DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville, MD 20857

ANDA 77-130

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

Dear Sir:

This is in reference to your abbreviated new drug application (ANDA) dated April 21, 2004, submitted pursuant to section 505(j) of the Federal Food, Drug, and Cosmetic Act (the Act), for Rivastigmine Tartrate Capsules, 1.5 mg (base), 3 mg (base), 4.5 mg (base), and 6 mg (base).

Reference is also made to our tentative approval letter dated June 13, 2006, and to your amendments dated January 21, March 31, and August 30, 2005; January 4, and March 17, 2006; and July 25, 2007.

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 Rivastigmine Tartrate Capsules, 1.5 mg (base), 3 mg (base), 4.5 mg (base), and 6 mg (base) to be bioequivalent and, therefore, therapeutically equivalent to the reference listed drug (RLD), Exelon Capsules, 1.5 mg (base), 3 mg (base), 4.5 mg (base), and 6 mg (base), respectively, of Novartis Pharmaceuticals Corp. (Novartis). Your dissolution testing should be incorporated into the stability and quality control program using the same method proposed in your ANDA.

The RLD upon which you have based your ANDA, Exelon Capsules of Novartis, is subject to periods of patent protection. As noted in the agency's publication titled Approved Drug Products with Therapeutic Equivalence Evaluations (the "Orange Book"), U.S. Patent Nos. 4,948,807 (the '807 patent) and 5,602,176 (the '176

patent) are scheduled to expire on August 14, 2012, and February 11, 2014, respectively.

Your ANDA contains paragraph IV certifications to each of these patents under section 505(j)(2)(A)(vii)(IV) of the Act stating that each patent is invalid, unenforceable, or will not be infringed by your manufacture, use, or sale of Rivastigmine Tartrate Capsules, 1.5 mg (base), 3 mg (base), 4.5 mg (base), and 6 mg (base), under this ANDA. Section 505(j)(5)(B)(iii) of the Act provides that approval of an ANDA shall be made effective immediately unless action was brought against Dr. Reddy's Laboratories Limited (DRL) for infringement of one or both of these patents that were the subjects of paragraph IV certifications. This action must have been brought against DRL prior to the expiration of 45 days from the date the notice you provided under section 505(j)(2)(B) was received by the NDA/patent holder(s). You notified the agency that DRL complied with the requirements of section 505(j)(2)(B) of the Act for each of the listed patents, and within the statutory 45-day period litigation for infringement of the '176 and '807 patents was brought against DRL in the United States District Court

Final approval of this ANDA is granted pursuant to sections 505(j)(5)(B)(iii)) and 505(j)(5)(F)(ii) of the Act, the expiration of the 7½ year period from the date of approval of the RLD, October 21, 2007.

With this approval, DRL is eligible to share 180-day generic drug exclusivity for Rivastigmine Tartrate Capsules, 1.5 mg (base), 3 mg (base), 4.5 mg (base), and 6 mg (base) under section 505(j)(5)(B)(iv) of the Act. This is because the agency has concluded that DRL was among the first ANDA applicants to submit a substantially complete ANDA for Rivastigmine Tartrate Capsules, 1.5 mg (base), 3 mg (base), 4.5 mg (base), and 6 mg (base), containing a paragraph IV certification to the '807 and '176 patents. This exclusivity will begin to run from the date of first commercial marketing of the drug product. Please submit correspondence to your ANDA to inform the agency of this date.

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.

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.

Sincerely yours,

{See appended electronic signature page}

Gary Buehler
Director
Office of Generic Drugs
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/

Robert L. West
10/31/2007 11:00:32 AM
for Gary Buehler