions outlined to bear the substantivity descriptor, the UVA in vivo testing also would have to be performed following the required immersions.⁴

While the Proposed Rule has maintained the test methodology, it mandates a change in the descriptors to water-resistant (40 minutes) and very water-resistant (80 minutes). This procedure seems reasonable, as no sunscreen under real-world conditions is likely to be completely waterproof.⁴

Labeling Claims—Other changes relating to the labeling are included in the document.⁴ One of the most unacceptable changes to most of the dermatology and industry communities is the prohibition of labeling claims for any protective value except sunburn. For example, no manufacturer could claim on the label or in marketing materials that their sunscreen protected against aging or cancer. While I think most of us believe that the consistent use of sunscreen does in fact prevent photoaging and the development of skin cancer, the FDA is correct in that the data do not support these claims. The only prospective human studies examining the effect of sunscreen on prevention of skin cancer have shown that sunscreen does lower the incidence of actinic keratosis and squamous cell

carcinoma. There are no studies showing sunscreen efficacy in prevention of basal cell carcinoma or melanoma.

Conclusion

In summary, the most recent Proposed Rule is a giant step forward in the proper development, testing, and labeling of sunscreen products. These recommendations should make our jobs a little easier, which is always a nice thing!

This editorial is the first of a 2-part series. The second part on the testing and labeling for UVA protection will appear in a future issue of Cutis®.

REFERENCES

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