DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 20-549/S-011 and S-012

GlaxoSmithKline
P.O. Box 13398
Five Moore Drive
Research Triangle Park, North Carolina 27709

Attention: Lorna C. Wilson
Director, Regulatory Affairs

Dear Ms Wilson:

Please refer to your supplemental new drug applications dated October 03, 2001, and February 08, 2002, received October 04, 2001, and February 11, 2002, respectively, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Flovent (fluticasone propionate inhalation powder) Rotadisk.

These supplemental new drug applications provide for the following revisions to the package insert:

S-011 - the addition of facial and oropharyngeal edema, cataracts, osteoporosis, immediate bronchospasm and pneumonia to the ADVERSE REACTIONS section and relocation of other adverse events and minor editorial revisions to the package insert and patients instructions for use.

S-012 - removal of the black box around the warning regarding patients who are transferred from systemically active corticosteroids to Flovent Rotadisk.

We completed our review of S-012 and it is approved, effective on the date of this letter, for use as recommended in the agreed-upon labeling text. With the approval of supplemental application S-012, supplemental application S-011 is superceded, therefore, we will not review this supplemental application but it will be retained in our files.

The final printed labeling (FPL) must be identical to the enclosed labeling text for the package insert, submitted February 11, 2002.

Please submit the FPL electronically according to the guidance for industry titled Providing Regulatory Submissions in Electronic Format – NDA. Alternatively, you may submit 20 paper copies of the FPL as soon as it is available, in no case 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, this submission should be designated "FPL for approved supplement NDA 20549/S-012." Approval of this submission by FDA is not required before the labeling is used.

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, HF-2
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 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

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
6/20/03 04:03:51 PM