



NDA 21-610/S-003

Endo Pharmaceuticals
100 Endo Blvd.
Chadds Ford, PA 19317

Attention: Ira Lentz
Associate Director, Regulatory Affairs/Labeling

Dear Mr. Lentz:

Please refer to your supplemental new drug application dated January 15, 2007, received January 17, 2007, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for OPANA[®] ER (Oxymorphone Hydrochloride) Extended-Release Tablets.

This "Changes Being Effected" supplemental new drug application provides for changes to the **DOSAGE AND ADMINISTRATION; Initiation of Therapy**; *Conversion from Other Oral Opioids to OPANA ER* subsection of the package insert.

We have completed our review of this application 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).

Within 21 days of the date of this letter, submit content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format, as described at <http://www.fda.gov/oc/datacouncil/spl.html>, that is identical in content to the enclosed labeling text for the package insert. For administrative purposes, designate this submission "**Content of Labeling for approved NDA 21-610/S-003.**" Upon receipt and verification that the content of labeling in SPL format is identical to the approved labeling text, we will transmit that version to the National Library of Medicine for public dissemination.

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

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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

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