DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 20-973/S-022

Eisai Medical Research Inc.
Attention: Kevin Ross, Ph. D.
Director, Regulatory Affairs
55 Challenger Road
Ridgefield Park, NJ 07660

Dear Dr. Ross:

Please refer to your supplemental new drug application dated December 28, 2007, received December 31, 2007, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Aciphex (rabeprazole sodium) Delayed Release Tablets.

We acknowledge receipt of your submissions dated January 29, 2008; February 28, 2008; March 7 & 19, 2008; April 7, 21, & 29, 2008; May 8, 2008, and June 26, 2008.

This supplemental new drug application provides for the use of Aciphex (rabeprazole sodium) Delayed Release Tablets for short-term treatment symptomatic GERD in adolescent patients 12 years of age and above.

We completed our review of this application, as amended. This application is approved for the 20 mg dose of Aciphex (rabeprazole sodium) Delayed Release Tablets for short-term treatment symptomatic GERD in adolescent patients 12 years of age and above, effective on the date of this letter, for use as recommended in the agreed-upon labeling text for the package insert, patient package insert, and carton container label.

The final printed labeling (FPL) must be identical to the enclosed labeling for the package insert, patient package insert, and carton container label as agreed upon on June 26, 2008.

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 supplement NDA 20-973/S-022**." Approval of this submission by FDA is not required before the labeling is used.

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:

Food and Drug Administration
Center for Drug Evaluation and Research
Division of Drug Marketing, Advertising, and Communications
5901-B Ammendale Road
Beltsville, MD 20705-1266

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
Food and Drug Administration
Suite 12B05
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 Chantal Phillips, Regulatory Project Manager, at (301) 796-2259.

Sincerely,

{See appended electronic signature page}

Joyce Korvick, M.D., M.P.H.
Deputy Director
Division of Gastroenterology Products
Office of Drug Evaluation III
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/

Joyce Korvick

6/30/2008 03:50:22 PM