potex Corp.
U.S. gent for potex Inc.
ttention: Kiran Krishnan
Senior Vice President, GR

Dear Kiran Krishnan:

This letter is in reference to your abbreviated new drug application ( ND ) received for review on March 29, 2017, submitted pursuant to section 505(j) of the Federal Food, Drug, and Cosmetic ct (FD&C ct) for Canagliflozin Tablets, 100 mg and 300 mg.

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. ccordingly the ND is **approved**, effective on the date of this letter. We have determined your Canagliflozin Tablets, 100 mg and 300 mg to be bioequivalent and therapeutically equivalent to the reference listed drug (RLD), Invokana Tablets, 100 mg and 300 mg, of Janssen Pharmaceuticals, Inc. (Janssen) ND - 204042.

The RLD upon which you have based your ANDA, Janssen's Invokana Tablets, 100 mg and 300 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 A | Expiration Date |
|---|---|
| 7,943,582 (the '582 patent) | ugust 26, 2029 |
| 7,943,788 (the '788 patent) | January 14, 2028 A |
| 8,513,202 (the '202 patent) | June 3, 2028 |

Your ND contains paragraph IV certifications to each of the patents under section 505(j)(2)( )(vii)(IV) of the FD&C ct stating that the patents are invalid, unenforceable, or will not be infringed by your manufacture, use, or sale of Canagliflozin Tablets, 100 mg and 300 mg, under this ND . You have notified the gency that potex Inc. ( potex) complied with the requirements of section 505(j)(2)(B) of the FD&C ct. A

Liti tion w s initi t d within th st tutory 45-d y p riod inst Apot x for infrin m ent of the '582 and '202 patents in the United States District Court for the District of N w J rs y [R s rch nd D v lopm ent, LLC], nd CILAG GMBH Int rn tion l v. Apot x, Inc. nd Apot x Corp., Civil Action No. 17-05005 (consolid t d)]. You h v lso notifi d th A ncy th t this c s w s dismiss d.

With r sp ct to 180-d y n ric dru xclusivity, w not th t Apot x w s first ANDA pplic nt for C n liflozin T bl ts, 100 m g nd 300 m g, to submit subst nti lly compl t ANDA with p r r ph IV c rtific tion. Th r for , with this pprov l, Apot x m ay b li ibl for 180 d ys of n ric dru xclusivity for C n liflozin T bl ts, 100 m g nd 300 m g. This xclusivity, which is provid d for und r 505(j)(5)(B)(iv) of th FD&C Act, would b in to run from th d t of th comm rci l m ark tin id ntifi d in s ction 505(j)(5)(B)(iv). Th A ncy not s th t Apot x f il d to obt in t nt tiv pprov l of this ANDA within 30 months ft r th d t of which th ANDA w s fil d. S s ction 505(j)(5)(D)(i)(IV) of th FD&C Act (forf itur of xclusivity for f ilur to obt in t nt tiv pprov l). Th A ncy is not, how v r, m akin form al d t rmin tion t this tim of Apotex's eligibility for 180-d y n ric dru xclusivity. We will do so only if subs qu nt p r r ph IV pplic nt b com es li ibl for full pprov l ( ) within 180 d ys ft r Apot x b ins comm rci l m ark tin of C n liflozin T bl ts, 100 m g nd 300 m , or (b) t ny tim e prior to the expiration of the '582 p t nt if Apot x h s not b un comm rci l m ark tin . l s submit corr spond nc to this ANDA notifyin th A ncy within 30 d ys of th d t of th first comm rci l m ark tin of this dru product or th RLD. If you do not notify th A ncy within 30 d ys, th d t of first comm rci l marketing will be deemed to be the date of the drug product's approval. See 21 CFR 314.107(c)(2).

l s not th t if FDA r quir s Risk Ev lu tion nd Miti tion Str t y (REMS) for list d dru , n ANDA r f r ncin th t list d dru lso will b r quir d to h v REMS. S s ction 505-1(i) of th FD&C Act.

## COMPENDIAL STANDARDS

A dru with n m e r co niz d in th offici l Unit d St t s h rm acop i or offici l N tion l Formul ry (US -NF) n r lly must comply with th comp ndi l st nd rd for str n th, qu lity, nd purity, unl ss th diff r nc in str n th, qu lity, or purity is pl inly st t d on its l b l (s FD&C Act § 501(b), 21 USC 351(b)). FDA typic lly c nnot sh r pplic tion-sp cific inform ation cont in d in submitt d r ul tory filin s with third p rti s, which includ s US -NF. To h lp nsur th t dru continu s to comply with comp ndi l st nd rds, pplic tion hold rs m ay work dir ctly with US -NF to r vis offici l US mono r phs. Mor inform ation on th US -NF is available on USP's w bsit t https://www.uspnf.com/.

## REQUIREMENTS AND RECOMMENDATIONS POST APPROVAL l

Und r pplic bl st tut s, r ul tions, nd uid nc s, your ANDA m ay b subj ct to 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- a nd-r sourc s- pprov d- nd s.

Sinc r ly yours,

*{See appended electronic signature page}* a

For K ndr S. St w rt, R. h., h rm.D.
CA T, Unit d St t s ublic H lth S rvic a
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

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Catherine
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