DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 20-393/S-004
NDA 20-394/S-005

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

Attention: Jeffrey R. Snyder
Senior Associate Director, Drug Regulatory Affairs

Please refer to your supplemental new drug applications dated November 26, 2002, received November 27, 2002, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Atrovent Nasal Spray (ipratropium bromide) 0.03% and 0.06%.

These "Changes Being Effected" supplemental new drug applications provide for revisions to the ADVERSE REACTIONS section of the package inserts for Atrovent Nasal Spray 0.03% and 0.06%.

We completed our review of these applications. These applications are approved, effective on the date of this letter, for use as recommended in the agreed-upon labeling text and with the minor editorial revisions listed below, which you agreed to implement by August 31, 2003.

> Include the amount of the drug substance per spray in the name of the drug product to be consistent with the recently approved nasal spray drug products. Revise the carton labels, immediate container labels and the package insert to reflect this change.

The final printed labeling (FPL) must be identical, and include the minor editorial revisions indicated, to the PACKAGE INSERT submitted November 26, 2002. These revisions are terms of the approval of these applications.

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 ten of the copies on heavy-weight paper or similar material. For administrative purposes, these submissions should be designated "FPL for approved supplement NDA 20-393/S-004, AND NDA 20-394/S-005. Approval of these submissions 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, HF-2
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).

If you have any questions, call Ms. Ladan Jafari, Regulatory Project Manager, at (301) 827-1084.

Sincerely,

{See appended electronic signature page}

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

Attached: Atrovent Package Insert

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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