scend Laboratories, LLC
U.S. gent for lkem Laboratories Limited
ttention: Hindy Schiff
VP-Regulatory ffairs

Dear Hindy Schiff:

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 ct (FD&C ct) 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 May 4, 2023, 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 ct. 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/1,000mg, 10 mg/500 mg, and 10 mg/1,000 mg, of straZeneca B (straZeneca) ND - 205649.

However, we are unable to grant final approval to your Dapagliflozin and Metformin Hydrochloride Extended-Release Tablets, 2.5 mg/1,000 mg, at this time because of the exclusivity issue noted below. Therefore, your ND is **approved** insofar as it pertains to 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. Your Dapagliflozin and Metformin Hydrochloride Extended-Release Tablets, 2.5 mg/1,000 mg, is **tentatively approved**. This determination is based upon information available to the gency at this time (e.g., information in your ND and the status of current good manufacturing practices (cGMPs) of the facilities used in the manufacturing and testing of the drug product). This determination is subject to change on the basis of new information that may come to our attention.

The RLD upon which you have based your ND , Xigduo XR Extended-Release Tablets, 2.5 mg/1,000 mg, 5 mg/500 mg, 5 mg/1,000mg, 10 mg/500 mg, and A

10 mg/1,000 mg, of Astr Z n c , is subj ct to p riods of p t nt prot ction. Th followin p t nts nd xpir tion d t s (with p di tric xclusivity dd d) r curr ntly list d in the Agency's publication titled *Approved Drug Products with Therapeutic Equivalence Evaluations* (the "Orange Book"):

U.S. t nt Numb r	Expir tion D t
7,919,598 (th '598 p t nt)	Jun 16, 20 0
8,501,698 (th '698 p t nt)	D c mb r 20, 2027
8,685,9 4 (th '9 4 p t nt)	Nov mb r 26, 20 0
9,616,028 (th '028 p t nt)	M y 12, 20 1

Your ANDA cont ins p r r ph IV c rtific tions to ch of th p t nts 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 m anuf ctur , us , or s l of D p liflozin nd M tformin Hydrochlorid Ext nd d-R l s T bl ts, 2.5 mg/1,000 mg, 5 mg/500 mg, 5 mg/1,000 mg, 10 mg/500 mg, nd 10 mg/1,000 mg, und r this ANDA. You h v notifi d th A ncy th t Alk m L bor tori s Limit d (Alk m) compli d with th r quir m ents of s ction 505(j)(2)(B) of th FD&C Act, nd th t no ction for infrin m nt w s brou ht inst Alk m within th st tutory 45-d y p riod.

How v r, w r un bl to r nt fin l pprov l with r sp ct to th 2.5 mg/1,000 mg str n th product t this time. rior to th submission of your ANDA, noth r pplic nt or pplic nts submitt d subst nti lly compl t ANDA providin for D p liflozin nd M etformin Hydrochlorid Ext nd d-R l s T bl ts, 2.5 mg/1,000 mg, nd cont inin p r r ph IV c rtific tion. Your ANDA for this str n th will b li ibl for fin l pprov l on th d t th t is 180 d ys ft r th comm rci l m ark tin d t id ntifi d in s ction 505(j)(5)(B)(iv) of th FD&C Act.

Upon th for oin , your ANDA is **approved** insof r s it p rt ins to th 5 mg/500 mg, 5 mg/1,000 mg, 10 mg/500 mg, nd 10 mg/1,000 mg str n th products. Your 2.5 mg/1,000 mg str n th product is **tentatively approved**.

I. Approval of 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

With r sp ct to 180-d y n ric dru xclusivity, w not th t Alk m 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 nd M etformin Hydrochlorid Ext nd d-R l s T bl ts,

5 mg/500 mg, 5 mg/1,000 mg, 10 mg/500 mg, and 10 mg/1,000 mg. Therefore, with this approval, Alkem is 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. 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). It is submitted 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).

It is noted that if FDA requires a Risk Evaluation and Mitigation Strategy (REMS) for the 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 include USP-NF. To help ensure that drug continues to comply with compendial standards, applicants 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/.

II. Tentative Approval of Dapagliflozin and Metformin Hydrochloride Extended-Release Tablets, 2.5 mg/1,000 mg

Our decision to tentatively approve your Dapagliflozin and Metformin Hydrochloride Extended-Release Tablets, 2.5 mg/1,000 mg, is based upon information currently available to the Agency (i.e., data in your ANDA and the status of current Good Manufacturing Practice (cGMP) of the facilities used in the manufacture and testing of the drug product). This decision is subject to change on the basis of new information that may come to our attention.

It is noted that if FDA requires a Risk Evaluation and Mitigation Strategy (REMS) for the 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.

RESUBMISSION

To request final approval, please submit an amendment titled "FINAL APPROVAL REQUESTED" with enough time to permit FDA review prior to the date you believe that your ANDA will b li ibl for fin l pprov l. A r qu st for fin l pprov l th t cont ins no n w d t , inform ation, or oth r ch n s to th ANDA n r lly r quir s p riod of months for A ncy r vi w. Accordin ly, such r qu st for fin l pprov l should b submitt d no l t r th n months prior to th d t on which you s k pprov l. A r qu st for fin l pprov l th t cont ins subst ntiv ch n s to this ANDA or ch n s in the status of the manufacturing and testing facilities' compliance with cGMPs will be cl ssifi d nd r vi w d ccordin to OGD policy in ff ct t th tim e of r c ipt. Applic nts should r vi w v il bl A ncy uid nc for industry r l t d to m endm ents und r th n ric dru us r f pro r m to d t rmin th dur tion of A ncy r vi w n d d to r vi w th ch n s submitt d. As p rt of this consid r tion, pplic nts should monitor ny ch n s to th RLD th t occur ft r t nt tiv pprov l, includin ch n s in l b lin , p t nt or xclusivity inform ation, or m ark tin st tus. Th submission of multipl m endm ents prior to fin l pprov l m ay lso r sult in d l y in th issu nc of th fin l pprov l l tt r.

Th m endm ent r qu stin fin l pprov l should provid th l l/r ul tory b sis for your r qu st for fin l pprov l nd should includ copy of court d cision, s ttl m ent or lic nsin r m ent, or oth r inform ation d scrib d in 21 CFR 14.107, s ppropri t . It should lso id ntify ch n s, if ny, in th conditions und r which th ANDA w s t nt tiv ly pprov d, i. ., upd t d inform ation such s fin l-print d l b lin , ch mistry, m anuf cturin , nd controls d t s ppropri t . This m endm ent should b submitt d v n if non of th s ch n s w r m ad , nd it should b d si n t d clearly in your cover letter as a "MINOR/MAJOR AMENDMENT TO ORIGINAL #2 – FINAL APPROVAL REQUESTED."

In ddition to th m endm ent r qu st d bov , th A ncy m ay r qu st, t ny tim e prior to th d t of fin l pprov l, th t you submit n ddition l m endm ent cont inin inform ation s sp cifi d by th A ncy. F ilur to submit ith r or, if r qu st d, both typ s of m endm ents d scrib d bov m ay r sult in d l y in th issu nc of th fin l pprov l l tt r.

This dru product m ay not b m ark t d without fin l A ncy pprov l und r s ction 505(j) of th FD&C Act. Th introduction or d liv ry for introduction into int rst t comm rc of this dru product b for th fin l pprov l d t is prohibit d und r s ction 01 of th FD&C Act. Also, until th A ncy issu s th fin l pprov l l tt r, this dru product will not b d m ed pprov d for m ark tin und r s ction 505(j) of th FD&C Act, nd will not b list d in th Or n Book.

REQUIREMENTS AND RECOMMENDATIONS POST APPROVAL

Und r pplic bl st tut s, r ul tions, nd uid nc s, your ANDA m ay b subj ct to a c rt in r quir m ents nd r comm nd tions post pprov l, includin r quir m ents

r rdin ch n s to pprov d ANDAs, postm ark tin r portin , promotion l m at ri ls, nd nnu l f cility f s, mon oth rs. For inform ation on post- pprov l r quir m ents nd r comm nd tions for ANDAs nd list of r sourc s for ANDA hold rs, w r f r you to https://www.fd . ov/dru s/ bbr vi t d-n w-dru - pplic tion- nd /r quir m ents- nd-r sourc s- pprov d- nd s.

For furth r inform ation on th st tus of this ANDA or upon submittin n m endm ent to th ANDA, pl s cont ct Xu n-M ai N uy n, R ul tory roj ct M an r, t (01) 796 - 945 .

Sinc r ly yours,

{See appended electronic signature page}

For K ndr S. St w rt, R. h., h rm.D.
CA T, Unit d St t s ublic H lth S rvic
Dir ctor
Offic of R ul tory Op r tions
Offic of G en ric Dru s
C nt r for Dru Ev lu tion nd R s rch l

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Kurtz I

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