



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
Rockville MD 20857

SEP 20 2005 0056 5 SEP 20 P2:13

David G. Adams  
Venable LLP  
575 F Street, N.W.  
Washington, D.C. 20004-1601

Re: Docket No. 2005P-0116/CP1

Dear Mr. Adams:

I am writing to inform you that the Food and Drug Administration (FDA) has not yet resolved the issues raised in your citizen petition submitted on March 24, 2005, on behalf of the Consumer Health Alliance for Safe Medication (CHASM). Your petition requests that the Agency take various actions with respect to the labeling and advertisement of compounded, aqueous-based drugs for inhalation.

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

2005P-0116

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