DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA20-833/S-015

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

Attention: Dawn Watson
Director, Regulatory Affairs

Dear Ms. Watson:

Please refer to your supplemental new drug application dated May 10, 2005, received May 11, 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 submission dated July 25, 2005.

This "Changes Being Effected in 30 days" supplemental new drug application proposes the addition of "anxiety" and the statement "Behavioral changes, including hyperactivity and irritability, have been reported very rarely and primarily in children." to psychiatry subsection of the ADVERSE REACTIONS section of the package insert.

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: Package insert

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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