DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 18-024/S-040

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

Attention: Ira Lentz
Associate Director, Regulatory Affairs - Labeling

Dear Mr. Lentz:

Please refer to your supplemental new drug application dated February 22, 2005, received February 24, 2005, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for NUBAIN® (nalbuphine HCl) Injection.

We also refer to our teleconference on August 22, 2005.

This "Changes Being Effected" supplemental new drug application provides for changes to the WARNINGS and ADVERSE REACTIONS sections of the labeling as a result of routine monitoring.

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 labeling text agreed upon during your August 22, 2005, teleconference with Lisa Basham-Cruz of this Division.

The final printed labeling (FPL) must be identical to the enclosed labeling (text for the package insert).

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 18-024/S-040**." 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, HFD-410
FDA
5600 Fishers Lane
Rockville, MD 20857

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-Cruz, Regulatory Project Manager, at (301) 827-7420.

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

8/23/2005 05:07:24 PM