DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 7-337/S-043

Endo Pharmaceuticals Inc.
177 Cantiague Rock Road
Westbury, NY 11590

Attention: Munira Rampersaud
Sr. Regulatory Associate

Dear Ms. Rampersaud:

Please refer to your supplemental new drug application dated February 9, 2006, received February 13, 2006, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Percodan® Tablets (Oxycodone and Aspirin Tablets, USP).

This "Changes Being Effected in 30 days" supplemental new drug application provides for the replacement of oxycodone terephthalate with oxycodone hydrochloride in Percodan® Tablets.

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 and immediate container and carton labels, which were submitted on February 9, 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 7-337/S-043**." 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
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}

Jim Vidra, PhD
Branch Chief
Branch VII, Division of Post-Marketing Evaluation
Office of New Drug Quality Assessment
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/

Jim Vidra

8/11/2006 11:47:30 AM