Based on a review of the information collection since our last request for OMB approval, we have made no adjustments to our burden estimate.

Dated: September 16, 2020.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2020–20960 Filed 9–22–20; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2020–N–1879]

Determination That PREXXARTAN (Valsartan) Oral Solution, 20 Milligrams/5 Milliliters and 80 Milligrams/20 Milliliters, Was Not Withdrawn From Sale for Reasons of Safety or Effectiveness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determined that PREXXARTAN (valsartan) oral solution, 20 milligrams (mg)/5 milliliters (mL) and 80 mg/20 mL, was not withdrawn from sale for reasons of safety or effectiveness. This determination will allow FDA to approve abbreviated new drug applications (ANDAs) for valsartan oral solution, 20 mg/5 mL and 80 mg/20 mL, if all other legal and regulatory requirements are met.

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, 240–402–4510, *robin.fastenau@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: In 1984, Congress enacted the Drug Price Competition and Patent Term Restoration Act of 1984 (Pub. L. 98–417) (the 1984 amendments), which authorized the approval of duplicate versions of drug products under an ANDA procedure. ANDA applicants must, with certain exceptions, show that the drug for which they are seeking approval contains the same active ingredient in the same strength and dosage form as the ''listed drug,'' which is a version of the drug that was previously approved. ANDA applicants do not have to repeat the extensive clinical testing otherwise necessary to gain approval of a new drug application (NDA).

The 1984 amendments include what is now section 505(j)(7) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)(7)), which 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 (§ 314.162 (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.

PREXXARTAN (valsartan) oral solution, 20 mg/5 mL and 80 mg/20 mL, is the subject of NDA 209139, held by Carmel Biosciences, Inc., and initially approved on December 19, 2017. PREXXARTAN is indicated for hypertension in adults and children 6 years and older, to lower blood pressure; for heart failure by significantly reducing hospitalization for patients who are unable to swallow valsartan tablets; and for stable left ventricular failure or left ventricular dysfunction following myocardial infarction.

PREXXARTAN (valsartan) oral solution, 20 mg/5 mL and 80 mg/20 mL, is currently listed in the ''Discontinued Drug Product List'' section of the Orange Book. Additionally, Carmel Biosciences has never marketed PREXXARTAN (valsartan) oral solution, 20 mg/5 mL and 80 mg/20 mL. In previous instances (see, *e.g.,* 72 FR 9763, March 5, 2007; 61 FR 25497, May 21, 1996), the Agency has determined that, for purposes of §§ 314.161 and 314.162, never marketing an approved drug product is equivalent to withdrawing the drug from sale.

Novitium Pharma LLC submitted a citizen petition dated January 30, 2020 (Docket No. FDA–2020–P–0511), under 21 CFR 10.30, requesting that the Agency determine whether PREXXARTAN (valsartan) oral solution, 20 mg/5 mL, was withdrawn from sale for reasons of safety or effectiveness. Although the citizen petition did not address the 80 mg/20 mL strength, that strength has also been discontinued. On our own initiative, we have also determined whether that strength was withdrawn for safety or effectiveness reasons.

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 PREXXARTAN (valsartan) oral solution, 20 mg/5 mL and 80 mg/20 mL, was not withdrawn for reasons of safety or effectiveness. The petitioner has identified no data or other information suggesting that this drug product was withdrawn for reasons of safety or effectiveness. We have carefully reviewed our files for records concerning the withdrawal of PREXXARTAN (valsartan) oral solution, 20 mg/5 mL and 80 mg/20 mL, from sale. We have also independently evaluated relevant literature and data for possible postmarketing adverse events. We have reviewed the available evidence and determined that this drug product was not withdrawn from sale for reasons of safety or effectiveness.

Accordingly, the Agency will continue to list PREXXARTAN (valsartan) oral solution, 20 mg/5 mL and 80 mg/20 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. ANDAs that refer to PREXXARTAN (valsartan) oral solution, 20 mg/5 mL and 80 mg/20 mL, 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: September 17, 2020.

Lauren K. Roth,

Associate Commissioner for Policy.

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