4164-01-P

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

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 proposed administrative order (proposed order) (OTC000039) entitled "Amending Over-the-Counter Monograph M020: Sunscreen Drug Products for Over-the-Counter Human Use." This proposed order, if finalized, will amend 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 would be generally recognized as safe and effective (GRASE) if it meets the conditions described in OTC Monograph M020 as amended by this proposed order, if finalized.

DATES: Submit electronic comments on the proposed order by [INSERT DATE 45 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].

ADDRESSES: The https://www.regulations.gov electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of [INSERT DATE 45 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]. Please note that late, untimely filed comments will not be considered. Instructions for submitting comments are contained in the proposed order OTC000039, which can be viewed in the OTC Monographs@FDA portal at https://www.accessdata.fda.gov/scripts/cder/omuf/. Comments must be submitted electronically.

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.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is issuing proposed order OTC000039 to amend OTC Monograph M020 to add bemotrizinol for use as a sunscreen active ingredient at concentrations up to 6 percent. FDA is issuing the proposed 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 is currently set forth in Final Administrative 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. The proposed order, if finalized, will amend the conditions described in OTC Monograph M020, currently set forth in the Final Administrative Order OTC000006, to add bemotrizinol at concentrations up to 6 percent as a sunscreen active ingredient. FDA proposes to determine that a sunscreen drug product containing bemotrizinol as an active ingredient is GRASE if it meets the conditions described in OTC Monograph M020 as amended by this proposed order. Among the conditions for drug products containing bemotrizinol as a sunscreen active ingredient specified by this proposed order, if finalized, are 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 proposed order, if finalized, would permit the following dosage forms: oil, lotion, cream, gel, butter, paste, ointment, stick, and spray, provided that the 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.

The proposed order can be viewed in the OTC Monographs@FDA portal at https://www.accessdata.fda.gov/scripts/cder/omuf/. The proposed order contains instructions for commenting on the proposed order. Comments to the proposed order must be submitted electronically to the Federal eRulemaking Portal at https://www.regulations.gov.

OTC Monographs@FDA provides a resource for the public to view administrative orders (proposed, final, and interim final orders) for OTC Monograph Drugs and view OTC Monographs. In the future, OTC Monographs@FDA will facilitate the public's ability to submit, search, and view comments and data for proposed and interim final orders.

II. Paperwork Reduction Act of 1995

The proposed 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 that results from this proposed order.

Lowell M. Zeta,

Acting Deputy Commissioner for Policy, Legislation, and International Affairs.

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