CENTER FOR DRUG EVALUATION AND RESEARCH

Approval Package for:

APPLICATION NUMBER:

206439Orig1s000

Trade Name:	Namzaric Capsules 14mg/10mg and 28mg/10mg.
Generic Name:	memantine hydrochloride extended-release/donepezil hydrochloride
Sponsor:	Forest Laboratories, Inc.
Approval Date:	December 23, 2014
Indication:	For the treatment of moderate to severe dementia of the Alzheimer's type in patients stabilized on either of the following regimens: • Memantine hydrochloride (10mg twice daily or 28 mg extended-release once daily) and donepezil hydrochloride 10 mg. • Memantine hydrochloride (5 mg twice daily or 14 mg extended-release once daily) and donepezil hydrochloride 10 mg.

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APPLICATION NUMBER:

206439Orig1s000

APPROVAL LETTER

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 206439

NDA APPROVAL

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

Dear Ms. Waldron:

Please refer to your New Drug Application (NDA) dated February 26, 2014, received February 26, 2014, submitted pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Namzaric (memantine hydrochloride extended-release/donepezil hydrochloride) Capsules 14mg/10mg and 28mg/10mg.

We acknowledge receipt of your amendments dated:

February 27, 2014	May 29, 2014	June 10, 2014
June 19, 2014	August 7, 2014	September 3, 2014
November 21, 2014	December 8, 2014	December 19, 2014
December 23, 2014		

This new drug application provides for the use of for Namzaric (memantine hydrochloride extended-release/donepezil hydrochloride) Capsules 14mg/10mg and 28mg/10mg for the treatment of moderate to severe dementia of the Alzheimer's type in patients stabilized on either of the following regimens:

- memantine hydrochloride (10 mg twice daily or 28 mg extended-release once daily) and donepezil hydrochloride 10 mg
- memantine hydrochloride (5 mg twice daily or 14 mg extended-release once daily) and donepezil hydrochloride 10 mg

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

WAIVER OF HIGHLIGHTS SECTION

We acknowledge your request to waive the requirements of 21 CFR 201.57(d)(8) regarding the length of the Highlights of Prescribing Information section. As previously communicated to you, we are denying your request.

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, and text for the patient package insert). Information on submitting SPL files using eLIST may be found in the guidance for industry *SPL Standard for Content of Labeling Technical Qs and As*, available at http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM072392.pdf.

The SPL will be accessible via publicly available labeling repositories.

CARTON AND IMMEDIATE CONTAINER LABELS

Submit final printed carton and immediate container labels that are identical to the carton and immediate container labels submitted on December 23, 2014, as soon as they are available, but no more than 30 days after they are printed. Please submit these labels electronically according to the guidance for industry *Providing Regulatory Submissions in Electronic Format – Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications (June 2008)*. Alternatively, you may submit 12 paper copies, with 6 of the copies individually mounted on heavy-weight paper or similar material. For administrative purposes, designate this submission "**Final Printed Carton and Container Labels for approved NDA 206439**." Approval of this submission by FDA is not required before the labeling is used.

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.

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.

We are waiving the pediatric study(ies) requirement for this application because dementia of the Alzheimer's type does not occur in children and the necessary studies are, therefore, impossible.

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