U.S. FOOD & DRUG ADMINISTRATION

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ND 210456 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 ugust 8, 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 (40 mL) and Vial 2 (10 mL), Pharmacy Bulk Package.

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

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 (40 mL) and Vial 2 (10 mL), Pharmacy Bulk Package, to be bioequivalent and therapeutically equivalent to the reference listed drug (RLD), Infuvite Pediatric Injection, of Sandoz Canada Inc., ND - 021265.

Please note that if FD requires a Risk Evaluation and Mitigation Strategy (REMS) for a listed drug, an ND referencing that listed drug also will be required to have a REMS. See section 505-1(i) of the FD&C ct.

COMPENDIAL STANDARDS

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 ct § 501(b), 21 USC 351(b)). FD 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/. A

REQUIREMENTS AND RECOMMENDATIONS POST APPROVAL

Under pplic ble st tutes, re ul tions, nd uid nces, your ANDA m ay be subject to cert in requirements nd recommend tions post pprov l, includin requirements re rdin ch n es to pproved ANDAs, postm arketin reportin , promotion l m teri ls, nd nnu l f cility fees, mon others. For inform ation on post- pprov l requirements nd recommend tions for ANDAs nd list of resources for ANDA holders, we refer you to https://www.fd . ov/dru s/ bbrevi ted-new-dru - pplic tion- nd /requirements- nd-resources- pproved- nd s.

Sincerely yours,

{See appended electronic signature page}

For Kendr S. Stew rt, R. h., h rm.D.
CA T, United St tes ublic He lth Service
Director
Office of Re ul tory Oper tions
Office of Generic Dru s
Center for Dru Ev lu tion nd Rese rch a

Paul c
Levi e c

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