CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

21-456

20-973/S-013

CORRESPONDENCE

Eisai Inc.
Regulatory Affairs Dept.
Glenpointe Centre West
500 Frank W. Burr Blvd.
Teaneck, New Jersey 07666
Telephone: 201 692-9160
Fax: 201-287-1409

VIA FEDERAL EXPRESS

December 11, 2001

Food & Drug Administration
PO Box 3060909
Mellon Client Service Center Rm 670
500 Ross Street
Pittsburgh, PA 15262-0001

RE:	**User Fee Payment for Type 6 New Drug Application #21-456**
User Fee Number:	**4237**
Product:	**Aciphex® (rabeprazole sodium) 20 mg delayed-release tablets**

Dear Sir or Madam:

Enclosed please find a check in the amount of $154,823.00 payable to the order of the Food and Drug Administration representing the User Fee amount for New Drug Application 21-456. This application is scheduled for submission to the Division of Special Pathogens and Immunologic Drug Products on December 26, 2001, to provide for a new use of Aciphex®.

The amount of $154, 823.00 was derived from the December 18, 2000 Federal Register notice of the "Establishment of Prescription Drug User Fee Rates for Fiscal Year 2001." In addition, this NDA has been categorized as a "Type 6" NDA based on an August 9, 2001 phone conversation with Ms. Maria Walsh, Project Manager with the FDA Division of Gastrointestinal and Coagulation Drug Products. Furthermore, in a phone conversation held on November 15, 2001, Ms. Beverly Friedman of the FDA Division of Regulatory Policy confirmed that a Type 6 NDA user fee payment amount is the same as that required for labeling supplements requiring clinical data.

If you have any questions or require additional information, please do not hesitate to contact me by telephone at (201) 287-2239 or by fax at (201) 287-1409.

Sincerely,
EISAI INC.

Matthew Biondi, RPh
Associate Director, Regulatory Affairs

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-456

Eisai
Attention: Matthew Biondi, R.Ph.
Associate Director, Regulatory Affairs
Glenpointe Centre West
500 Frank W. Burr Blvd.
Teaneck, New Jersey 07666-6741

Dear Mr. Biondi:

We have received your new drug application (NDA) submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for the following:

Name of Drug Product:	Aciphex (rabeprazole sodium delayed release tablets) Tablets, 20 mg
Review Priority Classification:	Standard (S)
Date of Application:	January 9, 2002
Date of Receipt:	January 10, 2002

Unless we notify you within 60 days of the receipt date that the application is not sufficiently complete to permit a substantive review, this application will be filed under section 505(b) of the Act on March 11, 2002, in accordance with 21 CFR 314.101(a). If the application is filed, the user fee goal date will be November 8, 2002

Please cite the NDA number listed above at the top of the first page of any communications concerning this application. Address all communications concerning this NDA as follows:

U.S. Postal Service:

Food and Drug Administration
Center for Drug Evaluation and Research
Division of Special Pathogen and Immunologic Drug Products, HFD-590
Attention: Division Document Room
5600 Fishers Lane
Rockville, Maryland 20857

Courier/Overnight Mail:

Food and Drug Administration
Center for Drug Evaluation and Research
Division of Special Pathogen and Immunologic Drug Products, HFD-590
Attention: Division Document Room
9201 Corporate Blvd.
Rockville, Maryland 20850-3202

If you have any questions, please call Yoon Kong, Pharm.D., Regulatory Project Manager, at (301) 827-2127.

Sincerely,

{See appended electronic signature page}

Ellen C. Frank, R.Ph.
Chief, Project Management Staff
Division of Special Pathogen and Immunologic Drug Products
Office of Drug Evaluation IV
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/

Ellen Frank
2/22/02 03:58:34 PM
NDA 21-456