ANDA 218755

ANDA APPROVAL

Amarant Lifesciences Pvt. Ltd.
U.S. Agent for Eskayef Pharmaceuticals Limited
Attention: Andrew Verderame
Principal Consultant

Dear Andrew Verderame:

This letter is in reference to your abbreviated new drug application (ANDA) received for review on August 21, 2023, submitted pursuant to section 505(j) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) for Paliperidone Extended-Release Tablets, 1.5 mg, 3 mg, 6 mg, and 9 mg.[1]

Reference is also made to the complete response letter issued by this office on November 14, 2024, and to any amendments thereafter.

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 Paliperidone Extended-Release Tablets, 1.5 mg, 3 mg, 6 mg, and 9 mg to be bioequivalent and therapeutically equivalent to the reference listed drug (RLD), Invega Extended-Release Tablets, 1.5 mg, 3 mg, 6 mg, and 9 mg, of Janssen Pharmaceuticals, Inc. (Janssen) NDA - 021999.

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 Malik Imam, PharmD, MBA
CDR, United States Public Health Service
Deputy Director
Office of Regulatory Operations
Office of Generic Drugs
Center for Drug Evaluation and Research

[1] We note that the RLD upon which you have based this ANDA, Janssen's Invega Extended-Release Tablets, 1.5 mg are no longer being marketed in the United States and are currently listed in the discontinued section of FDA's *Approved Drug Products with Therapeutic Equivalence Evaluations* (the "Orange Book"). The Agency has determined that Janssen's Invega Extended-Release Tablets, 1.5 mg were not withdrawn from sale for reasons of safety or effectiveness. FDA published this determination in the *Federal Register* (89 FR 52468; June 24, 2024). This determination allows the Agency to approve ANDAs for the discontinued drug products.

Catherine Poole

Digitally signed by Catherine Poole
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