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That JESDUVROQ (daprodustat) Tablets, 1 Milligram, 2 Milligrams, 4 Milligrams, 6 Milligrams, and 8 Milligrams, Were Not Withdrawn From Sale for Reasons of Safety or Effectiveness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or we) has determined that JESDUVROQ (daprodustat) tablets, 1 milligram (mg), 2 mg, 4 mg, 6 mg, and 8 mg, were not withdrawn from sale for reasons of safety or effectiveness.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approval of the drug's NDA or ANDA for reasons of safety or effectiveness or if FDA determines that the listed drug was withdrawn from sale for reasons of safety or effectiveness (21 CFR 314.162).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may petition the Agency to determine, or the Agency may determine on its own initiative, whether a listed drug was withdrawn from sale for reasons of safety or effectiveness.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.

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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.