



NDA 21-610/S-001

NDA 21-611/S-001

Endo Pharmaceuticals
100 Endo Blvd.
Chadds Ford, PA 19317

Attention: Robert A. Barto
Senior Director, Regulatory Affairs

Dear Mr. Barto:

Please refer to your supplemental new drug applications dated June 30, 2006, received July 3, 2006, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for OPANA ER (Oxymorphone Hydrochloride) Extended-Release Tablets and OPANA (Oxymorphone Hydrochloride) Immediate-Release Tablets.

These "Changes Being Effected" supplemental new drug applications provide for changes to the "**WARNINGS/Misuse, Abuse and Diversion of Opioids**" section of the package insert.

We have completed our review of these applications, 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 inserts) and submitted labeling (package inserts submitted June 30, 2006), and must be formatted in accordance with the requirements of 21 CFR.

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 21-610/S-001,**" and "**FPL for approved supplement NDA 21-611/S-001.**" Approval of these submissions by FDA is not required before the labeling is used.

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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 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
8/2/2006 08:34:00 PM