location of floodplains relative to the project area, GSA has assumed that the project area is located within a 1-percent-annual-chance or 0.2-percent-annual-chance floodplain for purposes of complying with Executive Order 11988 and the GSA Floodplain Management Desk Guide, and until such time that a floodplain hazard study can be conducted. In addition, based on a wetland delineation conducted for the project, approximately 3.3 acres of wetlands occur within the project area. GSA prepared a Floodplain and Wetlands Assessment and Statement of Findings addressing potential impacts on floodplains and wetlands, which is included in the Final EIS. Final design of the Grand Portage LPOE would incorporate standard measures, including those specified in GSA Interim Core Building Standards as well as by the authority having jurisdiction, to reduce or manage stormwater flows as well as any potential impacts to the floodplain if present. GSA would coordinate as necessary with the Grand Portage Band to obtain appropriate permits and approvals related to wetlands disturbance under the Clean Water Act. Further, GSA would consider options to minimize, avoid, or mitigate potential impacts, as required by the U.S. Army Corps of Engineers and/or the Grand Portage Band.

Russell Riberto,

Regional Commissioner, Great Lakes Region 5, U.S. General Services Administration.

[FR Doc. 2025–07964 Filed 5–8–25; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2025–N–0679]

Determination That VOSOL (Acetic Acid, Glacial) 2% Otic Solution/Drops; and Other Drug Products Were Not Withdrawn From Sale for Reasons of Safety or Effectiveness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The Food and Drug Administration (FDA or Agency) has determined that the drug products listed in this document were not withdrawn from sale for reasons of safety or effectiveness. This determination means that FDA will not begin procedures to withdraw approval of abbreviated new drug applications (ANDAs) that refer to these drug products, and it will allow FDA to continue to approve ANDAs that refer to the products as long as they meet relevant legal and regulatory requirements.

FOR FURTHER INFORMATION CONTACT: Stacy Kane, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6236, Silver Spring, MD 20993–0002, 301–796–8363, *Stacy.Kane@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 generally known as the ''Orange Book.'' Under FDA regulations, a drug is 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).

Under § 314.161(a) (21 CFR 314.161(a)), the Agency must determine whether a listed drug was withdrawn from sale for reasons of safety or effectiveness: (1) before an ANDA that refers to that listed drug may be approved, (2) whenever a listed drug is voluntarily withdrawn from sale and ANDAs that refer to the listed drug have been approved, and (3) when a person petitions for such a determination under 21 CFR 10.25(a) and 10.30. Section 314.161(d) provides that if FDA determines that a listed drug was withdrawn from sale for safety or effectiveness reasons, the Agency will initiate proceedings that could result in the withdrawal of approval of the ANDAs that refer to the listed drug.

FDA has become aware that the drug products listed in the table are no longer being marketed.

TABLE 1—DRUG PRODUCTS NOT WITHDRAWN FROM SALE FOR REASONS OF SAFETY OR EFFECTIVENESS

Application No.	Drug name	Active ingredient(s)	Dosage form/route	Strength(s)	Applicant
NDA 012179	VOSOL	Acetic Acid, Glacial	2%	Solution/Drops; Otic	Hikma.
NDA 012836	PERSANTINE	Dipyridamole	25 Milligrams (mg); 50 mg; 75 mg.	Tablet; Oral	Boehringer Ingelheim.
NDA 013790	CORDRAN	Flurandrenolide	0.05%	Lotion; Topical	Almirall.
NDA 016758	NAVANE	Thiothixene Hydrochloride	Equivalent to (EQ) 5 mg Base/Milliliters (mL).	Concentrate; Oral	Pfizer.
NDA 017604	NALFON	Fenoprofen Calcium	EQ 200 mg Base; EQ 400 mg Base.	Capsule; Oral	Key Therapeutics.
NDA 019737	METROGEL	Metronidazole	0.75%	Gel; Topical	Galderma Laboratories LP.
NDA 019909	ZOVIRAX	Acyclovir	200 mg/5 mL	Suspension; Oral	Norvium Bioscience.
NDA 019922	CORLOPAM	Fenoldopam Mesylate	EQ 10 mg Base/mL	Injectable; Injection	Hospira.
NDA 020212	ZINECARD	Dexrazoxane Hydrochloride.	EQ 250 mg Base/Vial; EQ 500 mg Base/Vial.	Injectable; Injection	Pfizer.
NDA 020605	ZOFRAN	Ondansetron Hydrochloride.	EQ 4 mg Base/5 mL	Solution; Oral	Sandoz.
NDA 020636	VIRAMUNE	Nevirapine	200 mg	Tablet; Oral	Boehringer Ingelheim.
NDA 020645	AMMONUL	Sodium Benzoate; Sodium Phenylacetate.	10%; 10% (5 Grams (g)/50 mL; 5 g/50 mL).	Solution; Intravenous	Bausch Health.
NDA 020934	LUXIQ	Betamethasone Valerate	0.12%	Aerosol, Foam; Topical	Norvium Bioscience.

TABLE 1—DRUG PRODUCTS NOT WITHDRAWN FROM SALE FOR REASONS OF SAFETY OR EFFECTIVENESS—Continued

Application No.	Drug name	Active ingredient(s)	Dosage form/route	Strength(s)	Applicant
NDA 021071	AVANDIA	Rosiglitazone Maleate	EQ 2 mg Base; EQ 4 mg Base.	Tablet; Oral	Woodward Pharma Services LLC.
NDA 021160	PHOSLO GELCAPS	Calcium Acetate	667 mg	Capsule; Oral	Fresenius Medical Care.
NDA 021360	SUSTIVA	Efavirenz	600 mg	Tablet; Oral	Bristol Myers Squibb.
NDA 021493	ZYMAR	Gatifloxacin	0.3%	Solution/Drops; Ophthalmic.	Allergan.
NDA 021656	TRICOR	Fenofibrate	48 mg; 145 mg	Tablet; Oral	Abbvie.
NDA 021759	ELOXATIN	Oxaliplatin	50 mg/10 mL (5 mg/mL); 100 mg/20 mL (5 mg/mL).	Injectable; Intravenous	Sanofi Aventis US.
NDA 021779	VENTAVIS	Iloprost	10 Micrograms (mcg)/mL (10 mcg/mL); 20 mcg/mL (20 mcg/mL).	Solution; Inhalation	Actelion.
NDA 021849	ZEGERID	Omeprazole; Sodium Bicarbonate.	20 mg, 1.1 g; 40 mg, 1.1 g.	Capsule; Oral	Salix.
NDA 022428	MOXEZA	Moxifloxacin Hydrochloride.	EQ 0.5% Base	Solution/Drops; Ophthalmic.	Harrow Eye.
NDA 050006	VIBRAMYCIN	Doxycycline	EQ 25 mg Base/5 mL	For Suspension; Oral	Pfizer.
NDA 050541	TOBREX	Tobramycin	0.3%	Solution/Drops; Ophthalmic.	Novartis.
NDA 050808	SOLODYN	Minocycline Hydrochloride	55 mg; 65 mg; 80 mg; 105 mg; 115 mg.	Tablet, Extended Release; Oral.	Bausch.
NDA 207987	ABLYSINOL	Alcohol	99% (1 mL)	Solution; Intra-Arterial	BPI Labs, LLC.
NDA 208183	ULTRAVATE	Halobetasol Propionate	0.05%	Lotion; Topical	Lacer Pharmaceuticals.

FDA has reviewed its records and, under § 314.161, has determined that the drug products listed were not withdrawn from sale for reasons of safety or effectiveness. Accordingly, the Agency will continue to list the drug products in the ''Discontinued Drug Product List'' section of the Orange Book. The ''Discontinued Drug Product List'' identifies, among other items, drug products that have been discontinued from marketing for reasons other than safety or effectiveness.

Approved ANDAs that refer to the drug products listed are unaffected by the discontinued marketing of the products subject to these applications. Additional ANDAs that refer to these products may also be approved by the Agency if they comply with relevant legal and regulatory requirements. If FDA determines that labeling for these drug products should be revised to meet current standards, the Agency will advise ANDA applicants to submit such labeling.

Dated: May 6, 2025.

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2025–08207 Filed 5–8–25; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2025–N–1090]

Prescription Drug User Fee Act VII; Independent Assessment of Communication Through Product Quality Information Requests During Application Review; Final Report; Availability; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability; request for comments.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a document entitled ''Product Quality Information Request Communications Assessment: Final Report.'' This report fulfills a commitment under the recent reauthorization of the Prescription Drug User Fee Act (PDUFA) to assess communication between FDA and applicants through product quality information requests during application review and to identify best practices and areas of improvement. The assessment of FDA and applicants in communicating through product quality information requests was conducted by an independent contractor, as described in the document entitled ''PDUFA Reauthorization Performance Goals and Procedures Fiscal Years 2023 Through 2027.'' As part of FDA performance commitments described in this document, FDA is publishing the final assessment report and soliciting public comments.

DATES: Submit either electronic or written comments on the final report by July 31, 2025.

ADDRESSES: You may submit either electronic or written comments as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *https://www.regulations.gov.*
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

- Mail/Hand delivery/Courier (for written/paper submissions): Dockets