

Why GAO Did This Study

Using sunscreen as directed with other sun protective measures may help reduce the risk of skin cancer—the most common form of cancer in the United States. In the United States, sunscreen is considered an over-the-counter drug, which is a drug available to consumers without a prescription. Some sunscreen active ingredients not currently marketed in the United States have been available in products in other countries for more than a decade. Companies that manufacture some of these ingredients have sought to market them in the United States by applying to add the ingredients to the sunscreen monograph, which lists ingredients that can be used in sunscreens without FDA's premarket approval. FDA reviews the applications and corresponding safety and effectiveness data for the ingredients.

The Sunscreen Innovation Act includes a provision for GAO to examine FDA's implementation of the act. This report examines (1) the extent to which FDA implemented requirements for reviewing applications for sunscreen active ingredients within mandated time frames, and (2) the status of the sunscreen applications. GAO reviewed FDA regulations and guidance documents, Federal Register notices, and FDA and sponsor documents for all eight sunscreen applications. GAO also interviewed FDA officials; sponsors of sunscreen applications; and stakeholders with interests in sunscreen, including health care providers, researchers, and industry groups. Stakeholders were selected based on knowledge of the monograph process and sunscreen active ingredients. The perspectives of these stakeholders are not generalizable.

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SUNSCREEN

FDA Reviewed Applications for Additional Active Ingredients and Determined More Data Needed

What GAO Found

The Food and Drug Administration (FDA), within the Department of Health and Human Services, implemented requirements for reviewing applications for sunscreen active ingredients within time frames set by the Sunscreen Innovation Act, which was enacted in November 2014. For example, the agency issued a guidance document on safety and effectiveness testing in November 2016.

As of August 2017, all applications for sunscreen active ingredients remain pending after the agency determined more safety and effectiveness data are needed. By February 2015, FDA completed its initial review of the safety and effectiveness data for each of the eight pending applications, as required by the act. FDA concluded that additional data are needed to determine that the ingredients are generally recognized as safe and effective (GRASE), which is needed so that products using the ingredients can subsequently be marketed in the United States without FDA's premarket approval. To make a GRASE determination, FDA requested that the application sponsors provide additional data, including human clinical studies, animal studies, and efficacy studies.

Sponsors of some of the sunscreen applications and some stakeholders GAO interviewed questioned FDA's requests, stating, for example, that the agency's recommended absorption test has never been conducted on sunscreen ingredients and there is a lack of knowledge on how to conduct it. At the same time, other stakeholders support the additional testing FDA requested. FDA reports that the increase in the amount and frequency of sunscreen usage, coupled with advances in scientific understanding and safety evaluation methods, has informed the agency's perspective that it needs additional data to determine that sunscreen active ingredients are GRASE. However, none of the sponsors reported current plans to provide the requested information—that is, they are either still considering whether to conduct the additional tests or they do not plan to do so. They cited the following reasons:

- **Return on investment.** The testing FDA requested is extensive, would cost millions of dollars, or take several years to conduct, according to sponsor representatives. Some stakeholders and sponsor representatives said that sponsors are currently working to develop newer sunscreen ingredients and are therefore reluctant to invest in the testing FDA requested for the older ingredients covered by the pending applications.
- **Alternatives not accepted.** Some sponsor representatives and stakeholders said that when they proposed alternative testing methods for absorption, for example, the agency rejected the alternatives.
- **Animal testing.** One stakeholder and some sponsor representatives reported concerns about the effect that the animal testing requested by FDA may have on companies' marketing of sunscreen products worldwide. Additionally, one stakeholder and representatives from one sponsor expressed concern that sunscreen manufacturers may face backlash from animal rights groups and shareholders if animal testing is conducted.

The Department of Health and Human Services provided technical comments on a draft of this report, which GAO incorporated as appropriate.