DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

APR 20 2007

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J. Martin Carroll
President & CEO
Boehringer Ingelheim Pharmaceuticals, Inc.
900 Ridgebury Road
Ridgefield, CT 06877

Docket No. 2006P-0428/CP1

Dear Mr. Carroll:

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 October 23, 2006. You request that FDA refrain temporarily from taking action to remove the chlorofluorocarbon (CFC) containing metered-dose ipratropium bromide and albuterol sulfate, in combination, administered by oral inhalation for human use (marketed as COMBIVENT) from the list of essential uses of CFCs.

FDA has been unable to reach a decision on your petition because it raises significant and 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 possible given the numerous demands on the Agency's resources.

Sincerely,

Jane A. Axelrad

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

2006P-0428

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