**DEPARTMENT OF HEALTH & HUMAN SERVICES**

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 16-023/S-039
NDA 18-101/S-014

Endo Pharmaceuticals
Attention: Ira Lentz, Associate Director
100 Endo Boulevard
Chadds Ford, PA 19317

Dear Mr. Lentz:

Please refer to your supplemental new drug applications dated August 31, 2006, received August 5, 2006, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Symmetrel® (amantadine) syrup and Symmetrel® (amantadine) tablets.

Reference is also made to your submissions dated February 1, 2007.

These supplemental new drug applications provide for:

- Revisions to the PRECAUTIONS section of the package insert to include statements regarding the concurrent use of Influenza Virus Vaccine.

- Revisions to the ADVERSE REACTIONS-Hematologic sub-section of the package insert to include Agranulocytosis based on post-marketing experience.

We completed our review of these applications, as amended. These applications are approved, effective on the date of this letter, for use as recommended in the agreed-upon labeling text.

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 Paras M. Patel, R.Ph., Regulatory Project Manager, at (301) 796-0783.

Sincerely,

*{See appended electronic signature page}*

Debra Birnkrant, M.D.
Director
Division of Antiviral Products
Office of Antimicrobial Products
Center for Drug Evaluation and Research

Enclosure (Approved Labeling)

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**This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.**

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/s/

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Jeffrey Murray

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