DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-395/S-022

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

Dear Ms. Pack:

Please refer to your supplemental new drug application dated December 19, 2007, received December 20, 2007, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Spiriva ®HandiHaler®.

We acknowledge receipt of your submission dated March 12, 2008.

This "Changes Being Effected" supplemental new drug application provides for changes to the ADVERSE REACTIONS section of the Package Insert (PI), clarifications to the Patient Instructions for Use (PPI), and revisions to the blister label and carton to include the statement "Do Not Swallow Capsules. For Use with HandiHaler Only."

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 enclosed agreed-upon labeling text.

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 the enclosed labeling text for the package insert and patient instructions for use submitted March 12, 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.".

CARTON AND CONTAINER

Submit final printed carton and container labels that are identical to the submitted carton and immediate container labels as soon as they are available, but no more than 30 days after they are printed. Please submit these labels electronically according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format – Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications (October 2005).* Alternatively, you may submit 12 paper copies, with 6 of the copies individually mounted on heavy-weight paper or similar material. For administrative purposes, designate this submission "**Final Printed Carton and Container Labels for approved NDA 21-395**." Approval of this submission by the 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
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.
Division 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 3/12/08

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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