



ANDA 216988

ANDA APPROVAL

Advagen Pharma Limited
U.S. Agent for Rubicon Research Limited
Attention: Daliya Bharati
Director, Regulatory & IP

Dear Daliya Bharati:

This letter is in reference to your abbreviated new drug application (ANDA) received for review on December 22, 2021, submitted pursuant to section 505(j) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) for Clonazepam Orally Disintegrating Tablets USP, 0.125 mg, 0.25 mg, 0.5 mg, 1 mg and 2 mg.¹

Reference is also made to any amendments submitted prior to the issuance of this letter.

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 Clonazepam Orally Disintegrating Tablets USP, 0.125 mg, 0.25 mg, 0.5 mg, 1 mg and 2 mg to be bioequivalent and therapeutically equivalent to the reference listed drug (RLD), Klonopin Orally Disintegrating Tablets, 0.125 mg, 0.25 mg, 0.5 mg, 1 mg and 2 mg, of Hoffmann-La Roche, Inc. (Roche) NDA – 020813.

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 at <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

¹ We note that the reference listed drug (RLD) upon which you have based this ANDA, Roche's Klonopin Orally Disintegrating Tablets, 0.125 mg, 0.25 mg, 0.5 mg, 1 mg and 2 mg, is no longer being marketed in the United States and is currently listed in the discontinued section of FDA's *Approved Drug Products with Therapeutic Equivalence Evaluations* (the "Orange Book"). The Agency has determined that Roche's Klonopin Orally Disintegrating Tablets, 0.125 mg, 0.25 mg, 0.5 mg, 1 mg and 2 mg, was not withdrawn from sale for reasons of safety or effectiveness. FDA published this determination in the *Federal Register* (79 FR 47648; August 14, 2014). This determination allows the Agency to approve ANDAs for the discontinued drug product.



Catherine
Poole

Digitally signed by Catherine Poole

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