DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 20-121/S-030, 20-548/S-020 and 20-549/S-016

GlaxoSmithKline
P.O. Box 13398
Five Moore Drive
Research Triangle Park, NC 27709-3398

Attention: Roger Gaby
Director, Rhinitis Drug Group
US Regulatory Affairs

Dear Mr. Gaby:

Please refer to your supplemental new drug applications dated September 25, 2004, received September 26, , submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Flonase (fluticasone propionate) Nasal Spray, Flovent (fluticasone propionate) Inhalation Aerosol and Flovent Rotadisk (fluticasone propionate inhalation powder).

We acknowledge receipt of your submissions dated March 19, 2004.

These "Changes Being Effected" supplemental new drug applications provide for the addition of a description of fluticasone propionate's interactions with ritonavir to the CLINICAL PHARMACOLOGY, WARNINGS, and PRECAUTIONS sections of the package insert and to the Patient's Instructions for Use leaflet.

We completed our review of these applications, as amended. These applications are approved, effective on the date of this letter, for use as recommended in the final printed labeling submitted on September 25, 2003 (Patient's Instructions for Use leaflet) and March 19, 2004 (package insert) (copies enclosed).

If you issue a letter communicating important information about these drug products (i.e., a "Dear Health Care Professional" letter), we request that you submit a copy of the letter to these NDAs and a copy to the following address:

MEDWATCH, HFD-410
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 Ladan Jafari, Regulatory Project Manager, at (301) 827-1084.

Sincerely,

{See appended electronic signature page}

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

Enclosure

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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