DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 19-891/S-002
NDA 19-892/S-002

Abbott Laboratories
Pharmaceutical Products Division
100 Abbott Park Road
D-491, AP6B-1
Abbott Park, Illinois 60064-6108

Attention: David C. Ross, PharmD, MBA
Director, PPD Regulatory Affairs

Dear Dr. Ross:

Please refer to your supplemental new drug application dated, June 18, 1997, received, June 26, 1997, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Dilaudid (hydromorphone HCl, USP) Oral Liquid, 1 mg/mL (NDA 19-891), and Dilaudid (hydromorphone HCl, USP) Tablets, 8 mg (NDA 19-892).

We acknowledge receipt of your submissions dated, September 24, 2001.

Your submissions of September 24, 2001, constituted a complete response to our, December 5, 2000 action letter.

These supplemental new drug applications provide for changes to the PHARMACOKINETICS section of the package insert.

We have completed our review of these supplemental new drug applications, as amended, and have concluded that adequate information has been presented to demonstrate that the drugs are safe and effective for use as recommended in the final printed labeling submitted on September 24, 2001. Accordingly, the supplemental new drug applications are approved effective on the date of this letter.

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
FDA
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 Lisa E. Basham-Cruz, Regulatory Project Manager, at (301) 827-7420.

Sincerely,

{See appended electronic signature page}

Bob Rappaport, MD
Acting Director
Division of Anesthetic, Critical Care, and
Addiction Drug 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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