ANDA 215636

ANDA APPROVAL

Zydus Pharmaceuticals (USA) Inc.
U.S. Agent for Zydus Worldwide DMCC
73-B Route 31 North
Pennington, NJ 08534
Attention: Srinivas Gurram
Senior Vice President

Dear Srinivas Gurram:

This letter is in reference to your abbreviated new drug application (ANDA) received for review on April 26, 2022, submitted pursuant to section 505(j) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) for Methylene Blue Injection USP, 10 mg/2 mL (5 mg/mL) and 50 mg/10 mL (5 mg/mL) Single-Dose Vials.

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 Methylene Blue Injection USP, 10 mg/2 mL (5 mg/mL) and 50 mg/10 mL (5 mg/mL) Single-Dose Vials to be bioequivalent and therapeutically equivalent to the reference listed drug (RLD), ProvayBlue Injection, 10 mg/2 mL (5 mg/mL) and 50 mg/10 mL (5 mg/mL), of Provepharm SAS.

We note that Zydus Worldwide DMCC (Zydus) was granted a Competitive Generic Therapy (CGT) designation for Methylene Blue Injection USP, 10 mg/2 mL (5 mg/mL) and 50 mg/10 mL (5 mg/mL) Single-Dose Vials. However, as noted in the February 23, 2021 CGT Designation – Grant Letter, your drug product is not eligible for CGT exclusivity under section 505(j)(5)(B)(v) of the FD&C Act because there were unexpired patents or exclusivities listed in FDA's *Approved Drug Products With Therapeutic Equivalence Evaluations* (Orange Book) for the RLD at the time of submission of your ANDA.

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 Edward M. Sherwood
Director
Office of Regulatory Operations
Office of Generic Drugs
Center for Drug Evaluation and Research

Sarah Kurtz

Digitally signed by Sarah Kurtz
Date: 12/05/2023 09:02:41AM
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