



NDA 20690 / S036
NDA 21720 / S009
NDA 22568 /S006

SUPPLEMENT APPROVAL

Eisai Inc.
Attention: Carlos Langezaal
Director, Global Regulatory Affairs
155 Tice Blvd
Woodcliff Lake, NJ 07677

Dear Mr. Langezaal:

We have received your Supplemental New Drug Applications (sNDA) submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA or the Act) for the following:

NDA NUMBERS: 20690
21720
22568

SUPPLEMENT NUMBERS: S-036
S-009
S-006

PRODUCT NAMES: Aricept (donepezil hydrochloride) 5mg and 10 mg Tablet
Aricept (donepezil hydrochloride) ODT
Aricept (donepezil hydrochloride) 23 mg Tablets

We acknowledge receipt of your amendments dated April 10, 2012 and May 16, 2012.

These Prior Approval supplemental new drug applications provide for labeling changes that reflect the results of two Clinical Pharmacology post-marketing requirements (PMR1662-2 and PMR1662-3), while using the content and format guidelines recommended in the recently released Drug-Drug interaction guidance for industry. The DRUG INTERACTIONS (Section 7) and CLINICAL PHARMACOLOGY (Section 12) sections have been revised to reflect the guidance recommended content and format, as well as, the results of the two Clinical Pharmacology post-marketing studies.

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

We note that your May 16, 2012, submissions include final printed labeling (FPL) for your: package insert, patient package insert. We have not reviewed this FPL. You are responsible for assuring that the wording in this printed labeling is identical to that of the approved content of labeling in the structured product labeling (SPL) format.

CONTENT OF LABELING

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, text for the patient 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).

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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
09/04/2012