DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 20-833/S-014

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

Attention: Dawn Watson
Director, Regulatory Affairs

Dear MS. Watson:

Please refer to your supplemental new drug application dated January 31, 2005, received February 1, 2005, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Flovent Diskus (fluticasone propionate inhalation powder).

We acknowledge receipt of your submissions dated March 1, and 25, and July 25, 2005.

This "Changes Being Effected in 30 days" supplemental new drug application provides for consistency across other fluticasone propionate containing products.

We completed our review of this supplemental new drug application, as amended. It is approved, effective on the date of this letter, for use as recommended in the final printed labeling (FPL) submitted on July 25, 2005.

If you issue a letter communicating important information about this drug product (i.e., a "Dear Health Care Professional" letter), we request that you submit a copy of the letter to this NDA 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 the requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

If you have any questions, call Ms. Ladan Jafari, Regulatory Project Manager, at (301) 827-1084.

Sincerely,

{See appended electronic signature page}

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

Enclosure: Pkg. Insert

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/s/

Badrul Chowdhury
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