December 11, 1998

NDA 20-121/S-009

GlaxoWellcome, Inc.
Five Moore Drive
P.O. Box 13398
Research Triangle Park, NC 27709

Attention: Alison Bowers
Project Director
Regulatory Affairs

Dear Ms. Bowers:

Please refer to your supplemental new drug application dated December 17, 1997, received December 18, 1997, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Flonase (fluticasone propionate) Nasal Spray, 50 mcg.

We acknowledge receipt of your submissions dated January 20, February 4, February 12, April 9, November 12, December 1, and December 4, 1998.

This supplemental new drug application provides for the use of Flonase (fluticasone propionate) Nasal Spray, 50 mcg, for an additional indication for the treatment of nasal symptoms of perennial nonallergic rhinitis in adults and pediatric patients 4 years and older.

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

The final printed labeling (FPL) must be identical to the submitted draft labeling (package insert submitted December 1, 1998, and patient package insert submitted December 1, 1998).

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 20-121/S-009." 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 send 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
Food and Drug Administration
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

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 Mr. David Hilfiker, Project Manager, at (301) 827-1046.

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