U.S. FOOD & DRUG ADMINISTRATION

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

November 13, 2024

Re: Docket No. FDA-2024-P-2514

Dear Petitioner:

This letter responds to your citizen petition received on May 22, 2024, requesting that the Food and Drug Administration (FDA) determine whether the Reference Listed Drug, Nuplazid (pimavanserin tartrate) tablet, equivalent (EQ) 17 milligrams (mg) base, held by Acadia Pharmaceuticals Inc., was voluntarily withdrawn from the commercial market or withdrawn from sale for safety or effectiveness reasons.

FDA has reviewed its records and determined that Nuplazid (pimavanserin tartrate) tablet, EQ 17 mg base, was not withdrawn from sale for reasons of safety or effectiveness. Thus, FDA will maintain Nuplazid (pimavanserin tartrate) tablet, EQ 17 mg base, in the "Discontinued Drug Product List" section of *Approved Drug Products With Therapeutic Equivalence Evaluations* (the Orange Book).

Enclosed is a copy of the *Federal Register* notice that announces the FDA determination. If you require any further information, please feel free to call me at (301) 796-8363.

Sincerely,

Stacy Kane

Stacy Kane
Office of Regulatory Policy
Center for Drug Evaluation and Research

Enclosure

U.S. Food & Drug Administration
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Silver Spring, MD 20993
w ww.fda.gov