New FDA Actions to Keep Consumers Safe From the Harmful Effects of Sun Exposure

There's no pill or capsule that can replace your sunscreen.

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Statement from FDA Commissioner Scott Gottlieb, M.D., on new FDA actions to keep consumers safe from the harmful effects of sun exposure, and ensure the long-term safety and benefits of sunscreens

Skin cancer is the most common cancer in the United States. Current estimates are that one in five Americans are at risk of developing skin cancer in their lifetime. Exposure to natural and artificial ultraviolet (UV) light has a direct impact on a person's risk of developing skin cancer — despite age or skin type. Most cases of melanoma — the deadliest form of skin cancer — can be attributed to ultraviolet exposure. We also know that the effects of exposure to UV radiation — whether from the sun or indoor tanning beds — are cumulative. They add up over one's lifetime.

Over the years, advancing better UV protection has been a key goal of efforts by the healthcare community and government agencies. As a nation, we've tackled skin cancer from several fronts. This includes national education and awareness efforts such as this Friday's Don't Fry Day, which was designated by the National Council on Skin Cancer Prevention to encourage sun safety awareness. It also includes policy efforts to promote innovation in sunscreen such as the 2014 Sunscreen Innovation Act (SIA), along with efforts by the industry to invest in better technologies.

We need to continue to take new steps to build on these goals and efforts. That starts with making sure that products marketed to offer protection from the sun's effects actually deliver these promises. It also includes new steps to help promote product innovation when it comes to better sunscreens. Today, we're announcing three new efforts as part of a comprehensive set of actions to advance the FDA's framework for sun protection products ahead of this coming summer.

This starts with making sure that the products consumers use deliver their advertised benefits.

Many of us make efforts to wear protective clothing and seek shade. But for times when we must, or want to be outside enjoying the weather, consumers should know that the products they're using to protect themselves are effective at guarding them from harmful UV radiation and safe to

use on themselves and their families. Unfortunately, this isn't always the case.

We've found products purporting to provide protection from the sun that aren't delivering the advertised benefits. Instead they're misleading consumers, and putting people at risk. Today we sent warning letters to companies illegally marketing pills and capsules labeled as dietary supplements that make unproven drug claims about protecting consumers from the harms that come from sun exposure without meeting the FDA's standards for safety and effectiveness.

These companies — marketing products called Advanced Skin Brightening Formula, Sunsafe Rx, Solaricare and Sunergetic — are putting people's health at risk by giving consumers a false sense of security that a dietary supplement could prevent sunburn, reduce early skin aging caused by the sun, or protect from the risks of skin cancer. These companies were instructed to correct all violations associated with their products and were advised to review product websites and product labeling to ensure that the claims they are making don't violate federal law.

Consumers should be watchful for unscrupulous companies making unproven claims. When the FDA sees companies taking advantage of people's desire to protect themselves from the harmful effects of the sun — we'll step in. There's no pill or capsule that can replace your sunscreen.

Legitimate sunscreens are made in a wide range of sun protection factor values, also known as SPF values, and are over-the-counter drugs that come in many forms. These include lotions, creams, sticks and sprays. All of these formulations are applied topically over the skin and must pass certain tests before they're sold. All sunscreens are tested to measure the amount of UV radiation exposure it takes to cause sunburn when using a sunscreen compared to how much UV exposure it takes to cause a sunburn when not using a sunscreen. Over the years, the FDA has updated the labeling requirements placed on sunscreens marketed without approved applications to reflect the latest science on UV exposure. And we're continuing to work to ensure that sunscreen active ingredients and the FDA's regulations reflect the most advanced science on determining safety and effectiveness.

We're also taking new steps to promote safe and effective innovations for sun protection.

To better achieve these goals, the FDA is encouraging industry to conduct research on additional sunscreen active ingredients that'll help us answer critical questions about their safety. There have been important changes to how sunscreens are used and delivered, including recommendations on use. When sunscreens first came on the market, they were used only occasionally at the beach. Now, people are encouraged to use them liberally whenever they are out in the sun. So our exposure to sunscreens has greatly increased. At the same time, there's also growing interest in how the active ingredients in sunscreens may be absorbed through the skin. When sunscreens first came on the U.S. market, sunscreen active ingredients were not thought to penetrate the skin. We now have evidence that it's possible for some sunscreen active ingredients to be absorbed through the skin. This combination of a large increase in the amount and frequency of sunscreen usage, together with advances in scientific understanding and safety evaluation methods, has given rise to new questions about what information is necessary and

available to support general recognition of safety and effectiveness (GRASE) of active ingredients for use in OTC sunscreens.

As part of the SIA, enacted in 2014 to provide a new process for the FDA to review the safety and effectiveness of sunscreen active ingredients, and as we've outlined in the safety and effectiveness guidance for sunscreen active ingredients being evaluated under the SIA pathway, we're issuing another new draft guidance today for industry regarding Maximal Usage Trials (MUsT) for topically-applied active ingredients being evaluated for inclusion in an OTC monograph, including the OTC monograph for sunscreens. This draft guidance, when finalized, will recommend that these studies be conducted to support the inclusion of an active ingredient in an OTC drug monograph. By laying out these principles in draft guidance, on how manufacturers can evaluate the absorption characteristics of topically applied active ingredients being considered for inclusion in an OTC monograph, we hope to encourage more product innovation.

The SIA is an important law that, among other things, it created new procedures for the review of additional sunscreen active ingredients and charged the FDA to update certain regulations regarding sunscreens. This week, as required by the SIA, we've issued a report to Congress on the FDA's progress implementing the SIA. I'm pleased to announce that we've met all the statutory obligations and deadlines under the Act. At the same time, we've advanced our scientific standards for evaluating the covered sunscreen active ingredients' safety and effectiveness.

The FDA is committed to reviewing additional sunscreen active ingredients as outlined in the SIA and to do our part to provide consumers with safe and effective sunscreen formulations. But we can't do it alone. To be successful, we need industry's help, and they need ours. That's why we've also been meeting with manufacturers to discuss sunscreen data recommendations and why we are providing relevant guidance to assist them. We're also holding sunscreen manufacturers responsible for the quality of their products.

Further, because this is a complex regulatory backdrop, today we've also issued guidance to industry describing our enforcement approach with respect to OTC sunscreen products marketed without approved applications during the period before a final OTC sunscreen monograph becomes effective. In the interim, unless the failure to pursue regulatory action poses a potential health hazard to the consumer, we do not intend to object to the marketing without an approved application of OTC sunscreen products that have all of the characteristics outlined in the guidance.

The FDA continues to evaluate scientific issues related to sunscreens as we work to finalize certain regulations concerning nonprescription sunscreen as required by the SIA. A forthcoming proposed rule that we have included in the Unified Agenda will update these regulations with the latest science to help ensure that consumers continue to have access to safe and effective sunscreens.

Consistent with the SIA, we also expect to address sunscreen dosage forms and the effectiveness of various SPF values. Through this rulemaking process, we're seeking to balance needed product innovation with ensuring consumers are properly protected from the sun's harmful effects, based

on the latest scientific evidence on these products.

The FDA's expectations for safety and effectiveness data for additional sunscreen active ingredients, which are being considered through the SIA process, are also meant to ensure consumers have access to sunscreens that are safe and effective, and are developed in a manner that is consistent with modern scientific thinking concerning safety and effectiveness of sunscreens.

The upcoming Don't Fry Day is a good reminder that we need to reduce the risks from harmful UV radiation. Given the recognized public health benefits of sunscreen use, the FDA is committed to finding ways to help bring a wider assortment of safe and effective sunscreen products to the public. Enjoy the summer — and protect yourselves and your loved ones from sun damage, knowing the FDA is continuing to take actions to ensure the products you use are safe and effective.

The FDA, an agency within the U.S. Department of Health and Human Services, protects the public health by assuring the safety, effectiveness, security of human and veterinary drugs, vaccines and other biological products for human use, and medical devices. The agency is also responsible for the safety and security of our nation's food supply, cosmetics, dietary supplements, products that give off electronic radiation, and for regulating tobacco products.

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