



NDA 21-395/S-001

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

Attention: Peter Fernandes, M.Pharm.
Director, Drug Regulatory Affairs

Dear Mr. Fernandes:

Please refer to your supplemental new drug application dated February 19, 2004, received February 23, 2004, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Spiriva HandiHaler (tiotropium bromide inhalation powder).

This supplemental new drug application provides for revisions to revisions to the carton labeling and Patient's Instructions for Use as requested in our January 30, 2004, approval letter.

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

The final printed labeling (FPL) must be identical to the enclosed, submitted labeling (Patient's Instructions for Use and carton labeling submitted February 19, 2004).

Please submit the FPL electronically 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, in no case more than 30 days after it is printed. Please individually mount 15 of the copies on heavy-weight paper or similar material. For administrative purposes, this submission should be designated "FPL for approved supplement NDA 21-395/S-001." 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, HFD-410
FDA
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).

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If you have any questions, call Anthony Zeccola, Regulatory Project Manager, at (301) 827-1051.

Sincerely,

Badrul A. Chowdhury, M.D., Ph.D.
Division Director
Division of Pulmonary and Allergy Drug Products
Office of Drug Evaluation II
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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