DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 20-291/S-030

SUPPLEMENT APPROVAL

Boehringer Ingelheim Pharmaceutical, Inc.
900 Ridgebury Rd.
PO box 368
Ridgefield, CT 06877-0368

Attention: Amy Van Andel DVM, MPH
Senior Associate Director, Drug Regulatory Affairs

Dear Ms. Van Andel:

Please refer to your Supplemental New Drug Application (sNDA) dated February 15, 2012, received February 15, 2012, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Combivent (ipratropium bromide and albuterol sulfate) Aerosol.

We acknowledge receipt of your amendment dated July 25, 2012.

This Prior Approval supplemental new drug application proposes revisions to the carton label to include a statement of product availability.

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.

CARTON LABELS

Submit final printed carton labels that are identical to the carton labels submitted on July 25, 2012 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 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 Labels for approved NDA 20-291/S-030**."
Approval of this submission by FDA is not required before the labeling is used.

PROMOTIONAL MATERIALS

You may request advisory comments on proposed introductory advertising and promotional labeling. To do so, submit the following, in triplicate, (1) a cover letter requesting advisory comments, (2) the proposed materials in draft or mock-up form with annotated references, and (3) the package insert(s) to:

Food and Drug Administration
Center for Drug Evaluation and Research
Office of Prescription Drug Promotion (OPDP)
5901-B Ammendale Road
Beltsville, MD 20705-1266

You must submit final promotional materials and package insert(s), accompanied by a Form FDA 2253, at the time of initial dissemination or publication [21 CFR 314.81(b)(3)(i)]. Form FDA 2253 is available at http://www.fda.gov/opacom/morechoices/fdaforms/cder.html; instructions are provided on page 2 of the form. For more information about submission of promotional materials to the Office of Prescription Drug Promotion (OPDP), see http://www.fda.gov/AboutFDA/CentersOffices/CDER/ucm090142.htm.

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 Angela Ramsey, Senior Regulatory Project Management Officer at (301) 796-2284.

Sincerely,

{See appended electronic signature page}

Badrul A. Chowdhury, M.D., Division Director
Office of Drug Evaluation II
Center for Drug Evaluation and Research

ENCLOSURE(S):
Carton Labeling

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
09/17/2012