ANDA 217213

ANDA APPROVAL

Novitium Pharma LLC
70 Lake Drive
East Windsor, NJ 08520
Attention: Muthusamy Shanmugam
Founder and President

Dear Muthusamy Shanmugam:

This letter is in reference to your abbreviated new drug application (ANDA) received for review on February 17, 2022, submitted pursuant to section 505(j) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) for Methsuximide Capsules USP, 300 mg.

Reference is also made to the complete response letter issued by this office on December 9, 2022, 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 Methsuximide Capsules USP, 300 mg, to be bioequivalent and therapeutically equivalent to the reference listed drug (RLD), Celontin Capsules, 300 mg of Parke, Davis & Company LLC (Parke Davis).

Reference is also made to FDA's Competitive Generic Therapy Designation – Grant letter dated April 12, 2022.

We note that Novitium Pharma LLC (Novitium) was granted a Competitive Generic Therapy (CGT) designation for Methsuximide Capsules USP, 300 mg. Novitium is the "first approved applicant" for Methsuximide Capsules USP, 300 mg, as defined in section 505(j)(5)(B)(v)(III) of the FD&C Act. Therefore, with this approval, Novitium is eligible for 180 days of CGT exclusivity for Methsuximide Capsules USP, 300 mg, under section 505(j)(5)(B)(v) of the FD&C Act. This exclusivity begins to run from the date of the first commercial marketing of the CGT (including the commercial marketing of the listed drug) by Novitium, as specified in section 505(j)(5)(B)(v) of the FD&C Act. Furthermore, in accordance with section 505(j)(5)(B)(v)(I) of the FD&C Act, this 180-day CGT exclusivity will not block approval of other applications until Novitium has commenced commercial marketing. Please submit a correspondence to this ANDA informing the Agency of the date you begin commercial marketing. Please also submit notice of first commercial marketing via e-mail to the Patent and Exclusivity Team at CDER-OGDPET@fda.hhs.gov. This e-mail should be sent the same day you

commence commercial marketing. Reference is also made to the Special Forfeiture Rule for Competitive Generic Therapy in section 505(j)(5)(D)(iv) of the FD&C Act. Please be aware that, pursuant to this forfeiture rule, you will forfeit your eligibility for the 180-day CGT exclusivity period for Methsuximide Capsules USP, 300 mg, if you fail to market this CGT within 75 days after the date on which the approval of this application is made effective.

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.

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

Catherine Poole

Digitally signed by Catherine Poole
Date: 5/01/2023 12:59:25PM
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