DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 20-973/S-020

Eisai Medical Research Inc
Attention: Matthew Biondi, RPh.
Director, Regulatory Affairs
55 Challenger Road
Ridgefield Park, New Jersey 07660

Dear Mr. Biondi:

Please refer to your supplemental new drug application dated December 1, 2003, received December 2, 2003, 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 December 3, 2004, and January 11 and May 20, 2005.

Your submission dated December 3, 2004 constituted a complete response to our June 1, 2004 action letter.

This supplemental new drug application provides for the addition of a patient package insert.

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

The final printed labeling (FPL) must be identical to the enclosed labeling (text for the patient package insert) and submitted labeling (patient package insert submitted May 20, 2005).

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-020**." Approval of this submission by FDA is not required before the labeling is used.

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 reporting requirements for an approved NDA (21 CFR 314.80 and 314.81).

If you have any questions, call Mary Lewis, Regulatory Project Manager, at (301) 827-7475.

Sincerely,

{See appended electronic signature page}
Brian E. Harvey, M.D., Ph.D., Director
Division of Gastrointestinal and
Coagulation Drug 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
6/3/05 02:48:11 PM
for Dr. B.E. Harvey