



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

APR 26 2004

2340 10 MAY -7 12:00

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

Docket No. 2003P-0501/CP1

Dear Mr. Pollack:

This letter responds to your citizen petition dated October 29, 2003, requesting that the Food and Drug Administration (FDA) determine that Pyridostigmine Bromide 30 mg (Solvay, ANDA 89-572, labeled for myasthenia gravis) was not withdrawn for reasons of safety or effectiveness.

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 possible, given the numerous demands on the Agency's resources.

Sincerely,

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

2003P-0501

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