

Significant Progress at the FDA

Finally, we are observing the start of meaningful reform in US regulation of sunscreens. Let me take you step by step on the series of events that contributed to these developments. First, it was the Sunscreen Reform Bill from Congress announced Nov. 9, 2025. Then, removal of Theresa Michele, the longtime director of the Office of Nonprescription Drugs, on Dec. 3. Finally, the announcement by FDA on Dec. 11 to propose adopting bemotrizinol as a permitted active in sunscreens.

Reopening the government was significant to the sunscreen industry as the Over-The-Counter Monograph Drug User Fee Amendments (OMUFA) for fiscal years 2026 to 2030 was sent to the President for his signature and authorization. The sunscreen reform appears in Section 6506 of the legislative text, entitled “Evidence and Testing Standards for Active Ingredients for Topical Administration.” (Yes, this means the use of ultraviolet filters in sunscreens!) Section 505G of the Federal Food, Drug & Cosmetic Act (21 USC 355h) is amended by adding at the end the three following provisions:

Evidence and Testing Standards

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for Active Ingredients for Topical Administration: “This provision utilizes standards that allow for the use of real-world evidence as part of a comprehensive evaluation of scientific evidence to demonstrate the safety and effectiveness of such active ingredients, to supplement evidence from traditional clinical trials.”

Non-Animal Testing Methods for Topical Active Ingredients: “The secretary shall consider the types of nonclinical tests described, improving access to Medicare, Medicaid, and CHIP, and strengthening Public Health Act of 2022 or any other alternative to animal testing that the secretary determines is appropriate, in the consideration of drugs intended for topical administration.”

Clarification. The Sunscreen Final Administrative Order: Final Administrative order on Non-Prescription Sunscreen Active Ingredients under section 3854 of the Coronavirus Aid, Relief, and Economic Security Act, shall:

- Account for historical data regarding the safety of sunscreen active ingredients that have previously been accepted for marketing in the US.
- Account for the role of broad-spectrum sunscreens with SPF 15 or higher in effective skin cancer prevention.
- Incorporate the evidence and testing standards for sunscreen active ingredients.

Basically, this Reform Bill requests the investigation of alternative non-animal testing, accounts for the role of broad-spectrum sunscreens, and adds the evidence of testing standards for sunscreen active ingredients. This OMUFA Amendment is non-specific

and not comprehensive enough, but it’s our hope that the FDA will consider the House and Senate language for fiscal year 2026. The negotiated agreement on performance goals and producers between the industry and the FDA allows for increased innovation and access to OTC products such as sunscreens.

Cross your fingers that we see soon real reform and innovation in the US. They should include the approval of sorely needed broad-spectrum UV filters to complement the lack of stable UVA filters in the US, and for the FDA finally to publish the Final Monograph on Sunscreens.

Finally, after nearly 20 years of petitions, many Time and Extent Applications (TEA) and continued negotiations with the FDA by the stakeholders, PCPC, the PASS Coalition and others, we have begun to see the light.

From where are all these developments emanating? Internal turmoil at the FDA? Here are some developments, in my opinion, that seem to have hastened the approval of the first new UV filter to be approved in two dozen years: the release of the Sunscreen Reform Bill from Congress; the appointment FDA Commissioner Marty Makary; FDA drug chief Richard Pazdur’s retirement announcement; and Michele’s removal.

Will this also spark the interest of the US scientific community in actively pursuing the creation of new improved UV filters as well? Regardless, I applaud this decision to have the US finally join the international community in allowing the use of more effective UV filters, especially full spectrum broad spectrum protection. Here’s to many more positive developments at the FDA! ■