DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 19-891/S-008
NDA 19-892/S-009

Abbott Laboratories
200 Abbott Park Road, D-491, AP30-1E
Abbott Park, IL 60064-6157

Attention: Greg Murawski, MBA, RAC
Regulatory Affairs Manager

Dear Mr. Murawski:

Please refer to your supplemental new drug applications dated June 16, 2003, received June 17, 2003, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Dilaudid (hydromorphone hydrochloride) Tablets and Dilaudid (hydromorphone) Syrup.

We acknowledge receipt of your submissions dated July 11, 2003, and August 15, 2005.

Your submission of August 15, 2005, constituted a complete response to our November 10, 2004, action letter.

These supplemental new drug applications provide for revisions to the **DESCRIPTION, CLINICAL PHARMACOLOGY, WARNINGS, PRECAUTIONS, DRUG ABUSE AND DEPENDENCE**, and **OVERDOSAGE** sections of the package insert.

We have completed our review of these applications, as amended, and they are approved, effective on the date of this letter, for use as recommended in the agreed-upon labeling text.

The final printed labeling (FPL) must be identical to the enclosed labeling text for the package insert agreed upon in your email dated May 31, 2006.

Please submit an electronic version of the FPL according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format - NDA*. 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. Individually mount 15 of the copies on heavy-weight paper or similar material. For administrative purposes, designate these submissions "**FPL for approved supplement NDA 19-891/S-008 and NDA 19-892/S-009**." Approval of these submissions by FDA is not required before the labeling is used.

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
WO 22, Room 4447
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

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 Jason Hartman, Regulatory Project Manager, at (301) 796-2203.

Sincerely,

{See appended electronic signature page}

Bob Rappaport, M.D.
Director
Division of Anesthesia, Analgesia and Rheumatology Products
Office of Drug Evaluation II
Center for Drug Evaluation and Research

Enclosure

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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