DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-719

Eisai Medical Research
Attention: Charles Callaghan
55 Challenger Road
Ridgefield Park, NJ 07660

Dear Mr. Callaghan:

Please refer to your new drug application (NDA) dated December 17, 2003, received December 18, 2004, submitted under section 505(b)(1) of the Federal Food, Drug, and Cosmetic Act for Aricept ® (donepezil HCl) Oral Solution.

We acknowledge receipt of your submission dated:

February 24, 2004	March 12, 2004	September 3, 2004
March 1, 2004	August 10, 2004	

We completed our review of this application, as amended. It is approved, effective on the date of this letter, for use as recommended in the agreed-upon labeling text.

However, this approval applies only to the product utilizing drug substance manufactured at the Groton, CT site. As you know, the Kashima; Ibaraki Japan drug substance manufacturing site has not been the subject of an Agency GMP inspection in nine years. Although we acknowledge that this is an approved site for the manufacture of drug substance used in marketed Aricept Tablets, and that we do not contemplate taking any action against this marketed product on the basis of the absence of a recent inspection of this site, we believe that this site must be inspected and found to be in compliance before any new products containing drug substance manufactured there are approved.

The final printed labeling (FPL) must be identical to the enclosed labeling (text for the package insert) and submitted labeling (immediate container and carton labels submitted September 3, 2004) Marketing the product with FPL that is not identical to the approved labeling text may render the product misbranded and an unapproved new drug.

Please submit an electronic version of the FPL according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format - NDA*. Alternatively, you may submit 20 paper copies of the FPL as soon as it is available but no more than 30 days after it is printed. Individually mount 15 of the copies on heavy-weight paper or similar material. For administrative purposes, designate this submission "**FPL for approved NDA 21-719"**.

All applications for new active ingredients, new dosage forms, new indications, new routes of administration, and new dosing regimens are required to contain an assessment of the safety and

effectiveness of the product in pediatric patients unless this requirement is waived or deferred. We are waiving the pediatric study requirement for this application.

In addition, submit three copies of the introductory promotional materials that you propose to use for this product. Submit all proposed materials in draft or mock-up form, not final print. Send one copy to this Division and two copies of both the promotional materials and the package insert directly to:

Division of Drug Marketing, Advertising,
and Communications, HFD-42
Food and Drug Administration
5600 Fishers Lane
Rockville, MD 20857

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 Melina Griffis, R.Ph., Senior 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

Enclosure

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

10/18/04 12:21:35 PM