DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 21395/S-029

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 dated November 17, 2008, received November 18, 2008, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for SPIRIVA® HandiHaler® (tiotropium bromide inhalation powder).

We acknowledge receipt of your submissions dated January 26 and 30, February 17, March 12, 13, and 20, April 17 and 21, June 22 and 24, July 22, September 10, November 13, and December 9, 15, and 16, 2009.

This Prior Approval supplemental new drug application provides for revisions to multiple sections of the package insert to reflect the results of Clinical Trials 205.235 (UPLIFT) and 205.266 (VA Study) in support of an exacerbation claim.

CONTENT OF LABELING

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

As soon as possible, but no later than 14 days from the date of this letter, please submit the content of labeling [21 CFR 314.50(l)(1)(i)] 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 (PI) and patient instructions for use (PIU) and patient information leaflet (PIL) submitted December 16, 2009. For administrative purposes, please designate this submission, "SPL for approved NDA 21395/S-029.

REQUIRED PEDIATRIC ASSESSMENTS

Under the Pediatric Research Equity Act (PREA) (21 U.S.C. 355c), all applications for new active ingredients, new indications, new dosage forms, new dosing regimens, or new routes of

administration are required to contain an assessment of the safety and effectiveness of the product for the claimed indication(s) in pediatric patients unless this requirement is waived, deferred, or inapplicable.

The PREA requirements do not apply to SPIRIVA® HandiHaler® since this product is used for the treatment of chronic obstructive pulmonary disease which does not occur in children.

PROMOTIONAL MATERIALS

You may request advisory comments on proposed introductory advertising and promotional labeling. To do so, submit, in triplicate, a cover letter requesting advisory comments, the proposed materials in draft or mock-up form with annotated references, and the package insert(s) to:

Food and Drug Administration
Center for Drug Evaluation and Research
Division of Drug Marketing, Advertising, and Communications
5901-B Ammendale Road
Beltsville, MD 20705-1266

As required under 21 CFR 314.81(b)(3)(i), you must submit final promotional materials, and the package insert(s), at the time of initial dissemination or publication, accompanied by a Form FDA 2253. For instruction on completing the Form FDA 2253, see page 2 of the Form. For more information about submission of promotional materials to the Division of Drug Marketing, Advertising, and Communications (DDMAC), see http://www.fda.gov/AboutFDA/CentersOffices/CDER/ucm090142.htm.

LETTERS TO HEALTH CARE PROFESSIONALS

If you issue a letter communicating important safety related information about this drug product (i.e., a "Dear Health Care Professional" letter), we request that you submit an electronic copy of the letter to both this NDA and to the following address:

MedWatch
Food and Drug Administration
5600 Fishers Lane, Room 12B05
Rockville, MD 20857

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 and Allergy Products
Office of Drug Evaluation II
Office of New Drugs
Center for Drug Evaluation and Research

Enclosure
Content of Labeling Submitted 12-16-09

Application Type/Number	Submission Type/Number	Submitter Name	Product Name
NDA-21395	SUPPL-29	BOEHRINGER INGELHEIM PHARMACEUTICALS INC	SPIRIVA HANDIHALER

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

/s/

BADRUL A CHOWDHURY
12/17/2009