



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

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JAN 23 2006

Charles J. Raubicheck
Frommmer, Lawrence & Haug, LLP
745 Fifth Avenue
New York, NY 10151

Re: Docket No. 2005P-0291/CP1

Dear Mr. Raubicheck:

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 July 25, 2005. Your petition requests that the Agency refuse the approval of an abbreviated new drug application or a Section 505(b)(2) new drug application for inhalation products with a combination of albuterol sulfate and ipratropium hydrobromide, unless the safety of the product is demonstrated by providing: 1) the results of studies that identify, quantitate, and limit impurities in the drug; 2) biological safety qualification testing of drug substance degradation or reaction impurities that exceed certain threshold levels; and 3) results of studies that identify, quantitate, and limit the amount of leachables from the container closure system.

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-0291

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