DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 21-720/S07
NDA 20-690/S031

SUPPLEMENT APPROVAL

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

Dear Dr. Langezaal:

Please refer to your Supplemental New Drug Application (sNDA) dated and received January 31, 2011, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Aricept (donepezil hydrochloride) 5 mg and 10 mg Orally Disintegrating Tablet (ODT).

Additional reference is made to your Supplemental New Drug Application (sNDA) dated August 24, 2011, received August 25, 2010, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Aricept (donepezil hydrochloride) 5 mg and 10 mg Film Coated Tablet (FCT).

We acknowledge receipt of your amendment to the Aricept 5 mg and 10 mg Film coated Tablet sNDA dated January 31, 2011.

These "Changes Being Effected" supplemental new drug applications provide for changes to the packaging components for Aricept 5 mg and 10 mg ODT and FCT tablets, which have been adapted to the new look of the approved packaging components of Aricept 23 mg, and the use of a different color not already used in the product line to differentiate the 10 mg packaging components.

We have completed our review of this supplemental application, as amended. It is approved, effective on the date of this letter.

CARTON AND IMMEDIATE CONTAINER LABELS

We acknowledge your January 31, 2011, submissions containing final printed carton and container labels.

Please submit these labels electronically according to the guidance for industry titled "Providing Regulatory Submissions in Electronic Format – Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications (June 2008)." Alternatively, you may submit 12 paper copies, with 6 of the copies individually mounted on heavy-weight paper or similar material. For administrative purposes, designate this submission "**Product Correspondence – Final Printed Carton and Container Labels for approved NDA 21-720/S-07 and NDA 20-690/S-031**." Approval of this submission by FDA is not required before the labeling is used.

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, Regulatory Project Manager, at (301) 796-1161.

Sincerely,

{See appended electronic signature page}

Russell G. Katz, MD
Director
Division of Neurology 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 G KATZ
04/04/2013