DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville, MD 20857

ANDA 090048

Dr. Reddy's Laboratories, Inc.
U.S. Agent for: Dr. Reddy's Laboratories Limited
Attention: Kumara Sekar, Ph.D.
Sr. Director, Global Regulatory Affairs
200 Somerset Corporate Blvd., 7th Floor
Bridgewater, NJ 08807

Dear Sir:

This is in reference to your abbreviated new drug application (ANDA) dated October 16, 2007, submitted pursuant to section 505(j) of the Federal Food, Drug, and Cosmetic Act (the Act), for Memantine Hydrochloride Tablets, 5 mg and 10 mg.

Reference is made to your amendments dated March 14, April 15, October 31, November 17, and December 2, 2008; December 2, 2009; and March 24, and April 2, 2010.

We have completed the review of this ANDA and have concluded that adequate information has been presented to demonstrate that the drug is safe and effective for use as recommended in the submitted labeling. Accordingly the ANDA is approved, effective on the date of this letter. The Division of Bioequivalence has determined your Memantine Hydrochloride Tablets, 5 mg and 10 mg, to be bioequivalent and, therefore, therapeutically equivalent to the reference listed drug (RLD), Namenda Tablets, 5 mg and 10 mg, respectively, of Forest Laboratories, Inc. (Forest). Your dissolution testing should be incorporated into the stability and quality control program using the same method proposed in your application.

The RLD upon which you have based your ANDA, Forest's Namenda Tablets, is subject to a period of patent protection. As noted in the agency's publication titled Approved Drug Products with Therapeutic Equivalence Evaluations (the "Orange Book"), U.S. Patent No. 5,061,703 (the '703 patent) is scheduled to expire on April 11, 2015.

Your ANDA contains a paragraph IV certification under section 505(j)(2)(A)(vii)(IV) of the Act stating that the '703 patent is invalid, unenforceable, or will not be infringed by your manufacture, use, or sale of Memantine Hydrochloride Tablets, 5 mg and 10 mg, under this ANDA. Section 505(j)(5)(B)(iii) of the Act provides that approval of an ANDA shall be made effective immediately, unless an action was brought against Dr. Reddy's Laboratories Limited (DRL) for infringement of the listed '703 patent. You notified the agency that DRL complied with the requirements of section 505(j)(2)(B) of the Act, and that litigation for infringement of the '703 patent was brought against DRL within the statutory 45-day period in the United States District Court for the District of Delaware [Forest Laboratories, Inc., Forest Laboratories Holdings, Ltd., Merz Pharma GmbH & Co. KGaA, and Merz Pharmaceuticals GmbH v. Dr. Reddy's Laboratories Limited, Civil Action No. 1:08-cv-0021]. You also notified the agency that Forest Laboratories, Inc. and DRL agreed to the dismissal of this case, making your ANDA eligible for approval.

With respect to 180-day generic drug exclusivity, we note that DRL was one of the first ANDA applicants to submit a substantially complete ANDA with a paragraph IV certification to the '703 patent. Therefore, with this approval, DRL is eligible for 180 days of generic drug exclusivity for Memantine Hydrochloride Tablets, 5 mg and 10 mg. This exclusivity, which is provided for under section 505(j)(5)(B)(iv) of the Act, will begin to run from the commercial marketing date identified in section 505(j)(5)(B)(iv). Please submit correspondence to this ANDA informing the agency of the date the exclusivity begins to run.

Under section 506A of the Act, certain changes in the conditions described in this ANDA require an approved supplemental application before the change may be made.

Please note that if FDA requires a Risk Evaluation & Mitigation Strategy (REMS) for a listed drug, an ANDA citing that listed drug also will be required to have a REMS. See section 505-1(i) of the Act.

Postmarketing reporting requirements for this ANDA are set forth in 21 CFR 314.80-81 and 314.98. The Office of Generic Drugs should be advised of any change in the marketing status of this drug.

Promotional materials may be submitted to FDA for comment prior to publication or dissemination. Please note that these submissions are voluntary. If you desire comments on proposed launch promotional materials with respect to compliance with applicable regulatory requirements, we recommend you submit, in draft or mock-up form, two copies of both the promotional materials and package insert directly to:

Food and Drug Administration
Center for Drug Evaluation and Research
Division of Drug Marketing, Advertising, and Communications
5901-B Ammendale Road
Beltsville, MD 20705

We call your attention to 21 CFR 314.81(b)(3) which requires that all promotional materials be submitted to the Division of Drug Marketing, Advertising, and Communications with a completed Form FDA 2253 at the time of their initial use.

Within 14 days of the date of this letter, submit updated content of labeling [21 CFR 314.50(1)] in structured product labeling (SPL) format, as described at http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm, that is identical in content to the approved labeling. For administrative purposes, please designate this submission as ***"LABELING/SPL FINAL for Approved ANDA 090048".***

Sincerely yours,

{See appended electronic signature page}

Keith Webber, Ph.D.
Deputy Director
Office of Pharmaceutical Science
Center for Drug Evaluation and Research

Application Type/Number	Submission Type/Number	Submitter Name	Product Name
ANDA-90048	ORIG-1	DR REDDYS LABORATORIES LTD	MEMANTINE HYDROCHLORIDE

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

/s/

ROBERT L WEST
04/14/2010
Deputy Director, Office of Generic Drugs
for Keith Webber, Ph.D.