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Michael J. Gaertner
Sara A. Lufrano
Lord, Bissell & Brook LLP
115 South LaSalle Street
Chicago, Illinois 60603-3901

Re: Docket No. 2004P-0562/CP1

Dear Mr. Gaertner and Ms. Lufrano:

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 December 23, 2004. Your petition requests, among other things, that FDA order all non-FDA-approved producers of dosage form methacholine chloride to stop introducing into interstate commerce any methacholine chloride that is not FDA approved or that is misbranded in violation of section 502 of the Federal Food, Drug, and Cosmetic Act.

We have been unable to reach a decision on your petition because it raises significant issues requiring extensive review 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 requests.

Sincerely,

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

2004P-0562

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