Editorial

Finally, the Final Rule on OTC Sunscreen Drug Products

Vincent A. DeLeo, MD

On June 17, the US Food and Drug Aministration (FDA) issued its final rule on testing and labeling sunscreens for effectiveness.[1] All in all, I think they have done a good job. We all remember the cumbersome and confusing recommendations that the FDA made in the proposed rule issued in August 2007.[2] The new and final rule makes it much easier for the industry to test their products, and the labeling that will be required is much more understandable for consumers.

The Changes

In 2007, it was proposed that the acronym *SPF* (*sun protection factor*) would be redefined as *sunburn protection factor* and would be termed *UVB SPF* with a number and descriptor (eg, low, medium, high, highest) on the front of the label.[2] Instead, SPF with only the number will suffice and the original term *sun protection factor* will be maintained.[1]

The 2007 proposed rule required that there be a UVA level indicated with a category descriptor (eg, low, medium, high, highest) as well as a 1- to 4-star rating.[2] Now the product must include "Broad Spectrum SPF (with the SPF number)" to indicate that the product has been shown to have UVA protection commensurate with its UVB protection in a pass/fail manner.[1]

Instead of the cumbersome and confusing method for determining UVA protection with a combination of in vitro and in vivo methodology, the requirement for broad spectrum will rely on the simple critical wavelength of at least 370 nm. Critical wavelength is defined as "the wavelength at which the area under the absorbance curve represents 90 percent of the total area under the curve in the UV region."[1]

The new substantivity ratings for the stated SPF will be simplified to "water resistant (40 minutes)" or "water resistant (80 minutes)."[1] There will be no very water resistant rating as previously suggested,[2] and the terms *waterproof*, *all-day protection* and *extended wear*, *sunblock*, and *sweatproof* will not be allowed.[1]

For products with a broad-spectrum SPF of 15 or higher, the FDA feels that there is enough evidence for manufacturers to claim that the product "if used as directed with other sun protection measures . . . decreases the risk of skin cancer and early skin aging caused by the sun." In contradistinction, products that do not fulfill the broad-spectrum criteria and/or have SPF of less than 15 can only claim protection from sunburn.[1]

In a separate document, the FDA continued with its intent to make SPF 50+ the maximum value; however, it is not the final rule on this issue.[3] The agency is open to submissions of evidence to allow higher ratings, so the top SPF essentially has not yet been decided.

In addition, in a third publication the FDA has asked for more information about efficacy and safety of a variety of new formulations including spray dosage forms.[4]

These guidelines seem quite reasonable, even if it has taken 33 years to reach this almost final rule!

REFERENCES

1. Labeling and effectiveness testing; sunscreen drug products for over-the-counter human use. *Fed Regist*. 2011;76(117):35620-35665. To be codified at 21 CFR §201 and 310.
2. Sunscreen drug products for over-the-counter human use; proposed amendment of final monograph; Proposed Rule. *Fed Regist*. 2007;72(165):49070-49122. To be codified at 21 CFR §347 and 352.
3. Revised effectiveness determination; sunscreen drug products for over-the-counter human use. *Fed Regist*. 2011;76(117):35672. To be codified at 21 CFR §201.
4. Sunscreen drug products for over-the-counter human use; request for data and information regarding dosage forms. *Fed Regist*. 2011;76(117):35669-35672. To be codified at 21 CFR §352.

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

Dr. DeLeo is a consultant for Estée Lauder, Inc; La Roche-Posay Laboratoire Dermatologique; and Mary Kay Inc.