DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville, MD 20857

ANDA 076786

Ranbaxy Inc.
U.S. Agent for: Ranbaxy Laboratories Limited
Attention: Scott D. Tomsky
600 College Road East
Princeton, NJ 08540

Dear Sir:

This is in reference to your abbreviated new drug application (ANDA) dated June 30, 2003, submitted pursuant to section 505(j) of the Federal Food, Drug, and Cosmetic Act (the Act), for Donepezil Hydrochloride Tablets, 5 mg and 10 mg.

Reference is also made to the tentative approval letters issued by this office on February 23, 2005, and December 5, 2007, and to your amendments dated June 28, July 12, September 14, September 24, October 26 and November 24, 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 Donepezil Hydrochloride Tablets, 5 mg and 10 mg, to be bioequivalent and, therefore, therapeutically equivalent to the reference listed drug, Aricept Tablets, 5 mg and 10 mg, respectively, of Eisai Inc. (Eisai). Your dissolution testing should be incorporated into the stability and quality control program using the same method proposed in your ANDA.

The reference listed drug (RLD) upon which you have based your ANDA, Eisai's Aricept Tablets, 5 mg and 10 mg, is subject to periods of patent protection. The following unexpired patents and expiration dates are currently listed in the agency's publication titled Approved Drug Products with Therapeutic Equivalence Evaluations (the "Orange Book") for this drug product:

Patent Number	Expiration Date
5,985,864 (the '864 patent)	December 30, 2016
6,140,321 (the '321 patent)	December 30, 2016
6,245,911 (the '911 patent)	December 1, 2018
6,372,760 (the '760 patent)	March 31, 2019

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 Donepezil Hydrochloride Tablets, 5 mg and 10 mg, under this ANDA. You have notified the agency that Ranbaxy Inc. (Ranbaxy) complied with the requirements of section 505(j)(2)(B) of the Act, and that no action for patent infringement of any of these patents was brought against Ranbaxy within the statutory 45-day period, which action would have resulted in a 30-month stay of approval under section 505(j)(5)(B)(iii).

With respect to 180-day generic drug exclusivity, we note that Ranbaxy was the first ANDA applicant for Donepezil Hydrochloride Tablets, 5 mg and 10 mg, to submit a substantially complete ANDA with paragraph IV certifications to the '864, '321, '911 and '760 patents. Therefore, with this approval, Ranbaxy is eligible for 180 days of generic drug exclusivity for Donepezil Hydrochloride Tablets, 5 mg and 10 mg. This exclusivity, which is provided for under section 505(j)(5)(8)(iv) of the Act,[1] will begin to run from the earlier of the commercial marketing or court decision dates identified in section 505(j)(5)(B)(iv). Please submit correspondence to the 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.

The agency approved a revision to the labeling of the RLD within 60 days of the expiration of the '841 patent, which expired on November 25, 2010. This revision to the labeling of the RLD does not include a change to the WARNINGS section, and the agency has not determined that the continued presence of the labeling in effect before the revision will adversely impact the safe use of

[1] Because your ANDA was filed before the date of enactment of the Medicare Prescription Drug, Improvement and Modernization Act (MMA)(Public Law 108-173) on December 8, 2003, this reference to the 180-day exclusivity provision is to the section of the Act as in effect prior to December 8, 2003. See MMA § 1102(b)(1).

the drug. The agency has also determined that your ANDA meets the applicable standards for approval under section 505(j), and was otherwise eligible for approval but for expiration of the '841 patent. Therefore, under section 505(j)(10) of the Act, your ANDA is eligible for approval with labeling that differs from that of the RLD. You are hereby notified that you are required to change the labeling of your product to contain the revision that was approved on November 24, 2010 for Aricept Tablets, 5 mg and 10 mg. Acceptance of this letter constitutes your agreement to submit a "Supplement – Changes Being Effected" containing such revised labeling no later than 60 days from the date of the notification.

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.

As soon as possible, but no later than 14 days from the date of this letter, submit, using the FDA automated drug registration and listing system (eLIST), the content of labeling [21 CFR 314.50(l)] 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 (including the package insert, and any patient package insert and/or Medication Guide that may be required). Information on submitting SPL files using eLIST may be found in the guidance for industry titled "SPL Standard for Content of Labeling Technical Qs and As" at http://www.fda.gov/downloads/DrugsGuidanceComplianceRegulatoryInformation/Guidances/U_CM072392.pdf

The SPL will be accessible via publicly available labeling repositories.

Sincerely yours,

{See appended electronic signature page}

Keith Webber, Ph.D.
Deputy Director
Office of Pharmaceutical Science
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

11/26/2010

Deputy Director, Office of Generic Drugs
for Keith Webber, Ph.D.