II. Notification of Intent To Participate in Periodic Patient and Consumer Advocacy Group Stakeholder Consultation Meetings

If you intend to participate in these continued periodic stakeholder consultation meetings regarding BsUFA reauthorization, please provide notification by email to *BSUFAReauthorization@fda.hhs.gov* by January 30, 2026. Your email should contain complete contact information, including name, title, affiliation, address, email address, phone number, and notice of any special accommodations required because of disability. Stakeholders will receive confirmation and additional information about the first meeting after FDA receives this notification. Information concerning BsUFA, including the text of the law, the BsUFA III Commitment Letter, key **Federal Register** documents, BsUFA-related guidances, performance reports, and financial reports may be found on the FDA website at *https://www.fda.gov/industry/fda-user-fee-programs/biosimilar-user-fee-amendments.*

Lowell M. Zeta,

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

[FR Doc. 2025–22619 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–6077]

Pfizer Inc., U.S. Agent for King Pharmaceuticals LLC, et al.; Withdrawal of Approval of 20 Abbreviated New Drug Applications

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is withdrawing approval of 20 abbreviated new drug applications (ANDAs) from multiple applicants. The applicants notified the Agency in writing that the drug products were no longer marketed and requested that the approval of the applications be withdrawn.

DATES: Approval is withdrawn as of January 12, 2026.

FOR FURTHER INFORMATION CONTACT: Martha Nguyen, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 75, Rm. 1676, Silver Spring, MD 20993–0002, 301–796–3471, *Martha.Nguyen@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: The applicants listed in table 1 have informed FDA that these drug products are no longer marketed and have requested that FDA withdraw approval of the applications under the process in § 314.150(c) (21 CFR 314.150(c)). The applicants have also, by their requests, waived their opportunity for a hearing. Withdrawal of approval of an application or abbreviated application under § 314.150(c) is without prejudice to refiling.

TABLE 1—ANDAS FOR WHICH APPROVAL IS WITHDRAWN

Application No.	Drug	Applicant
ANDA 040320	TAPAZOLE (methimazole) tablets, 5 milligrams (mg) and 10 mg.	Pfizer Inc., U.S. Agent for King Pharmaceuticals LLC, 66 Hudson Blvd. East, New York, NY 10001.
ANDA 060582	NEOSPORIN (gramicidin; neomycin sulfate; polymyxin B sulfate) solution/drops, 0.025 mg/milliliter (mL); Equivalent to (EQ) 1.75 mg base/mL; 10,000 units/mL.	Pfizer Inc., U.S. Agent for Monarch Pharmaceuticals, LLC, a subsidiary of Pfizer Inc., 66 Hudson Blvd. East, New York, NY 10001.
ANDA 060707	NEOSPORIN G.U. Irrigant (neomycin sulfate; polymyxin B sulfate) solution, EQ 40 mg base/mL; 200,000 units/mL.	Do.
ANDA 062310	HUMATIN (paromomycin sulfate) capsule, EQ 250 mg base	Pfizer Inc., U.S. Agent for Monarch Pharmaceuticals, LLC.
ANDA 062414	Gentamicin Sulfate in sodium chloride 0.9% in plastic container, injectable, EQ 1.2 mg base/mL, EQ 1.4 mg base/mL, EQ 1.6 mg base/mL, EQ 1.8 mg base/mL, EQ 2 mg base/mL, EQ 60 mg base/100 mL, EQ 70 mg base/100 mL, EQ 80 mg base/100 mL, EQ 90 mg base/100 mL, and EQ 100 mg base/100 mL.	Hospira, Inc., 275 North Field Dr., Building H1–3S, Lake Forest, IL 60045.
ANDA 063165	ADRIAMYCIN PFS (doxorubicin HCl) injectable, 2 mg/mL and 200 mg/100 mL.	Pfizer Inc.
ANDA 072320	Pancuronium Bromide injectable, 1 mg/mL	Hospira, Inc.
ANDA 075221	ALFENTANIL (alfentanil HCl) injectable, EQ 0.5 mg base/mL	Do.
ANDA 075458	Enalaprilat injectable, 1.25 mg/mL	Do.
ANDA 075885	Milrinone Lactate in Dextrose 5% in plastic container, injectable, EQ 20 mg base/100 mL (EQ 0.2 mg base/mL) and EQ 40 mg base/200 mL (EQ 0.2 mg base/mL).	Do.
ANDA 076304	Fluconazole in Dextrose 5% in plastic container, injectable, 200 mg/100 mL (2mg/mL) and 400 mg/200 mL (2 mg/mL).	Do.
ANDA 077394	Sodium Bicarbonate injectable, 0.9 milliequivalent (mEq)/mL and 1 mEq/mL.	Do.
ANDA 089070	Procainamide HCl injectable, 500 mg/mL	Do.
ANDA 090621	Zoledronic Acid injectable, EQ 4 mg base/5 mL	Do.
ANDA 202837	Zoledronic Acid injectable, EQ 5 mg base/100 mL	Do.
ANDA 203709	Fludeoxyglucose F 18 injectable, 20–500 millicurie (mCi)/mL	B&H Consulting Services, Inc., U.S. Agent for Wisconsin Medical Radiopharmacy, LLC, 50 Division St., Suite 206, Somerville, NJ 08876.
ANDA 203883	Adenosine solution, 60 mg/20 mL (3mg/mL) and 90 mg/30 mL (3 mg/mL).	Hospira, Inc.
ANDA 204118	Indomethacin Sodium injectable, EQ 1 mg base/vial	Do.
ANDA 208016	Lurasidone HCl tablets, 20 mg, 40 mg, 60 mg, 80 mg, and 120 mg.	Watson Laboratories, Inc. (an indirect, wholly-owned subsidiary of Teva Pharmaceuticals USA, Inc.), 400 Interpace Parkway, Building A, Parsippany, NJ 07054.

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.

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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