DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 20833/S-021 **SUPPLEMENT APPROVAL**

GlaxoSmithKline
5 Moore Drive
P.O. Box 13398
Research Triangle Park, NC 27709

Attention: Dawn Watson
Director, U.S. Regulatory Affairs, Respiratory

Dear Ms. Watson:

Please refer to your Supplemental New Drug Application (sNDA) dated February 20, 2009, received February, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Flovent Diskus, (fluticasone propionate) inhalation powder, 50/100/250 mcg.

We acknowledge receipt of your submissions dated, June 2, July 14, October 14, and November 13, 2009 and February 19, 2010.

This Prior Approval supplemental new drug application provides for conversion of the current approved labeling to the Physician Labeling Rule format and revisions to Section 12.3, Pharmacokinetics to include absolute bioavailability data for fluticasone propionate. In addition, the labeling was revised for consistency with other more recently approved products.

We have completed our review of this supplemental application, as amended. It is approved, effective on the date of this letter, for use as recommended in the enclosed, agreed-upon labeling text and with the minor editorial revisions indicated in the enclosed labeling.

As soon as possible, but no later than 14 days from the date of this letter, submit, using the FDA automated drug registration and listing system (eLIST), the content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format, as described at http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm, that is identical to the enclosed labeling (text for the package insert and text for the patient information leaflet). Information on submitting SPL files using eLIST may be found in the guidance for industry titled "SPL Standard for Content of Labeling Technical Qs and As" at http://www.fda.gov/downloads/DrugsGuidanceComplianceRegulatoryInformation/Guidances/UCM072392.pdf.

The SPL will be accessible via publicly available labeling repositories.

If you decide to issue a letter communicating important safety-related information about this drug product (i.e., a "Dear Health Care Professional" letter), we request that you submit, at least 24 hours prior to issuing the letter, an electronic copy of the letter to this NDA, to CDERMedWatchSafetyAlerts@fda.hhs.gov, and to the following address:

MedWatch
Food and Drug Administration
Suite 12B-05
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 Carol Hill, Regulatory Health Project Manager, at (301) 796-1226.

Sincerely,

{See appended electronic signature page}

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

ENCLOSURE:
Content of Labeling

Application Type/Number	Submission Type/Number	Submitter Name	Product Name
NDA-20833	SUPPL-21	GLAXOSMITHKLINE	FLOVENT DISKUS 50

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

/s/

BADRUL A CHOWDHURY
05/03/2010