DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 19-892/S-015

Abbott Laboratories
200 Abbott Park Road, Dept PA71/AP30-1E
Abbott Park, IL 60064-6157

Attention: Michael J. Walters
Senior Regulatory Affairs Specialist

Dear Mr. Walters:

Please refer to your supplemental new drug application dated July 9, 2007, received July 10, 2007, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for DILAUDID® (Hydromorphone HCL) Tablets, 8 mg.

We acknowledge receipt of your submission dated August 20, 2007.

This supplemental new drug application provides for 2-mg and 4-mg strength tablets.

We have completed our review of this supplemental new drug application, as amended, and it is approved, effective on the date of this letter, for use as recommended in the final printed labeling (FPL) submitted on July 9, 2007. We remind you of your agreement in a telephone conversation on November 7, 2007, with Lisa Basham, Regulatory Project Manager, to implement the following changes to the package labels at the next printing:

1. On the bottle, blister and carton labeling, ensure that the established name (e.g., Hydromorphone Hydrochloride) is at least ½ the size of the proprietary name and that it appears prominently in accordance with 21 CFR 201.10(g)(2). Additionally, please use the same style and font as the proprietary name.

2. On the bottle, blister and carton labeling, the product strength (i.e., 2 mg, 4 mg, or 8 mg) should include a space between the number and milligram abbreviation to improve readability on the container labels and carton labeling.

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
Food and Drug Administration
5515 Security Lane
HFD-001, Suite 5100
Rockville, MD 20852

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) 796-1175.

Sincerely,

{See appended electronic signature page}

Bob Rappaport, MD
Director
Division of Anesthesia, Analgesia and
Rheumatology 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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