

Sunscreens may be among the most confusing products available to consumers. From the sheer volume of available options—cosmetics and facial moisturizers with sunscreens; suncreening lotions, creams, and sprays—it can be tough to select an optimal formulation. Add in all the marketing claims a consumer must wade through, and the task of product selection becomes more daunting.

Recognizing these challenges, physicians, health advocates, and even sunscreen manufacturers have argued for label revisions that might ease the selection process for consumers. But no one knows if label changes, to be outlined in an FDA monograph update due next month (after numerous delays), will clarify anything. Some observers worry that patients are at risk for even more confusion. As pointed out in this month's cover story, one of the most significant problems associated with sunscreens, and which the monograph is not expected to address, is proper application of sunscreen formulations. Patients rarely apply enough product or reapply it often enough. This month's feature article on atopic dermatitis management notes that failure to prescribe eczema patients an appropriate *volume* of topical medication foils treatment. The same holds true for sunscreens: if patients don't use enough product, they won't reap the full benefits of it.

Most consumers would probably be shocked to learn just how much sunscreen they are supposed to use. The average recommended amount of sunscreen to cover all sun-exposed skin for an adult is one ounce. That's a shot-glass full. But many sunscreens come in just a three- or four-ounce bottle. With proper initial application and recommended reapplication at two-hour intervals, most individuals should use up a bottle of sunscreen in a *single* day, not a weekend, week, or full summer! By contrast, consumers are used to similar-sized containers of body washes, shampoos, or toothpaste lasting for weeks.

Even if they help, label changes aren't going to solve the problems associated with sunscreen misuse and application. Education is key, and that has to start with dermatologists. It is impossible to underestimate the public's understanding of concepts like SPF, UVB versus UVA, and the limitations of sunscreens. If and when label changes are announced and implemented, be prepared to field questions from patients. Consider reaching out to local media and/or other venues through which you can help inform patients. And remember that UV safety education is a never-ending process. ■



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Inside the Forthcoming Sunscreen Label Revisions

New regulations for sunscreens may be unveiled next month.
Experts discuss likely changes and their impact.

By Ted Pigeon, Senior Associate Editor

It comes in a plastic bottle, can be found in the aisle at any local pharmacy or shopping market, and is an integral component of dermatologists' efforts to protect patients from UV exposure. Yet it is one of the most widely misused and misunderstood products used by the general public:

Sunscreen.

Sunscreens offer individuals protection from sunburns, premature aging, and potentially skin cancers. But their shortcomings—particularly with regard to public misunderstanding—limit their usefulness. This fact has led to a plethora of dialogue over many years about changing sunscreen labeling to ensure maximum understanding on the part of consumers. Talks have intensified recently at the FDA regarding significant labeling changes, and reports suggest new labeling requirements—expected late last year—could be unveiled next month. Whether or not consumers will notice or be influenced by these changes immediately remains to be seen, but if current descriptions of the proposed monograph hold true, these labeling changes will represent a major shift in the emphasis of education and research about sunscreens and sun protection.

Years in the Making

The Sun Protection Factor (SPF) has been the primary standard for measuring sunscreen effectiveness for several decades in the US. According to Barbara A. Gilchrest, MD, Chair, Department of Dermatology, Boston University, the SPF remains a reliable system for what it is designed to measure. “It provides an accurate measurement for a given sunscreen’s ability to block UVB and prevent sunburn,” she notes. In addition, Dr. Gilchrest observes, “the SPF was chosen because it can be measured very readily, as well as accurately.” It takes mere minutes to determine the transmission of UVB wavelengths in the skin, according to Dr. Gilchrest.

Take-Home Tips. Long-awaited sunscreen monograph revisions could be published next month, leading to new product labeling. Expected changes include an SPF cap at 50+, introduction of a four-star UVA rating system, and elimination of “sweat-proof” and similar claims. Experts worry that labeling doesn’t address proper application of sunscreens and won’t help educate patients about UV risks. Dermatologists will maintain the responsibility to educate patients/consumers. ●

However, in recent years, the focus of UV research has shifted from UVB to UVA light. During this time, many studies have explored the potential role of UVA as an independent risk factor in rising rates of melanoma and non-melanoma skin cancer, as well as photoaging. According to Henry Lim, MD, Professor of Dermatology at Henry Ford Hospital in Detroit, the existing data draws a convincing connection between UVA and these conditions. “There is now enough published data that would allow us to say that UVA is a spectrum within UV light that contains risks for skin cancer and photoaging,” he notes. Therefore, researchers and clinicians are now dually focused on UVA and UVB in the education and research efforts to promote sun protection.

With an increased emphasis on UVA, physicians and scientists have raised questions about sunscreen labeling, likely resulting from sentiments brewing for the better part of 30 years, according to Dr. Gilchrest. Ten years ago, when the FDA proposed establishing a standardized UVA rating system, conjecture over how to most effectively evaluate UVA protection and incorporate it into labeling emerged. In 2007, the FDA again issued a proposed update to sunscreen labeling. First, the new labeling would implement a separate, four-star rating system for measuring a sunscreen’s effectiveness in blocking UVA. In addition, the SPF system would be modified to prohibit manufacturers from claiming an SPF rating higher than 50; anything higher would simply be labeled SPF 50+. Finally, the proposed changes would also put an end to terms such as “waterproof,” “sweat-proof,” and “all-day protection.”

However, despite the introduction of legislation in Congress to speed up the process of approving labeling changes, the proposed update remains on the cusp of approval. “When the FDA proposed a monograph in 2007, it received more than 4,000 comments, which led to re-evaluation,” says Darrell Rigel, MD, Clinical Professor of Dermatology at NYU Medical Center. Dr. Rigel observes that this cycle of submit-and-evaluate has occurred multiple times over the last decade and

notably in the last two years. According to Dr. Rigel, the current monograph does not appear to differ significantly from the proposals made 10 years ago. “The only major difference between the current proposal and that of 10 years ago is that the cap on SPF will be 50 instead of 30,” Dr. Rigel says. Nevertheless, he explains, though the star system still stands as the likely UVA rating framework, uncertainty persists among clinicians and researchers about how to concisely and accurately inform patients about both UVB and UVA.

For its part, in anticipation of forthcoming label changes, the AAD has retired its short-lived “Seal of Approval” for sunscreens, indicating that the seal could be redundant and possibly confusing in light of new label language.

The UVA Angle

Despite wide consensus that UVA plays a role in the onset of premature photoaging and skin cancer development, determining a sound paradigm to measure its effect on the skin and its health impact has proven difficult. “Although there is data suggesting which wavelengths are responsible for photoaging and skin cancer, these data have limitations,” says Dr. Gilchrest. For example, a majority of data is based on animal models. It’s also worth noting, according to Dr. Gilchrest, that data has been interpreted with a variety of models and according to different measurements. “While current data alerts us to important questions about UVA, it is also imperfect and offers no way to definitively measure the action spectrum of UVA in the skin,” she explains.

These considerations may help to explain why a solid measurement system of UVA for sunscreen labeling still does not exist. Dr. Rigel notes that, “most dermatologists would agree that patients should know about UVA and that manufacturers should be working to formulate better sunscreens that offer true broad-band protection.” But he suggests that the execution of an accurate, concise measurement and label system inevitably leads to disagreement.

There have been ongoing discussions in both the private and public sectors regarding UVA and how

to translate current scientific findings into sunscreen labeling information. There has been no indication from the FDA to this point that the star system will be jettisoned or replaced, according to Dr. Lim. "Given its use in Europe, it seems to be the most accessible system to inform consumers about UVA protection," he adds.

While the star system is straightforward for consumers, there are still questions about its accuracy and legitimacy. Dr. Rigel points out one major criticism of the star system concerns the difficulty of achieving maximum protection. "The way it has been designed, with a combination of *in vitro* and *in vivo* testing, it is virtually impossible for a sunscreen to achieve four stars," he notes. This may be a by-product of the lack of definitive data on UVA measurements, thus reflecting a greater uncertainty about UVA, according to Dr. Gilchrest. The elusive four-star rating may therefore appear impossible to achieve because it hasn't been defined yet. "UVA is very subtle compared to UVB," says Dr. Gilchrest. "It is approximately one one-thousandth or less as biologically active as UVB," she explains, indicating that an all-encompassing measurement system may not be feasible. "We simply don't know as much about UVA that we do UVB at this time," Dr. Gilchrest says, in spite of the increasing amount of data.

Patient Instructions

There is no indication if or how product directions will be modified. However, data suggest that most individuals are not aware of the proper amount of sunscreen to apply, nor when or how to apply and re-apply it.

SPF Cap

The maximum posted UVB protection level, as indicated by SPF, will be 50+. Many experts believe that SPF scores above 50 provide only modest additional benefit.



Anticipated Label Changes

UVA Star Rating

A 4-star rating system will be introduced to indicate the level of UVA protection a product provides. There are, however, no definitive methods for measuring UVA, and it seems unlikely any product currently will earn the maximum UVA protection rating. Furthermore, debate continues in the scientific community about the specific effects of UVA on the skin.

"-Proof" Statements

Non-specific terms like "waterproof," "sweat-proof," and "all day protection" will not be permitted under new regulations.

The Right Consumer Model

Aside from the star system and the weight that should be given to UVA, a larger question still looms within the labeling debate. Sunscreens are widely consumed and available, and therefore labeling is especially important for consumer knowledge.

The current monograph proposes to significantly change the language of sunscreen labeling, as well as increase the amount of information on the label. Dr. Rigel suggests that it may be difficult to predict how a label containing more information may influence consumers. Dr. Gilchrest fears that the sheer amount of information may be too much to process for the average consumer. Listing two separate measurement systems may be confusing for consumers, she suggests, especially since they represent differ-

ent forms of measurement and that the effects of UVA and UVB are not comparable. “Patients and consumers simply don’t have the skills and knowledge to grasp the significance of different wavelengths of UV light and determine which product is appropriate,” says Dr. Gilchrest. “Many individuals already do not comprehend SPF, and the addition of another rating system for a different wavelength of UV light may actually undermine the patient’s ability to learn and understand,” Dr. Gilchrest asserts. Importantly, current sunscreen labeling does not include an explanation of how SPF numbers are determined. “It is a relatively simple concept that can be completely confusing without the proper explanation,” Dr. Gilchrest says.

The FDA’s current proposal attempts to remedy the lack of consumer knowledge with the cap on SPF at 50. “The main advantages to capping SPF at 50 is that the level of protection provided by increasingly high SPF is less significant as the SPF number gets higher,” says Dr. Lim. The original recommendation for a cap was SPF 30, but according to Dr. Lim there is good reason to upgrade the cap to 50, as the differences in UVB prevention is significant. However, Dr. Gilchrest reminds that these measurements don’t amount to much if patients aren’t using the amount of sunscreens recommended by manufacturers and the FDA. “One important area that the current proposal does not address is the recommended amount of sunscreen to apply,” says Dr. Gilchrest.

According to Dr. Lim, true SPF protection can only be delivered if patients apply the recommended $2\text{mg}/\text{cm}^2$ to the skin, which is likely more than people actually use. “In reality, consumers tend to use half of the recommended, which immediately cuts level of protection by at least half,” Dr. Lim adds. Therefore, most people are getting much less protection than they expect when applying sunscreen.

Dr. Gilchrest agrees. “Consumers aren’t aware that unless they apply a very thick layer of sunscreen to the skin, their SPF 50 sunscreen is actually more like an SPF 5,” she observes. The reason for the current recommended application amount is that it ensures that measurement of UV light

protection is accurate, says Dr. Gilchrest. Although it is impractical to expect that consumers will actually apply sunscreen in these amounts, the FDA opted for the higher amount because it is more measurable, she adds.

“Broad-Band” and “Broad-Spectrum.” Another point of controversy concerning sunscreen labeling is the meaning of “broad-band” protection. In recent years, sunscreen manufacturers have developed more sunscreens with UVA filters, in response to the growing interest in UVA. “The expert community has become energized about UVA, and manufacturers have naturally responded to the buzz with taglines and phrases such as ‘broad-band’ and ‘broad-spectrum.’” However, sunscreens donning the “broad-band” tag provide varying levels of true broad-band protection. Dr. Lim points out that manufacturers may use such terms if a given sunscreen contains at least one UVA and UVB filter. “The problem is that not all UVA filters are the same. They can be short-wave or long-wave, each of which protects against UVA in different ways,” he says. Although FDA is strict about the language of sunscreen labeling, both Dr. Lim and Dr. Gilchrest agree that UVA protection should be better defined in order for sunscreens to carry labeling without potentially misleading information.

Dr. Rigel suggests that true “broad-band” or “broad-spectrum” protection would include equal measures of protection for both UVA and UVB. “We cannot be assured that patients will use sunscreens as they are recommended to achieve broad-band protection, but the term itself should be modified to correspond to an SPF of at least 30, and a UVA rating of at least three stars,” suggests Dr. Rigel.

Cancer Controversy. Since sunscreens are not classified as drugs, many questions remain about UVA and its link to skin cancer. According to Dr. Lim, this has become a controversial point in the discussion about labeling. “Manufacturers are currently restricted from making claims about the association between blocking UVA light and the prevention of skin cancer,” explains Dr. Lim. However, he notes, although the data are complex,

it's become clearer that regular and proper use of sunscreen does indeed reduce one's skin cancer risk.

Researchers will continue to grapple with UVA and how to best inform sunscreen users about it in coming years. In regards to the data for UVA, Dr. Gilchrest reminds that it represents a relatively new area of research that dermatologists will learn much more about over time. Nevertheless, manufacturers have responded to the enthusiasm with which the research community has taken to UVA. Dr. Gilchrest notes this mutual interest has opened the door to incorporating UVA in sunscreen labeling. According to Dr. Rigel, only time will tell if the increased notice of UVA will offset the concerns and questions that will inevitably surround the measurement system used for sunscreen labels. "Manufacturers will certainly struggle to accommodate the new regulations, especially given the challenge of improving UVA protection," says Dr. Rigel. Despite encouraging data, UVA will likely be defined by ambiguity and controversy until its specific effects can be measured.

Implications for Clinicians

Given the history of inactivity regarding the update of sunscreen labeling, Drs. Rigel, Lim, and Gilchrest all agree that it is hard to predict what the future holds if and when new regulations pass. There is legitimate concern that both the amount of information and the content of the proposed monograph will lead to increased confusion among consumers, and maybe even fuel speculation regarding the legitimacy of sunscreens.

Although there may be no ideal system for measuring UVA or for presenting information on a bottle of sunscreen, Dr. Gilchrest suggests that the task of identifying these measures should be a balanced effort from both the research and commercial communities. If the long-standing dialogue about reforming sunscreen regulation is any indication, there is still much to be learned about UVA, UVB, and models for informing patients about the need for protection from both, observes Dr. Rigel. He also indicates that inquiries in coming years

into the immunosuppressive, biological, and chemical components of UV light will reveal new methods of measuring it and formulating sunscreens to protect from it.

Emphasize Liberal Sunscreen Use. No matter what the final monograph looks like, Dr. Lim suggests that a large effort on the part of dermatologists and sunscreen manufacturers will be needed to educate consumers. "Public messages should emphasize the liberal use of sunscreen, both in terms of the amount applied and the frequency of application," says Dr. Lim. For clinicians who consult patients in everyday practice, Dr. Lim recommends a focus on striking a balance between the recommended amounts of sunscreen to apply and what patients are more likely to actually apply. "Patients should understand that they will only receive the desired protection if they use sunscreens appropriately," he notes. Regarding sunscreen selection, he argues that patients should be looking for higher SPF sunscreens as well as those that provide the highest UVA protection.

Recommend Additional Strategies. Patient education will likely be an ongoing measure in the effort to inform consumers about UV light and the role of sunscreens in sun protection. According to Dr. Gilchrest, it's especially important to remind patients that sunscreens represent one part of an overall effort to be conscious about UV light. "Sunscreens should not be viewed as the only measure of sun protection," Dr. Gilchrest explains. "Sensible approaches, such as general avoidance in mid-day and wearing sun-protective clothing are just as essential toward building a greater awareness and widespread practice of UV protection."

Participate in the Dialogue. Finally, for dermatologists seeking to take part in the dialogue about sunscreen labeling changes, Dr. Rigel simply advises clinicians to stay alert and to be prepared to answer questions from colleagues and patients. "There is no right answer," he observes, concerning the debate over getting the label right. But physicians can take an active role in the proceedings by voicing their concerns and informing patients and consumers inside and outside the practice walls. ■