August 13, 2024

To,
Division of Docket management
Food and Drug Administration
Department of Health and Human Services,
5630, Fisher Lane, Room 1061 (HFA -305)
Rockville, MD 20852

SUITABILITY PETITION

Dear Sir/Madam:

The undersigned (petitioner) submits this Suitability Petition pursuant to Section 505(j)(2)(C) of the Federal Food, Drug and Cosmetic Act ("FDC Act") and in accordance with 21 C.F.R. § 314.93 and 21 C.F.R. §§ 10.20 and 10.30, to request that the Commissioner of the U.S. Food and Drug Administration ("FDA") determine that the drug product Pimavanserin Tablets, 34 mg, is suitable for submission in an Abbreviated New Drug Application ("ANDA").

I. ACTION REQUESTED

The petitioner requests that FDA declare that Pimavanserin Tablets, 34 mg is suitable for submission as an ANDA. As designated in FDA's Approved Drug Products with Therapeutic Equivalence Evaluations ("Orange Book"), the Reference Listed Drug ("RLD") upon which this petition is based is ACADIA PHARMACEUTICALS INC's NUPLAZID®(pimavanserin) Tablets, which was approved for prescription use under New Drug Application ("NDA") 207318 in 10 mg and 17 mg (where 17 mg is currently listed as discontinued, however petitioner had filed Citizen Petition to 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(RLD), NUPLAZID® (pimavanserin) tablets, 17 mg (NDA# N207318) held by Acadia Pharmaceuticals Inc., has been voluntarily withdrawn from the commercial market or withdrawn from sale for safety or effectiveness reasons (Docket # FDA-2024-P-2514)). The petitioner seeks to introduce new 34 mg strength for prescription use. The active ingredients, route of administration, dosage form and dosage regimen for use are the same as that of the RLD.

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Zydus Pharmaceuticals (USA) Inc.
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II. STATEMENT OF GROUNDS

FDC Act § 505(j)(2)(A)(iii) provides for the submission of an ANDA for a drug product that differs in strength from that of the Reference Listed Drug provided FDA has first approved a petition permitting the submission of such an application.

NUPLAZID®(pimavanserin) Tablets is approved under NDA N207318 contains 10 mg and 17 mg of Pimavanserin in an immediate release oral tablet dosage form for treatment of hallucinations and delusions associated with Parkinson's disease psychosis. The prescribing information of RLD given in PIL (attached) recommends once a day dose of 34 mg for the treatment of hallucinations and delusions associated with Parkinson's disease psychosis. A copy of the current Orange Book entry for NUPLAZID®(pimavanserin) Tablets (NDA 207318) is included in **Attachment 1**. The proposed drug product also contains pimavanserin in an immediate release oral tablet dosage form, but in 34 mg strength. The petition is thus seeking addition of drug product strength of 34 mg to that of the RLD's 10 mg and 17 mg.

Pimavanserin Tablets is currently marketed under NUPLAZID® as 10 mg strength only (17 mg strength is currently discontinued). In order to achieve required daily dose of 34 mg, (screenshot of RLD PI as below), patient needs to switch from tablets dosage form to capsule dosage form which is currently marketed under NUPLAZID® (NDA N210793). The prescribing information of NUPLAZID® marketed under tablet dosage form (NDA N207318) and capsules dosage form (NDA N210793) is same.

2 DOSAGE AND ADMINISTRATION
2.1 Recommended Dosage
The recommended dose of NUPLAZID is 34 mg taken orally once daily, without titration.

The availability of new 34 mg strength in tablet dosage form will provide a prescribing physician and patients with a greater degree of flexibility in achieving recommended dose without change in dosage form.

The proposed addition of strength from that of the RLD does not raise questions of safety or efficacy for the proposed drug product. Therefore, FDA should conclude that clinical investigations are not necessary to demonstrate safety or effectiveness of the proposed drug product.

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The labeling for the proposed 34 mg drug product strength would be consistent with that of the RLD except that it would differ with respect to identification of drug product strength and manufacturer specific information. The uses, dosage form, route of administration, indications, warnings, and directions for use will remain the same as that of the RLD. Prescribing Information (Revised 9/2023) of NUPLAZID® (NDA N207318) is provided with this petition as **Attachment 2**.

Therefore, the Petitioner requests that FDA find that introduction of additional strength of Pimavanserin Tablets 34 mg to Pimavanserin Tablets 10 mg and 17 mg raises no questions of safety or effectiveness.

The Pediatric Research Equity Act ("PREA"), enacted in December 2003, amended the FDC Act by requiring certain applications for a drug submitted under FDC Act § 505 to contain an assessment of the safety and effectiveness of the product in pediatric patients unless this requirement is deferred or waived. See FDC Act § 505B(a)(1)(A)(i). Specifically, PREA applies to all applications for a new active ingredient, dosage form, indication, route of administration, or dosing regimen. *See id*. ANDAs submitted under an approved suitability petition for a change in strength are ***not*** subject to PREA requirements. *See FDA, Draft Guidance for Industry, How to Comply with the Pediatric Research Equity Act, 4 (Sep. 2005).* Petitioner asserts that PREA is not applicable to the proposed Pimavanserin Tablets 34 mg, drug product because the proposed change concerns only a new strength. As such, PREA should not serve as an impediment to the Agency granting this petition.

III. ENVIROMENTAL IMPACT

A claim for categorical exclusion of the requirements for an environmental assessment is made pursuant to 21 C.F.R. § 25.31.

IV. 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. Petitioner hereby commits to promptly provide this information, if requested.

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V. CERTIFICATION

The petitioner certifies that, to the best of knowledge and belief of Petitioner, 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.

Sincerely,

Srinivas Gurram

Digitally signed by Srinivas Gurram
Date: 2024.08.13 16:38:07 -04'00'

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

Attachment:

Attachment 1: Orange Book Pages of RLD NUPLAZID®(pimavanserin) Tablets

Attachment 2: Approved labeling for NUPLAZID®(pimavanserin) Tablets (NDA N207318)
Attachment 3: Proposed labelling of product with strength of 34 mg of tablet

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