DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 17-111/S-062

Endo Pharmaceuticals
Attention: Ira Lentz
Associate Director, Regulatory Affairs/Labeling
100 Endo Blvd.
Chadds Ford, PA 19317

Dear Mr. Lentz:

We acknowledge receipt of your supplemental new drug application submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Moban (molindone hydrochloride) tablets, dated and received February 20, 2008.

We additionally refer to e-mail communication from the Agency dated January 23, 2008, requesting revisions to your prescriber labeling.

This supplemental new drug application, submitted under "Changes Being Effected" provides for revisions to the Adverse Reactions-Extrapyramidal Symptoms-Dystonia section of labeling.

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 enclosed labeling text submitted on February 20, 2008.

We expect that the revised labeling would be available on your website within 10 days of receipt of this letter and that it would accompany any newly shipped product in a reasonable amount of time. Drug product already in distribution with currently approved labeling may remain in distribution.

Failure to make these changes within the specified period of time could make your product misbranded under 21 USC 321(n) and 352(a).

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 Sonny Saini, Pharm. D., Safety Regulatory Project Manager, at (301) 796-0532.

Sincerely,

{See appended electronic signature page}

Thomas Laughren, M.D.
Director
Division of Psychiatry Products
Office of Drug Evaluation I
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/

Thomas Laughren

3/12/2008 12:52:04 PM