DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 20-690/S-011

Eisai Inc.
Attention: Rhea Williams, MPH
Glenpointe Centre West
500 Frank W. Burr Blvd
Teaneck, New Jersey 07666-6741

Dear Ms. Williams:

Please refer to your supplemental new drug application dated submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Aricept® (donepezil) 5 mg and 10 mg Tablets.

We acknowledge receipt of your submissions dated April 8, 2004 and April 19, 2004.

Your submission of November 21, 2003 constituted a complete response to our July 29, 2003 action letter.

This supplemental new drug application provides for changes to the Precautions (Drug –Drug Interactions and Carcinogenesis) section of labeling and the addition of a Geriatric use subsection.

We completed our review of this supplemental new drug application. It is are approved, effective on the date of this letter, for use as recommended in the final printed labeling (FPL) submitted on April 19, 2004.

If you issue a letter communicating important information about this drug product (i.e., a "Dear Health Care Professional" letter), we request that you submit a copy of the letter to this NDA and a copy to the following address:

MEDWATCH, HFD-410
FDA
5600 Fishers Lane
Rockville, MD 20857

We remind you that you must comply with the requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

If you have any questions, call Melina Griffis, R.Ph., Sr. Regulatory Project Manager, at (301) 594-5526.

Sincerely,

{See appended electronic signature page}

Russell Katz, M.D.
Director
Division of Neuropharmacological Drug Products
Office of Drug Evaluation I
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/

Russell Katz

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