DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 20-121/S-011, S-013, and S-020

GlaxoSmithKline, 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 applications dated January 5, 1999, August 27, 1999, and October 20, 2000, received January 6, 1999, August 30, 2000, and October 23, 2000, respectively, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Flonase (fluticasone propionate) Nasal Spray.

We acknowledge receipt of your submissions dated April 12, 2000 (S-013) and November 21, 2000 (S-011). Your submission of April 12, 2000 and November 21, 2000, constituted complete responses to our February 25, 2000 and August 25, 2000, action letters.

These supplemental new drug applications provide for:

S-011: revisions to the PRECAUTIONS and ADVERSE REACTIONS sections of the package inserts to include information on the growth suppressive effects of inhaled corticosteroids, as requested in our letter dated November 6, 1998.

S-013: revised labeling in response to the August 27, 1997, Federal Register, requesting the addition of a Geriatric Use subsection to the package insert.

S-020: the addition of a cytochrome P450 3A4 inhibitor drug-drug interaction to the CLINICAL PHARMACOLOGY section of the package insert.

We have completed the review of these supplemental applications, as amended, 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 agreed upon labeling text. Accordingly, these supplemental applications are approved effective on the date of this letter.

The final printed labeling (FPL) must combine the submitted draft labeling (package inserts submitted April 13, October 23, and November 22, 2000).

Please submit the copies of final printed labeling (FPL) electronically to each application according to

the guidance for industry titled *Providing Regulatory Submissions in Electronic Format - NDA* (January 1999). Alternatively, you may submit 20 paper copies of the FPL as soon as it is available but no 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 20-121/S-011, S-013, and S-020." Approval of these submissions by FDA is not required before the labeling is used.

If a letter communicating important information about this drug product (i.e., a "Dear Health Care Professional" 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, call Mrs. Sandy Barnes, Chief, Project Management Staff, at (301) 827-1055.

Sincerely,

***{See appended electronic signature page}***

Robert J. Meyer, M.D.
Director
Division of Pulmonary and Allergy Drug Products
Office of Drug Evaluation II
Center for Drug Evaluation and Research

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**This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.**

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/s/

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Robert Meyer
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