



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

SEP 13 2006

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

Re: Docket No. 2006P-0125/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 received on March 20, 2006. Your petition requests that the FDA determine whether Dexedrine (dextroamphetamine sulfate) Oral Solution 5mg/5mL has been withdrawn from sale for safety or efficacy reasons.

FDA has been unable to reach a decision on your petition because it raises complex issues requiring extensive review and analysis by Agency officials. 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
Associate Director for Policy
Center for Drug Evaluation and Research

2006P-0125

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