ANDA 214493

ANDA APPROVAL

Zydus Pharmaceuticals (USA) Inc.
73-B, Route 31 North
Pennington, NJ 08534
Attention: Srinivas Gurram
Sr VP & Head of RA & CQA Lead - Americas

Dear Srinivas Gurram:

This letter is in reference to your abbreviated new drug application (ANDA) received for review on April 29, 2020, submitted pursuant to section 505(j) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) for Pimavanserin Capsules, 34 mg.

Reference is also made to the tentative approval letter issued by this office on December 30, 2021, 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 Pimavanserin Capsules, 34 mg, to be bioequivalent and therapeutically equivalent to the reference listed drug (RLD), Nuplazid Capsules, 34 mg, of Acadia Pharmaceuticals Inc. (Acadia).

Reference is also made to FDA's Competitive Generic Therapy Designation – Grant letter dated June 29, 2020.

The RLD upon which you have based your ANDA, Acadia's Nuplazid Capsules, 34 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
7,601,740 (the '740 patent)	April 29, 2030
7,659,285 (the '285 patent)	August 24, 2026
7,732,615 (the '615 patent)	June 3, 2028
7,923,564 (the '564 patent)	September 26, 2025

10,449,185 (the '185 patent)	August 27, 2038
10,646,480 (the '480 patent)	August 27, 2038
10,849,891 (the '891 patent)	August 27, 2038
11,452,721 (the '721 patent)	August 27, 2038

Your ANDA contains paragraph IV certifications to each of the patents[1], 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 Pimavanserin Capsules, 34 mg, under this ANDA. You have notified the Agency that Zydus Pharmaceuticals (USA) Inc. (Zydus) 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 Zydus for infringement of the '740, '615, and '185 patents in the United States District Court for the District of Delaware [Acadia Pharmaceuticals, Inc. v. Zydus Pharmaceuticals (USA) Inc. and Cadila Healthcare Limited, Civil Action No. 20-01021]. You have also notified the Agency that this case was dismissed.

With respect to 180-day generic drug exclusivity, we note that Zydus was one of the first ANDA applicants to submit a substantially complete ANDA with a paragraph IV certification for Pimavanserin Capsules, 34 mg. Therefore, with this approval, Zydus is eligible for 180 days of shared generic drug exclusivity for Pimavanserin Capsules, 34 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, begins to run from the date of the commercial marketing by any first 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).

We note that Zydus was granted a Competitive Generic Therapy (CGT) designation for Pimavanserin Capsules, 34 mg. However, as noted in the June 29, 2020, CGT Designation – Grant Letter, your drug product is not eligible for CGT exclusivity under section 505(j)(5)(B)(v) of the FD&C Act because there were unexpired patents or exclusivities listed in FDA's *Approved Drug Products With Therapeutic Equivalence Evaluations* (Orange Book) for the RLD at the time of submission of your ANDA.

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 Edward M. Sherwood
Director
Office of Regulatory Operations
Office of Generic Drugs
Center for Drug Evaluation and Research

[1] The Agency notes that the '480, '891, and '721 patents were submitted to the Agency after submission of your ANDA. Litigation, if any, with respect to these patents would not create a statutory stay of approval.

Catherine Poole

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