DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 20-692
NDA 21-077

GlaxoSmithKline
P.O. Box 13398
Five Moore Drive
Research Triangle Park, NC 27709-3398

Attention: Tracey L. Fisher, Pharm.D.
Manager, U.S., Regulatory Affairs

Dear Dr. Fisher:

Please refer to your supplemental new drug applications dated February 22, 2006, received February 23, 2006, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Serevent Diskus (salmeterol xinafoate inhalation powder), and Advair Diskus (fluticasone propionate and salmeterol inhalation powder).

We acknowledge receipt of your submissions dated February 24, and 27, 2006.

These supplemental new drug applications provide for changes to the Package Insert, including the addition of a Medication Guide, to provide adequate information for the safe and effective use of these medications.

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.

We acknowledge receipt of your labeling in Structured Product Labeling format (SPL) dated February 27, 2006, we will comment on the SPL, as necessary, at a later date.

The final printed labeling (FPL) must be identical to the submitted labeling, (package insert submitted February 27, 2006) copy enclosed.

Please submit an electronic version of the FPL 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 but no more than 30 days after it is printed. Individually mount 15 of the copies on heavy-weight paper or similar material. For administrative purposes, designate these submissions "**FPL for approved supplement NDA 20-692/S-029, and NDA 21-077/S-028**." Approval of these submissions by FDA is not required before the labeling is used.

In addition, submit three copies of the introductory promotional materials that you propose to use for these products. Submit all proposed materials in draft or mock-up form, not final print. Send one copy to this Division and two copies of both the promotional materials and the package inserts directly to:

Food and Drug Administration
Center for Drug Evaluation and Research
Division of Drug Marketing, Advertising, and Communications
Food and Drug Administration
5901-B Ammendale Road
Beltsville, MD 20705-1266

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
Food and Drug Administration
WO 22, Room 4447
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

Please submit one market package of the drug product when it is available.

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. Akilah Green, Regulatory Project Manager, at (301) 796-1219.

Sincerely,

{See appended electronic signature page}

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

Enclosures

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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