DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-487/SCF-006

Forest Laboratories, Inc.
Attention: Janice Kitson, Ph.D.
Harborside Financial Center, Plaza Three, Suite 602
Jersey City, NJ 07311

Dear Dr. Kitson:

Please refer to your supplemental new drug application dated February 25, 2005, received February 25, 2005 submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Namenda (memantine hydrochloride) Tablets, 5, 10, 15, 20 mg.

We acknowledge receipt of your submission dated April 28, 2005.

This supplemental new drug application provides for an alternative formulation that will eliminate the **(b)(4)** from the degradation profile of the drug product.

We completed our review of this application, as amended. This application is approved, effective on the date of this letter, for use as recommended in the agreed-upon labeling text.

The final printed labeling (FPL) must be identical to the submitted labeling (package insert submitted April 28, 2005.

Please submit an electronic version of the FPL according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format - NDA.* Alternatively, you may submit 20 paper copies of the FPL as soon as it is available but no more than 30 days after it is printed. Individually mount 15 of the copies on heavy-weight paper or similar material. For administrative purposes, designate this submission "**FPL for approved supplement NDA 21-487/SCF**-006. Approval of this submission by FDA is not required before the labeling is used.

If you have any questions, call Melina Griffis, R.Ph., Regulatory Project Manager, at (301) 594-5526.

Sincerely,

{See appended electronic signature page}

Russell Katz, M.D.
Director
Division of Neuropharmacological 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
5/17/05 08:37:19 AM