DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 20-291/S-023

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

Attention: Kelly Billingham
Associate Director, Regulatory Affairs

Dear Ms. Billingham:

Please refer to your supplemental new drug application dated, July 25, 2007, received July 26, 2007, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Combivent Inhalation Aerosol (ipratropium bromide and albuterol sulfate).

We acknowledge receipt of your submissions dated February 5 and April 29, 2008. The April 29, 2008, submission constitutes a complete response to our July 25, 2007, action letter.

This "Changes Being Effected" supplemental new drug application provides for the harmonization of Combivent® inhalation aerosol package insert with that of your other ipratropium products.

We have completed our review of this application, as amended. This application is approved, effective on the date of this letter, for use as recommended in the agreed-upon labeling text.

As soon as possible, but no later than 14 days from the date of this letter, please submit the content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format as described at http://www.fda.gov/oc/datacouncil/spl.html that is identical to the submitted labeling (package insert and patient instructions for use) submitted April 29, 2008. Upon receipt, we will transmit that version to the National Library of Medicine for public dissemination. For administrative purposes, please designate this submission, "SPL for approved NDA 20-291/S-023.

If you issue a letter communicating important information about this drug product (i.e., a "Dear Health Care Professional" letter), we request that you submit a copy of the letter to this NDA and a copy to the following address:

MEDWATCH
Food and Drug Administration
Suite 12B05
5600 Fishers Lane
Rockville, MD 20857

We remind you that you must comply with reporting requirements for an approved NDA (21 CFR 314.80 and 314.81).

If you have any questions, call Angela Robinson, Regulatory Project Manager, at (301) 796-2284.

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

Enclosure: Approved Labeling

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

Badrul Chowdhury
11/10/2008 08:47:05 AM