DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

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Robert W. Pollock
Lachman Consultant Services, Inc.
1600 Stewart Avenue
Westbury, NY 11590

Re: Docket No. 2006P-0462

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 received on November 13, 2006. Your petition requests that the Agency determine whether Prevacid NapraPAC 250, 15 mg/250 mg (copackaged lansoprazole delayed-release 15 mg capsules and naproxen 250 mg tablets) (TAP NDA No. 021-507) was voluntarily withdrawn or withheld from sale for safety or efficacy reasons.

FDA has been unable to reach a decision on your petition due to 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 we have reached a decision on your request.

Sincerely,

Jane A. Axelrad

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

2006P-0462

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