FDA Proposes UVA Rating on Sunscreen Labels

BY ELIZABETH MECHCATIE
Senior Writer

A rating system that would use stars on the label of a sunscreen to indicate the degree of ultraviolet A protection provided by the product is among the main elements of a long-awaited Food and Drug Administration proposed regulation on sunscreen labeling.

Other main features of the proposed regulation include the requirement that a bolded warning be placed in the "Drug Facts" box that ultraviolet sun exposure "increases the risk of skin cancer, premature skin aging, and other skin damage," and that it is important to reduce ultraviolet exposure "by limiting time in the sun, wearing protective clothing, and using a sunscreen."

The proposed UVA rating would be based on a standard testing protocol using an in vivo and an in vitro test. The maximum sun protection factor (SPF) claim allowed would also be increased from SPF 30+ to SPF 50+.

The proposed rule amends the 1999 rule that addressed UVB testing and labeling requirements for sunscreen products, which was stayed to allow the agency to address testing and labeling requirements for the UVA protection provided by sunscreen products, according to the FDA.

The FDA proposal "identifies how to label sunscreens so that consumers can clearly understand the level of UVA and UVB protection sunscreens provide and to understand the importance of protecting themselves from both types of UV light," Matthew R. Holman, Ph.D., a senior scientific reviewer in the FDA's Office of Nonprescription Products (ONP), said during a teleconference held on Aug. 23. The proposed label "would help consumers quickly and easily identify the level of UVA protection a sunscreen product offers," with the term UVA clearly labeled on the package, followed by one to four stars, corresponding to low, medium, high or highest UVA protection. This rating will appear in equally prominent print to the UVB rating.

"Until now, much of the focus has been on reducing the exposure of UVB light while we worked to understand the science of assessing the effects of UVA light," said Dr. Douglas Throckmorton, deputy director of the FDA's Center for Drug Evaluation and Research (CDER).

Determining how to accurately measure UVA protection has been challenging because there are no internationally accepted standards for evaluating the effectiveness of a sunscreen that protects against UVA, and there are about 12 different tests. The standardized testing protocol proposed by the FDA is based on the agency's analyses of data and information on available testing methods.

The changes would likely not appear until 2009 at the earliest, considering the 90-day comment period following the announcement, the time the FDA will take to consider comments and finalize the rule, and the time manufacturers would take to comply with the requirements.

The American Academy of Dermatology has been waiting for the FDA to propose rules about UVA in sunscreen since 1999.

"We think this will be an excellent way for consumers to evaluate sunscreen products," said Dr. Diane Baker, president of the American Academy of Dermatology. The four-star system is "simple and easy to understand, and they are making an excellent effort to educate the public about the difference between UVA and UVB," which has been confusing for consumers, she added.

Both Dr. Baker, who is in private practice in Portland, Ore., and Dr. Henry Lim, chair of dermatology at Henry Ford Hospital, Detroit, and chair of the Academy's council of science and research, commended the proposal to add the sun alert statement that emphasizes the risk of sun exposure, the importance of wearing protective clothing and limiting sun exposure, in addition to using sunscreen.

This is a "very reasonable proposal" to address UVA protection, in addition to UVB protection in sunscreens, Dr. Lim said in an interview. While the recommendations are long overdue, the issue of UVA protection is complex, so it took time for the FDA to come up with the final recommendations of the specific in vitro and in vivo methods.

This proposal is a "long time coming and … is a welcome step forward," said Dr. Allan Halpern, chief of the dermatology

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service at Memorial Sloan Kettering Cancer Center in New York. Using both an in vivo and an in vitro test to assess UVA protection "will hopefully address concerns raised about each test," added Dr. Halpern.

He expressed hope that responses during the comment period won't slow down the process of implementing the regulations. He added that capping the SPF at 50+ is an improvement, but was concerned that this might be a disincentive for the manufacturing of ultrahigh SPF sunscreens.

Under the proposed regulation, manufacturers of over-the-counter sunscreen products would be required to test their products for UVA protection using a specific test to measure the product's ability to reduce the amount of UVA light that passes through it and a test that measures the product's ability to prevent tanning. The UVA rating would be based on the lowest of the two test results. If a manufacturer does not perform the tests, or the tests find no UVA protection, then the label will have to state "no UVA protection."

UVB protection will continue to be based on the SPF rating, but the FDA has proposed changes to the SPF testing methods to make the results more accurate and reproducible.

Under the regulation, companies would also be able to combine avobenzone with either zinc oxide or ensulizole, which Dr. Holman said would increase the number of sunscreen products available. The agency would consider revising the upper SPF limit allowed in the packages if data become available that support accurate testing of sunscreens with an SPF greater than 50.

During the comment period, the FDA is requesting comments and more information about the safety of sunscreen ingredients that use nanotechnology, because of the potential risk of nanoparticle ingredients penetrating consumers' skin, and on novel sunscreen formulations, such as foams, sprays, and towelettes. The proposal does not apply to insect repellant products combined with sunscreens, but it does apply to cosmetic products that contain sunscreen and SPF claims.

The FDA is accepting written comment on the proposal for 90 days following the announcement, until Nov. 26. ■

More information, including how to make a written comment, is available online at www.fda.gov/cder/drug/infopage/sunscreen/default.htm.

Combination Gel Improves Acne in Phase III Study

CHICAGO — An aqueous gel formula that combines 0.025% tretinoin and 1.2% clindamycin phosphate significantly reduces both inflammatory and noninflammatory acne lesions, Dr. James Leyden said in a poster presented at the annual meeting of the Society for Pediatric Dermatology.

The combination gel, marketed as Ziana, has been approved by the Food and Drug Administration for once-daily topical treatment of acne vulgaris in children aged 12 years and older.

In a phase III study, 1,710 patients aged 12-18 years were randomized into four groups to receive the combination gel, a tretinoin-only gel, a clindamycin phosphate–only gel, or a placebo gel. The baseline acne conditions ranged from mild to severe; patients were required to have 20-100 noninflammatory lesions, 20-50 inflammatory lesions, and two nodules to enroll in the study.

Overall, the patients in the combination gel group showed significantly greater reductions in the number of inflammatory lesions, noninflammatory lesions, and total lesion counts after 12 weeks of daily treatment, compared with the other groups, wrote Dr. Leyden of Broomall, Pa. He has received financial support from several drug manufacturers, including Medicis Pharmaceutical Corp., which manufactures Ziana and sponsored the study.

The average reductions for inflammatory and noninflammatory lesions, respectively, were 46% and 35% for the combination group; 35% and 26% for the tretinoin group; 36% and 23% for the clindamycin phosphate group; and 16% and 9% for the placebo group. The average reduction in total lesion count was 39% for the combination group, 30% for the tretinoin group, 29% for the clindamycin phosphate group, and 12% for the placebo group.

In addition, tolerability data from a subset of 45 patients were presented in a separate poster at the meeting. The findings showed that the clindamycin phosphate/tretinoin combination gel was as well tolerated as 0.1% adapalene gel and significantly better tolerated than 0.1% tretinoin microsphere gel based on clinical evaluation of redness and scaling and patient reports of burning, stinging, and itching, Dr. Leyden reported.

—Heidi Splete