



NDA 22568/S-004
NDA 20690/S-033
NDA 21720/S-006

SUPPLEMENT APPROVAL

Eisai Inc.
Attention: Martina Struck, Ph.D.
Senior Director, Global Regulatory Affairs CFU
300 Tice Blvd.
Woodcliff Lake, NJ 07677

Dear Dr. Struck:

Please refer to your Supplemental New Drug Applications (sNDA) dated and received November 9, 2010, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Aricept (donepezil hydrochloride) 23 mg, 10 mg, 5 mg and ODT Tablets.

These supplements provide for the inclusion of the pharmacological class in the Highlights Section of the label, the correction of typographical errors, revisions to text that would make formatting consistent, and minor changes to Section 2 (“DOSAGE AND ADMINISTRATION”) and Section 17 (“PATIENT COUNSELING INFORMATION”) as requested by the Agency.

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.

CONTENT OF LABELING

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(1)] in structured product labeling (SPL) format, as described at <http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm>, that is identical to the enclosed labeling (text for the package insert) and include the labeling changes proposed in any pending “Changes Being Effected” (CBE) supplements. 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.

LETTERS TO HEALTH CARE PROFESSIONALS

If you decide to issue a letter communicating important safety-related information about this drug product (i.e., a “Dear Health Care Professional” letter), we request that you submit, at least 24 hours prior to issuing the letter, an electronic copy of the letter to this NDA to the following address:

MedWatch Program
Office of Special Health Issues
Food and Drug Administration
10903 New Hampshire Avenue
Building 32, Mail Stop 5353
Silver Spring, MD 20993

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

ENCLOSURE:
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
12/02/2010