DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-395/S-007

Boehringer Ingelheim Pharmaceuticals, Inc.
P.O. Box 358
Ridgefield, CT 06877-0368

Attention: Tacy Pack
Senior Associate Director, Drug Regulatory Affairs

Dear Ms. Pack:

Please refer to your supplemental new drug application dated October 26, 2005, received Octotber 27.2005, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Spiriva HandiHaler.

We acknowledge receipt of your submission dated September 13, 2006.

This supplemental new drug application provides for changes to the proprietary name as it appears in the package insert, blister foils and carton labels.

We 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 and with the minor editorial revisions listed below.

Remove the triangle above the second capital I in the proprietary name.

The final printed labeling (FPL) must be identical, and include the minor editorial revisions indicated, to the enclosed labeling . These revisions are terms of the approval of this application.

Please submit an electronic version of the FPL according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format - NDA.* Alternatively, you may submit 20 paper copies of the FPL as soon as it is available but no more than 30 days after it is printed. Individually mount 15 of the copies on heavy-weight paper or similar material. For administrative purposes, designate this submission "**FPL for approved supplement NDA 21-395/S-007**." Approval of this submission by FDA is not required before the labeling is used.

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
5515 Security Lane

HFD-001, Suite 5100
Rockville, MD 20852

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 Anthony M. Zeccola , Senior Regulatory Management Officer, at (301) 796-1318.

Sincerely,

{See appended electronic signature page}

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

Enclosure

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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