



Simplifying Sun Safety: A Guide to the New FDA Sunscreen Monograph

Roman Bronfenbrener, MD

Dermatologists are instrumental in educating their patients about safe sun practices. As residents, we should begin to instill this teaching point into our daily patient encounters. The new US Food and Drug Administration sunscreen guidelines, instituted fully in December 2012, help consumers make more educated decisions about sunscreens they purchase but also introduce new classifications and claims with which dermatologists should be intimately familiar. This article aims to concisely summarize the revisions as well as any continued controversies with the guidelines.

Cutis. 2014;93:E17-E19.

You can always pick out the dermatologists on the beach, donning wide-brimmed hats and sun-protective clothing and setting egg timers for sunscreen reapplication. The long-term benefits of UV protection have been instilled in our brains from early in our residency training. Sunscreen is an invaluable tool in this armamentarium and provides an easily applied method of sun protection that can be used daily. Prior to the new US Food and Drug Administration (FDA) guidelines, whose compliance deadline passed in December 2012,¹ sunscreen marketing and labeling allowed for wide discrepancies between manufacturers' claims of efficacy and actual consumer experience. These better-defined guidelines will not only help patients find a suitable sunscreen

but will resolve the discrepancies between the dermatologist's recommendations and the sunscreen label's claims of efficacy.

Claims of Broad-Spectrum Efficacy

Sun protection factor (SPF) is a ratio that indicates how much UVB protection is afforded by a sunscreen. For instance, an SPF of 10 allows for 10 times more UVB to contact the skin before a given amount of erythema is reached; therefore, if a patient normally burns in 5 minutes, properly applied SPF 10 sunscreen will prolong the burn time to 50 minutes. Previously, consumers relied only on SPF values to determine their sunscreen's efficacy, which is a serious flaw considering UVA protection is not factored into SPF. Exposure to UVA has been shown to increase the risk for skin cancer, and its deeper dermal penetration with resultant elastolysis is partially responsible for skin aging.^{2,3} The ideal sunscreen would provide uniform coverage against the entire UVA and UVB range, and the new guidelines allow for manufacturers to place the broad-spectrum designation on products that function in this manner.⁴ The degree of UVA protection offered by a sunscreen is measured with in vitro testing of the critical wavelength (370 nm). A sunscreen must have 90% of its absorbance at 370 nm or greater to meet minimum UVA-blocking requirements for classification as broad spectrum.⁵

Usage Claims

Sunscreens that meet the requirements for being considered broad spectrum and are rated SPF 15 or higher can now be labeled with several FDA-approved claims. These claims, which state that sunscreen use can not only reduce the risk for skin cancer but also decrease signs of sun-induced skin aging, are in line with dermatologist recommendations. Allowing companies to put these claims on products

From the Department of Dermatology, State University of New York, Stony Brook.

The author reports no conflict of interest.

Correspondence: Roman Bronfenbrener, MD, 181 N Belle Mead Rd, Suite 5, East Setauket, NY 11733

(roman.bronfenbrener@stonybrookmedicine.edu).

incentivizes better sunscreen manufacturing and encourages patient compliance.⁴

Resiliency Claims

Prior to these recent guidelines, many sunscreen manufacturers made various unsubstantiated claims of resiliency and durable efficacy, even under extreme conditions. Many sunscreen labels frequently touted products as being waterproof and/or sweatproof. Although certain sunscreens are more efficacious in high-moisture environments, the new guidelines restrict claims of water resistance to times of either 40 or 80 minutes, a stark contrast from some prior claims that promised all-day protection.⁴ Sunscreens not labeled as water resistant are required to suggest the use of a water-resistant sunscreen during wet activities such as swimming or sweating on the drug information label. Labels also are required to state that sunscreen should be reapplied at least every 2 hours, after towel drying, and more frequently when swimming or sweating (Figure).⁶

Sunscreens Are Only a Single Component of Sun-Safe Practice

Although sunscreen is an invaluable component of sun protection, it is only one piece of a puzzle and should not be considered the only, or even the best, form of protection against UV damage. New sunscreen labels reinforce this notion with practical tips,

such as seeking shade during peak hours (between 10 AM and 2 PM) and wearing appropriate sun-protective clothing and eyewear.⁶

Vehicle for Sunscreen

The new FDA monograph only pertains to products in certain formulations. Products designed as powders, shampoos, and bodywashes are not included, as they have questionable efficacy, especially in real-world applications. Companies can individually seek to monograph their product, which would be done on a case-by-case basis and requires manufacturers of new or novel sunscreen formulations to prove their efficacy to the FDA when used as directed before they will receive approval for marketing as a sunscreen.⁴

Final Thoughts

Although these guidelines benefit consumers in many ways, they do not address all the concerns associated with sunscreen; for instance, the regulations make no final decision regarding spray sunscreens whose efficacy has shown substantial variation between in-vitro testing and real-world application by consumers. Similarly, controversy regarding potential inhalation of sunscreen products in aerosol form has not been addressed.

Another focus of attention is the maximum SPF rating to be allowed by the FDA. The FDA is proposing a limit on the maximum SPF at 50+,⁷ a measure

Example of new product label according to the US Food and Drug Administration monograph with updated recommendations for use and efficacy claims for sunscreens. (This figure is in the public domain, courtesy of the US Food and Drug Administration).⁶



already undertaken by both European and Australian regulatory bodies. Proponents for this regulation argue that sunscreens with higher SPF ratings expose the skin to higher concentrations of potentially irritating or sensitizing chemicals while only minimally raising the percentage of UVB blocked. Higher SPF numbers also provide false security to consumers who may apply the product less frequently and decrease their use of other sun protective measures.⁸ As a counterpoint, allowing higher SPF sunscreens may actually protect consumers because many do not apply their product at the same 2 mg/cm² used in the laboratory to determine SPF and UVA-blocking parameters. Higher SPF sunscreens would therefore allow greater protection in real-world use, as compared to marginal differences in the laboratory setting.^{6,8}

Finally, it is important to remain vigilant about our patients' concerns, many relating to prevalently held beliefs regarding safety of various sunscreen components as well as vitamin D synthesis. Although the FDA is unlikely to address these issues in its monographs, our job as dermatologists is to continue to educate our patients to ensure they make rational, science-based decisions with regard to their sun protection habits.

On the whole, these recently implemented guidelines are invaluable in enlightening consumers and encouraging educated purchases. Prior unconfirmed statements made by sunscreen marketers on product labels and advertising have been replaced by evidence-based claims that are consistent across the entire range of sunscreen products. These regulations also simplify the recommendations we make to our patients. Currently, I recommend that my patients use a broad-spectrum product with an SPF of 30 or higher; if the sunscreen meets these criteria, I am satisfied with any brand or vehicle that the patient

prefers. It will be important to stay abreast of new developments, as further FDA decisions as well as exciting technological advances will continue to change the face of sun protection.

REFERENCES

1. Labeling and effectiveness testing; sunscreen drug products for over-the-counter human use; delay of compliance dates. *Fed Regist.* 2012;77(92):27591-27593. To be codified at 21 CFR §201 and 310.
2. Understanding UVA and UVB. Skin Cancer Foundation Web site. <http://www.skincancer.org/prevention/uva-and-uvb/understanding-uva-and-uvb>. Accessed February 28, 2014.
3. Wang S, Setlow R, Berwick M, et al. Ultraviolet A and melanoma: a review. *J Am Acad Dermatol.* 2001;44:837-846.
4. FDA sheds light on sunscreens. US Food and Drug Administration Web site. <http://www.fda.gov/forconsumers/consumerupdates/ucm258416.htm>. Updated August 20, 2013. Accessed March 1, 2014.
5. What is Critical Wavelength anyway? Critical Wavelength Web site. http://criticalwavelength.com/CRITICAL_WAVELENGTH_.html. Accessed February 24, 2014.
6. Sunscreen labeling according to 2011 final rule. US Food and Drug Administration Web site. <http://www.fda.gov/downloads/ForConsumers/ConsumerUpdates/UCM258718.pdf>. Accessed February 7, 2014.
7. Revised effectiveness determination; sunscreen drug products for over-the-counter human use. *Fed Regist.* 2011;76(117):35672-35678. To be codified at 21 CFR §201.
8. Wang SQ. Ask the expert: does a higher-SPF (sun protection factor) sunscreen always protect your skin better? Skin Cancer Foundation Web site. <http://www.skincancer.org/skin-cancer-information/ask-the-experts/does-a-higher-spf-sunscreen-always-protect-your-skin-better>. Accessed March 1, 2014.