DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 21487/S-010, 012, 014
NDA 21627/S-008

SUPPLEMENT APPROVAL

Forest Laboratories, Inc.
Attention: Kathleen Waldron, MBA
Director, Regulatory Affairs
Harborside Financial Center
Plaza Five, Suite 1900
Jersey City, NJ 07311

Dear Ms. Waldron:

Please refer to your Supplemental New Drug Applications (sNDA), submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Namenda (memantine hydrochloride) Tablets, 5mg and 10mg, as described below:

Supplement 010
This "Changes Being Effected" supplemental new drug application, dated March 15, 2007, and received March 16, 2007, provides for the following changes to the Prescribing Information:

- addition of reported post-marketing events into the section titled "Adverse Reactions"
- addition of post-marketing experience into the section titled "Overdosage"

Supplement 012
This "Prior Approval" supplemental new drug application, dated May 9, 2007, and received May 10, 2007, proposes the following changes to the Prescribing Information:

- incorporation of results from study MEM-TX-23, "Memantine: Toxicity Study in the Juvenile Rat" into the section titled "Animal Toxicology"

Supplement 014
This "Prior Approval" supplemental new drug application, dated May 14, 2009, and received May 15, 2009, proposes the following changes to the Prescribing Information:

- updated formatting for compliance with the Federal Register final rule issued January 24, 2006, "Requirements on Content and Format of Labeling for Human Prescription Drug and Biological Products" [21 CFR 201.56 and 201.57], commonly referred to as the physician labeling rule (PLR).
- inclusion of results from the drug-drug interaction study MRZ90001-0519/1, "A Single Centre, Randomized, Double-Blinded, Placebo-Controlled, Multiple Dose, Three-Period One-Sequence Cross-Over Study of the Pharmacokinetics

Interaction of 30 mg Memantine on CYP2B6 with its Substrate Bupropion in Healthy Male Volunteers", into the section titled "Drug Interactions"

- inclusion of results from the drug-drug interaction study 11653A, "Randomized, Double-Blind, Placebo-Controlled, Two-Sequence Crossover Interaction Study Investigating the Effect of Memantine on the Pharmacokinetics and Pharmacodynamics of Warfarin in Healthy Men", into the section titled "Drug Interactions"
- addition of reported post-marketing events received through September 30, 2008, into the section titled "Adverse Reactions"
- addition of post-marketing experience received through September 30, 2008, into the section titled "Overdosage"

Please also refer to your Supplemental New Drug Application (sNDA) dated May 14, 2009, received May 15, 2009, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Namenda (memantine hydrochloride) Solution, as described below:

Supplement 008
This "Prior Approval" supplemental new drug application proposes changes identical to supplement 014, as stated above.

We acknowledge receipt of your amendments dated April 11, 2007, February 16, 2010, April 27, 2012, and May 30, 2013.

We have completed our review of these supplemental applications, as amended. They are approved, effective on the date of this letter, for use as recommended in the enclosed, agreed-upon labeling text.

CONTENT OF LABELING

As soon as possible, but no later than 14 days from the date of this letter, submit the content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format using the FDA automated drug registration and listing system (eLIST), as described at http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm. Content of labeling must be identical to the enclosed labeling (text for the package insert, text for the patient package insert, and instructions for use), with the addition of any labeling changes in pending "Changes Being Effected" (CBE) supplements, as well as annual reportable changes not included in the enclosed labeling.

Information on submitting SPL files using eList may be found in the guidance for industry titled "SPL Standard for Content of Labeling Technical Qs and As at http://www.fda.gov/downloads/DrugsGuidanceComplianceRegulatoryInformation/Guidances/UCM072392.pdf

The SPL will be accessible from publicly available labeling repositories.

Also within 14 days, amend all pending supplemental applications that includes labeling changes for this NDA, including CBE supplements for which FDA has not yet issued an action letter, with the content of labeling [21 CFR 314.50(l)(1)(i)] in MS Word format, that includes the changes approved in these supplemental applications, as well as annual reportable changes and annotate each change. To facilitate review of your submission, provide a highlighted or marked-up copy that shows all changes, as well as a clean Microsoft Word version. The marked-up copy should provide appropriate annotations, including supplement number(s) and annual report date(s).

REQUIRED PEDIATRIC ASSESSMENTS

Under the Pediatric Research Equity Act (PREA) (21 U.S.C. 355c), all applications for new active ingredients, new indications, new dosage forms, new dosing regimens, or new routes of administration are required to contain an assessment of the safety and effectiveness of the product for the claimed indication(s) in pediatric patients unless this requirement is waived, deferred, or inapplicable.

Because none of these criteria apply to your application, you are exempt from this requirement.

REPORTING REQUIREMENTS

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 Tracy Peters, Regulatory Project Manager, at (301) 796-2953.

Sincerely,

{See appended electronic signature page}

Eric Bastings, M.D.
Acting Director
Division of Neurology Products
Office of Drug Evaluation I
Center for Drug Evaluation and Research

ENCLOSURE(S):
Content of Labeling

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

/s/

ERIC P BASTINGS
10/24/2013