DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring, MD 20993

NDA 207318/S-005

**SUPPLEMENT APPROVAL/
FULFILLMENT OF POSTMARKETING
COMMITMENT**

ACADIA Pharmaceuticals Inc.
Attention: Lewis Gryziewicz, PharmD
Executive Director, Regulatory Affairs
3611 Valley Centre Drive, Suite 300
San Diego, CA 92130

Dear Dr. Gryziewicz:

Please refer to your Supplemental New Drug Application (sNDA) dated and received December 21, 2017, and your amendments, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Nuplazid (pimavanserin) 17 mg immediate-release, film-coated oral tablets.

This supplemental new drug application provides for revisions to Section 13.2 (Animal Toxicology) based upon a postmarketing commitment (PMC) study 3069-4.

APPROVAL & LABELING

We have completed our review of this supplemental application, as amended. It is approved, effective on the date of this letter, for use as recommended in the enclosed, agreed-upon labeling text.

We note that your May 23, 2018, submission includes final printed labeling (FPL) for your package insert. We have not reviewed this FPL. You are responsible for assuring that the wording in this printed labeling is identical to that of the approved content of labeling in the structured product labeling (SPL) format.

CONTENT OF LABELING

As soon as possible, but no later than 14 days from the date of this letter, submit the content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format using the FDA automated drug registration and listing system (eLIST), as described at http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm. Content of labeling must be identical to the enclosed labeling (text for the package insert), with the

addition of any labeling changes in pending "Changes Being Effected" (CBE) supplements, as well as annual reportable changes not included in the enclosed labeling.

Information on submitting SPL files using eList may be found in the guidance for industry titled "SPL Standard for Content of Labeling Technical Qs and As" at http://www.fda.gov/downloads/DrugsGuidanceComplianceRegulatoryInformation/Guidances/UCM072392.pdf.

The SPL will be accessible from publicly available labeling repositories.

Also within 14 days, amend all pending supplemental applications that include labeling changes for this NDA, including CBE supplements for which FDA has not yet issued an action letter, with the content of labeling [21 CFR 314.50(l)(1)(i)] in MS Word format, that includes the changes approved in this supplemental application, as well as annual reportable changes and annotate each change. To facilitate review of your submission, provide a highlighted or marked-up copy that shows all changes, as well as a clean Microsoft Word version. The marked-up copy should provide appropriate annotations, including supplement number(s) and annual report date(s).

REQUIRED PEDIATRIC ASSESSMENTS

Under the Pediatric Research Equity Act (PREA) (21 U.S.C. 355c), all applications for new active ingredients, new indications, new dosage forms, new dosing regimens, or new routes of administration are required to contain an assessment of the safety and effectiveness of the product for the claimed indication(s) in pediatric patients unless this requirement is waived, deferred, or inapplicable.

Because none of these criteria apply to your application, you are exempt from this requirement.

FULFILLMENT OF POSTMARKETING COMMITMENT

We have received your submission dated December 21, 2017, containing the final report for the following postmarketing commitment listed in the April 29, 2016, approval letter.

3069-4 Perform microscopic re-evaluation of lung tissue samples using special stains to detect collagen from high dose (30 mg/kg/day male and female groups) of the 6-month rat study (b) (4).146.02), the high dose groups (30 mg/kg/day male and 50 mg/kg/day female) from the 2-year rat carcinogenicity study ((b) (4)-6160004), and also the high dose groups (25/60 mg/kg/day) from the 12-month monkey study ((b) (4).146.01). If drug-related inflammation is detected in the lungs of any of the re-evaluated high dose groups from a particular study, then re-evaluation of lung tissue samples from the low and mid dose groups of that study should be conducted in order to identify a No Observed Effect Level (NOEL) for inflammation in the lungs of animals.

We have reviewed your submission and conclude that the above commitment was fulfilled.

We remind you that there are postmarketing commitments listed in the April 29, 2016, approval letter that are still open.

REPORTING REQUIREMENTS

We remind you that you must comply with reporting requirements for an approved NDA (21 CFR 314.80 and 314.81).

If you have any questions, please email Simran Parihar, PharmD, at simran.parihar@fda.hhs.gov.

Sincerely,

{See appended electronic signature page}

Mitchell V. Mathis, M.D.
Director
Division of Psychiatry Products
Office of Drug Evaluation I
Center for Drug Evaluation and Research

ENCLOSURE:
Content of Labeling

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

MITCHELL V Mathis
06/06/2018