CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

21-627

APPROVAL LETTER

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-627

18-APR-05

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 new drug application (NDA) dated May 1, 2003 received May 2, 2003, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Namenda™ Oral Solution.

We acknowledge receipt of your submission dated February 15, 2005 which constituted a complete response to our February 20, 2004 action letter. We also acknowledge your submission dated April 14, 2005.

We completed our review of this application, as amended. It 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 enclosed labeling (text for package insert and patient package insert) and submitted labeling (immediate container and carton labels). Marketing the product(s) with FPL that is not identical to the approved labeling text may render the product misbranded and an unapproved new drug.

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 NDA 21-627.**" Approval of this submission by FDA is not required before the labeling is used.

Your request for a 24-month expiration dating period for Memantine HCl Oral Solution, 2 mg/mL is granted.

All applications for new active ingredients, new dosage forms, new indications, new routes of administration, and new dosing regimens are required to contain an assessment of the safety and effectiveness of the product in pediatric patients unless this requirement is waived or deferred. We are waiving the pediatric study requirement for this application.

In addition, submit three copies of the introductory promotional materials that you propose to use for this product. Submit all proposed materials in draft or mock-up form, not final print. Send one copy to this division and two copies of both the promotional materials and the package insert directly to:

Division of Drug Marketing, Advertising,
and Communications, HFD-42
Food and Drug Administration
5600 Fishers Lane
Rockville, MD 20857

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 Melina Griffis, R.Ph, Sr. 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

Enclosure

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Forest Laboratories, Inc.
Attention: Jehan Rowlands, Pharm. D.
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Dear Dr. Rowlands:

Please refer to your new drug application (NDA) dated May 1, 2003 received May 2, 2003, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Namenda™ Oral Solution.

We acknowledge receipt of your submissions dated:

July 3, 2003	August 28, 2003	February 10, 2004
August 8, 2003	December 29, 2003	

We completed our review of this application, as amended, and it is approvable. Before the application may be approved, however, it will be necessary for you to describe in the proposed product labeling how individual doses of memantine oral solution will be accurately measured. Currently, you have proposed [redacted] for measurement, however, [redacted] is not an accurate means of measuring individual doses, especially for a 5 mg dose of the memantine oral solution. We recommend that you look at approved labeling of other oral solution formulations of drugs for the treatment of Alzheimer's Disease which contain special instructions as to how individual doses should be measured (with a syringe). It is likely that you will also need to prepare a patient/caregiver instruction sheet to provide guidance in preparing and administering appropriate doses.

In addition, it will be necessary for you to submit draft/final labeling revised as follows:

1. Dosage and Administration-See embedded "note to sponsor" comment in the attached approvable labeling.

2. Container Labeling- The term "oral solution" should be part of the established name, and not appear with the strength.

We are recommending an [redacted] month expiration period for this drug product.

Validation of the regulatory methods has not been completed. At the present time, it is the policy of the Center not to withhold approval because the methods are being validated. Nevertheless, we expect your continued cooperation to resolve any problems that may be identified.

If additional information relating to the safety or effectiveness of this drug becomes available, revision of the labeling may be required.

Within 10 days after the date of this letter, you are required to amend this application, notify us of your intent to file an amendment, or follow one of your other options under 21 CFR 314.110. If you do not follow one of these options, we will consider your lack of response a request to withdraw the application under 21 CFR 314.65. Any amendment should respond to all the deficiencies listed. We will not process a partial reply as a major amendment nor will the review clock be reactivated until all deficiencies have been addressed.

The drug product may not be legally marketed until you have been notified in writing that the application is approved.

If you have any questions, call Melina Griffis, R.Ph., Sr. 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

20 Page(s) Withheld

_____ § 552(b)(4) Trade Secret / Confidential

✓ § 552(b)(4) Draft Labeling

_____ § 552(b)(5) Deliberative Process

Withheld Track Number: Approvable Letter- 1

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
2/20/04 01:58:55 PM