



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
Rockville, MD 20857

NDA 21-395/S-008, S-015

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

Attention: Kelly S. Billingham

Dear Ms Billingham,

Please refer to your supplemental new drug applications dated October 28, 2005 (S-008) and September 11, 2006 (S-015), submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Spiriva HandiHaler (tiotropium bromide inhalation powder).

These "Changes Being Effected" supplemental new drug applications provide for revisions to the ADVERSE REACTIONS and PATIENT INSTRUCTIONS FOR USE sections of the labeling as listed below.

S-008 – The addition of dizziness, hoarseness, tachycardia and throat irritation to Post Marketing subsection of the ADVERSE REACTIONS Section and revisions to the PATIENT INSTRUCTIONS FOR USE Section.

S-015 – The addition of dysphasia, intestinal obstruction including ileus paralytic, intraocular pressure increased, oral candidiasis to the ADVERSE REACTION Section.

We completed our review of these supplemental new drug applications. They are approved, effective on the date of this letter, for use as recommended in the final printed labeling (FPL) submitted on September 8, 2006.

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 the requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

If you have any questions, call Anthony M. Zeccola, 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

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/s/

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Badrul Chowdhury  
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