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

Re: Docket No. 2004P-0520/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 received on November 22, 2004, on behalf of IVAX Pharmaceuticals, Inc. (IVAX). Your petition requests that the Agency confirm that IVAX is entitled to 180-day exclusivity with regard to ANDA 76-724 for ipratropium bromide and albuterol sulfate inhalation solution, a generic version of Duoneb, if IVAX is the first applicant to both submit a paragraph IV certification and satisfy the statutory notice requirement for that certification. Your petition notes that you are not seeking a determination that IVAX is entitled to the 180-day exclusivity, but a confirmation of the standard that FDA will use to determine whether IVAX is entitled to exclusivity.

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

2004P-0520

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