ANDA 211156

ANDA APPROVAL

NDA Partners
U.S. Agent for Inventia Healthcare Limited
Attention: Kaitlyn Ta

Dear Kaitlyn Ta:

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 Tablets, 5 mg and 10 mg.

Reference is also made to the tentative approval letter issued by this office on November 20, 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 Tablets, 5 mg and 10 mg, to be bioequivalent and therapeutically equivalent to the reference listed drug (RLD), Farxiga Tablets, 5 mg and 10 mg, of AstraZeneca AB (AstraZeneca) NDA - 202293.

The RLD upon which you have based your ANDA, AstraZeneca's Farxiga Tablets, 5 mg and 10 mg, is subject to periods of patent protection. The following patents and expiration dates (including attached pediatric exclusivity) 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
7,851,502 (the '502 patent)	February 19, 2029
7,919,598 (the '598 patent)	June 16, 2030
8,221,786 (the '786 patent)	September 21, 2028
8,329,648 (the '648 patent)	February 18, 2027
8,361,972 (the '972 patent)	September 21, 2028
8,501,698 (the '698 patent)	December 20, 2027

8,685,934 (the '934 patent)	November 26, 2030
8,716,251 (the '251 patent)	September 21, 2028
8,721,615 (the '615 patent)	July 18, 2030
8,906,851 (the '851 patent)	February 18, 2027
10,973,836 (the '836 patent)	September 9, 2040*
11,826,376 (the '376 patent)	January 18, 2040*
11,903,955 (the '955 patent)	September 9, 2040*
12,213,988 (the '988 patent)	October 1, 2041*
12,409,186 (the '186 patent)	October 1, 2041*
12,472,194 (the '194 patent)	January 18, 2040*

* 10 mg strength only

Your ANDA contains paragraph IV certifications to the '502, '598, '786, '648, '972, '698, '934, '251, '615 and '851 patents**Error! Reference source not found.** 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 Tablets, 5 mg and 10 mg, under this ANDA. You have notified the Agency that Inventia Healthcare Limited (Inventia) complied with the requirements of section 505(j)(2)(B) of the FD&C Act and that no action for infringement was brought against Inventia within the statutory 45-day period.

With respect to the '836, '376, '955, '988, '186 and '194 patents, your ANDA contains statements under section 505(j)(2)(A)(viii) of the FD&C Act that these are method-of-use patents that do not claim any indication or other conditions of use for which you are seeking approval under your ANDA.

With respect to 180-day generic drug exclusivity, we note that Inventia was one of the first ANDA applicants to submit a substantially complete ANDA with a paragraph IV certification for Dapagliflozin Tablets, 5 mg and 10 mg. Therefore, with this approval, Inventia is eligible for 180 days of shared generic drug exclusivity for Dapagliflozin Tablets, 5 mg and 10 mg. FDA notes that after issuance of this approval letter, eligibility for 180-day exclusivity is subject to future events that may result in forfeiture of exclusivity under section 505(j)(5)(D) of the FD&C Act. This exclusivity, which is provided for under section 505(j)(5)(B)(iv) of the FD&C Act, begins 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 at: 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

Anh Pham

Digitally signed by Anh Pham
Date: 4/06/2026 01:08:00PM
GUID: 54e4c56f00060bb2c61b878bc7a7bf95