



NDA 17-118/S-017

Endo Pharmaceuticals
Attention: Robert A. Barto
Manager, Regulatory Affairs
100 Painters Drive
Chadds, PA 19317

Dear Mr. Barto:

Please refer to your supplemental new drug application dated February 11, 2003 received February 13, 2003, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Symmetrel (Amantadine Hydrochloride) Syrup.

This "Changes Being Effectuated" supplemental new drug application 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 completed our review of this supplemental new drug application. It is approved, effective on the date of this letter, for use as recommended in the final printed labeling (FPL) submitted on February 11, 2003.

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 the requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

If you have any questions, call CDR Teresa Wheelous, Sr. Regulatory Management Officer, at (301) 594-2850.

Sincerely Yours

Russell Katz, M.D.
Division Director
Division of Neuropharmacology Drug Products
Office of Drug Evaluation I
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/

Russell Katz

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