



NDA 022272/S-011

**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 (sNDA) dated November 21, 2011, received November 22, 2011, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for OxyContin (oxycodone hydrochloride) Controlled-Release Tablets.

We acknowledge receipt of your amendment dated December 13, 2011, and January 12, 2012.

This supplemental new drug application proposes changes to the package insert to include “hyperalgesia” in the **ADVERSE REACTIONS** section as well as the inclusion of drug-drug interaction information pertaining to a post-marketing study requirement (for NDA 020553/S-060) to conduct an in vivo drug metabolism/drug interaction study in normal volunteers to assess the effect of ketoconazole on the metabolism of oxycodone and its known metabolites.

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.

Please also refer to your sNDA (S-010), dated August 17, 2011, which provides for the Extended-Release/Long Acting (ER/LA) Opioid Class REMS. With that effort, the package inserts for all ER/LA opioids with a pain indication have been standardized and revised to current standards. The revisions derived from both sNDAS have been combined in the attached approved labeling.

**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 and text for the

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

Sincerely,

*{See appended electronic signature page}*

Bob A. Rappaport, M.D.  
Director  
Division of Anesthesia, Analgesia,  
and Addiction Products  
Office of Drug Evaluation II  
Center for Drug Evaluation and Research

ENCLOSURE(S):  
Content of Labeling

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**This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.**  
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/s/  
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JUDITH A RACOOSIN on behalf of BOB A RAPPAPORT  
07/09/2012