DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2024–P–3482]

Determination That JESDUVROQ (daprodustat) Tablets, 1 Milligram, 2 Milligrams, 4 Milligrams, 6 Milligrams, and 8 Milligrams, Were Not Withdrawn From Sale for Reasons of Safety or Effectiveness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, Agency, or we) has determined that JESDUVROQ (daprodustat) tablets, 1 milligram (mg), 2 mg, 4 mg, 6 mg, and 8 mg, were not withdrawn from sale for reasons of safety or effectiveness. This determination will allow FDA to approve abbreviated new drug applications (ANDAs) for JESDUVROQ (daprodustat) tablets, 1 mg, 2 mg, 4 mg, 6 mg, and 8 mg, if all other legal and regulatory requirements are met.

FOR FURTHER INFORMATION CONTACT: Awo Archampong-Gray, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6243, Silver Spring, MD 20993–0002, 301–796–0110, *Awo.Archampong-Gray@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approval of the drug's NDA or ANDA for reasons of safety or effectiveness or if FDA determines that the listed drug was withdrawn from sale for reasons of safety or effectiveness (21 CFR 314.162).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may petition the Agency to determine, or the Agency may determine on its own initiative, whether a listed drug was withdrawn from sale for reasons of safety or effectiveness.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.

JESDUVROQ (daprodustat) tablets, 1 mg, 2 mg, 4 mg, 6 mg, and 8 mg, are the subject of NDA 216951, held by GlaxoSmithKline Intellectual Property (No. 2) Limited England, and initially approved on February 1, 2023. JESDUVROQ is a hypoxia-inducible factor prolyl hydroxylase (HIF PH) inhibitor indicated for the treatment of anemia due to chronic kidney disease in adults who have been receiving dialysis for at least 4 months. JESDUVROQ (daprodustat) tablets, 1 mg, 2 mg, 4 mg, 6 mg, and 8 mg, are currently listed in the ''Discontinued Drug Product List'' section of the Orange Book.

Qilu Pharmaceutical (Hainan) Co., Ltd., submitted a citizen petition dated July 24, 2024 (Docket No. FDA–2024–P–3482), under 21 CFR 10.30, requesting that the Agency determine whether JESDUVROQ (daprodustat) tablets, 1 mg, 2 mg, 4 mg, 6 mg, and 8 mg, were withdrawn from sale for reasons of safety or effectiveness.

After considering the citizen petition and reviewing Agency records and based on the information we have at this time, FDA has determined under § 314.161 that JESDUVROQ (daprodustat) tablets, 1 mg, 2 mg, 4 mg, 6 mg, and 8 mg, were not withdrawn for reasons of safety or effectiveness. The petitioner has identified no data or other information suggesting that JESDUVROQ (daprodustat) tablets, 1 mg, 2 mg, 4 mg, 6 mg, and 8 mg, were withdrawn for reasons of safety or effectiveness. We have carefully reviewed our files for records concerning the withdrawal of JESDUVROQ (daprodustat) tablets, 1 mg, 2 mg, 4 mg, 6 mg, and 8 mg, from sale. We have also independently evaluated relevant literature and data for possible postmarketing adverse events. We have found no information that would indicate that this drug product was withdrawn from sale for reasons of safety or effectiveness.

Accordingly, the Agency will continue to list JESDUVROQ (daprodustat) tablets, 1 mg, 2 mg, 4 mg, 6 mg, and 8 mg, 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. ANDAs that refer to JESDUVROQ (daprodustat) tablets, 1 mg, 2 mg, 4 mg, 6 mg, or 8 mg, may be approved by the Agency as long as they meet all other legal and regulatory requirements for the approval of ANDAs. If FDA determines that labeling for this drug product should be revised to meet current standards, the Agency will advise ANDA applicants to submit such labeling.

Dated: November 7, 2024.

Kimberlee Trzeciak,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2024–26915 Filed 11–18–24; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2024–N–4860]

Pfizer, Inc., et al.; Withdrawal of Approval of 26 New Drug Applications

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is withdrawing approval of 26 new drug applications (NDAs) 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 December 19, 2024.

FOR FURTHER INFORMATION CONTACT: Kimberly Lehrfeld, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6226, Silver Spring, MD 20993–0002, 301–796–3137, *Kimberly.Lehrfeld@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—NDAS FOR WHICH APPROVAL IS WITHDRAWN

Application No.	Drug	Applicant
NDA 012541	Depo-Provera (medroxyprogesterone acetate) Injectable, 100 milligrams (mg)/milliliter (mL) and 400 mg/mL.	Pfizer Inc., 66 Hudson Blvd. East, New York, NY 10001.
NDA 012945	Diamox (acetazolamide) Extended-Release Capsules, 500 mg.	Teva Branded Pharmaceutical Products R&D, Inc., 145 Brandywine Parkway, West Chester, PA 19380.
NDA 013132	Deca-Durabolin (nandrolone decanoate) Injectable, 50 mg/mL,100 mg/mL, and 200 mg/mL.	Woodward Specialty, LLC, 16825 West 116th St., Lenexa, KS 66219.
NDA 018063	Corgard (nadolol) Tablets, 20 mg, 40 mg, 80 mg, 120 mg, and 160 mg.	USWM, LLC, 4441 Springdale Rd., Louisville, KY 40241.
NDA 019950	Diflucan in Dextrose 5% in Plastic Container (fluconazole), Injectable, 200 mg/100 mL and 400 mg/200 mL. Diflucan in Sodium Chloride 0.9% (fluconazole), Injectable, 200 mg/100 mL and 400 mg/200 mL. Diflucan in Sodium Chloride 0.9% in Plastic Container (fluconazole), Injectable, 200 mg/100 mL and 400 mg/200 mL.	Pfizer Inc., 66 Hudson Blvd. East, New York, NY 10001.
NDA 020001	Capex (fluocinolone acetonide) Shampoo, 0.01%	Galderma Laboratories, L.P., 2001 Ross Ave., Suite 1600, Dallas, TX 75201.
NDA 020938	Mobic (meloxicam) Tablets, 7.5 mg and 15 mg	Boehringer Ingelheim Pharmaceuticals, Inc., 900 Ridgebury Rd., Ridgefield, CT 06877.
NDA 021333	Minirin (desmopressin acetate) Metered Nasal Spray, 0.01 mg/spray.	Ferring Pharmaceuticals Inc., 100 Interpace Parkway, Parsippany, NJ 07054.
NDA 021372	Aloxi (palonosetron hydrochloride (HCl)) Injectable, Equivalent to (EQ) 0.075 mg base/1.5 mL and EQ 0.25 mg base/5 mL.	Helsinn Healthcare SA c/o Helsinn Therapeutics (U.S.), Inc., 200 Wood Ave. South, Suite 100, Iselin, New Jersey 08830.
NDA 021689	Nexium IV (esomeprazole sodium) Injectable, EQ 20 mg base/vial and EQ 40mg base/vial.	AstraZeneca Pharmaceuticals LP, 1800 Concord Pike, Wilmington, DE 19803.
NDA 021861	Patanase (olopatadine HCl) Metered Nasal Spray, 0.665 mg/spray.	Novartis Pharmaceuticals Corp., 1 Health Plaza, East Hanover, NJ 07936.
NDA 022025	Totect (dexrazoxane HCl) Injectable, EQ 500 mg base/vial ..	Clinigen, Inc., 45 Great Valley Parkway, Malvern, PA 19355.
NDA 022204	Gelnique (oxybutynin chloride) Transdermal Gel, 10% (100 mg/packet).	AbbVie Inc., 1 North Waukegan Rd., North Chicago, IL 60064.
NDA 022233	Aloxi (palonosetron HCl) Capsules, EQ 0.5 mg base	Helsinn Healthcare SA c/o Helsinn Therapeutics (U.S.), Inc.
NDA 022502	Differin (adapalene) Lotion, 0.1%	Galderma Laboratories.
NDA 022524	Zuplenz (ondansetron) Oral Film, 4 mg and 8 mg	Aquestive Therapeutics, 30 Technology Dr., Warren, NJ 07059.
NDA 050297	Ery-Ped (erythromycin ethylsuccinate) Chewable Tablets, EQ 200 mg base. E.E.S. (erythromycin ethylsuccinate) Chewable Tablets, EQ 200 mg base.	Azurity Pharmaceuticals, Inc., 8 Cabot Rd., Woburn, MA 01801.
NDA 050611	PCE (erythromycin) Coated Particles in Tablets, 333 mg and 500 mg.	Do.
NDA 050824	Omeclamox-Pak (amoxicillin Capsules, 500 mg; clarithromycin Tablets, 500 mg; and omeprazole Delayed-Release Capsules, 20 mg).	Cumberland Pharmaceuticals Inc., 1600 West End Ave., Suite 1300, Nashville, TN 37203.
NDA 203667	Minastrin 24 Fe (ethinyl estradiol/norethindrone acetate) Tablets, 0.02 mg/1 mg.	Allergan Pharmaceuticals International Ltd. c/o AbbVie Inc., 1 N Waukegan Rd., North Chicago, IL 60064.
NDA 204427	Kerydin (tavabarole) Topical Solution, 5%	Anacor Pharmaceuticals Inc., 445 Eastern Point Rd., Groton, CT 06340.
NDA 205103	Yosprala (aspirin/omeprazole) Delayed-Release Tablets, 81 mg/40 mg and 325 mg/40 mg.	Genus Lifesciences Inc., 514 North 12th St., Allentown, PA 18102.
NDA 205383	Oraltag (iohexol) for Oral Solution, 9.7 gram/bottle	Interpharma Praha AS c/o Otsuka Pharmaceutical Development and Commercialization Inc., 508 Carnegie Center Dr., Princeton, NJ 08540.
NDA 207930	Utibron (glycopyrrolate, indacaterol maleate) Inhalation Powder, 15.6 microgram/inhaler and 27.5 microgram/inhaler.	Novartis Pharmaceuticals Corp.
NDA 207923	Seebri Neohaler (glycopyrrolate) Inhalation Powder, 15.6 microgram/inhaler.	Do.
NDA 216951	Jesduvroq (daprodustat) Tablets, 1 mg, 2 mg, 4 mg, 6 mg, and 8 mg.	GlaxoSmithKline Intellectual Property (No. 2) Ltd. England c/o GSK, 2929 Walnut St., Suite 1700, Philadelphia, PA 19104.

Therefore, approval of the applications listed in table 1, and all amendments and supplements thereto, is hereby withdrawn as of December 19, 2024. Approval of each entire application is withdrawn, including any strengths and dosage forms included in the application but inadvertently missing from table 1. Introduction or delivery for introduction into interstate commerce of products listed in table 1 without an approved NDA 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 December 19, 2024 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.

Dated: November 7, 2024.

Kimberlee Trzeciak,

Deputy Commissioner for Policy, Legislation, and International Affairs.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Submission to OMB for Review and Approval; Public Comment Request; Rural Health Care Services Outreach Program Measures

AGENCY: Health Resources and Services Administration (HRSA), Department of Health and Human Services.

ACTION: Notice.

SUMMARY: In compliance with the Paperwork Reduction Act of 1995, HRSA submitted an Information Collection Request (ICR) to the Office of Management and Budget (OMB) for review and approval. Comments submitted during the first public review of this ICR will be provided to OMB. OMB will accept further comments from the public during the review and approval period. OMB may act on HRSA's ICR only after the 30-day comment period for this notice has closed.

DATES: Comments on this ICR should be received no later than December 19, 2024.

ADDRESSES: Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under Review—Open for Public Comments'' or by using the search function.

FOR FURTHER INFORMATION CONTACT: To request a copy of the clearance requests submitted to OMB for review, email Joella Roland, the HRSA Information Collection Clearance Officer, at *paperwork@hrsa.gov* or call (301) 443–3983.

SUPPLEMENTARY INFORMATION:

Information Collection Request Title: Rural Health Care Services Outreach Program Measures, OMB No. 0906–0009—Revision.

Abstract: The Rural Health Care Services Outreach Program is authorized by section 330A(e) of the Public Health Service Act (42 U.S.C. 254c(e)) to ''promote rural health care services outreach by improving and expanding the delivery of health care services to include new and enhanced services in rural areas.'' The goals for the Rural Health Care Services Outreach Program are as follows: (1) expand the delivery of health care services in rural communities; (2) deliver health care services through a strong consortium, in which every consortium member organization is actively involved and engaged in the planning and delivery of services; (3) utilize and/or adapt an evidence-based or innovative, evidence-informed model(s) in the delivery of health care services; and (4) improve population health and demonstrate health outcomes and sustainability. HRSA collects information from grant recipients that participate in this program using an OMB-approved set of performance measures and seeks to extend its approved information collection.

A 60-day notice was published in the **Federal Register** on June 21, 2024, 89 FR 52069–70. There were no public comments. However, following publication of the 60-day notice, HRSA increased the average burden per response and total burden hours due to personnel changes resulting in training needs of new hires common among rural healthcare workforce in the Outreach Program.

Need and Proposed Use of the Information: For this program, performance measures were drafted to provide data to the program and to enable HRSA to provide aggregate program data required by Congress under the Government Performance and Results Act of 1993. These measures cover the principal topic areas of interest to the Federal Office of Rural Health Policy (FORHP), including: (1) access to care, (2) population demographics, (3) consortium/network, (4) sustainability, (5) project specific domains, and (6) clinical measures. All measures will speak to FORHP's progress toward meeting the goals set. FORHP collects this information to quantify the impact of grant funding on access to health care, quality of services, and improvement of health outcomes. FORHP uses the data for program improvement and grantees use the data for performance tracking. No substantive changes are proposed from the current data collection effort; FORHP proposes updating hyperlinks for the clinical measures and including an option for text entry to capture names of counties for the number of counties served measure.

Likely Respondents: The respondents would be recipients of the Rural Health Care Services Outreach Program grants.

Burden Statement: Burden in this context means the time expended by persons to generate, maintain, retain, disclose, or provide the information requested. This includes the time needed to review instructions; to develop, acquire, install, and utilize technology and systems for the purpose of collecting, validating, and verifying information, processing and maintaining information, and disclosing and providing information; to train personnel and to be able to respond to a collection of information; to search data sources; to complete and review the collection of information; and to transmit or otherwise disclose the information. The total annual burden hours estimated for this ICR are summarized in the table below.

TOTAL ESTIMATED ANNUALIZED BURDEN HOURS

Form name	Number of respondents	Number of responses per respondent	Total responses	Average burden per response (in hours)	Total burden hours
Rural Health Care Services Outreach Performance Measures	61	1	61	8	488
Total	61		61		488