DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 20-553/S-035

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

Attention: J. Christopher Prue, R.Ph.
Senior Director, US Regulatory Affairs

Dear Mr. Prue:

Please refer to your supplemental new drug application dated June 11, 2003, received June 12, 2003, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for OxyContin (oxycodone hydrochloride) Controlled-Release Tablets.

This "Changes Being Effected" supplemental new drug application provides for a revised **ADVERSE REACTIONS** section of the package insert. The language *"and symptoms associated with either an anaphylactic or anaphylactoid reaction"* is added under **"General"** subsection.

We have completed our review of this application, and it is approved, effective on the date of this letter.

The final printed labeling (FPL) must be identical to the package insert submitted on June 11, 2003.

Please submit the FPL electronically according to the guidance for industry titled Providing Regulatory Submissions in Electronic Format – NDA. Alternatively, you may submit 20 paper copies of the FPL as soon as it is available, in no case more than 30 days after it is printed. Please individually mount 15 of the copies on heavy-weight paper or similar material. For administrative purposes, this submission should be designated "FPL for approved supplement NDA 20-553/S-035." Approval of this submission by FDA is not required before the labeling is used.

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, HFD-410
FDA
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).

If you have any questions, call Lisa Basham-Cruz, Regulatory Project Manager, at (301) 827-7410.

Sincerely,

{See appended electronic signature page}

Bob Rappaport, M.D.
Director
Division of Anesthetic, Critical Care, and Addiction Drug Products
Office of Drug Evaluation II
Center for Drug Evaluation and Research

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

/s/

Bob Rappaport

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