U.S. FOOD & DRUG ADMINISTRATION

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

Docket No. FDA-2024-P-0435

Dear Srinivas Gurram:

This is in response to your petition received on January 22, 2024, by the U.S. Food and Drug Administration (FDA or Agency), requesting permission to submit an Abbreviated New Drug Application (ANDA) for the following drug product: Pimavanserin Tablets, 34 mg. The listed drug product to which you refer in your petition is Nuplazid (Pimavanserin Tablets, 10 mg and 17 mg), approved under NDA 207318 and held by Acadia Pharmaceuticals Inc.

Your petition requests a change in strength from that of the listed drug product (i.e., from 10 mg and 17 mg to 34 mg). A change in strength is the type of change that is permissible under section 505(j)(2)(C) of the Federal Food, Drug, and Cosmetic Act (Act), subject to FDA approval of a petition submitted under that section of the Act.

However, FDA will not approve a petition submitted under section 505(j)(2)(C) of the Act if "the reference listed drug has been voluntarily withdrawn from sale and the agency has not determined whether the withdrawal is for safety or effectiveness reasons." 21 CFR 314.93(e)(1)(v). Therefore, FDA denies your petition because the reference listed drug to which you refer in your petition, Nuplazid (Pimavanserin Tablets, 17 mg), approved under NDA 207318, held by Acadia Pharmaceuticals Inc., has been voluntarily withdrawn from sale and the agency has not determined whether the withdrawal is for safety or effectiveness reasons.

If you disagree with our determination concerning the approvability of your petition as originally submitted, you may seek a reconsideration of the decision not to approve your petition following the procedures set forth in 21 CFR 10.33. Requests for reconsideration must be based solely on the information contained in your original petition and must be submitted in accordance with 21 CFR 10.20, in the format outlined in § 10.33 and no later than 30 days after the date of the decision involved. Petitions for reconsideration should be filed with the Dockets Management Branch at the address listed below. If there is additional information not included as part of your original submission that you would like the Agency to consider, you should submit a new petition including all the necessary information to the Dockets Management Branch.

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,

William Chong, M.D.
Director, Office of Safety and Clinical Evaluation
For Iilun Murphy, M.D.
Director
Office of Generic Drugs
Center for Drug Evaluation and Research

U.S. Food & Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993
www.fda.gov

William Chong

Digitally signed by William Chong
Date: 5/20/2024 02:11:05PM
GUID: 508da7450002bdd54805b3a331b19b0d