

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration Rockville, MD 20857

WRITTEN REQUEST – AMENDMENT

NDA 20-973

Eisai, Inc. Attention: Kevin L. Ross, Ph.D. Director, Regulatory Affairs 55 Challenger Road Ridgefield Park, New Jersey 07660

Dear Dr. Ross:

Please refer to the December 31, 2001 Written Request for pediatric studies for Aciphex[®] (rabeprazole sodium) Delayed-Release Tablets.

As currently stated in your Written Request, the due date for the corresponding final study reports is December 31, 2005. At this time we want to inform you that this due date is amended to December 31, 2008.

A consolidated Written Request incorporating all changes to this point will be sent at a later date.

If you have any questions, call Melissa Furness, Regulatory Project Manager, at 301-796-0893.

Sincerely,

[See appended electronic signature page] Brian E. Harvey, M.D., Ph.D. Director Division of Gastroenterology Products 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/ Joyce Korvick 12/20/2005 09:28:27 AM for Dr. Brian Harvey