ANDA 214921

ANDA APPROVAL

MSN Pharmaceuticals Inc.
U.S. Agent for MSN Laboratories Private Limited
20 Duke Road
Piscataway, NJ 08854-3714
Attention: Kondal Reddy Bairy
Associate Vice President

Dear Kondal Reddy Bairy:

This letter is in reference to your abbreviated new drug application (ANDA) received for review on May 12, 2020, submitted pursuant to section 505(j) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) for Brivaracetam Tablets, 10 mg, 25 mg, 50 mg, 75 mg, and 100 mg.

Reference is also made to the tentative approval letter issued by this office on November 9, 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 Brivaracetam Tablets, 10 mg, 25 mg, 50 mg, 75 mg, and 100 mg to be bioequivalent and therapeutically equivalent to the reference listed drug (RLD), Briviact Tablets, 10 mg, 25 mg, 50 mg, 75 mg, and 100 mg, of UCB, Inc. (UCB) NDA - 205836.

The RLD upon which you have based your ANDA, UCB's Briviact Tablets, 10 mg, 25 mg, 50 mg, 75 mg, and 100 mg, 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
6,911,461 (the '461 patent)	February 21, 2026
10,729,653 (the '653 patent)	April 9, 2030

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 Brivaracetam Tablets, 10 mg, 25 mg, 50 mg, 75 mg, and 100 mg, under this ANDA. You have notified the Agency that MSN Laboratories Private Limited (MSN) 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 MSN for infringement of the '461 patent in the United States District Court for the District of Delaware [UCB, Inc. and UCB Biopharma SRL v. MSN Pharmaceuticals Inc., MSN Laboratories Private Ltd. et al., Civil Action No. 20-00987]. The 7.5 year period identified in sections 505(j)(5)(B)(iii) and 505(j)(5)(F)(ii) of the FD&C Act, during which FDA was precluded from approving your ANDA, has expired.

With respect to 180-day generic drug exclusivity, we note that MSN was one of the first ANDA applicants to submit a substantially complete ANDA with a paragraph IV certification for Brivaracetam Tablets, 10 mg, 25 mg, 50 mg, 75 mg, and 100 mg. Therefore, with this approval, MSN is eligible for 180 days of shared generic drug exclusivity for Brivaracetam Tablets, 10 mg, 25 mg, 50 mg, 75 mg, and 100 mg. 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, will begin to run from the date of the commercial marketing by any first approved applicant, as 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 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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