ANDA 212069

ANDA APPROVAL

Sandoz Inc.
Attention: Gregory Seitz
Head, U.S. Regulatory Affairs Generics

Dear Gregory Seitz:

This letter is in reference to your abbreviated new drug application (ANDA) received for review on June 29, 2018, submitted pursuant to section 505(j) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) for Vasopressin Injection USP, 200 units/10 mL (20 Units/mL) Multiple-Dose Vial.

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

We have completed the review of this ANDA 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 ANDA is **approved**, effective on the date of this letter. We have determined your Vasopressin Injection USP, 200 units/10 mL (20 Units/mL) Multiple-Dose Vial to be bioequivalent and therapeutically equivalent to the reference listed drug (RLD), Vasostrict Injection USP, 200 units/10 mL (20 Units/mL) Multiple-Dose Vial, of PH Health Limited (PH Health) NDA - 204485.

The RLD upon which you have based your ANDA, PH Health's Vasostrict Injection USP, 200 units/10 mL (20 Units/mL) Multiple-Dose Vial, is subject to periods of patent protection. The following patents and expiration dates are currently listed in the Agency's publication titled *Approved Drug Products with Therapeutic Equivalence Evaluations* (the "Orange Book"):

U.S. Patent Number	Expiration Date
9,375,478 (the '478 patent)	January 30, 2035
9,687,526 (the '526 patent)	January 30, 2035
9,744,209 (the '209 patent)	January 30, 2035
9,744,239 (the '239 patent)	January 30, 2035

9,750,785 (the '785 patent)	January 30, 2035
9,937,223 (the '223 patent)	January 30, 2035

Your ANDA contains paragraph IV certifications to each of the patents, under section 505(j)(2)(A)(vii)(IV) of the FD&C Act stating that the patents are invalid, unenforceable, or will not be infringed by your manufacture, use, or sale of Vasopressin Injection USP, 200 units/10 mL (20 Units/mL) Multiple-Dose Vial, under this ANDA. You have notified the Agency that Sandoz Inc. (Sandoz) complied with the requirements of section 505(j)(2)(B) of the FD&C Act. Litigation was initiated within the statutory 45-day period against Sandoz for infringement of the '478, '526, '209, '239, '785 and '223 patents in the United States District Court for the District of New Jersey [Par Pharmaceutical, Inc., Par Sterile Products, LLC, And Endo Par Innovation Company, LLC v. Sandoz Inc., Civil Action No. 18-14895]. You have also notified the Agency that this case was dismissed.

With respect to 180-day generic drug exclusivity, we note that Sandoz was the first ANDA applicant to submit a substantially complete ANDA with a paragraph IV certification for Vasopressin Injection USP, 200 units/10 mL (20 Units/mL) Multiple-Dose Vial. Therefore, with this approval, Sandoz is eligible for 180 days of generic drug exclusivity for Vasopressin Injection USP, 200 units/10 mL (20 Units/mL) Multiple-Dose Vial. 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 identified in section 505(j)(5)(B)(iv). Please 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).

Please note that if FDA requires a Risk Evaluation and Mitigation Strategy (REMS) for a 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 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/.

REQUIREMENTS AND RECOMMENDATIONS POST APPROVAL

Under applicable statutes, regulations, and guidances, your ANDA may be subject to certain requirements and recommendations post approval, including requirements regarding changes to approved ANDAs, postmarketing reporting, promotional materials, and annual facility fees, among others. For information on post-approval requirements and recommendations for ANDAs and a list of resources for ANDA holders, we refer you to https://www.fda.gov/drugs/abbreviated-new-drug-application-anda/requirements-and-resources-approved-andas.

Sincerely yours,

{See appended electronic signature page}

For Kendra S. Stewart, R.Ph., Pharm.D.
CAPT, United States Public Health Service
Director
Office of Regulatory Operations
Office of Generic Drugs
Center for Drug Evaluation and Research

Paul
Levine

Digitally signed by Paul Levine
Date: 5/06/2026 02:42:08PM
GUID: 56323ddc003554a87fad6698c2baa467