DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 7-337/S-029

Endo Pharmaceuticals
100 Painters Drive
Chadds Ford, PA 19317

Attention: Ira C. Lentz
Manager, Regulatory Affairs, Labeling

Dear Mr. Lentz:

Please refer to your supplemental new drug application dated July 2, 2001, received July 3, 2001, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for PERCODAN®/PERCODAN®-Demi (Oxycodone and Aspirin Tablets, USP).

We acknowledge receipt of your submissions dated December 13, 2001, and July 7 and December 11, 2003.

Your submission of December 11, 2003, constituted a complete response to our June 30, 2003, action letter.

We also refer to our teleconference on June 10, 2004.

This supplemental new drug application provides for substantial changes to the package inserts for PERCODAN® and PERCODAN-Demi.

We have completed our review of this application, as amended, and it is approved, effective on the date of this letter, for use as recommended in the labeling text agreed upon during our June 10, 2004, teleconference.

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

Please submit the FPL electronically 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, in no case more than 30 days after it is printed. Please individually mount 15 of the copies on heavy-weight paper or similar material. For administrative purposes, this submission should be designated "FPL for approved supplement NDA 7-337/S-029." 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, M.D.
Director
Division of Anesthetic, Critical Care, and
Addiction Drug 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/

Rigoberto Roca
6/10/04 06:10:47 PM
for Bob Rappaport, M.D.