DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville, MD 20857

ANDA 77-131

Kendle Regulatory Affairs
Attention: Anthony Celeste, Senior Vice President
U.S. Agent for: Sun Pharmaceutical Industries, Ltd.
7361 Calhoun Place, Suite 500
Rockville, MD 20855

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 the tentative approval letter issued by this office on March 29, 2006, and to your amendments dated April 22, and September 21, 2005, and August 31, and October 9, 2007.

We have completed the review of this ANDA and have concluded that adequate information has been provided 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, Novartis' Exelon Capsules, 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 under section 505(j)(2)(A)(vii)(IV) of the Act

stating that each of these patents 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 Sun Pharmaceutical Industries, Ltd. (Sun) for infringement of one or both of these patents that were the subjects of paragraph IV certifications. This action must have been brought against Sun 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 Sun 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 Sun in the United States District Court for the Northern District of Illinois Eastern Division [Novartis Pharmaceuticals Corp., Novartis AG, Novartis Pharma AG and Novartis International Pharmaceutical Ltd. v. Sun Pharmaceutical Industries, Ltd., Civil Action No. 04C 5477.

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, Sun 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 Sun 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.

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
10/22/2007 04:40:02 PM
for Gary Buehler