DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 16-023/SLR-037
NDA 18-101/SLR-009

Endo Pharmaceuticals
Attention: Ira Lentz
Manager, Regulatory Affairs, Labeling
100 Painters Drive
Chadds, PA 19317

Dear Mr. Lentz:

Please refer to your Labeling Supplement-Changes Being Effected, dated October 15, 2003, received October 20, 2003, 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 provides for revisions to the WARNING, PRECAUTIONS, OVERDOSAGE, and ADVERSE REACTIONS sections of labeling as requested in an Agency letter dated June 19, 2002.

We have reviewed the final printed labeling that you submitted and have concluded that adequate information has been presented to demonstrate that the drug products are safe and effective for use as recommended in the agreed upon labeling text. Accordingly, this supplemental application is approved effective on the date of this letter. We note the Division of Neuropharmacological Drug Products has already approved these changes under NDA 17-118/S-008/S-009/S-011/S-014/S-015 in an approval letter issued on September 3, 2003.

We remind you that you must comply with the requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

If you have any questions, please contact Donald W. Reese, PharmD, MBA, Regulatory Project Manager, at (301) 827-2335.

Sincerely,

{See appended electronic signature page}

Jeffrey Murray, M.D., MPH
Deputy Division Director
Division of Antiviral Drug Products
Office of Drug Evaluation 4
Center for Drug Evaluation and Research

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

/s/

Jeffrey Murray
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