

NDA 20-394/S-001

Boehringer Ingelheim Pharmaceuticals, Inc.
900 Ridgebury Road
Ridgefield, Connecticut 06877

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

Dear Dr. Tamorria:

Please refer to your supplemental new drug application dated December 19, 1997, received December 19, 1997, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Atrovent (ipratropium bromide) Nasal Spray 0.06%.

We acknowledge receipt of your submissions dated March 11, July 14, September 2, and October 14, 1998. The user fee goal date for this application is December 19, 1998.

This supplemental new drug application provides for use in the symptomatic relief of rhinorrhea associated with the common cold in children age 5 to 11 years.

We have completed the review of this supplemental application, as amended, and it is approved effective on the date of this letter with the revisions listed below.

1. The abbreviations TID and QID should be revised to "three times daily and four times daily" in the last sentence of the ADVERSE REACTIONS section and the CLINICAL PHARMACOLOGY, Clinical Trials subsection.
2. In the PRECAUTIONS section, the word "General" should be in bold.

The final printed labeling (FPL) must be identical to the submitted draft labeling (package insert submitted October 14, 1998) except for the revisions noted above.

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 supplement NDA 20-394/S-001." Approval of this submission by FDA is not required before the labeling is used.

In addition, please submit three copies of the introductory promotional materials that you propose to use for this product. 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 materials and

the package insert directly to:

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

If a letter communicating important information about this drug product (i.e., a “Dear Health Care Practitioner” letter) is 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 20857

Please submit one market package of the drug product when it is available.

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

Sincerely,

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