DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 11-707/S-031

Endo Pharmaceuticals, Inc.
100 Endo Boulevard
Chadds Ford, PA 19317

Attention: Robert Barto
Senior Director, Regulatory Affairs

Dear Mr. Barto:

Please refer to your supplemental new drug application dated April 14, 2006, received April 17, 2006, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for OPANA (Oxymorphone Hydrochloride) Injection.

We acknowledge receipt of your submissions dated July 17, August 24, and September 29, 2006.

This supplemental new drug application provides for changes to the **DESCRIPTION**, **CLINICAL PHARMACOLOGY**, **INDICATIONS AND USAGE**, **CONTRAINDICATIONS**, **WARNINGS**, **PRECAUTIONS**, **ADVERSE REACTIONS**, **OVERDOSAGE**, **DOSAGE AND ADMINISTRATION**, and **HOW SUPPLIED** sections of the Package Insert, as well as updated carton and container labels.

We have completed our review of this application, as amended, and it is 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 and immediate container and carton labels) submitted September 29, 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 this submission "**FPL for approved supplement NDA 11-707/S-031**." Approval of this submission 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
5515 Security Lane
HFD-001, Suite 5100
Rockville, MD 20852

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 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

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

10/16/2006 12:09:24 PM