DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-610/S-005

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

Attention: Mary Alice Raudenbush, MS
Vice President, Regulatory Affairs

Dear Ms. Raudenbush:

Please refer to your supplemental new drug application dated July 9, 2007, received July 10, 2007, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for OPANA ER (oxymorphone HCl) Extended-Release Tablets, 5 mg, 10 mg, 20 mg, and 40 mg.

This "Changes Being Effected in 30 days" supplemental new drug application provides for a change in the code imprint for all strengths of OPANA ER Tablets from black ink imprinting to debossing, with a change in the characters of the imprint code.

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 attached package insert and patient package insert, and the content of labeling [21 CFR 314.50(1)] in structured product labeling (SPL) format submitted on July 9, 2007.

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) 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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