ANDA 206310

ANDA APPROVAL

AB Pharmaceuticals, LLC
U.S. Agent for Macleods Pharmaceuticals Limited
Attention: Andrej Gasperlin
President

Dear Andrej Gasperlin:

This letter is in reference to your abbreviated new drug application (ANDA) received for review on January 23, 2014, submitted pursuant to section 505(j) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) for Memantine Hydrochloride Extended-Release Capsules, 7 mg, 14 mg, 21 mg and 28 mg.[1]

Reference is also made to the tentative approval letter issued by this office on February 19, 2016, the complete response letter issued by this office on April 6, 2023, 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 Memantine Hydrochloride Extended-Release Capsules, 7 mg, 14 mg, 21 mg and 28 mg to be bioequivalent and therapeutically equivalent to the reference listed drug (RLD), Namenda XR Capsules, 7 mg, 14 mg, 21 mg, and 28 mg of AbbVie Inc. (AbbVie) NDA - 022525.

The RLD upon which you have based your ANDA, AbbVie's Namenda XR Capsules, is subject to a period of patent protection. The following patent and expiration date (with pediatric exclusivity added) is currently listed in the Agency's publication titled *Approved Drug Products with Therapeutic Equivalence Evaluations* (the "Orange Book"):

U.S. Patent Number	Expiration Date
8,039,009 (the '009 patent)	September 24, 2029

You have notified the Agency that Macleods Pharmaceuticals Limited (Macleods) 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 Macleods for infringement of the '009 patent in the United States District Court for the District of Delaware [Forest Laboratories, LLC, Forest Laboratories Holdings, LTD., Allergan USA, Inc., and Adamas

Pharma, LLC. v. Macleod Pharmaceuticals, Ltd. and Macleod Pharma USA, Inc., Civil Action No. 17-00672]. You have also notified the Agency that this case was dismissed.

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, post marketing 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

[1] We note that the reference listed drug (RLD) upon which you have based this ANDA, AbbVie's Namenda XR Capsules, 7 mg, 14 mg, 21 mg, and 28 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 AbbVie's Namenda XR Capsules, 7 mg, was not withdrawn from sale for reasons of safety or effectiveness. FDA published this determination in the *Federal Register* (89 FR 64928; August 8, 2024). The Agency has determined that AbbVie's Namenda XR Capsules, 14 mg, 21 mg, and 28 mg were not withdrawn from sale for reasons of safety or effectiveness. FDA will publish this determination in the Federal Register as soon as is practicable. This determination allows the Agency to approve ANDAs for the discontinued drug product(s).

Paul
Levine

Digitally signed by Paul Levine
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