TABLE 1—ANDAS FOR WHICH APPROVAL IS WITHDRAWN—Continued

Application No.	Drug	Applicant
ANDA 208833	Celecoxib capsules, 50 mg, 100 mg, 200 mg, and 400 mg ...	Amneal Pharmaceuticals of New York, LLC, 50 Horseblock Rd., Brookhaven, NY 11719.

Therefore, approval of the applications listed in table 1, and all amendments and supplements thereto, are hereby withdrawn as of January 12, 2026. Approval of each entire application is withdrawn, including any strengths and dosage forms inadvertently missing from table 1. Introduction or delivery for introduction into interstate commerce of products listed in table 1 without an approved new drug application or ANDA violates sections 505(a) and 301(d) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(a) and 331(d)). Drug products that are listed in table 1 that are in inventory on January 12, 2026 may continue to be dispensed until the inventories have been depleted or the drug products have reached their expiration dates or otherwise become violative, whichever occurs first.

Lowell M. Zeta,

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

[FR Doc. 2025–22683 Filed 12–11–25; 8:45 am]

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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 January 26, 2026.

ADDRESSES: The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of January 26, 2026. 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.

[FR Doc. 2025–22649 Filed 12–11–25; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2025–N–4732]

Determination That ZANTAC (Ranitidine Hydrochloride) Injection, Equivalent to 25 Milligrams Base/Milliliter, Has Not Been Withdrawn From Sale for Reasons of Safety or Effectiveness

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) has determined that ZANTAC (ranitidine hydrochloride (HCl)) injection, equivalent to (EQ) 25 milligram (mg) base/milliliter (mL), has not been withdrawn from sale for reasons of safety or effectiveness to the extent that the drug can be manufactured or formulated in a manner that satisfies any applicable acceptable intake limit for nitrosamine impurities. This determination means that FDA will not begin procedures to withdraw approval of abbreviated new drug applications (ANDAs) that refer to this drug product, and it will allow FDA to continue to approve ANDAs that refer to the product as long as they meet relevant legal and regulatory requirements, including satisfying any applicable acceptable intake limit for nitrosamine impurities.

FOR FURTHER INFORMATION CONTACT: Robin Fastenau, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6236, Silver Spring, MD 20993–0002, 240–893–4962, *robin.fastenau@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: Section 505(j) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 355(j)) allows the submission of an ANDA to market a generic version of a previously approved drug product. To obtain approval, the ANDA applicant must show, among other things, that the generic drug product: (1) has the same active ingredient(s), dosage form, route of administration, strength, conditions of use, and (with certain exceptions) labeling as the listed drug, which is a version of the drug that was previously approved, and (2) is bioequivalent to the listed drug. ANDA applicants do not have to repeat the extensive clinical testing otherwise necessary to gain approval of a new drug application (NDA).

Section 505(j)(7) of the FD&C Act requires FDA to publish a list of all approved drugs. FDA publishes this list as part of the ''Approved Drug Products With Therapeutic Equivalence Evaluations,'' which is known generally as the ''Orange Book.'' Under FDA regulations, drugs are removed from the list if the Agency withdraws or suspends approval of the drug's NDA or ANDA for reasons of safety or effectiveness or if FDA determines that the listed drug was withdrawn from sale for reasons of safety or effectiveness (21 CFR 314.162).

A person may petition the Agency to determine, or the Agency may determine on its own initiative, whether a listed drug was withdrawn from sale for reasons of safety or effectiveness. This determination may be made at any time after the drug has been withdrawn from sale, but must be made prior to approving an ANDA that refers to the listed drug (§ 314.161 (21 CFR 314.161)). FDA may not approve an ANDA that does not refer to a listed drug.

ZANTAC (ranitidine HCl) injection, EQ 25 mg base/mL, is the subject of NDA 019090, held by Pharmaceutical Associates, Inc. (PAI) Pharma, and initially approved on October 19, 1984. ZANTAC (ranitidine HCl) injection, EQ 25 mg base/mL is indicated in some hospitalized patients with pathological hypersecretory conditions or intractable duodenal ulcers, or as an alternative to the oral dosage form for short-term use in patients who are unable to take oral medication.

On March 31, 2020, FDA requested that all manufacturers voluntarily withdraw their ranitidine products from the market because accumulated data showed levels of N-Nitrosodimethylamine (NDMA) above the acceptable daily intake limit in many ranitidine-containing products.[1] This request applied to all ranitidine applicants, including the applicant for ZANTAC (ranitidine HCl) injection, EQ 25 mg base/mL, NDA 019090. ZANTAC (ranitidine HCl) injection, EQ 25 mg base/mL, NDA 019090, was withdrawn from sale prior to March 31, 2020. ZANTAC (ranitidine HCl) injection, EQ 25 mg base/mL, is currently listed in the ''Discontinued Drug Product List'' section of the Orange Book.

After reviewing Agency records and based on the information we have at this time, FDA has determined under § 314.161 that ZANTAC (ranitidine HCl) injection, EQ 25 mg base/mL, has not been withdrawn for reasons of safety or effectiveness to the extent that the drug can be manufactured or formulated in a manner that satisfies any applicable acceptable intake limit for nitrosamine impurities.

Accordingly, the Agency will continue to list ZANTAC (ranitidine HCl) injection, EQ 25 mg base/mL, in the ''Discontinued Drug Product List'' section of the Orange Book. The ''Discontinued Drug Product List'' delineates, among other items, drug products that have been discontinued from marketing for reasons other than safety or effectiveness. FDA will not begin procedures to withdraw approval of approved ANDAs that refer to this drug product. Additional ANDAs for this drug product may be approved by the Agency as long as they meet all other legal and regulatory requirements for the approval of ANDAs, including satisfying any applicable acceptable intake limit for nitrosamine impurities.

[1] Nitrosamine impurities in the drug supply are an important public health concern. As explained in the guidance for industry entitled ''Control of Nitrosamine Impurities in Human Drugs'' published September 2024 (available at *https://www.fda.gov/media/141720/download*) (at 4–5), ''Nitrosamine compounds are potent genotoxic agents in several animal species and some are classified as probable or possible human carcinogens by the International Agency for Research on Cancer. They are referred to as *cohort of concern* compounds in the International Council for Harmonisation of Technical Requirements for . . . Human Use (ICH) guidance for industry *M7(R2) Assessment and Control of DNA Reactive (Mutagenic) Impurities in Pharmaceuticals to Limit Potential Carcinogenic Risk* (July 2023).'' Many drug products have been found to contain levels of nitrosamines that are unacceptable or require further evaluation. FDA's current understanding is that nitrosamine levels in affected drug products have different causes and may be controlled using different strategies, including formulation design (*i.e.,* adding antioxidants or adding pH adjusters that modify the microenvironment to base or neutral pH) and supplier qualification programs.