DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 022328/S-004

SUPPLEMENT APPROVAL

Purdue Pharmaceutical Products L.P.
Attention: Edward Liao, PharmD
Director, US Regulatory Affairs
One Stamford Forum
Stamford, CT 06901

Dear Dr. Liao:

Please refer to your Supplemental New Drug Application (sNDA) dated August 10, 2015, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Intermezzo (zolpidem tartrate) 1.75 mg and 3.5 mg sublingual tablets.

We acknowledge receipt of your amendment dated September 2, 2015.

This "Prior Approval" supplemental new drug application provides for the addition of a new subsection (6.2) to the Adverse Reactions section of Intermezzo labeling consistent with our July 14, 2015 letter. The specific additions are as follows:

6.2 Postmarketing Experience
The following adverse reactions have been identified during post-approval use of Intermezzo. Because these reactions are reported voluntarily from a population of uncertain size, it is not always possible to establish a causal relationship to drug exposure.

- *Application site reactions, primarily in the sublingual area, have been reported. These application site reactions included oral ulcers, blisters, and mucosal inflammation.*

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 September 2, 2015, submission includes final printed labeling (FPL) for your package insert, patient package insert, and Medication Guide. 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, text for the patient package insert, and Medication Guide, 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 includes 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).

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, contact Dr. Brendan Muoio, Regulatory Project Manager, at (240) 402-4518 or brendan.muoio@fda.hhs.gov.

Sincerely,

{See appended electronic signature page}

Mitchell V. Mathis, MD
Director
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
09/11/2015