



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

JAN 3 2005

Robert W. Pollock
Vice President
Lachman Consultant Services, Inc.
1600 Stewart Avenue
Westbury, New York 11590

Re: Docket No. 2004P-0285/CP1

Dear Mr. Pollock:

I am writing to inform you that the Food and Drug Administration (FDA) has not yet resolved the issues raised in your citizen petition submitted on July 6, 2004. Your petition requests that the Agency determine whether Aciphex (rabeprazole sodium) delayed-release tablets, 10 mg (NDA 20-973), manufactured by Eisai, Inc., was voluntarily withdrawn or withheld from sale for safety or efficacy reasons.

FDA has been unable to reach a decision on your petition because of the need to address other Agency priorities. This interim response is provided in accordance with FDA regulations on citizen petitions (21 CFR 10.30(e)(2)). We will respond to your petition as soon as possible given the numerous demands on the Agency's resources.

Sincerely,

Jane A. Axelrad
Associate Director for Policy
Center for Drug Evaluation and Research

2004P-0285

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