Navigating the FDA's Regulatory Path for Sunscreen

Center Forward Basics

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Overview

The Food and Drug Administration (FDA) regulates sunscreen products in the United States to ensure their safety and effectiveness in protecting against the sun's harmful rays. These regulations include testing requirements for Sun Protection Factor (SPF) levels, broad-spectrum protection against UVA and UVB rays, water resistance claims, and labeling guidelines. Manufacturers must adhere to stringent testing protocols to validate their product's efficacy and safety before their products can be marketed to consumers. Additionally, the FDA continues to evaluate new scientific data and update regulations to reflect the latest understanding of sun protection and skin health.

Sunscreens have long been a consumer go-to for the prevention of sun damage and skin cancer across the globe. In the U.S., The American Academy of Dermatology (AAD), the Surgeon General, and the FDA recommend individuals use sunscreens as part of their daily sun protection plan, especially when engaged in outdoor activities. Though the FDA has monitored and regulated sunscreens and their ingredient profiles for decades, recent developments have led to reevaluations. In recent years, the FDA has taken steps to modernize sunscreen regulations to address concerns over ingredient safety and efficacy. This includes evaluating the safety of commonly used sunscreen ingredients like oxybenzone and proposing new regulations to assess their potential risks better. Additionally, the FDA has proposed updates to sunscreen labeling requirements to provide consumers with clearer information about product ingredients and usage instructions. These efforts aim to enhance consumer confidence in sunscreen products while ensuring they offer effective protection against sunburn, skin cancer, and premature skin aging.

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Center Forward brings together members of Congress, not-for profits, academic experts, trade associations, corporations and unions to find common ground. Our mission: to give centrist allies the information they need to craft common sense solutions, and provide those allies the support they need to turn those ideas into results.

In order to meet our challenges we need to put aside the partisan bickering that has gridlocked Washington and come together to find common sense solutions.

For more information, please visit www.center-forward.org

FDA Approval Process

Sunscreens are classified by the FDA as over-the-counter drug products, which means sunscreens require more stringent safety, stability, compatibility, and efficacy testing than what is required for cosmetics products like skincare and makeup. The UV filters that give sunscreens their protective abilities are considered "active ingredients." Only FDA-approved UV filters can be included in U.S. sunscreen products and the FDA's UV filter OTC Monograph of active sunscreen ingredients. Once products have passed all necessary tests and are deemed FDA-approved UV filters, only then can they be labeled as sunscreens.

OTC Monograph is a "rule book" for each therapeutic category that establishes conditions, such as active ingredients, uses, doses, labeling, and testing. In this 'rule book', an OTC drug is GRASE (generally recognized as safe and effective) and can then be marketed without a new drug application and FDA pre-market approval. Oils, lotions, creams, gels, butters, pastes, ointments, and sticks are considered GRASE by the FDA. Spray sunscreens are GRASE subject to testing and labeling requirements, and powder sunscreens are not considered GRASE because additional data is needed to determine their

safety and efficacy. It is worth noting the FDA currently does not recommend spray and powder sunscreen formulations due to the risk of inhalation.

The FDA also includes maximum percentages that each UV filter can be included in a given sunscreen formula. Approving a UV filter as an active ingredient can be time-consuming and expensive. It requires extensive safety, toxicology, and efficacy testing, which is done either on animals or on humans. Sunscreen labels are also strictly regulated by the FDA. Products must undergo testing on a minimum of ten study participants to verify their SPF rating, broad spectrum status, and water resistance capabilities. Products may only list their function as "helps to prevent sunburn" but may not make any label claims related to the prevention of skin cancer or early skin aging unless other studied ingredients support these claims.

Comparisons Across Countries

In the U.S., only some physical and chemical filters are permitted, as they tend to either leave chalky residues or make the skin feel greasy. Many consumers have reported sunscreens available in other countries, primarily the European Union, Australia, and Japan, are much better regarding those complaints. The EU allows 27 active ingredients to block sunburn and skin damage, whereas the FDA has only approved 17 for the United States. The FDA's approval of UV filters lags significantly behind other countries, and new UV filters have not been added to the FDA's approved list for sale in the U.S. since 2002. The number of approved ingredients matters because not all filters can seamlessly be formulated into sunscreens or other suitable products for skin application. Sunscreens produced in these different countries are often known for being effective and less expensive than those offered in the United States.

Recent Legislation

In 2019, the FDA issued a proposed rule on sunscreens, which offered to revise the requirements for sunscreen active ingredients, maximum sun protection factor levels, broad-spectrum requirements, and dosage forms, among other considerations. The proposed rule also included updates on how sunscreens are labeled to make it easier for consumers to identify essential information. This 2019 proposal aimed to bring sunscreens up to date with the latest science, including new information showing certain sunscreen ingredients can be absorbed through the skin into the body.

The Sunscreen Innovation Act, known as SIA, was enacted on November 26, 2014, to provide an alternative process for reviewing the safety and effectiveness of nonprescription sunscreen active ingredients. The SIA supplemented the regulation of the FDA's Time and Extent Application, TEA, with new statutory procedures. TEAs are responsible for assessing marketing timelines and scopes to determine eligibility. The SIA also required the FDA to establish timeframes to review TEAs for OTC drugs other than sunscreen active ingredients. The SIA ended at the end of Fiscal Year 2022.

Then came the 2020 Coronavirus Aid, Relief, and Economic Security Act, also known as the CARES Act, which Congress enacted in March 2020 in response to COVID-19. Most of its provisions focused on economic relief to individuals, families, businesses, and other groups. However, the CARES Act also reformed and modernized how the FDA regulates certain OTC Monograph drugs, specifically sunscreen. The CARES Act replaced the rulemaking process for OTC Monograph drugs with an administrative order process for issuing, revising, and amending the OTC Monographs. The administrative order process gives the FDA new tools to help revise the OTC Monographs if science changes, innovation progresses, new data becomes available, or emerging safety signals arise.

Links to Other Resources

- CATO Institute - Trade in Real Life: How the FDA Burns Consumers with Sunscreen Regulations
- FDA - Sunscreen Innovation Act (SIA) | FDA

- FDA - Sunscreen: How to Help Protect Your Skin from the Sun | FDA
- FDA - Update on Sunscreen Requirements: The Deemed Final Order and the Proposed Order | FDA
- PAVISE - How the FDA Regulates Sunscreen and Recent Updates from the FDA
- ScienceDirect - Application habits and practices of regular sunscreen users in the United States