DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 20-553/S-022

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

Attention: Beth Connelly
Senior Regulatory Associate, U.S. Regulatory Affairs

Dear Ms. Connelly:

Please refer to your supplemental new drug application dated December 5, 2000, received December 6, 2000, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for OxyContin (oxycodone hydrochloride) 10, 20, 40, 80, and 160 mg Tablets.

We also refer to your amendments to the supplement, dated April 30, June 7, June 18, June 22, June 27, and July 12, 2001, and your meetings with the Agency on April 23, June 14, and July 16, 2001.

This supplemental new drug application provides for changes to the label that address the abuse, misuse and diversion of OxyContin.

We have completed the review of this supplemental application, as amended, and it is approved, effective as of the date of this letter.

The final printed labeling (FPL) must be identical to the enclosed labeling (text for the package insert).

Please submit the copies of final printed labeling (FPL) electronically according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format - NDA* (January 1999). Alternatively, you may submit 20 paper copies of the FPL as soon as it is available but no more than 30 days after it is printed. Please individually mount ten 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-022." Approval of this submission by FDA is not required before the labeling is used.

We acknowledge your agreement to issue a Dear Health Care Provider letter and to implement a focused Communication Plan regarding the changes added to the package insert regarding these findings and the Dear Health Care Provider letter.

In addition, please submit three copies of the introductory promotional materials that you propose to use for this product. All proposed materials should be submitted in draft or mock-up form, not final

print. Please submit one copy to this Division and two copies of both the promotional materials and the package insert directly to:

Division of Drug Marketing, Advertising, and Communications, HFD-42
Food and Drug Administration
5600 Fishers Lane
Rockville, Maryland 20857

We remind you that you must comply with the requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

If you have any questions, call Lisa Basham, Regulatory Project Manager, at (301) 827-7420.

Sincerely,

{See appended electronic signature page}

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

Enclosure