Editorial

Proposed FDA Rule on Sunscreens, Part 2: UVA

Vincent A. DeLeo, MD

Part 1 of this series was a review of the US Food and Drug Administration (FDA) August 2007 Proposed Rule on sunscreen drug products for over-the-counter human use.[1,2] For the first time, the FDA has indicated the methods that will be used to test sunscreens for their ability to protect the skin from long-wavelength UVA radiation at 320 to 400 nm, which is one of the most important aspects of this monograph. The document also outlines the specific labeling for UVA protection that will be required for all sunscreens.[2]

Testing for UVA Protection

To determine the protective value of a sunscreen against UVA radiation, the FDA will require that 2 evaluations be done on each product, one in vivo and one in vitro.[2] The in vivo method will measure persistent pigment darkening, which is determined in a similar manner to sunburn protection factor (SPF) testing, except that the light source utilized is solar-simulated UVA radiation and the end point is pigmentation instead of erythema. As with SPF testing, a ratio is developed from the amount of radiation it takes to produce pigmentation with the sunscreen divided by the amount of radiation it takes to produce pigmentation without the sunscreen. This number is considered the UVA protection factor for the product.[2] This test system has been in use for some time in research laboratories. Persistent pigment darkening is produced by photons at the 330- to 370-nm range[3] and is an adequate measure for broad-spectrum UVA protection. In this time of globalization by consumer product manufacturers, this assay also is a good choice because it is the one method favored by sunscreen manufacturers in Japan and the European Union.[3]

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

Dr. DeLeo is a consultant for Johnson & Johnson Consumer Products, Inc, and L'Oréal, and is on the advisory board for Schering-Plough Corporation.

The in vitro test method that is mandated in the monograph is somewhat more complicated and controversial. It is based on the proportionality of UVA1 protection at 340 to 400 nm to total protection of the sunscreen.[2]

All of the in vitro methods for assaying UVA protection are based on determining the absorption spectrum of the product.[2] The sunscreen is placed on a surface through which UV radiation is delivered. The percentage of light transmitted at each wavelength from 290 to 400 nm can be determined, and the inverse—the percentage of each wavelength absorbed—can be calculated and an absorption spectrum generated.[2]

In the assay outlined in the monograph, known as the Boots adaptation of the Diffey/Robson test method, a ratio is generated of the protection afforded by the sunscreen product from UVA1 compared to the protection from total UV radiation (UVB and UVA) at 290 to 400 nm. This ratio would represent the score for the product in the in vitro test.[2]

The product label would be based on the lower of the 2 test scores as determined by the in vivo and in vitro methods. The label would carry a star category and a category descriptor (Table).[2]

Another widely used in vitro method known as the critical wavelength is preferred by many and is the standard endorsed by the European Commission.[4] This assay also is based on determination of the absorption spectrum of the product in vitro. Once the spectrum is generated, the wavelength below which 90% of solar-simulated UV radiation at 290 to 400 nm is absorbed by the product will be considered the critical wavelength for that product. Critical wavelength could be used in a similar fashion to score agents in a 4-star system.[4] Support for this method, including that of the American Academy of Dermatology, is based on the concern that the Boots adaptation of the Diffey/Robson test method places too much emphasis on the UVA1 spectrum. Many people believe that UVA1 radiation is much less important in the generation of damage to the skin as compared to UVA2 radiation at 320 to 340 nm.

Proposed Rating Categories for Sunscreens[2]

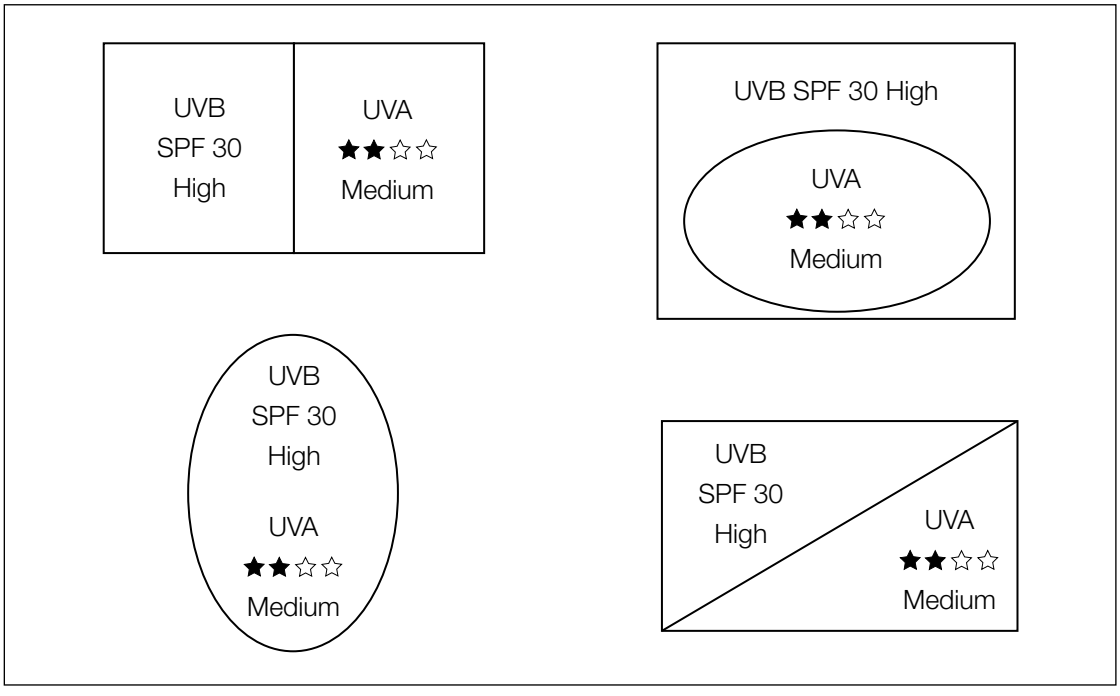
Star Category	Category Descriptor	In Vitro UVA1/UV Ratio	In Vivo PPD
No star	No UVA claim	0 to <0.20	<2
★☆☆☆	Low	0.20 to 0.39	2 to <4
★★☆☆	Medium	0.40 to 0.69	4 to <8
★★★☆	High	0.70 to 0.95	8 to <12
★★★★	Highest	>0.95	12+

Abbreviation: PPD, persistent pigment darkening.

The Label

Whichever combination of test systems is accepted will finally offer healthcare professionals and consumers the necessary information to choose products that offer the best protection for a given individual, which is a giant step forward and will make US sunscreen labels comparable to those presently utilized in Europe and Asia. One downside to this new labeling system is that the protection against UVB (the SPF) and the protection against UVA (the 4-star system) will appear, from looking at the label, to be of equal value (Figure).

UVA participates in all of the damage that sun exposure can induce in the skin but much less efficiently than UVB by orders of magnitude in most cases. Although there is usually 10 times as much UVA as UVB in the sunshine to which we are exposed, the damage to our skin, be it cancer, sunburn, or aging, is primarily due to UVB rays. If an individual uses a UVB-predominant sunscreen with little UVA protection, the skin may be exposed to much greater quantities of UVA. When individuals use these sunscreens to allow longer periods of time



Examples of UVA/UVB protection designators for product labeling. SPF indicates sunburn protection factor.[2]

in the sun, skin damage may be related more to UVA, in relative terms. But if consumers focus more on the UVA protective value and less on UVB SPF, then protection may be compromised.

It is likely that the new testing and labeling mandates combined with competition in the industry will lead to the development and marketing of products with proportionality and similar UVA and UVB ratings. It is unlikely that products with very high UVB protection and proportionally much lower UVA protection (eg, High UVB SPF 45/Low UVA ★), or the reverse, will appear attractive to most consumers.

Education will be the key to consumers understanding the meaning of the new labeling. Dermatologists collaborating with the industry should take the lead in this process. With our help, informed consumers will be able to choose proper protection and their purchasing patterns will drive the development of better products.

Even fantastic sunscreens will never be the complete answer to good photoprotection. Education will still need to focus on programs such as the American Academy of Dermatology's "Be Sun Smart[SM]" and the Women's Dermatologic Society's "Families Play Safe in the Sun." These educational initiatives are essential to our ongoing effort of helping to curb the rapid rise in skin cancer and other sun-related ills in our population.

REFERENCES

1. DeLeo VA. Proposed FDA rule on sunscreens, part 1: a new label [editorial]. *Cutis*. 2008;81:460-462.
2. Sunscreen drug products for over-the-counter human use; proposed amendment of final monograph; Proposed Rule (21 CFR Parts 347 and 352). Food and Drug Administration, HHS. *Fed Regist*. 2007;72: 49070-49122.
3. Moyal D, Chardon A, Kollias N. UVA protection efficacy of sunscreens can be determined by the persistent pigment darkening (PPD) method. (Part 2). *Photodermatol Photoimmunol Photomed*. 2000;16:250-255.
4. Diffey BL. A method for broad-spectrum classification of sunscreens. *Int J Cosmet Sci*. 1994;16:47-52.