ANDA 211583

ANDA APPROVAL

Teva Pharmaceuticals USA, Inc.
Attention: Mahendra Barot
Director, Regulatory Affairs

Dear Mahendra Barot:

This letter is in reference to your abbreviated new drug application (ANDA) received for review on January 8, 2018, submitted pursuant to section 505(j) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) for Dapagliflozin and Metformin Hydrochloride Extended-Release Tablets, 2.5 mg/1,000 mg, 5 mg/500 mg, 5 mg/1,000 mg, 10 mg/500 mg, and 10 mg/1,000 mg.

Reference is also made to the tentative approval letter issued by this office on August 3, 2022, the complete response letter issued by this office on November 25, 2025, and to any amendments thereafter.

We have completed the review of this ANDA and have concluded that adequate information has been presented to demonstrate that the drug meets the requirements for approval under the FD&C Act. Accordingly, the ANDA is **approved**, effective on the date of this letter. We have determined your Dapagliflozin and Metformin Hydrochloride Extended-Release Tablets, 2.5 mg/1,000 mg, 5 mg/500 mg, 5 mg/1,000 mg, 10 mg/500 mg, and 10 mg/1,000 mg, to be bioequivalent and therapeutically equivalent to the reference listed drug (RLD), Xigduo XR Extended-Release Tablets, 2.5 mg/1,000 mg, 5 mg/500 mg, 5 mg/1,000 mg, 10 mg/500 mg, and 10 mg/1,000 mg, of AstraZeneca AB (AstraZeneca), NDA - 205649.

The RLD upon which you have based your ANDA, AstraZeneca's Xigduo XR Extended-Release Tablets, 2.5 mg/1,000 mg, 5 mg/500 mg, 5 mg/1,000 mg, 10 mg/500 mg, and 10 mg/1,000 mg, is subject to periods of patent protection. The following patents and expiration dates (with pediatric exclusivity added) are currently listed in the Agency's publication titled *Approved Drug Products with Therapeutic Equivalence Evaluations* (the "Orange Book"):

U.S. Patent Number	Expiration Date
7,919,598 (the '598 patent)	June 16, 2030
8,501,698 (the '698 patent)	December 20, 2027
8,685,934 (the '934 patent)	November 26, 2030
9,616,028 (the '028 patent)	May 12, 2031

Your ANDA contains paragraph IV certifications to each of the patents under section 505(j)(2)(A)(vii)(IV) of the FD&C Act stating that the patents are invalid, unenforceable, or will not be infringed by your manufacture, use, or sale of Dapagliflozin and Metformin Hydrochloride Extended-Release Tablets, 2.5 mg/1,000 mg, 5 mg/500 mg, 5 mg/1,000 mg, 10 mg/500 mg, and 10 mg/1,000 mg, under this ANDA. You have notified the Agency that Teva Pharmaceuticals USA, Inc. (Teva) complied with the requirements of section 505(j)(2)(B) of the FD&C Act and that no action for infringement was brought against Teva within the statutory 45-day period.

With respect to 180-day generic drug exclusivity for the 2.5 mg/1,000 mg strength, we note that Teva was the first ANDA applicant to submit a substantially complete ANDA with a paragraph IV certification for Dapagliflozin and Metformin Hydrochloride Extended-Release Tablets, 2.5 mg/1,000 mg. Therefore, with this approval, Teva is eligible for 180 days of generic drug exclusivity for Dapagliflozin and Metformin Hydrochloride Extended-Release Tablets, 2.5 mg/1,000 mg. It is noted that this ANDA was not tentatively approved within the 30-month period described in section 505(j)(5)(D)(i)(IV) of the FD&C Act. Nevertheless, the Agency has determined that Teva has not forfeited its eligibility for 180-day generic drug exclusivity.[1] This exclusivity, which is provided for under section 505(j)(5)(B)(iv) of the FD&C Act, will begin to run from the date of the commercial marketing by any first applicant, as identified in section 505(j)(5)(B)(iv). Please submit a correspondence to this ANDA informing the Agency of the date you begin commercial marketing. If you do not notify the Agency within 30 days, the date of first commercial marketing will be deemed to be the date of the drug product's approval. See 21 CFR 314.107(c)(2).

With respect to 180-day generic drug exclusivity for the 5 mg/500 mg, 5 mg/1,000 mg, 10 mg/500 mg, and 10 mg/1,000 mg strengths, we note that Teva was one of the first ANDA applicants to submit a substantially complete ANDA with a paragraph IV certification for Dapagliflozin and Metformin Hydrochloride Extended-Release Tablets, 5 mg/500 mg, 5 mg/1,000 mg, 10 mg/500 mg, and 10 mg/1,000 mg. Therefore, with this approval, Teva may be eligible for 180 days of shared generic drug exclusivity for Dapagliflozin and Metformin Hydrochloride Extended-Release Tablets, 5 mg/500 mg, 5 mg/1,000 mg, 10 mg/500 mg, and 10 mg/1,000 mg. The Agency notes that Teva failed to obtain tentative approval of its ANDA within 30 months after the date on which the ANDA was filed. See section 505(j)(5)(D)(i)(IV) of the FD&C Act (forfeiture of

exclusivity for failure to obtain tentative approval). The Agency is not, however, making a formal determination at this time of Teva's eligibility for 180-day generic drug exclusivity.

At least one first applicant remains eligible for 180-day generic drug exclusivity for Dapagliflozin and Metformin Hydrochloride Extended-Release Tablets, 5 mg/500 mg, 5 mg/1,000 mg, 10 mg/500 mg, and 10 mg/1,000 mg, absent forfeiture under section 505(j)(5)(D) of the FD&C Act.[2] This exclusivity, which is provided for under section 505(j)(5)(B)(iv) of the FD&C Act, would begin to run from the date of the commercial marketing by any first applicant, as identified in section 505(j)(5)(B)(iv). Please submit correspondence to this ANDA notifying the Agency within 30 days of the date of the first commercial marketing of this drug product or the RLD. If you do not notify the Agency within 30 days, the date of first commercial marketing will be deemed to be the date of the drug product's approval. See 21 CFR 314.107(c)(2).

Please note that if FDA requires a Risk Evaluation and Mitigation Strategy (REMS) for a listed drug, an ANDA referencing that listed drug also will be required to have a REMS. See section 505-1(i) of the FD&C Act.

COMPENDIAL STANDARDS

A drug with a name recognized in the official United States Pharmacopeia or official National Formulary (USP-NF) generally must comply with the compendial standard for strength, quality, and purity, unless the difference in strength, quality, or purity is plainly stated on its label (see FD&C Act § 501(b), 21 USC 351(b)). FDA typically cannot share application-specific information contained in submitted regulatory filings with third parties, which includes USP-NF. To help ensure that a drug continues to comply with compendial standards, application holders may work directly with USP-NF to revise official USP monographs. More information on the USP-NF is available on USP's website as: https://www.uspnf.com/.

REQUIREMENTS AND RECOMMENDATIONS POST APPROVAL

Under applicable statutes, regulations, and guidances, your ANDA may be subject to certain requirements and recommendations post approval, including requirements regarding changes to approved ANDAs, postmarketing reporting, promotional materials, and annual facility fees, among others. For information on post-approval requirements and recommendations for ANDAs and a list of resources for ANDA holders, we refer you to: https://www.fda.gov/drugs/abbreviated-new-drug-application-anda/requirements-and-resources-approved-andas.

Sincerely yours,

{See appended electronic signature page}

For Kendra S. Stewart, R.Ph., Pharm.D.
CAPT, United States Public Health Service
Director
Office of Regulatory Operations
Office of Generic Drugs
Center for Drug Evaluation and Research

[1] Teva's ANDA 211583 submitted a substantially complete new strength amendment for the 2.5 mg/1,000 mg strength on October 29, 2018. The Agency finds that Teva's failure to obtain tentative approval within 30 months was caused by a change in or review of the requirements for approval.
[2] See also draft guidance for industry on 180-Day Exclusivity: Questions and Answers, Q. 42, at 26 (Jan. 2017).

Anh Pham

Digitally signed by Anh Pham
Date: 4/06/2026 01:52:05PM
GUID: 54e4c56f00060bb2c61b878bc7a7bf95