CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER: 20-553/S-024

APPROVAL LETTER

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 20-553/S-024

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

Attention: J. Christopher Prue, R.Ph.
Director, U.S. Regulatory Affairs

Dear Mr. Prue:

Please refer to your supplemental new drug application dated August 2, 2001, received August 3, 2001, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Oxycontin Controlled Release Tablets (oxycodone HCl) .

We acknowledge receipt of your submissions dated October 9, and December 7, 2001, and January 7 and 10, 2002.

This supplemental new drug application provides for a patient package insert for the drug product.

We have completed the review of this supplemental application, as amended, 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 agreed upon labeling text. Accordingly, the supplemental application is approved effective on the date of this letter.

The final printed labeling (FPL) must be identical to the enclosed labeling (text for the patient 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 heavyweight paper or similar material. For administrative purposes, this submission should be designated "FPL for approved supplement NDA 20-553/S-024." Approval of this submission by FDA is not required before the labeling is used.

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

If a letter communicating important information about this drug product (i.e., a "Dear Health Care Professional" letter) is issued to physicians and others responsible for patient care, we request that you submit a copy of the letter to this NDA and a copy to the following address:

MEDWATCH, HF-2
Food and Drug Administration
5600 Fishers Lane
Rockville, MD 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 Kimberly Compton, Regulatory Project Manager, at (301) 827-7432.

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

PATIENT INFORMATION

OXYCONTIN® Schedule II
(Oxycodone HCl Controlled-Release) Tablets

OxyContin® Tablets, 10 mg
OxyContin® Tablets, 20 mg
OxyContin® Tablets, 40 mg
OxyContin® Tablets, 80 mg
OxyContin® Tablets, 160 mg

Read this information carefully before you take OxyContin® (ox-e-CON-tin) tablets. Also read the information you get with your refills. There may be something new. This information does not take the place of talking with your doctor about your medical condition or your treatment. Only you and your doctor can decide if OxyContin is right for you. Share the important information in this leaflet with members of your household.

What Is The Most Important Information I Should Know About OxyContin®?

- **Use OxyContin the way your doctor tells you to.**
- **Use OxyContin only for the condition for which it was prescribed.**
- **OxyContin is not for occasional ("as needed") use.**
- **Swallow the tablets whole**. Do not break, crush, dissolve, or chew them before swallowing. OxyContin® works properly over 12 hours only when swallowed whole. **If a tablet is broken, crushed, dissolved, or chewed, the entire 12 hour dose will be absorbed into your body all at once. This can be dangerous, causing an overdose, and possibly death.**
- **Keep OxyContin® out of the reach of children.** Accidental overdose by a child is dangerous and may result in death.
- **Prevent theft and misuse.** OxyContin contains a narcotic painkiller that can be a target for people who abuse prescription medicines. Therefore, keep your tablets in a secure place, to protect them from theft. Never give them to anyone else . Selling or giving away this medicine is dangerous and against the law.

What is OxyContin®?

OxyContin® is a tablet that comes in several strengths and contains the medicine oxycodone (ox-e-KOE-done). This medicine is a painkiller like morphine. OxyContin treats moderate to severe pain that is expected to last for an extended period of time. Use OxyContin regularly during treatment. It

contains enough medicine to last for up to twelve hours.

Who Should Not Take OxyContin®?

Do not take OxyContin® if

- your doctor did not prescribe OxyContin® for you.
- your pain is mild or will go away in a few days.
- your pain can be controlled by occasional use of other painkillers.
- you have severe asthma or severe lung problems.
- you have had a severe allergic reaction to codeine, hydrocodone, dihydrocodeine, or oxycodone (such as Tylox, Tylenol with Codeine, or Vicodin. A severe allergic reaction includes a severe rash, hives, breathing problems, or dizziness.
- you had surgery less than 12 - 24 hours ago and you were not taking OxyContin just before surgery.
-

Your doctor should know about all your medical conditions before deciding if OxyContin is right for you and what dose is best. Tell your doctor about all of your medical problems, especially the ones listed below:

- trouble breathing or lung problems
- head injury
- liver or kidney problems
- adrenal gland problems, such as Addison's disease
- convulsions or seizures
- alcoholism
- hallucinations or other severe mental problems
- past or present substance abuse or drug addiction

If any of these conditions apply to you, and you haven't told your doctor, then you should tell your doctor before taking OxyContin.

If you are pregnant or plan to become pregnant, talk with your doctor. OxyContin may not be right for you. **Tell your doctor if you are breast feeding**. OxyContin will pass through the milk and may harm the baby.

Tell your doctor about all the medicines you take, including prescription and non-prescription medicines, vitamins, and herbal supplements. They may cause serious medical problems when taken with OxyContin, especially if they cause drowsiness.

How Should I Take OxyContin®?

- **Follow your doctor's directions exactly**. Your doctor may change your dose based on your reactions to the medicine. Do not change your dose unless your doctor tells you to change it. Do not take OxyContin more often than prescribed.
- **Swallow the tablets whole. Do not break, crush, dissolve, or chew before swallowing. If the**

tablets are not whole, your body will absorb too much medicine at one time. This can lead to serious problems, including overdose and death.

- **If you miss a dose**, take it as soon as possible. If it is almost time for your next dose, skip the missed dose and go back to your regular dosing schedule. Do not take 2 doses at once unless your doctor tells you to.
- **In case of overdose**, call your local emergency number or poison control center right away.
- **Review your pain regularly with your doctor** to determine if you still need OxyContin.
- **You may see tablets in your stools (bowel movements)**. Do not be concerned. Your body has already absorbed the medicine.

If you continue to have pain or bothersome side effects, call your doctor.

Stopping OxyContin. Consult your doctor for instructions on how to stop this medicine slowly to avoid uncomfortable symptoms. You should not stop taking OxyContin all at once if you have been taking it for more than a few days.

After you stop taking OxyContin, flush the unused tablets down the toilet.

What Should I Avoid While Take OxyContin®?

- **Do not drive, operate heavy machinery, or participate in any other possibly dangerous activities** until you know how you react to this medicine. OxyContin can make you sleepy.

- **Do not drink alcohol while using OxyContin. It may increase the chance of getting dangerous side effects.**

- **Do not take other medicines without your doctor's approval.** Other medicines include prescription and non-prescription medicines, vitamins, and supplements. Be especially careful about products that make you sleepy.

What are the Possible Side Effects of OxyContin®?.

Call your doctor or get medical help right away if

- your breathing slows down
- you feel faint, dizzy, confused, or have any other unusual symptoms

Some of the common side effects of OxyContin® are nausea, vomiting, dizziness, drowsiness, constipation, itching, dry mouth, sweating, weakness, and headache. Some of these side effects may decrease with continued use.

There is a risk of abuse or addiction with narcotic painkillers. If you have abused drugs in the past, you may have a higher chance of developing abuse or addiction again while using OxyContin. We do not know how often patients with continuing (chronic) pain become addicted to narcotics, but the risk has been reported to be small.

These are not all the possible side effects of OxyContin. For a complete list, ask your doctor or pharmacist.

General Advice About OxyContin

- Do not use OxyContin for conditions for which it was not prescribed.
- Do not give OxyContin to other people, even if they have the same symptoms you have. Sharing is illegal and may cause severe medical problems, including death.

This leaflet summarizes the most important information about OxyContin. If you would like more information, talk with your doctor. Also, you can ask your pharmacist or doctor for information about OxyContin that is written for health professionals.

CAUTION: Federal law prohibits dispensing without prescription.

Distributed by: PURDUE PHARMA L.P.
Stamford, CT 06901-3431, USA
January 10, 2002

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/s/

Cynthia McCormick
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CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER: 20-553/S-024

ADMINISTRATIVE DOCUMENTS

Project Manager's Labeling Review

NDAs: 20-553/S-024

Products: OxyContin (oxycodone HCl controlled-release) Tablets

Sponsor: Purdue

Date submitted: August 16, 2002

This submission contains the Final Printed Labeling (FPL) as requested in the approval letter dated January 15, 2002. The FPL submitted on August 16, 2002, is identical to the labeling text approved on January 15, 2002. The labeling should be acknowledged and retained.

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Parinda Jani
Chief, Project Management Staff

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/s/

Parinda Jani
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CSO

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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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:

We acknowledge receipt of your August 16, 2002, submission containing final printed labeling in response to our January 15, 2002, letter approving your supplemental new drug application for OxyContin (oxycodone HCl controlled-release) Tablets.

We have reviewed the labeling that you submitted in accordance with our January 15, 2002, letter and we find it acceptable.

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

Sincerely,

{See appended electronic signature page}

Parinda Jani
Chief, Project Management Staff
Division of Anesthetic, Critical Care, and Addiction Drug Products
Office of Drug Evaluation II
Center for Drug Evaluation and Research

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/s/

Parinda Jani
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