DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-395/S-027

Boehringer Ingelheim
900 Ridgebury Road
PO Box 368
Ridgefield, CT 06877

Attention: Tacy Pack
Director, Drug Regulatory Affairs

Dear Ms. Pack:

Please refer to your supplemental new drug application dated May 19, 2008, received May 20, 2008, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Spiriva® HandiHaler® inhalation powder.

This "Prior Approval" supplemental new drug application provides for changes to the CLINICAL PHARMACOLOGY, Electrophysiology section of the Package Insert (PI).

We have completed our review of this application. This application is approved, effective on the date of this letter, for use as recommended in the enclosed agreed-upon labeling text and with the minor editorial revisions indicated in the enclosed labeling and agreed to in a communication November 7, 2008.

CONTENT OF LABELING

As soon as possible, but no later than 14 days from the date of this letter, please submit the content of labeling [CFR 314.50(1)] in structured product labeling (SPL) format as described at http://www.fda.gov/oc/datacouncil/spl/html that is identical to, except for including the revisions indicated, the enclosed labeling text for the package insert submitted May 19, 2008, Upon receipt, we will transmit that version to the National Library of Medicine for public dissemination. For administrative purposed, please designate this submission, "SPL for approved NDA 21-395.".

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 Miranda Raggio, Regulatory Project Manager, at (301) 796-2109.

Sincerely,

{See appended electronic signature page}

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

Enclosure: Labeling submitted May 19, 2008, including agreed upon changes

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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

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