DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 20-393/S-001

APR - 1 1998

Boehringer Ingelheim Pharmaceuticals, Inc.
900 Ridgebury Road
P.O. Box 368
Ridgefield, Connecticut 06877

Attention: C.R. Tamorria, Ph.D.
Senior Associate Director
Drug Regulatory Affairs

Dear Dr. Tamorria:

Please refer to your supplemental new drug application dated March 31, 1997, received April 1, 1997, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Atrovent (ipratropium bromide) Nasal Spray 0.03%.

We acknowledge receipt of your submissions dated August 18, 1997, and March 11, and 27, 1998. The user fee goal date for this application is April 1, 1998.

The supplemental application provides for use in the symptomatic relief of rhinorrhea associated with allergic and nonallergic perennial rhinitis in children age 6 to 11 years.

We have completed the review of this supplemental application including the draft labeling submitted on March 27, 1998, and have concluded that adequate information has been presented to demonstrate that the drug product is safe and effective for use as recommended in the enclosed marked-up labeling. Accordingly, the supplemental application is approved effective on the date of this letter.

The final printed labeling (FPL) must be identical to the enclosed marked-up draft physician labeling and patient's instructions for use.

Please submit 20 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, this submission should be designated "FPL for approved supplemental NDA 20-393/S-001." Approval of this submission by FDA is not required before the labeling is used.

We remind you of our January 12, 1998, letter which recommended that the name of this product be changed to include the dose of ipratropium per spray expressed in micrograms rather than the current reference to the concentration of ipratropium in the solution. Atrovent

(ipratropium bromide) Nasal Spray 0.03% should be changed to Atrovent (ipratropium bromide) Nasal Spray 21 mcg. This change should be made in the physician labeling, patient's instructions for use, and container and carton labeling. We request that you submit your plans to effect this change for our review within 60 days of the date of this letter.

Should additional information relating to the safety and effectiveness of the drug become available, revision of the labeling may be required.

In addition, please submit three copies of the introductory promotional material that you propose to use for this change. All proposed materials should be submitted in draft or mock-up form, not final print. Please submit one copy to this Division and two copies of both the promotional material and the package insert directly to:

Food and Drug Administration
Division of Drug Marketing, Advertising
and Communications, HFD-40
5600 Fishers Lane
Rockville, Maryland 20857

Should a letter communicating important information about this drug product (i.e., a "Dear Doctor" letter) be issued to physicians and others responsible for patient care, 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 20852-9787

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, please contact Ms. Denise Toyer, Project Manager, at (301) 827-5584.

Sincerely yours,

John K. Jenkins, M.D., F.C.C.P.
Director
Division of Pulmonary Drug Products
Office of Drug Evaluation II
Center for Drug Evaluation and Research