



ANDA 220043

ANDA APPROVAL

Cardinal Health Regulatory Sciences
U.S. Agent for Hainan Poly Pharm. Co., Ltd.
Attention: Yin Hwa Lai
Principal Scientist

Dear Yin Hwa Lai:

This letter is in reference to your abbreviated new drug application (ANDA) received for review on September 27, 2024, submitted pursuant to section 505(j) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) for Voriconazole Injection, 200 mg/20 mL (10 mg/mL) Single-Dose Vial.

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

Reference is also made to the ANDA Suitability Petition (FDA-2023-P-5094/CP1) submitted on November 15, 2023, under Section 505(j)(2)(C) of the FD&C Act, and approved on June 13, 2024. This petition requested the Agency make a determination as to whether an application for Voriconazole Injection, 200 mg/20 mL (10 mg/mL) Single-Dose Vial was suitable for submission as an ANDA. This determination was necessary because dosage form proposed in your ANDA differs from the dosage form reference listed drug product (RLD), Vfend for Injection, 200 mg/ml of PF Prism C.V. NDA - 021267.

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 Voriconazole Injection, 200 mg/20 mL (10 mg/mL) Single-Dose Vial can be expected to have the same therapeutic effect as that of the listed drug product upon which the Agency relied as the basis of safety and effectiveness.

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 as <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
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