



U.S. Food and Drug Administration

Center for Drug Evaluation and Research

Finding of No Significant Impact

Bemotrizinol, up to 6%

June 5, 2026

The National Environmental Policy Act of 1969 (NEPA) requires Federal agencies to assess the environmental impact of their actions. The Food and Drug Administration (FDA) is required under NEPA to consider the environmental effect of its major federal actions, which generally include, among other activities, the establishment or amendment of monographs describing the conditions of use under which over-the-counter human drug products have been found to be generally recognized as safe and effective (GRASE).

FDA is issuing Final Administrative Order OTC000039, and, with this action, will amend the requirements for sunscreen drug products for over-the-counter (OTC) human use in Over-the-Counter Monograph M020: Sunscreen Drug Products for Over-the-Counter Human Use (OTC Monograph M020).¹ Final Administrative Order OTC000039 amends OTC Monograph M020 to add bemotrizinol (BEMT), at concentrations up to 6 percent, as a sunscreen active ingredient.

On September 23, 2024, DSM Nutritional Products LLC (DSM or Requestor) submitted a Tier 1 OTC monograph order request (OMOR)² to add BEMT, at concentrations up to 6 percent,³ to OTC Monograph M020 for use as a sunscreen active ingredient. BEMT is an organic sunscreen active ingredient that is highly photostable and has a broad-spectrum coverage across UVB (280 to 320 nm) and UVA (320 to 400 nm) ranges.

¹ OTC Monograph M020 was initially set forth in Final Administrative Order OTC000006 Over-the-Counter Monograph M020: Sunscreen Drug Products for Over-the-Counter Human Use, available via the OTC Monographs@FDA portal at <https://www.accessdata.fda.gov/scripts/cder/omuf/>. On September 24, 2021, FDA issued Proposed Administrative Order OTC000008 Amending Over-the-Counter Monograph M020: Sunscreen Drug Products for Over-the-Counter Human Use, available via the OTC Monographs@FDA portal at <https://www.accessdata.fda.gov/scripts/cder/omuf/>. The final order contained in this document does not address Proposed Administrative Order OTC000008 which, if finalized, would amend and revise OTC Monograph M020 to establish certain new conditions under which nonprescription sunscreen drug products would be determined to be generally recognized as safe and effective (GRASE). If OTC000008 is finalized, all sunscreen drug products marketed under OTC Monograph M020, including products containing bemotrizinol as a sunscreen active ingredient, would be required to meet the conditions described in OTC Monograph M020, as amended by OTC000008.

² An OTC monograph order request (OMOR) means a request for an order submitted under section 505G(b)(5) of the FD&C Act (see section 744L(7) of the FD&C Act (21 U.S.C. 379j-71(7))). A Tier 1 OMOR means any OMOR not determined to be a Tier 2 OMOR (see section 744L(8) of the FD&C Act (21 U.S.C. 379j-71(8))). An OMOR requesting the addition of an active ingredient to an OTC monograph is not categorized as a Tier 2 OMOR and is, therefore, a Tier 1 OMOR.

³ For the purposes of OTC Monograph M020, FDA interprets a concentration up to 6 percent to mean up to and including 6 percent.

The Requestor submitted an initial environmental assessment (EA) that evaluated the potential adverse environmental effects from the use of BEMT at concentrations up to 6 percent, as an OTC sunscreen active ingredient. The CDER EA reviewers reviewed the initial EA. After this review, the CDER EA reviewers and the Requestor engaged in extensive communications through meetings and correspondence in order for the Requestor to produce a progressively more refined EA. In these communications, the CDER EA reviewers focused primarily on obtaining additional environmental fate and ecotoxicity data for benthic organisms in sediments, as well as revisions of the risk assessment approach. Following the CDER EA reviewers' recommendations, the Requestor conducted additional studies, obtained more data, and ultimately submitted an updated, final EA on May 8, 2026. The CDER EA reviewers noted in their scientific review some errors and disagreements with information and/or conclusions presented in the final EA, but nevertheless CDER EA reviewers concluded that the final EA, when considered together with information they reviewed, was sufficient to determine whether the issuance of Final Administrative Order OTC000039 may significantly affect the quality of the human environment. The final EA, supplemented by the scientific review, is adequate for this action.^{4,5}

FDA has carefully considered potential adverse environmental effects due to FDA's issuance of the Final Administrative Order OTC000039 and determines the issuance of this final order is not expected to have significant effects on the quality of the human environment. Therefore, FDA is issuing a finding of no significant impact (FONSI), and an environmental impact statement will not be prepared.⁶

⁴ See 21 CFR 25.15(a).

⁵ FDA generally requires the entity requesting a particular FDA action to make necessary corrections to its environmental assessment (EA). 21 CFR 25.40(b). In this case, while the Requestor made various updates to its initial EA, in some areas the final EA was not corrected as requested by the Agency. Consequently, CDER included additional information in its review. See *id.*

⁶ 21 CFR 25.15(b), 25.40, and 25.41.

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