DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-077/S-022
NDA 20-236/S-030
NDA 20-692/S-026

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

Attention: C. Elaine Jones, Ph.D.
Vice President, US Regulatory Affairs

Dear Dr. Jones:

Please refer to your supplemental new drug applications dated February 24, 2004, received February 25, 2004, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Advair Diskus (fluticasone propionate and salmeterol xinafoate inhalation powder), Serevent Inhalation Aerosol (salmeterol xinafoate), and Serevent Diskus (salmeterol xinafoate inhalation powder).

We acknowledge receipt of your submissions dated April 26, May 24, and 28, June 8, July 29, August 12, 25, and 27, and September 8, and 14, 2004.

These supplemental new drug applications provide for revisions to the package insert to update the results of the Serevent Multi-Center Asthma Research Trial.

We completed our review of these applications, as amended. These applications are approved, effective on the date of this letter, for use as recommended in the agreed-upon labeling text.

The final printed labeling (FPL) must be identical to the enclosed labeling (package insert submitted September 14, 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, these submissions should be designated "FPL for approved supplement NDA 21-077S-022, NDA 20-236/S-030, and NDA 20-692/S-026." Approval of these submissions by FDA is not required before the labeling is used.

We remind you of your agreement (refer to the telephone conversation dated September 27, 2004, between Robert Bohinski of your office and Ladan Jafari of this Division) to implement the new labeling within 3-4 months of approval of these supplements.

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 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: Pkg. Insert for Advair Diskus, Serevent Inhalation Aerosol, and Serevent Diskus

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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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