ANDA 217468

ANDA APPROVAL

Navinta LLC
Attention: Chirag Patel
Regulatory Affairs

Dear Chirag Patel:

This letter is in reference to your abbreviated new drug application (ANDA) received for review on November 29, 2022, submitted pursuant to section 505(j) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) for Diazepam Rectal Gel Rectal Delivery System, 2.5 mg, 10 mg and 20 mg.

Your product is a combination product as defined by 21 CFR 3.2(e) and is comprised of drug and device constituent parts.

Reference is also made to the complete response letter issued by this office on December 20, 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 Diazepam Rectal Gel Rectal Delivery System, 2.5 mg, 10 mg and 20 mg to be bioequivalent and therapeutically equivalent to the reference listed drug (RLD), Diastat Rectal Delivery System, 2.5 mg and Diastat AcuDial Rectal Delivery System, 10 mg and 20 mg of Bausch Health US LLC (Bausch) NDA - 020648.

Reference is also made to FDA's Competitive Generic Therapy Designation – Grant letter dated June 21, 2022.

We note that Navinta LLC (Navinta) was granted a Competitive Generic Therapy (CGT) designation for Diazepam Rectal Gel Rectal Delivery System, 2.5 mg, 10 mg and 20 mg. However, Navinta is not a "first approved applicant" for such competitive generic therapies, as defined in section 505(j)(5)(B)(v)(III) of the FD&C Act, because eligibility for 180-day patent challenge exclusivity under section 505(j)(5)(B)(iv) has previously been forfeited by all applicants for these drugs pursuant to section 505(j)(5)(D) of the FD&C Act.[1] See section 505(j)(5)(B)(v)(III)(bb)(CC) of the FD&C Act. Therefore, these drug products are not eligible for CGT exclusivity under section 505(j)(5)(B)(v) of the FD&C Act.

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

[1] Further information may be found on FDA's Paragraph IV Certifications List, available at https://www.fda.gov/drugs/abbreviated-new-drug-application-anda/patent-certifications-and-suitability-petitions#List.

Catherine Poole

Digitally signed by Catherine Poole
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