ND 214924 A

ANDA APPROVAL

MSN Pharmaceuticals Inc.
U.S. gent for MSN Laboratories Private Limited
ttention: Kondal Reddy Bairy
Senior Vice President

Dear Kondal Reddy Bairy:

This letter is in reference to your abbreviated new drug application (ND) received for review on May 12, 2020, submitted pursuant to section 505(j) of the Federal Food, Drug, and Cosmetic ct (FD&C ct) for Brivaracetam Injection, 50 mg/5 mL (10 mg/mL), Single-Dose Vials.

Reference is also made to the tentative approval letter issued by this office on December 1, 2025, and to any amendments thereafter.

We have completed the review of this ND and have concluded that adequate information has been presented to demonstrate that the drug meets the requirements for approval under the FD&C ct. ccordingly, the ND is **approved**, effective on the date of this letter. We have determined your Brivaracetam Injection, 50 mg/5 mL (10 mg/mL), Single-Dose Vials to be bioequivalent and therapeutically equivalent to the reference listed drug (RLD), Briviact Injection, 50 mg/5 mL (10 mg/mL), of UCB, Inc., ND - 205837.

Please note that if FD requires a Risk Evaluation and Mitigation Strategy (REMS) for a listed drug, an ND referencing that listed drug also will be required to have a REMS. See section 505-1(i) of the FD&C ct.

COMPENDIAL STANDARDS

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 ct § 501(b), 21 USC 351(b)). FD 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 A compendial standards, application holders may work directly with USP-NF to revise A 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

Und r pplic bl st tut s, r ul tions, nd uid nc s, your ANDA m ay b subj ct to c rt in r quir m ents nd r comm nd tions post pprov l, includin r quir m ents r v rdin ch n s to pprovvd ANDAs, postm ark tin r portin , promotion l m t ri ls, nd nnu l f cility f s, mon oth rs. For inform ation on post- pprov l r quir m ents nd r comm end tions for ANDAs nd list of r sourc s for ANDA hold rs, w r f r you to https://www.fd . ov/dru s/ bbr vi t d-n w-dru - pplic tion- nd /r quir m ents- nd-r sourc s- pprov d- nd s.

Sinc r ly yours,

{See appended electronic signature page}

For K ndr S. St w rt, R. h., h rm.D.
CA T, Unit d St t s ublic H lth S rvic
Dir ctor
Offic of R ul tory Op r tions
Offic of G en ric Dru s
C nt r for Dru Ev lu tion nd R s rch v

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