HFA-305

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

DEC 16 2003

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

Re: Docket No. 2003P-0284/CP 1

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 June 19, 2003, on behalf of Lachman Consultant Services. Your petition requests that the Agency determine whether Lexapro (escitalopram oxalate) Tablets, 5 mg, have been withheld from sale 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 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

2003P-0284

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