DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 21527/S-027

APPROVAL LETTER

Boehringer Ingelheim Pharmaceuticals, Inc.
Attention: Adrian Wai-Hing Cheung, PhD., Associate Director
Regulatory Affairs
900 Ridgebury Road
PO Box 368
Ridgefield, CT 06877

Dear Dr. Cheung:

Please refer to your Supplemental New Drug Application (sNDA) dated November 2, 2015, received November 2, 2015, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Atrovent®HFA (ipratropium bromide HFA) Inhalation Aerosol.

This "Prior Approval" supplemental new drug application provides for revised draft carton and canister labels for Atrovent®HFA Inhalation Aerosol.

We have completed our review of this supplemental new drug application. This supplement is approved.

Submit final printed carton and immediate container labels that are identical to the immediate-container labels submitted on November 2, 2015, 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 *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 "**Final Printed Carton and Container Labels for approved NDA 21527/S-027**." Approval of this submission by FDA is not required before the labeling is used.

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 Yvonne Knight, Regulatory Project Manager, at (301) 796-2133.

Sincerely,

{See appended electronic signature page}

Ramesh Raghavachari, Ph.D.
Chief, Branch I
Division of Post Marketing Activities I
Office of Lifecycle Drug Products
Office of Pharmaceutical Quality
Center for Drug Evaluation and Research

Ramesh Raghavachari

Digitally signed by Ramesh Raghavachari
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