

## Weigh In Regarding Proposed Changes to Sunscreen Labeling and UVA Rating

The comment period for the FDA's proposed label revisions ends next month. Here's a recap of key points.

By Jonathan Wolfe, MD

It may be hard to believe that ongoing conversation about sunscreen labeling traces back to 1993 and FDA's publication of a tentative final monograph for OTC sunscreen drug products. That monograph, which proposed the current conditions under which OTC sunscreen drug products would be generally recognized as safe and effective, formalized standards for assessment of SPF as a protection against UVB and noted the importance of protection against UVA. But the monograph did not propose a standard for assessing UVA protection. Several amendments, proposals, and deadline changes later (including action in December 2001 to stay implementation of the so-called final monograph for OTC sunscreen drug products "in order to address formulation, labeling, and testing requirements for both UVB and UVA radiation protection"), the FDA is now proposing label changes that will alter SPF numerical ratings, implement graphical designators of UVA protection, and change drug facts and information statements on sunscreen formulations.

The proposal, assessable for review online ([www.regulations.gov](http://www.regulations.gov)), is open for comment until November 26 (you can submit comments via the website [fda.gov/dockets/ecomments](http://fda.gov/dockets/ecomments)). Following is a summary of some key proposals.

### Key Proposals

**SPF 50+.** The final monograph

would have allowed labeled SPF values up to but not exceeding 30. Any product with an SPF higher than 30 would be labeled "30+." This amendment proposes to increase the specific labeled SPF value to 50, and designates "50+" as the maximum labeled SPF for any formulations whose score exceed 50.

**Sunburn Protection.** Under the new proposal, labeling would now include the phrase "sunburn protection" in place of the current term "sun protection" and will insert the term "UVB" before the term "SPF" on the principal display panel. Furthermore, the proposal sug-

gests the use of "UVB" before the term "sunburn."

**Low, Medium, Highest.** The new proposal establishes new product category designations (PCD) intended to help patients assess the level of protection afforded by various SPF ranges. "Highest UVB sunburn protection product" will apply to products that provide an SPF value over 50. Other new PCDs include "low" and "medium" to replace the current category descriptors of "minimal" and "moderate" respectively.

**Seeing Stars.** In the new proposal, a

## New In Your Practice

**Weighing in on Vitamin D.** When it comes to vitamin D, deficiency may have less to do with exposure to UV light and more to do with the weight of the individual. A study published in the *Journal of Clinical Endocrinology & Metabolism* (August 2007), analyzed information on 381 men and women age 65 or older participating in a study of calcium and vitamin D supplementation to prevent bone loss. Splitting people into four groups based on body fat percentage, researchers found no difference among the groups in time spent outdoors, percent of skin exposed to the sun, or sunscreen use. They did find that people with the highest percentage of body fat had 20 percent lower blood levels of vitamin D than those with the least body fat. Researchers concluded that an excess of fat may prevent from vitamin D from reaching the bloodstream.

**Phase Up.** There's new hope for patients suffering from systemic lupus erythematosus. Immunomedics, Inc. recently reported results from a study showing epratuzumab—a humanized monoclonal antibody that targets the CD22 antigen found on B-cells—inhibits activation of B-cells from patients suffering from SLE. Under all experimental conditions tested, epratuzumab stopped the over-activation of B-cells from SLE patients but not normal B-cells, when activated by certain immune stimulating agents.

### At-a-Glance History of UVA Rating<sup>1</sup>

**May 1993.** FDA publishes a tentative final monograph (TFM) for OTC sunscreen drug products. It outlined the conditions under which OTC sunscreen drug products would be generally recognized as safe and effective (GRASE) and not misbranded. The TFM did not propose a method for UVA assessment but stated that a product could be labeled as “broad spectrum” or a similar claim if it protected against UVA radiation.

**April 1994.** FDA reopens the administrative record for three months to allow additional submissions on UVA-related issues and announces a public meeting to discuss UVA testing procedures.

**August 1996.** Zinc oxide and titanium dioxide gain prominence as FDA allows additional submissions on these UVA-absorbing sunscreen ingredients as well as sunscreen photostability.

**September 1996 and October 1998.** FDA adds the UVA-absorbing sunscreen ingredients avobenzone and zinc oxide to the proposed list of monograph ingredients.

**May 1999.** FDA publishes the final monograph (FM) for OTC sunscreen drug products with an effective date of May 21, 2001 but defers UVA testing and labeling for future regulatory action.

**June 8, 2000.** FDA opens a comment period on high SPF and UVA radiation testing and labeling.

**December 2001.** FDA stays the December 31, 2002 effective date of the FM for OTC sunscreen drug products until further notice. The agency states intentions to address formulation, labeling, and testing requirements for both UVB and UVA radiation protection.

combination text and graphic rating system will designate the level of UVA protection offered by OTC sunscreen drug products. A four star system is suggested:

- Low/One star
- Medium/Two star
- High/Three star
- Highest/Four star.

**New Warning.** FDA proposes a new statement to appear in bold type as the first statement in the drug “Warnings” section, “so that the labeling of OTC sunscreen drug products include the most accurate information, based on the available scientific evidence, concerning the relationship of sunscreen use to the prevention of sunburn, skin cancer, and premature skin aging caused by UV exposure.”<sup>1</sup> The proposed verbiage states, “UV exposure from the sun increases the risk of skin cancer, premature skin aging, and other skin damage. It is important to decrease UV exposure by limiting time in the sun, wearing protective clothing, and using a sun-

screen.”

This new statement notes the importance of limiting sun exposure and wearing protective clothing, “because FDA has tentatively determined that it is critical for consumers to understand the role of sunscreen use in a comprehensive sun protection program.” The agency notes that evidence strongly suggests that consumers rely heavily on sunscreens alone as a form of protection against UVR. Furthermore, evidence suggests that labeling indicating a greater level of protection may increase an individual’s reliance on sunscreens alone.

In the “Other Information” section of the label text, the current proposal allows manufacturers to include the optional statement, “Higher SPF products give more sun protection, but are not intended to extend the time spent in the sun.” That latter portion—but are not intended to extend the time spent in the sun—represents an addition to current label phrasing.

### Written in the Stars?

The proposed changes seem to indicate progress with regard to the marketing of sunscreen formulations and patients’ use of them. We as dermatologists have made concerted efforts in recent years to raise public awareness of the true nature of the SPF rating as a marker for protection against UVB only and the importance of protection against UVA. The star rating system should help patients identify formulations that offer the most appropriate levels of broad-spectrum protection. Labeling that educates patients about the need for additional UV protection measures beyond use of sunscreens is welcome.

It is unclear whether consumers/patients may be confused by the differing nature of the UVB and UVA protection rating systems (numeric versus graphic/textual). The use of a graphic rating system for UVA may reflect a response to criticism of the potentially misleading numeric SPF rating system. Patients often assume a formulation with SPF 30 offers double to protection of a formulation with SPF 15. Extension of the SPF numeric system through 50 may perpetuate false security.

FDA estimates total one-time incremental cost of this proposed rule at \$53 million but notes that incremental cost for the UVA testing could be less “because many manufacturers may voluntarily comply with the proposed rule when reformulating current products or marketing new products.” Certainly this will be a costly undertaking, and the stakes are potentially high for patients and us who care for them. Even with new labeling in place, dermatologists will face the challenges of educating patients about appropriate UV protection strategies. Hopefully changes in labeling and marketing will make the task at least a bit easier. ☺

1. Federal Register, August 27, 2007. 21 CFR Parts 347 and 352 Sunscreen Drug Products for Over-the-Counter Human Use; Proposed Amendment of Final Monograph; Proposed Rule. Docket No. 1978N-0038