Highlights and implications of the 2019 proposed rule on sunscreens by the US Food and Drug Administration

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On February 26, 2019, the US Food and Drug Administration (FDA) issued a proposed rule to put into effect a final monograph for nonprescription, over-the-counter sunscreen drug products.[1] The public has a 90-day period (until May 28, 2019) to provide comments to the FDA. Given the importance of sunscreens as part of an overall sun protection strategy, it is important that dermatologists and our patients be aware of the proposed new rule.

HIGHLIGHTS OF THE PROPOSAL

Proposed generally recognized as safe and effective (GRASE) status of active ingredients

Currently, there are 16 ultraviolet (UV) filters that are listed in the US FDA 1999 final monograph.[2] According to the proposed new rule, these 16 existing filters would now be classified into 3 categories: GRASE (zinc oxide and titanium dioxide), not GRASE (para-aminobenzoic acid and trolamine salicylate, no longer on the market in the United States), and insufficient safety data to determine GRASE status. The FDA is seeking additional safety testing on the 12 remaining filters without sufficient safety data to determine GRASE status, although the agency is not concerned about their efficacy and does not consider them unsafe.

Dosage forms

Oils, lotions, creams, gels, butters, pastes, ointments, and sticks are considered GRASE. Sprays are considered GRASE, subject to final formulation testing on particle size and flammability. Powders are not GRASE. For wipes, towelettes, body washes, and shampoos, the FDA has not received data showing that they are eligible for inclusion in the monograph.

Sun protection factor (SPF) and broad spectrum

The FDA proposes to raise the maximum SPF value manufacturers can claim from 50+ to 60+. To ensure uniform UVB and UVA protection, the FDA proposes to add to the current broad spectrum test a requirement that sunscreens meet a UVA-I (340-400 nm)-to-UVA+UVB (290-400 nm) ratio of $\geq$0.7.

Labeling

The FDA proposed new label requirements to assist consumers to easily identify key information (active ingredients, skin cancer, and skin aging alert).

Proposed process

The FDA has been mandated by the Sunscreen Innovation Act, enacted on November 26, 2014, to issue a final sunscreen monograph within 5 years (ie, November 26, 2019). Recognizing the significant challenge of the testing requirement, the FDA is looking for a consortium led by the industry and supplemented by other stakeholders to conduct these studies in a coordinated manner.

IMPLICATIONS OF THE PROPOSED RULES

Given recent public discussions regarding the environmental impacts of organic UV filters,[3] the proposed rules requiring additional safety data on these ingredients might add another layer of confusion and uncertainty among the public on

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Funding sources: None.
Conflicts of interest: Dr Lim has received research funding from Estee Lauder, Ferndale, Unigen, and Incyte and has served as a speaker at educational session supported by Pierre Fabre. Dr Wang has no conflicts of interest to disclose.

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J Am Acad Dermatol 2019;81:650-1.
0190-9622/$36.00

https://doi.org/10.1016/j.jaad.2019.04.007

the safety of sunscreens and photoprotection in general.

Dermatologists must continue to remind the public that the adverse effects of excessive sun exposure are scientifically well established. The public should continue to practice comprehensive photoprotection, which includes seeking shade; wearing clothing, hats, and sunglasses; and on exposed areas, using broad spectrum sunscreen with SPF >30. For those concerned about the environmental impact of UV filters, sunscreens containing titanium dioxide or zinc oxide may be used. It is also important that we continue to educate the public that sunscreens are safe and effective.

REFERENCES

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2. Sunscreen drug products for over-the-counter human use (64 FR 27666, May 21, 1999) (now stayed) (stayed 1999 final monograph).
3. Schneider SL, Lim HW. Review of environmental effects of oxybenzone and other sunscreen active ingredients. *J Am Acad Dermatol*. 2019;80(1):266-271.