DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 20-291/S-020

Boehringer Ingelheim Pharmaceuticals, Inc
900 Ridgebury Road
P.O. Box 368
Ridgefield, CT 06877-0368

Attention: Kelly S. Billingham
Manager, Drug Regulatory Affairs,
Product Labeling

Dear Ms. Billingham:

Please refer to your supplemental new drug application dated October 14, 2005, received October 17, 2005, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Combivent (ipratropium bromide/albuterol sulfate) Inhalation Aerosol.

This "Changes Being Effected" supplemental new drug application provides for the revision of the product labeling to address the issue of proper shaking of the drug product

We completed our review of this supplemental new drug application. It is approved, effective on the date of this letter, for use as recommended in the final printed labeling (FPL) submitted on October 14, 2005 (copy of text enclosed).

We remind you that you must comply with the requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

If you have any questions, call Lori Garcia, Regulatory Project Manager, at (301) 796-1212.

Sincerely,

{See appended electronic signature page}

Badrul A. Chowdhury, M.D., Ph.D.
Director
Division of Pulmonary Allergy Products
Office of Drug Evaluation II
Center for Drug Evaluation and Research

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/s/

Badrul Chowdhury

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