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Vincent DeLeo weighs in on the new sunscreen regulations

COMMENTARY

Sunscreen Regulations and Advice for Your Patients

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If by now you have not had a patient ask, "Doctor, what sunscreen should I use NOW?" you will soon.

The US Food and Drug Administration (FDA) recently published a press release detailing a proposed rule on how manufacturers will be required to test and label sunscreens in the United States.[1,2] Although the press release was complicated and contained much information, the media specifically latched onto the FDA's consideration of only 2 active sunscreen ingredients—zinc oxide and titanium dioxide—as generally recognized as safe and effective (GRASE). In response, some patients may assume that most sunscreens on the market are dangerous.

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How did this new proposed rule come about? To understand the process, it takes some explanation of the history of the FDA's regulation of sunscreens.

How are sunscreens regulated by the FDA?

The regulatory process for sunscreens in the United States is complicated. The FDA regulates sunscreens as over-the-counter (OTC) drugs rather than as cosmetics, which is how they are regulated

in most of the rest of the world.

The US sunscreen regulation process began in 1978 with an advance notice of proposed rulemaking from the FDA that included recommendations from an advisory review panel on the safe and effective use of OTC sunscreen products.[3] At that time, 21 active sunscreen ingredients and their maximum use concentrations were listed and determined to be safe, or GRASE. It also gave manufacturers guidance on how to test for efficacy with the methodology for determining the sun protection factor (SPF) as well as various labeling requirements. Over the years, the FDA has issued a number of other sunscreen guidelines, such as removing padimate A and adding avobenzone and zinc oxide to the list of GRASE ingredients in the 1990s.[4,5]

In 1999, the FDA issued a final rule that listed 16 active sunscreen ingredients and concentrations as GRASE.[6] There were some restrictions as to certain combinations of ingredients that could not be used in a finished product. Labeling requirements, including a maximum SPF of 30, also were put in place. This final rule established a final sunscreen monograph that was supposed to have been effective by 2002; however, in 2001 the agency delayed the effective date indefinitely because they had not yet established broad-spectrum (UVA) protection testing and labeling.[7]

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The FDA published a proposed rule in 2007 as well as a final rule in 2011 that again listed the same 16 ingredients as GRASE and specified labeling and testing methods for establishing SPF, broad-spectrum protection, and water-resistance claims.[8,9] The final rule limited product labels to a maximum SPF of 50+; provided directions for use with regard to other labeling elements (eg, warnings); and identified specific claims that would not be allowed on product labels, such as “waterproof” and “all-day protection.”[9]

Nevertheless, an effective final OTC monograph for sunscreen products has not yet been published.

What is the Sunscreen Innovation Act?

In 2014, the US Congress enacted the Sunscreen Innovation Act[10] primarily to mandate that the FDA develop a more efficient way to determine the safety and efficacy of new active sunscreen ingredients that were commonly used in Europe and other parts of the world at the time. Many of these agents were thought to be more protective in the UVA and/or UVB spectrum, and if added to the list of GRASE ingredients available to US manufacturers, they would lead to the development of products that would improve the protection offered by sunscreens marketed to US consumers. The time and extent application (TEA) was established, a method that allowed manufacturers to apply for FDA

approval of specific agents. The TEA also suggested allowing data generated in other countries where these agents were already in use for years to be considered in the FDA's evaluation of the agents as GRASE. In addition, Congress mandated that a final monograph on OTC sunscreens be published by the end of 2019. A number of manufacturers have submitted TEAs for new active sunscreen ingredients, and so far, all have been rejected.

Why is the FDA interested in more safety data?

Since then, the FDA has become concerned not only with the safety and efficacy of newly proposed agents through the TEA but also with the original 16 active sunscreen ingredients listed as GRASE in the 2011 final rule. In the 1970s and 1980s, sunscreen use was limited to beach vacations or outdoor sporting events, but sun-protective behaviors have changed dramatically since that time, with health care providers now becoming cognizant of the growing threats of skin cancer and melanoma as well as the cosmetic concerns of photoaging, thereby recommending daily sunscreen use to their patients. In addition, the science behind sunscreens with higher concentrations of active ingredients intended to achieve higher and higher SPFs and their respective penetration of the skin has evolved, leading to new concerns about systemic toxicity. Early limited research frequently touted by the lay media has suggested that some of these agents might lead to hormonal changes, reproductive toxicity, and carcinogenicity.

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In November 2016, the FDA issued a guidance for manufacturers that outlined the safety data that would be required to establish an OTC sunscreen active ingredient as GRASE.[11] It also provided detailed information about both clinical and nonclinical safety testing, including human irritation and sensitization studies as well as human photosafety studies. In vitro dermal and systemic carcinogenicity studies and animal developmental and reproductive toxicity studies also were required as well studies regarding safety in children.

Many of these recommendations were already being utilized by manufacturers; however, one important change was the requirement for human absorption studies by a maximal usage trial, which more accurately addresses the absorption of sunscreen agents according to actual use. Such studies will be required at the highest allowable concentration of an agent in multiple vehicles and over large body surface areas for considerable exposure times.

This guidance to sunscreen manufacturers was announced to the public in a press release in May 2018.[12]

What are the new regulations?

All of this has culminated in the recent proposed rule, which includes several important proposals[2]:

- Of the 16 currently marketed active sunscreen ingredients, only 2—zinc oxide and titanium dioxide—are considered GRASE. Two ingredients—trolamine salicylate and para-aminobenzoic acid—are considered non-GRASE, but there is not enough information at this time to determine if the remaining 12 ingredients are GRASE. The FDA is working with manufacturers to obtain sufficient information to make this determination.
- Approved dosage formulations include sprays, oils, lotions, creams, gels, butters, pastes, ointments, and sticks. Further information is needed regarding powders before they can be considered.
- The maximum SPF will be increased from 50+ to 60+.
- Sunscreens with an SPF of 15 or higher are required to provide broad-spectrum protection commensurate with the SPF, expanding on critical wavelength testing.
- There are new labeling changes, including a requirement that active ingredients be listed on the front of the packaging.
- Sunscreen products that contain insect repellents are considered non-GRASE.

What's next?

The process for the proposed final rule has now entered a 90-day public comment period that will end on May 27, 2019; however, it is unlikely that a final monograph as mandated by Congress will be produced by the end of this year.

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Sunscreen manufacturers currently are coordinating a response to the proposed rule through the Personal Care Products Council and the Consumer Healthcare Products Association Sunscreen Task Force. It is likely that the new required testing will be costly, with estimates exceeding tens or even hundreds of millions of dollars. In all likelihood, the number of active ingredients that the industry will agree to support with costly testing will be fewer than the 12 that are now on the list. It also is likely that this process will lead to fewer sunscreen products for consumers to choose from and almost certainly at a higher cost.

What do we tell patients in the meantime?

According to the FDA's rules, it was necessary that this process was made public, but it will almost certainly concern our patients as to the safety of the sunscreen products they have been using. We should be concerned that some of our patients may limit their use of sunscreens because of safety concerns.

There is no question that, as physicians, we want to "first, do no harm," so we should all be interested in assuring our patients that our sunscreen recommendations are safe and we support the FDA proposal for additional data. The good news is that when this process is completed, a large number of agents will likely be found to be GRASE. When the FDA finally gives its *imprimatur* to sunscreens, it will hopefully help to silence those naysayers who report that sunscreens are dangerous for consumers; however, it has been suggested by some in industry that the new testing required may take at least 5 years.

What should dermatologists do when we are asked, "What sunscreen should I use NOW?" For most patients, I would explain the regulatory process and assure them that the risk-benefit ratio at this point suggests they should continue using the same sunscreens that they are currently using. For special situations such as pregnant women and children, it may be best to suggest products that contain only the 2 GRASE inorganic agents.

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