



Food and Drug Administration  
Rockville MD 20857

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

Re: Docket No. 03P-0006/CP1

Dear Mr. Pollack:

I am writing to inform you that the Food and Drug Administration (FDA) has not yet resolved the issues raised in your citizen petition dated January 3, 2003. Your petition requests that FDA determine whether Levo-Dromoran (levorphanol tartrate) Tablets, 2 milligrams, has been voluntarily withdrawn from sale for reasons of safety or effectiveness.

FDA has been unable to reach a decision on your request because it raises issues that require additional review and analysis by the Agency. 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

03P-0006

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