DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 022272/S-005 **SUPPLEMENT APPROVAL**

Purdue Pharma L.P.
One Stamford Forum
Stamford, CT 06901-3431

Attention: Beth Connelly
Associate Director, Regulatory Affairs

Dear Ms. Connelly:

Please refer to your supplemental new drug application dated and received June 11, 2010, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for OxyContin (Oxycodone Hydrochloride Controlled-Release) Tablets, 10 mg, 15 mg, 20 mg, 30 mg, 40 mg, 60 mg, and 80 mg.

This "Prior Approval" supplemental new drug application provides for proposed modifications to the approved risk evaluation and mitigation strategy (REMS).

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

RISK EVALUATION AND MITIGATION STRATEGIES (REMS) REQUIREMENTS

The REMS for OxyContin (Oxycodone Hydrochloride Controlled-Release) Tablets was originally approved on April 5, 2010. The REMS consists of a Medication Guide, elements to assure safe use, and a timetable for the submission of assessments of the REMS. Your proposed modifications to the REMS are revisions to the Training Guide for Healthcare Providers that include adding "(oxycodone hydrochloride controlled-release)" to the headline page and indication, editorial corrections for the purpose of consistency with the approved final printed labeling, relocating the Table of Contents, renumbering references, and other minor typographical corrections and editorial revisions.

Your modified REMS, submitted on June 11, 2010, and appended to this letter, is approved. The timetable for submission of assessments of the REMS will remain the same as that approved on April 5, 2010.

There are no changes to the REMS assessment plan described in our April 5, 2010 letter.

We remind you that the requirements for assessments of an approved REMS under section 505-1(g)(3) include, in section 505-1(g)(3)(A), an assessment of the extent to which the elements to assure safe use are meeting the goal or goals to mitigate a specific serious risk listed in the labeling of the drug, or whether the goal or goals or such elements should be modified.

Assessments of an approved REMS must also include, under section 505-1(g)(3)(B) and (C), information on the status of any postapproval study or clinical trial required under section 505(o) or otherwise undertaken to investigate a safety issue. With respect to any such postapproval study, you must include the status of such study, including whether any difficulties completing the study have been encountered. With respect to any such postapproval clinical trial, you must include the status of such clinical trial, including whether enrollment has begun, the number of participants enrolled, the expected completion date, whether any difficulties completing the clinical trial have been encountered, and registration information with respect to requirements under subsections (i) and (j) of section 402 of the Public Health Service Act. You can satisfy these requirements in your REMS assessments by referring to relevant information included in the most recent annual report required under section 506B and 21 CFR 314.81(b)(2)(vii) and including any updates to the status information since the annual report was prepared. Failure to comply with the REMS assessments provisions in section 505-1(g) could result in enforcement action.

In addition to the assessments submitted according to the timetable included in the approved REMS, you must submit a REMS assessment and may propose a modification to the approved REMS when you submit a supplemental application for a new indication for use as described in section 505-1(g)(2)(A) of FDCA.

Prominently identify submissions containing REMS assessments or proposed modifications of the REMS with the following wording in bold capital letters at the top of the first page of the submission, as appropriate:

NDA 022272
REMS ASSESSMENT

NEW SUPPLEMENT FOR NDA 022272 -PRIOR APPROVAL SUPPLEMENT
PROPOSED REMS MODIFICATION
REMS ASSESSMENT

NEW SUPPLEMENT (NEW INDICATION FOR USE)
FOR NDA 022272
REMS ASSESSMENT
PROPOSED REMS MODIFICATION (if included)

If you do not submit electronically, please send 5 copies of REMS-related submissions.

LETTERS TO HEALTH CARE PROFESSIONALS

If you decide to issue a letter communicating important safety-related information about this drug product (i.e., a "Dear Health Care Professional" letter), we request that you submit, at least 24 hours prior to issuing the letter, an electronic copy of the letter to this NDA, to CDERMedWatchSafetyAlerts@fda.hhs.gov, and to the following address:

MedWatch
Food and Drug Administration
Suite 12B-05
5600 Fishers Lane
Rockville, MD 20857

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, call Lisa E. Basham, Senior Regulatory Health Project Manager, at (301) 796-1175.

Sincerely,

{See appended electronic signature page}

Larissa Lapteva, M.D., M.H.S.
Deputy Director for Safety
Division of Anesthesia and Analgesia Products
Office of Drug Evaluation II
Center for Drug Evaluation and Research

Enclosures:
- Package Insert
- REMS
  - Medication Guide
  - Dear Healthcare Professional Letter
  - The Healthcare Provider Guide, "Prescribing OxyContin Tablets: A Training Guide For Healthcare Providers
  - OxyContin Education Confirmation Form

Application Type/Number	Submission Type/Number	Submitter Name	Product Name
NDA-22272	SUPPL-5	PURDUE PHARMA INC	OXYCONTIN

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

/s/

LARISSA LAPTEVA
06/29/2010