DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 22568/S-005
NDA 20690/S-035
NDA 21720/S-008

SUPPLEMENT APPROVAL

Eisai Inc.
Attention: Carlos Langezaal, PhD
Director, Global Regulatory Affairs CFU
1155 Tice Boulevard
Woodcliff Lake, NJ 07677

Dear Dr. Langezaal:

Please refer to your Supplemental New Drug Applications (sNDA) dated February 24, 2012, received February 24,2012, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Aricept **(**donepezil hydrochloride) Tablets 23 mg, Aricept **(**donepezil hydrochloride) Tablets 5 mg and 10 mg, Aricept **(**donepezil hydrochloride) ODT (orally disintegrating tablets) 5 mg and 10 mg.

These Prior Approval supplemental new drug applications provide for the removal of the last sentence of the first paragraph of *Study Outcome Measures*: under **Study of 23 mg/day** found in the Clinical Studies Section (14.2) of labeling. The specific deleted sentence follows:

"This study showed that patients on 23 mg/day experienced important clinical benefit on both measures compared to 10 mg/day."

We have completed our review of these supplemental applications. They are approved, effective on the date of this letter, for use as recommended in the enclosed, agreed-upon labeling text.

As soon as possible, but no later than 14 days from the date of this letter, submit the content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format using the FDA automated drug registration and listing system (eLIST), as described at http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm. Content of labeling must be identical to the enclosed labeling (text for the package insert), with the addition of any labeling changes in pending "Changes Being Effected" (CBE) supplements, as well as annual reportable changes not included in the enclosed labeling.

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/UCM072392.pdf.

The SPL will be accessible from publicly available labeling repositories.

Also within 14 days, amend all pending supplemental applications for this NDA, including CBE supplements for which FDA has not yet issued an action letter, with the content of labeling [21 CFR 314.50(l)(1)(i)] in MS Word format, that includes the changes approved in this supplemental application, as well as annual reportable changes and annotate each change. To facilitate review of your submission, provide a highlighted or marked-up copy that shows all changes, as well as a clean Microsoft Word version. The marked-up copy should provide appropriate annotations, including supplement number(s) and annual report date(s).

REPORTING REQUIREMENTS

We remind you that you must comply with reporting requirements for an approved NDA (21 CFR 314.80 and 314.81).

If you have any questions, call Teresa Wheelous, Sr. Regulatory Project Manager, at (301) 796-1161.

Sincerely,

{See appended electronic signature page}

Russell G. Katz, M.D.
Director
Division of Neurology Products
Office of Drug Evaluation I
Center for Drug Evaluation and Research

ENCLOSURE(S):
Content of Labeling

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

/s/

RUSSELL G KATZ
03/07/2012