ND 210671 A

ANDA APPROVAL A

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

Dear Kiran Krishnan:

This letter is in reference to your abbreviated new drug application (ND) received for review on December 6, 2017, submitted pursuant to section 505(j) of the Federal Food, Drug, and Cosmetic ct (FD&C ct) for Multiple Vitamins Injection (Pediatric), Vial 1 (4 mL) and Vial 2 (1 mL), Single-dose Vials.

Reference is also made to any amendments submitted prior to the issuance of this letter.

Reference is also made to FDA's Competitive Generic Therapy Designation – Grant letter dated December 1, 2017.

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 Multiple Vitamins Injection (Pediatric), Vial 1 (4 mL) and Vial 2 (1 mL), Single-dose Vials, to be bioequivalent and therapeutically equivalent to the reference listed drug (RLD), Infuvite Pediatric Injection, of Sandoz Canada Inc., ND - 021265.

We note that potex Inc. (potex) was granted a Competitive Generic Therapy (CGT) designation for Multiple Vitamins Injection (Pediatric), Vial 1 (4 mL) and Vial 2 (1 mL), Single-dose Vials. Apotex is the "first approved applicant" for Multiple Vitamins Injection (Pediatric), Vial 1 (4 mL) and Vial 2 (1 mL), Single-dose Vials, as defined in section 505(j)(5)(B)(v)(III) of the FD&C ct. Therefore, with this approval, potex is eligible for 180 days of CGT exclusivity for Multiple Vitamins Injection (Pediatric), Vial 1 (4 mL) and Vial 2 (1 mL), Single-dose Vials, under section 505(j)(5)(B)(v) of the FD&C ct. This exclusivity begins to run from the date of the first commercial marketing of the CGTs (including the commercial marketing of the listed drug) by potex, as specified in section 505(j)(5)(B)(v) of the FD&C ct. Furthermore, in accordance with section 505(j)(5)(B)(v)(I) of the FD&C ct, this 180-day CGT exclusivity will not block approval of other applications until potex has commenced commercial marketing. Please submit a correspondence to this ND informing the gency of the date you begin commercial A

m ark tin . l s lso submit notic of first comm rci l m ark tin vi -m ail to th t nt nd Exclusivity T m t CDER-OGD ET@fd .hhs. ov. This -m ail should b s nt th s m e d y you comm nc comm rci l m ark tin . R f r nc is lso m ad to th Sp ci l Forf itur Rul for Comp titiv G en ric Th r py in s ction 505(j)(5)(D)(iv) of th FD&C Act. l s b w r th t, pursu nt to this forf itur rul , you will forf it your li ibility for th 180-d y CGT xclusivity p riod for Multipl Vit mins Inj ction (di tric), Vi l 1 (4 mL) nd Vi l 2 (1 mL), Sin l -dos Vi ls, if you f il to m ark t th s CGTs within 5 d ys ft r th d t on which th pprov l of this pplic tion is m d ff ctiv .

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/. l

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 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 t 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 end 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.

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 a

Paul 8
Levi e 8

i i a l si ed b Paul Levi e
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