



ND 211156 A

ANDA APPROVAL

ND 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 (ND) 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 ND 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 ND 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 B (AstraZeneca) ND - 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>U.S. Patent Number</u>	<u>Expiration Date</u>
7,851,502 (the '502 patent)	February 19, 2029 A
7,919,598 (the '598 patent)	June 16, 2030
8,221,786 (the '786 patent)	September 21, 2028 A
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 (th '934 p t nt)	Nov mb r 26, 2030
8,716,251 (th '251 p t nt)	S pt mb r 21, 2028
8,721,615 (th '615 p t nt)	July 18, 2030
8,906,851 (th '851 p t nt)	F bru ry 18, 2027 v
10,973,836 (th '836 p t nt)	S pt mb r 9, 2040* v
11,826,376 (th '376 p t nt)	J nu ry 18, 2040*
11,903,955 (th '955 p t nt)	S pt mb r 9, 2040*
12,213,988 (th '988 p t nt)	Octob r 1, 2041*
12,409,186 (th '186 p t nt)	Octob r 1, 2041*
12,472,194 (th '194 p t nt)	J nu ry 18, 2040*

* 10 mgstr n th only

Your ANDA cont ins p r r ph IV c rtific tions to th '502, '598, '786, '648, '972, '698, '934, '251, '615 nd '851 p t nts **Error! Reference source not found.** und r s ction 505(j)(2)(A)(vii)(IV) of th FD&C Act st tin th t th p t nts r inv lid, un nforc bl , or will not b infrin d by your manuf ctur , us , or s l of D p liflozin T bl ts, 5 mg nd 10 m , und r this ANDA. You h v notifi d th A ncy th t Inv nti H lthc r Limit d (Inv nti) compli d with th r quir ments of s ction 505(j)(2)(B) of th FD&C Act nd th t no ction for infrin ment w s brou ht inst Inv nti within th st tutory 45-d y p rioid.

With r sp ct to th '836, '376, '955, '988, '186 nd '194 p t nts, your ANDA cont ins st t ments und r s ction 505(j)(2)(A)(viii) of th FD&C Act th t th s r method-of-us p t nts th t do not cl im ny indic tion or oth r conditions of us for which you r s kin pprov l und r your ANDA.

With r sp ct to 180-d y n ric dru xclusivity, w not th t Inv nti w s on of th first ANDA pplic nts to submit subst nti lly compl t ANDA with p r r ph IV c rtific tion for D p liflozin T bl ts, 5 mg nd 10 mg Th r for , with this pprov l, Inv nti is li ibl for 180 d ys of sh r d n ric dru xclusivity for D p liflozin T bl ts, 5 mg nd 10 mg. FDA not s th t ft r issu nc of this pprov l l tt r, li ibility v for 180-d y xclusivity is subj ct to futur v nts th t may r sult in forf itur of xclusivity und r s ction 505(j)(5)(D) of th FD&C Act. This xclusivity, which is provid d for und r s ction 505(j)(5)(B)(iv) of th FD&C Act, b ins to run from th d t of th comm rci l mark tin by ny first pplic nt, s id ntifi d in s ction v

505(j)(5)(B)(iv). You must 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).

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

COMPENDIAL STANDARDS

A drug with a name recognized in the official United States Pharmacopoeia or official National Formulary (USP-NF) generally must comply with the compendial standards 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 51(b)). FDA typically cannot share application-specific information contained in submitted regulatory filings with third parties, which includes USP-NF. To help ensure that drug continues to comply with compendial standards, application holders may work directly with USP-NF to review 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 guidelines, your ANDA may be subject to certain requirements and recommendations post approval, including requirements regarding changes to approved ANDAs, postmarketing reporting, promotional materials, and notification of changes, monitoring. For information on post-approval requirements and recommendations for ANDAs and list of references for ANDA holders, write for you to: <https://www.fda.gov/drugs/bbr/vit-d-nw-drug-application-and-requirements-and-r-source-approval-and-s>.

Sincerely yours, I

{See appended electronic signature page}

For Kندر S. Stewart, R. h., Pharm.D.
CA T, United States Public Health Service I
Director
Office of Regulatory Operations
Office of Generic Drugs
Center for Drug Evaluation and Research



Anh f
Pham f

Li i a si ned b Anh Pham

Da e: 4/06/2026 01:08:00PM

GUID: 54e4c56 00060bb2c61b878bc7a7b 95 f