



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2025-N-6494]

Amending Over-the-Counter Monograph M020: Sunscreen Drug Products for Over-the-Counter Human Use, and Related Information

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: In response to an over-the-counter (OTC) monograph order request (OMOR), the Food and Drug Administration (FDA) is announcing the availability on its website of the final administrative order (final order) (OTC000039) titled “Amending Over-the-Counter Monograph M020: Sunscreen Drug Products for Over-the-Counter Human Use, and Related Information.” This final order amends “Over-the-Counter Monograph M020: Sunscreen Drug Products for Over-the-Counter Human Use” (OTC Monograph M020) to add bemotrizinol at concentrations up to 6 percent as a sunscreen active ingredient. A sunscreen drug product containing bemotrizinol is generally recognized as safe and effective (GRASE) if it meets the conditions described in OTC Monograph M020 as amended by this final order.

DATES: The announcement of the availability on FDA’s website of the final order is published in the *Federal Register* on [INSERT DATE OF PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES: For access to final order OTC000039, go to the OTC Monographs@FDA portal at <https://www.accessdata.fda.gov/scripts/cder/omuf/index.cfm>. See the SUPPLEMENTARY INFORMATION section for more information on electronic access to the final order.

FOR FURTHER INFORMATION CONTACT: Shannon Liu, Center for Drug Evaluation and Research (HFD-600), Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993-0002, 240-402-2484, Shannon.Liu@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is issuing final order OTC000039 to amend the requirements for sunscreen drug products for OTC human use, as described in OTC Monograph M020, to add bemotrizinol for use as a sunscreen active ingredient at concentrations up to 6 percent. FDA is issuing the final order pursuant to section 505G(b)(1) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 355h(b)(1)).

OTC Monograph M020 describes the conditions under which OTC sunscreen drug products are GRASE under section 201(p)(1) of the FD&C Act (21 U.S.C. 321(p)(1)). OTC Monograph M020 was previously set forth in final order OTC000006, as deemed by sections 505G(b)(8) and 505G(k)(2)(B) of the FD&C Act, and was effective upon enactment of the Coronavirus Aid, Relief, and Economic Security Act (Pub. L. 116-136) on March 27, 2020. The conditions described in OTC Monograph M020 may be amended, revoked, or otherwise modified in accordance with the procedures of section 505G(b) of the FD&C Act.

On September 23, 2024, DSM Nutritional Products LLC submitted a Tier 1 OMOR requesting FDA issue an administrative order finding that a sunscreen drug product containing bemotrizinol as an active ingredient is GRASE under the conditions described in OTC Monograph M020.

Final order OTC000039 amends the conditions described in OTC Monograph M020, as set forth in final order OTC000006, to add bemotrizinol at concentrations up to 6 percent as a sunscreen active ingredient. The final order establishes that for a sunscreen drug product containing bemotrizinol as a sunscreen active ingredient to be legally marketed without an approved application under section 505 of the FD&C Act (21 U.S.C. 355), among other requirements, it must conform to certain conditions that address the concentration of bemotrizinol in the sunscreen drug product, permitted combinations of bemotrizinol with other sunscreen active ingredients and with skin protectant active ingredients, and permitted dosage

forms. Specific to dosage forms, the final order permits sunscreen drug products containing bemotrizinol to be in the following dosage forms: oil, lotion, cream, gel, butter, paste, ointment, stick, and spray, provided that the sunscreen drug product in spray dosage form is manufactured and packaged with no propellant or is manufactured and packaged in a spray delivery system where all propellant is isolated from the drug product formulation within the container closure system, and there is no contact between the propellant and the drug product formulation.

Final order OTC000039 also includes minor stylistic and formatting changes to improve the readability, clarity, and presentation of OTC Monograph M020.

A notice of availability of the proposed order titled “Amending Over-the-Counter Monograph M020: Sunscreen Drug Products for Over-the-Counter Human Use” was announced in the *Federal Register* on December 12, 2025 (90 FR 57765). FDA considered timely submitted comments on the proposal to amend OTC Monograph M020 to add bemotrizinol as a sunscreen active ingredient. After considering comments, FDA did not make changes to the final order.

II. Paperwork Reduction Act of 1995

Final order OTC000039 is issued under section 505G(b)(1) of the FD&C Act. Under section 505G(o) of the FD&C Act, the Paperwork Reduction Act of 1995 (Chapter 35 of title 44, United States Code) does not apply to collections of information made under section 505G of the FD&C Act. Therefore, clearance by the Office of Management and Budget under the Paperwork Reduction Act of 1995 is not required for collections of information, if any, in a final order issued under section 505G.

III. Electronic Access

The final order can be accessed on the OTC Monographs@FDA portal at <https://www.accessdata.fda.gov/scripts/cder/omuf/index.cfm>. Under the “Administrative Orders” banner, click on the desired link under the “Order ID” heading and follow the prompts. FDA established this information technology system with a web portal that can be accessed

through FDA's website. The OTC Monographs@FDA portal provides a resource for the public to view administrative orders (proposed, final, and interim final orders), as well as related supporting documents, for OTC Monograph Drugs and view OTC Monographs. In the future, the OTC Monographs@FDA portal will facilitate the public's ability to submit, search, and view comments and data for proposed and interim final orders.

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

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