DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 019516/S-043
NDA 022272/S-023

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 Applications (sNDAs) dated April 17, 2014, received April 23, 2014, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for MS CONTIN (morphine sulfate extended-release tablets) and OXYCONTIN (oxycodone hydrochloride extended-release tablets).

These "Changes Being Effected" supplemental new drug applications provide for revised immediate container labels for both drugs as well as revised carton labels and blister packs for OXYCONTIN. The revisions include changing the dosage form from "controlled-release tablets" to "extended-release tablets," and changing the established name and dosage form expression from " (drug substance controlled-release) Tablets" to " (drug substance extended-release tablets)" to conform with FDA and USP current standards.

APPROVAL & LABELING

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

CARTON AND IMMEDIATE CONTAINER LABELS

We acknowledge your April 17, 2014, submissions containing final printed carton and container labels for MS CONTIN and OXYCONTIN Tablets.

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}

Sharon Hertz, MD
Acting Director
Division of Anesthesia, Analgesia,
and Addiction Products
Office of Drug Evaluation II
Center for Drug Evaluation and Research

ENCLOSURE:
Carton and Container Labels

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

/s/

SHARON H HERTZ
10/22/2014