DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring, MD 20993

NDA 019034/S-025

SUPPLEMENT APPROVAL

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

Attention: Linda Camera
Senior Director, Regulatory Affairs CMC

Dear Ms. Camera:

Please refer to your Supplemental New Drug Application (sNDA) dated and received June 11, 2015, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Dilaudid® Injection (hydromorphone hydrochloride) 1 mg/mL, 2 mg/mL, and 4 mg/mL and Dilaudid-Hp® Injection (hydromorphone hydrochloride injection) 10 mg/mL.

We acknowledge receipt of your amendment dated December 2, 2015, which constituted a complete response to our November 13, 2015, action letter.

This prior approval supplemental application proposes the following changes:

1. a new packaging configuration for hydromorphone hydrochloride injection in a prefilled glass syringe and associated changes in manufacturer, manufacturing process and testing laboratories, with the 1 mg/mL, 2 mg/mL, and 4 mg/mL prefilled glass syringes having a clear plunger rod, and the 10 mg/mL strength prefilled glass syringes having a gray plunger rod,

2. a new active pharmaceutical ingredient manufacturer, (b) (4) for hydromorphone hydrochloride for use with the prefilled syringe product only,

3. new syringe labels, blister labels, product cartons, and stand-alone package insert for the prefilled syringe product,

4. (b) (4)

APPROVAL & LABELING

We have completed our review of this supplemental application, as amended. It is approved, effective on the date of this letter, for use as recommended in the agreed-upon labeling text approved today, December 16, 2016, with Supplement S-027.

CARTON AND IMMEDIATE CONTAINER LABELS

Submit final printed carton and immediate container labels that are identical to the enclosed carton and immediate container labels as soon as they are available, but no more than 30 days after they are printed. Please submit these labels electronically according to the guidance for industry *Providing Regulatory Submissions in Electronic Format – Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications (June 2008).* Alternatively, you may submit 12 paper copies, with 6 of the copies individually mounted on heavy-weight paper or similar material. For administrative purposes, designate this submission "**Final Printed Carton and Container Labels for approved NDA 019034/S-025**." Approval of this submission by FDA is not required before the labeling is used.

Marketing the product(s) with FPL that is not identical to the approved labeling text may render the product misbranded and an unapproved new drug.

PROMOTIONAL MATERIALS

You may request advisory comments on proposed introductory advertising and promotional labeling. To do so, submit the following, in triplicate, (1) a cover letter requesting advisory comments, (2) the proposed materials in draft or mock-up form with annotated references, and (3) the package insert(s) to:

OPDP Regulatory Project Manager
Food and Drug Administration
Center for Drug Evaluation and Research
Office of Prescription Drug Promotion (OPDP)
5901-B Ammendale Road
Beltsville, MD 20705-1266

Alternatively, you may submit a request for advisory comments electronically in eCTD format. For more information about submitting promotional materials in eCTD format, see the draft Guidance for Industry (available at: http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM443702.pdf).

You must submit final promotional materials and package insert(s), accompanied by a Form FDA 2253, at the time of initial dissemination or publication [21 CFR 314.81(b)(3)(i)]. Form FDA 2253 is available at http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM083570.pdf. Information and Instructions for completing the form can be found at http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM375154.pdf. For more information about submission of promotional materials to the Office of Prescription Drug Promotion (OPDP), see http://www.fda.gov/AboutFDA/CentersOffices/CDER/ucm090142.htm.

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 Diana L. Walker, Senior Regulatory Project Manager, at (301) 796-4029.

Sincerely,

{See appended electronic signature page}

Sharon Hertz, M.D.
Director
Division of Anesthesia, Analgesia, and
Addiction Products
Office of Drug Evaluation II
Center for Drug Evaluation and Research

ENCLOSURE:
Carton and Container Labeling

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
12/16/2016