



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
Rockville, MD 20857

NDA 20-553/S-059

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

Attention: Beth Connelly  
Assistant Director, US Regulatory Affairs

Dear Ms. Connelly:

Please refer to your supplemental new drug application dated October 26, 2007, received October 29, 2007, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for OxyContin (Oxycodone Hydrochloride) Controlled-Release Tablets.

We acknowledge receipt of your submission dated October 31, 2007.

This "Changes Being Effected" supplemental new drug application provides for changes to the PHARMACOKINETICS AND METABOLISM, DRUG ABUSE AND ADDICTION, ADVERSE REACTIONS, and PATIENT INFORMATION sections of the package insert.

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 agreed-upon labeling text.

The final printed labeling (FPL) must be identical to the enclosed labeling (text for the package insert, text for the patient package insert) and submitted labeling (package insert and patient package insert submitted October 31, 2007).

If you issue a letter communicating important information about this drug product (i.e., a "Dear Health Care Professional" letter), we request that you submit a copy of the letter to this NDA and a copy to the following address:

MEDWATCH  
Food and Drug Administration  
Suite 12B05  
5600 Fishers Lane  
Rockville, MD 20857

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

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If you have any questions, call Lisa Basham, Regulatory Project Manager, at (301) 796-1175.

Sincerely,

*{See appended electronic signature page}*

Bob Rappaport, MD  
Director  
Division of Anesthesia, Analgesia and  
Rheumatology Products  
Office of Drug Evaluation II  
Center for Drug Evaluation and Research

Enclosure

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**This is a representation of an electronic record that was signed electronically and  
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/s/

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Bob Rappaport  
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