DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 20-553

DEC 12 1995

Purdue Pharma L.P.
100 Connecticut Avenue
Norwalk, Connecticut 06850-3590

Attention: James H. Conover, Ph.D.
Executive Director
Drug Regulatory Affairs and Compliance

Dear Dr. Conover:

Please refer to your December 28, 1994 new drug application submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for OxyContin (oxycodone hydrochloride) Controlled-Release Tablets, 10 mg, 20 mg, and 40 mg.

We acknowledge receipt of your amendments dated February 8, April 25, June 13, August 3, August 16, August 31, September 13, September 27, and November 29, 1995.

This new drug application provides for the management of moderate to severe pain in patients where use of an opioid analgesic is indicated for more than a few days.

We have completed the review of this application including the submitted draft labeling and have concluded that adequate information has been presented to demonstrate that the drug product is safe and effective for use as recommended in the enclosed draft labeling. Accordingly, the application is approved effective on the date of this letter.

The final printed labeling (FPL) must be identical to the enclosed draft labeling. Marketing the product with FPL that is not identical to this draft labeling may render the product misbranded and an unapproved new drug.

Please submit sixteen copies of the FPL as soon as it is available, in no case 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 "FINAL PRINTED LABELING" for approved NDA 20-553. Approval of this labeling by FDA is not required before it is used.

Should additional information relating to the safety and effectiveness of the drug become available, revision of that labeling may be required.

We remind you of your Phase 4 commitment specified in your submission dated December 1, 1995. This commitment, along with any completion dates agreed upon, is listed below:

> You have agreed to perform a pharmacokinetic study in a target pediatric population using a protocol to be developed jointly between you and the agency.

The protocol, data, and final report should be submitted to your IND for this product and a copy of the cover letter sent to this NDA. Should an IND not be required to meet your Phase 4 commitment, please submit the protocol, data and final report to this NDA as correspondence. For administrative purposes, all submissions, including labeling supplements, relating to this Phase 4 commitment must be clearly designated "Phase 4 Commitment". Please submit the protocol for this study as soon as possible. The original copy of the Phase 4 study protocol and reports should be submitted to this Division, with a copy to the Division of Drug Information Resources, HFD-80. Since that Division is responsible for tracking Phase 4 studies, a copy of all future communications regarding Phase 4 studies should also be sent to them.

Validation of the regulatory methods has not been completed. At the present time, it is the policy of the Center not to withhold approval because the methods are being validated. Nevertheless, we expect your continued cooperation to resolve any deficiencies that may occur.

Please submit one market package of the drug when it is available.

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, please contact:

Bonnie McNeal
Project Manager
(301) 443-3741

Sincerely yours,

Robert F. Bedford

Robert F. Bedford, M.D.
Acting Director
Division of Anesthetic, Critical Care
and Addiction Drug Products, HFD-170
Office of Drug Evaluation III
Center for Drug Evaluation and Research

ENCLOSURE (Labeling)

cc:
Original NDA 20-553
HFD-170/Div. files
HFD-170/CSO/B.McNeal
HFD-170/RBedford
HFD-170/CWright CW 12/8/95
HFD-170/PMaturu
HFD-170/BHayes
HFD-550/DBashaw
HFD-550/HLeung

HFD-2/M.Lumpkin
DISTRICT OFFICE
HF-2/medwatch (with labeling)
HFD-80 (with labeling)
HFD-240/S.Sherman (with labeling)
HFD-613 (with labeling - Only for applications with labeling.)
HFD-735/DBarash (with labeling)

drafted: BMc/December 1, 1995/nda20553.apr on N drive under cso/Bonnie

R/D Init. by: cMoody, cWright, mTheodorakis
final typed by: bMcNeal

Final Draft Init. by:

Peer: MO [illegible] 12-8-95
Peer: Chem _____
Peer: Pharm [illegible] 12-8-95
Peer: PK _____
Peer: Stat. _____

Acting Division Director,
Dr. Robert Bedford_____

APPROVAL