DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 16-023/S-041
NDA 18-101/S-016

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

Dear Mr. Lentz:

Please refer to your supplemental new drug application dated and received January 26, 2009, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Symmetrel (amantadine hydrochloride) Syrup and Tablets.

These "Changes Being Effected" supplemental new drug applications update labeling to include revisions approved by the Division of Neurology Products (DNP) on December 31, 2008 for NDA 17-118/S-019. These additional changes from DNP provided information regarding melanoma and impulse control disorder to the PRECAUTIONS section of the package insert. In addition, Final Printed Labeling was provided to NDA 17-118 to incorporate the revisions approved by the Division of Antiviral Products on September 24, 2008 for NDA's 16-023/S-040 and 18-101/S-015. These revisions included a statement regarding resistance mutations in the INDICATIONS AND USAGE section.

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

CONTENT OF LABELING
The final printed labeling (FPL) must be identical to the submitted labeling (package insert submitted January 26, 2009).

PROMOTIONAL MATERIALS
You may request advisory comments on proposed introductory advertising and promotional labeling. To do so, submit, in triplicate, a cover letter requesting advisory comments, the proposed materials in draft or mock-up form with annotated references, and the package insert(s) to:

Food and Drug Administration
Center for Drug Evaluation and Research
Division of Drug Marketing, Advertising, and Communications
5901-B Ammendale Road
Beltsville, MD 20705-1266

As required under 21 CFR 314.81(b)(3)(i), you must submit final promotional materials, and the package insert(s), at the time of initial dissemination or publication, accompanied by a Form FDA 2253. For instruction on completing the Form FDA 2253, see page 2 of the Form. For more information about submission of promotional materials to the Division of Drug Marketing, Advertising, and Communications (DDMAC), see www.fda.gov/cder/ddmac.

LETTERS TO HEALTH CARE PROFESSIONALS
If you issue a letter communicating important safety related information about this drug product (i.e., a "Dear Health Care Professional" letter), we request that you submit an electronic copy of the letter to both this NDA and to the following address:

MedWatch
Food and Drug Administration
Suite 12B05
5600 Fishers Lane
Rockville, MD 20857

REPORTING REQUIREMENTS
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 Elizabeth Thompson, MS, Regulatory Project Manager, at (301) 796-0824.

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 (clean copy of approved label)

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

/s/

Kendall Marcus

2/2/2009 10:33:59 AM