



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
Rockville, MD 20857

NDA 21-487/SLR-008  
NDA 21-627/SLR-001

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

Dear Dr. Rowlands:

Please refer to your supplemental new drug applications submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Namenda (memantine hydrochloride) Tablets and Oral Solution.

These supplemental new drug applications provide for new wording to the Clinical Pharmacology and Precautions sections of labeling to describe Study MEM-PK-15 conducted in patients with hepatic impairment.

We completed our review of these applications, as amended. These applications are approved, effective on the date of this letter, for use as recommended in the labeling text submitted August 31, 2006

The final printed labeling (FPL) must be identical to the submitted labeling (package insert submitted March 8, 2006).

Please submit an electronic version of the FPL according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format - NDA*. For administrative purposes, designate this submission "**FPL for approved supplement NDA 21-487/SLR-007 and NDA 21-627/SLR-002**". 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 Neurology 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  
10/4/2006 04:52:30 PM