Date – May 22, 2024

VIA ELECTRONIC SUBMISSION

Division of Dockets
Management Food and
Drug Administration
Department of Health and Human
Services 5630 Fishers Lane,
Room 1061 (HFA-305)
Rockville, MD 20852

Citizen Petition

Dear Sir/ Madam,

The undersigned, for Zydus Pharmaceuticals (USA) Inc., respectfully submits this petition pursuant to the Federal Food, Drug and Cosmetic Act ("FDC Act") and in accordance with regulations at 21 C.F.R. §10.25(a), § 10.30, and 21 C.F.R. § 314.161 and 314.122, requesting the Commissioner of Food and Drug Administration to provide a determination on whether a listed drug has been withdrawn for reasons of safety or effectiveness as outlined below.

A. Action Requested

The Petitioner requests that the Commissioner of the Food and Drug Administration determine whether the Reference Listed Drug (RLD), NUPLAZID® (pimavanserin) tablets, 17 mg (NDA# N207318) held by Acadia Pharmaceuticals Inc., has been voluntarily withdrawn from the commercial market or withdrawn from sale for safety or effectiveness reasons.

B. Statement of Grounds

The Food and Drug Administration maintains a list of drug products in the Orange Book. The list, Approved Drug Products with Therapeutic Equivalence Evaluations, referred to as the "Orange Book", lists all FDA approved drug products. These drug products are eligible

Office of Regulatory Affairs
Zydus Pharmaceuticals (USA) Inc.
(A wholly owned subsidiary of Zydus Lifesciences Limited)
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for submission under Section 505(j) of the FD&C Act as ANDAs. NUPLAZID® (pimavanserin) tablets, 10 mg and 17 mg (NDA# N207318) held by Acadia Pharmaceuticals Inc., was Approved on June 28, 2018 and April 29, 2016, respectively. The product was then considered to be a "Reference Listed Drug Product" in the Orange Book.

NUPLAZID® (pimavanserin) tablets, 17 mg now appears in the "Discontinued Section" of the Orange Book (refer **Attachment-I**), indicating that it is currently not available for sale. Currently, the orange book displays Pimavanserin Tablets, 10 mg (A214502) of ZYDUS WORLDWIDE DMCC is also approved and commercially available as mentioned in the below **Attachment-I**.

If an RLD appears in the discontinued section of the Orange Book and the FDA has not determined whether the drug was withdrawn from sale for reasons of safety or effectiveness, a person wishing to submit an ANDA for the drug must submit a citizen petition under 21 C.F.R. § 10.25(a) and § 10.30 before or at the same time of the ANDA submission, seeking a determination on whether the listed drug has been withdrawn from sale for safety or effectiveness reasons. Such a petition must contain all evidence available to the petitioner concerning the reason that the drug product was withdrawn from sale under 21 C.F.R. § 314.122(a).

The regulations provide that the Agency must make a determination as to whether a listed drug is withdrawn from sale for reasons of safety or effectiveness before an ANDA that refers to that listed drug may be approved (21 C.F.R. § 314.161 (a)(1)).

If the FDA determines that the listed drug was withdrawn from sale for reasons of safety and effectiveness (or if FDA withdraws or suspends NDA approval for reasons of safety or effectiveness), then the drug listing is removed from the Orange Book. See id. *See* 21 C.F.R. § 314.122, § 314.161, and § 314.162. If FDA determines that the listed drug was not withdrawn from sale for reasons of safety and effectiveness, then the drug listing remains in the Orange Book and may be cited in an ANDA as a RLD.

Petitioner is further unaware of any reason why NUPLAZID® (pimavanserin) tablets, 17 mg (NDA# N207318) may have been removed from sale and believes the discontinuation of NUPLAZID® (pimavanserin) tablets, 17 mg (NDA# N207318) was due to only commercial considerations. Petitioner requests that FDA determine whether the NDA holder for NUPLAZID® (pimavanserin) tablets, and 17 mg (NDA# N207318) has withdrawn the product for reason of safety or effectiveness.

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C. Environmental Impact

In Accordance with the requirements set forth in 21 C.F.R. § 25.31 (a), the petitioner hereby requests a Categorical Exclusion from the requirements to prepare an Environmental Impact Assessment

D. Economic Impact

In accordance with 21 C.F.R. § 10.30(b), economic impact information is to be submitted only when requested by the Commissioner following review of the petition. The Petitioner hereby commits to promptly provide this information, if so requested.

E. Certification

The undersigned certifies that, to the best knowledge and belief of the undersigned, this petition includes all information and views on which the petition relies, and that it includes representative data and information known to the petitioner which is unfavorable to the petition.

For Zydus Pharmaceuticals (USA) Inc.

Srinivas Gurram

Digitally signed by Srinivas Gurram
Date: 2024.05.22 14:35:02 -04'00'

Srinivas Gurram (Srini)
Senior Vice President - Head of RA and CQA lead –Americas
Zydus Pharmaceuticals (USA) Inc.

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Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations

Mkt.Status	Active Ingredient	Proprietary Name	Appl. No.	Dosage Form	Route	Strength	TE Code	RLD	RS	Applicant Holder
RX	PIMAVANSERIN TARTRATE	NUPLAZID	N207318	TABLET	ORAL	EQ 10MG BASE	AB	RLD	RS	ACADIA PHARMACEUTICALS INC
RX	PIMAVANSERIN TARTRATE	PIMAVANSERIN	A214502	TABLET	ORAL	EQ 10MG BASE	AB			ZYDUS WORLDWIDE DMCC
DISCN	PIMAVANSERIN TARTRATE	NUPLAZID	N207318	TABLET	ORAL	EQ 17MG BASE		RLD		ACADIA PHARMACEUTICALS INC