DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 20-549/S-014

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

Attention: Patrick D. Wire, Pharm.D.
Director, US Regulatory Affairs

Dear Dr. Wire:

Please refer to your supplemental new drug application dated April 7, 2003, received April 8, 2003, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Flovent Rotadisk (fluticasone propionate inhalation powder).

1. Revisions to the DESCRIPTION section, the ADVERSE REACTIONS and the CONTRAINDICATIONS section of the package insert to include information for patients with a history of milk protein allergy who may experience a hypersensitivity to dry powder inhalers containing lactose.

2. Revisions to the PRECAUTIONS section of the package insert to included adrenal crisis.

3. The addition of anaphylactic reactions to the Observed During Clinical Practice: Non-Site Specific subsection of the ADVERSE REACTIONS section of the package insert.

We completed our review of this supplemental new drug application, it is approved, effective on the date of this letter, for use as recommended in the final printed labeling (FPL) submitted on April 7, 2003.

We remind you that you must submit patent information on form FDA 3542, *Patent Information Submitted Upon and After Approval of an NDA or Supplement*, within 30 days of the date of this letter as required by 21 CFR 314.53(c)(2)(ii) and 314.53(d)(2) at the address provided by 21 CFR 314.53(d)(4). The form may be obtained at http://www.fda.gov/opacom/morechoices/fdaforms/cder.html. To expedite review of this patent declaration form, we request you submit an additional copy of the form to this/these application(s) and to the Center for Drug Evaluation and Research "Orange Book" staff at

Food and Drug Administration
Office of Generic Drugs, HFD-610
Orange Book Staff
7500 Standish Place

Metro Park North II
Rockville, MD 20855-2773

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 Ladan Jafari, Regulatory Project Manager, at (301) 827-1084.

Sincerely,

{See appended electronic signature page}

Badrul A. Chowdhury, M.D., Ph.D.
Division 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
10/8/03 02:43:37 PM