DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-487/S-002

Forest Laboratories, Inc.
Attention: Jehan Rowlands, Pharm. D.
Harborside Financial Center
Plaza 3, Suite 602
Jersey City, NJ 07311

Dear Dr. Rowlands:

Please refer to your supplemental new drug application dated May 24, 2004, received May 26, 2004, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Namenda tablets.

This supplemental new drug application provides for the establishment of a new regulatory analytical method and new specification for a recently discovered degradation product.

We completed our review of this supplemental new drug application. It is approved, effective on the date of this letter.

We remind you of the postmarketing study commitment in your submission dated September 22, 2004. The commitment is listed below.

1. To conduct a screen of 2 *in vitro* genotoxicity studies (point mutation and chromosomal aberration) to complete the requirements for qualification of the (b)(4)
   These study reports should be submitted within 3 months of the date of this letter.

Submit clinical protocols to your IND for this product. Submit nonclinical and chemistry, manufacturing, and controls protocols and all study final reports to this NDA. In addition, under 21 CFR 314.81(b)(2)(vii) and 314.81(b)(2)(viii), you should include a status summary of each commitment in your annual report to this NDA. The status summary should include expected summary completion and final report submission dates, any changes in plans since the last annual report, and, for clinical studies, number of patients entered into each study. All submissions, including supplements, relating to these postmarketing study commitments must be prominently labeled "**Postmarketing Study Protocol**", "**Postmarketing Study Final Report**", or "**Postmarketing Study Correspondence**."

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 Melina Griffis, R.Ph., Regulatory Project Manager, at (301)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

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