Sunscreen Guidance: What's New

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In June 2011, the US Food and Drug Administration (FDA) released a guidance regarding sunscreens.[1] This type of communication is different than a monograph. Sunscreens are considered over-the-counter (OTC) drugs and therefore are regulated by a monograph that outlines the ingredients that can be used, the concentrations of the allowed ingredients, and the combinations of sunscreen ingredients that are permissible. The monograph is considered law and sunscreen manufacturers currently are working within the guidelines of a tentative monograph that is awaiting finalization following a public opinion period. The guidance provides recommendations for manufacturers with a deadline of June 18, 2012, for labeling compliance, but it is not a substitute for the monograph. This article will discuss the specifics of the June 2011 guidance and the implications in dermatology.

The June 2011 guidance described the final rule on effectiveness, testing, and labeling for sunscreen products[2]; the proposed rule on SPF (sun protection factor) exceeding 50; an advance notice of proposed rulemaking on sunscreen dosage forms; and a request for comments on the proposed rules.

Although this verbiage may seem confusing, further discussion of the sunscreen guidance will allow the dermatologist to recognize that most of the ideas presented are in alignment with the opinions of the American Academy of Dermatology (AAD). In fact, the FDA released the guidance with members of the AAD at the podium, representing an important cooperative effort between dermatologists and regulatory authorities. Furthermore, much of the guidance is directed at international harmonization of sunscreen requirements, which is important as companies begin to market sunscreens both inside and outside the United States.

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Effectiveness, Testing, and Labeling for Sunscreen Products

The final rule on effectiveness, testing, and labeling for sunscreen products presented new ideas for how well sunscreens should work, how they should be tested for performance, and how they should be labeled for better consumer education. The final rule did not approve any new sunscreen ingredients and did not finalize the current tentative monograph.[2]

Broad Spectrum: UVA Protection and Rating Methodologies

The guidance addresses the labeling of UVA protection, which is an important area of sunscreen controversy. For a product to be labeled as providing broad-spectrum protection, it must contain active ingredients with absorption spectra extending to 370 nm and greater, as verified by approved testing methodologies.

No rating system currently is available for sunscreen packaging that allows the consumer to assess UVA photoprotection. In 2007, a 4-star rating system was proposed to alert consumers to the degree of UVA photoprotection in a given sunscreen, with 1 star indicating low, 2 stars indicating medium, 3 stars indicating high, and 4 stars indicating highest. This rating system was to correspond with an in vivo UVA protection factor with 1 star indicating 2 to less than 4, 2 stars indicating 4 to less than 8, 3 stars indicating 8 to less than 12, and 4 stars indicating 12 and greater. In addition to these in vivo categories, in vitro/UV absorbance ratio criteria had to be met. The June 2011 guidance eliminated the in vivo testing requirement and indicated that the 4-star rating system was no longer being considered for use on product labels. This decision is probably good, as the 4-star system raised much controversy among both dermatologists and manufacturers.

At present, a separate rating system for UVA photoprotection has been replaced by claims of broad-spectrum protection on packaging. Consumers should look for this claim to be sure that they are getting both UVB and UVA protection, in addition to the SPF number. The broad-spectrum claim can be used if the critical wavelength is 370 nm or greater. However, if the SPF is less than 15,

a warning must be placed on the packaging that states, "Spending time in the sun increases your risk of skin cancer and early skin aging. This product has been shown only to help prevent sunburn, not skin cancer or early skin aging."[2]

The elimination of efforts to develop UVA testing methodologies probably is worthwhile. One concern is that patients who participate in the testing would have been exposed to high UVA levels, which might raise some medical ethics issues. Other concerns include problems with reproducibility, test expenses, and assessment of different Fitzpatrick skin types. Although the UVA protection factor method is used for UVA claims in other areas of the world, it will not be implemented in the United States.

Based on this information, the consumer should look for 2 items on product labels to ensure purchase of a quality sunscreen. As SPF increases, UVA protection also must increase to maintain the required critical wavelength result. The critical wavelength ensures the wavelength below which 90% of the absorbance is present. The critical wavelength for the claim of broad-spectrum protection is 370 nm; thus patients should look for *broad spectrum* on the label of the sunscreen they purchase. Furthermore, patients should purchase the highest appropriate SPF sunscreen that balances efficacy with aesthetics, remembering that SPF now stands for *sun protection factor* instead of the old *sunburn protection factor.*

SPF Testing Criteria

Testing is required to establish an SPF for all marketed sunscreens. Currently, testing is performed using the 2006 international SPF test method developed by the European Cosmetic, Toiletry and Perfumery Association. This standard methodology is used worldwide, and the United States is moving toward conformity with international standards. In the past, sunscreens were compared to a control formulation with an SPF 4, but the June 2011 guidance requires comparison to an SPF 15 control formulation. The testing is performed with a solar simulator on 10 to 13 patients with 2 mg/cm^2 of sunscreen applied to at least 5 exposure sites at 16 to 24 hours postexposure. This guidance represents a change, as 20 to 25 patients were required for testing in the past. At least 10 valid results from 10 to 13 patients are required to validate the SPF. In summary, SPF testing retains its importance to assess UVB photoprotection directly and UVA photoprotection indirectly.

Water Resistance Testing

A sunscreen's ability to stay on in the presence of water is an important patient consideration. Products no longer can be labeled as waterproof, but the term *water resistant* can be used if products pass the testing requirements. Water resistance claims are based on existing testing methodologies, which did not change with the June 2011 guidance. The testing includes either 40 or 80 minutes total of water exposure, with 15 minutes of drying/resting time between each 20 minutes in the water, on patients with Fitzpatrick skin types I, II, or III. The erythema readings are performed at 16 to 24 hours after UV exposure. The skin is irradiated with a solar simulator with an emission spectrum from 290 to 400 nm with a limit of 1500 W.

Proposed Rule on SPF Exceeding 50

There is a proposal by the FDA to limit SPF ratings to a ceiling of 50. A variety of sunscreens are available from many different manufacturers that post an SPF higher than 50, and there are data to support the photoprotective value of these higher SPF products; however, it is a highly controversial issue, and the FDA currently is accepting comments as to the value of the proposed rule. I personally believe that higher SPF products should be identified to consumers who also may be patients with photosensitive dermatoses, such as lupus or polymorphous light reaction. Opinions were filed by the AAD regarding this rule by September 11, 2011. It may surprise you to know that presently there are more than 200 different sunscreen manufacturers making approximately 4000 different sunscreen-containing products, allowing for many different opinions on this issue.

Advance Notice of Proposed Rulemaking on Sunscreen Dosage Forms

The FDA also is soliciting opinions on the various sunscreen dosage forms, including lotions, creams, gels, butters, pastes, ointments, sticks, and sprays. Other forms of sunscreen delivery that are in question include wipes, towelettes, powders, bodywashes, and shampoos. The FDA feels that these dosage forms do not meet the requirements for the OTC sunscreen monograph and accepted comments until September 15, 2011. Sunscreen sprays also are under scrutiny, as there are concerns regarding their efficacy and safety. Sprays may produce an uneven film if not rubbed into the skin properly, and inhalation might cause secondary respiratory issues. It will be interesting to see how alternate sunscreen dosage forms are handled from a regulatory standpoint.

New Labeling Requirements

Probably one of the most remarkable aspects of the guidance is the change in sunscreen labeling. Sunscreen labels now must indicate that a product helps prevent sunburn and that it must be used as directed with other sun

protection measures to decrease the risk for skin cancer and early skin aging caused by the sun. However, the product must possess an SPF of 15 to use this wording. In addition, sunscreens will list a caution that the product must be reapplied at least every 2 hours. Other labeling requirements also were posted, but these 2 issues are important for dermatologists. There is some industry concern that there is insufficient space on sunscreen-containing products to list all of the verbiage, especially on lip and eye products. Look for smaller font and a lot more text on most sunscreen packaging!

Summary

The new sunscreen guidance provides important information for dermatologists and their patients. Properly reading the label is necessary to insure that adequate sun protection has been achieved. For now, the best recommendations are to pick sunscreens labeled as broad spectrum and select an SPF that is higher than 30. The higher SPF ratings are indicative of better UVA protection, but the highest valuable SPF rating for patients has not been determined. The dermatologist may need to help patients balance aesthetics and SPF for daily-wear moisturizers but may want to encourage higher SPF products for prolonged sun exposure during prolonged outdoor activities.

References

1. US Department of Health and Human Services. *Guidance for Industry: Enforcement Policy—OTC Sunscreen Drug Products Marketed Without an Approved Application.* Silver Spring, MD: US Dept of Health and Human Services; June 2011. http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM259001.pdf. Accessed November 2, 2011.
2. 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. ■