DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 21395/S-033

SUPPLEMENT APPROVAL

Boehringer Ingelheim
900 Ridgebury Road
PO Box 368
Ridgefield, CT 06877-0368

Attention: Tacy Pack, Director
Drug Regulatory Affairs

Dear Ms. Pack:

Please refer to your Supplemental New Drug Application (sNDA) dated January 28, 2011, received January 31, 2011, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Spiriva ®HandiHaler® (tiotropium bromide inhalation powder).

We also acknowledge your amendment dated July 25, 2011.

This "Prior Approval" supplemental new drug application proposes new text to the patient's Instructions for Use (IFU) regarding potential swallowing of the Spiriva capsule fragments, additional revisions to the IFU based on market research testing with patients and healthcare providers to create a more user-friendly document, and revisions to the HIGHLIGHTS and DRUG INTERACTIONS, Antichloinergics, section and of the Package Insert (PI) to make it more consistent with the recently approved Atrovent® HFA PI.

We have completed our review of this supplemental application, as amended. It 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, submit the content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format using the FDA automated drug registration and listing system (eLIST), as described at http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm. Content of labeling must be identical to the enclosed labeling text for the PI and IFU, with the addition of any labeling changes in pending "Changes Being Effected" (CBE) supplements, as well as annual reportable changes not included in the enclosed labeling.

Information on submitting SPL files using eLIST may be found in the guidance for industry titled "SPL Standard for Content of Labeling Technical Qs and As" at

http://www.fda.gov/downloads/DrugsGuidanceComplianceRegulatoryInformation/Guidances/UCM072392.pdf.

The SPL will be accessible from publicly available labeling repositories.

Also within 14 days, amend all pending supplemental applications for this NDA, including CBE supplements for which FDA has not yet issued an action letter, with the content of labeling [21 CFR 314.50(l)(1)(i)] in MS Word format, that includes the changes approved in this supplemental application, as well as annual reportable changes and annotate each change. To facilitate review of your submission, provide a highlighted or marked-up copy that shows all changes, as well as a clean Microsoft Word version. The marked-up copy should provide appropriate annotations, including supplement number(s) and annual report date(s).

CARTON AND IMMEDIATE CONTAINER LABELS

Submit final printed carton labels that are identical to the carton labels submitted on January 31, 2011, except with the revisions listed below, as soon as they are available, but no more than 30 days after they are printed:

1. Use a different color font for the important warning statements "Do not swallow Spiriva capsules", "For use with HandiHaler only", and "For oral inhalation only".

2. Increase the font size of "Do not swallow Spiriva capsules" to increase the prominence of this warning statement.

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 (June 2008)." 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 "**Product Correspondence – Final Printed Carton and Container Labels for approved NDA 21395/S-033**." Approval of this submission by FDA is not required before the labeling is used.

REPORTING REQUIREMENTS

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

Sincerely,

{See appended electronic signature page}

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

ENCLOSURE(S):
Content of Labeling submitted 7-25-11

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

/s/

MIRANDA B RAGGIO
07/28/2011

BADRUL A CHOWDHURY
07/28/2011