



**Suitability Petition  
Completeness Assessment Correspondence**

Zydus Pharmaceuticals (USA) Inc.  
73- B Route 31 North  
Pennington, NJ 08534  
Attn: Srinivas Gurram

Sent via email to: [ddesai@zydususa.com](mailto:ddesai@zydususa.com)

Docket No. FDA-2024-P-0435

Dear Srinivas Gurram:

This is in reference to your petition received on January 22, 2024, by the U.S. Food and Drug Administration (FDA or Agency), requesting permission, in accordance with 21 C.F.R. §314.93(b), to submit an Abbreviated New Drug Application (ANDA) for the following drug product: Pimavanserin Tablets, 34 mg. The petition was examined for initial completeness (i.e. Completeness Assessment) under CFR 10.30 and the Agency has made a threshold determination that the petition is complete.

This petition is subject to the provisions of the Generic Drugs User Fee Amendments of 2022 (GDUFA III) whereby any suitability petitions submitted in FY 2024-2027 will receive a goal date of 6 months after the completeness assessment. The GDUFA goal date for review of this petition is August 9, 2024.

If you have any questions, contact [ANDAFiling@fda.hhs.gov](mailto:ANDAFiling@fda.hhs.gov).

A copy of this letter will be placed on public display in the Dockets Management Branch, Room 1061, Mail Stop HFA-305, 5630 Fishers Lane, Rockville, MD 20852.

Sincerely,

*{See appended electronic signature page}*

Bijal Patel, Pharm.D., BCPS  
Team Leader  
Division of Filing Review  
Office of Regulatory Operations  
Office of Generic Drugs  
Center for Drug Evaluation and Research



Bijal  
Patel

Digitally signed by Bijal Patel

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