DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 20-833/S-012

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

Attention: Malcolm W. Cass, Ph.D.
Assistant Director, CMC Regulatory Affairs

Dear Dr. Cass:

Please refer to your supplemental new drug application dated August 16, 2004, received August 17, 2004, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Flovent Diskus (fluticasone propionate inhalation powder) 50 mcg.

We acknowledge receipt of your submissions dated October 13, and November 5, 19, and 29, 2004.

This supplemental new drug application provides for the addition of a new manufacturing facility for the (b)(4) drug substance, new aerodynamic particle size distribution (APSD) specifications for the drug product, new (b)(4) equipment, a modified target for mean emitted dose, and new labeling.

We completed our review of this application, as amended. This application is approved, effective on the date of this letter, for use as recommended in the agreed-upon labeling text.

1. We remind you of your agreement as listed in your submission dated March 30, 2000, to the Flovent Diskus NDA, to provide an updated assessment of the impact of the suggested change to the sampling scheme on the proposed new specifications, 12 months after launch of the product." This pertains to assessing the aerodynamic particle size distribution of the drug product using a reduced number of blisters.

2. We remind you of your agreement dated November 19, 2004, to implement the same changes in the container closure system (i.e., addition of a (b)(4) for Flovent Diskus as agreed for Advair Diskus, in the first quarter 2007, provided that such changes improve the stability of the product. This agreement also provides for tightened acceptance criteria. We recommend that this agreement also be applied to Serevent Diskus. In connection with this commitment, we recommend that you ensure that the overwrap provides an adequate seal through shelf life of product.

The final printed labeling (FPL) must be identical to the enclosed labeling submitted October 13, 2004.

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 15 of the copies on heavy-weight paper or similar material. For administrative purposes, this submission should be designated "FPL for approved supplement NDA 20-833/S-012." Approval of this submission by FDA is not required before the labeling is used.

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}

Richard Lostritto, Ph.D.
Chemistry Team Leader
Division of Pulmonary and Allergy Drug Products, HFD-570
DNDC II, Office of New Drug Chemistry
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/

Alan Schroeder
12/17/04 01:21:47 PM
Signed for Richard Lostritto, Ph.D.