DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 20-692/S-016

GlaxoSmithKline
PO Box 13398
Five Moore Drive
Research Triangle Park, NC 27709

Attention: Robert J. Bohinski
Associate Director, Regulatory Affairs

Dear Mr. Bohinski:

Please refer to your supplemental new drug application dated May 25, 2001, received May 25, 2001, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Serevent Diskus (salmeterol xinafoate) inhalation powder.

We acknowledge receipt of your submissions dated September 5, and 17, October 17, and 26, November 9, 2001, and February 8, and 28, and March 18, 19, 20 and 22, 2002.

This supplemental new drug application provides for the use of Serevent Diskus (salmeterol xinafoate) inhalation powder for the long-term, twice-daily (morning and evening) administration in the maintenance treatment of bronchospasm associated with COPD (including emphysema and chronic bronchitis).

We have completed the review of this supplemental application, as amended, and have concluded that adequate information has been presented to demonstrate that the drug product is safe and effective for use as recommended in the agreed upon enclosed labeling text. Accordingly, the supplemental application is approved effective on the date of this letter.

The final printed labeling (FPL) must be identical to the enclosed labeling (text for the package insert and the patient's instructions for use both dated March 22, 2002) and the container and carton labeling dated March 19, 2002.

Please submit the copies of final printed labeling (FPL) electronically according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format - NDA* (January 1999). 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. Please individually mount ten of the copies on heavyweight paper or similar material. For administrative purposes, this submission should be designated "FPL for approved supplemental NDA 20-692/S-016." Approval of this submission by FDA is not required before the labeling is used.

We acknowledge your commitment to revise the container and carton labeling at the next printing as discussed on March 22, 2002, between Dr. Craig Ostroff, of this division, and Mr. Robert Bohinski, of your firm. The commitments were as follows:

1. Increase the prominence of the storage statement on your carton and container labels. Patients and health professionals need to be sensitized to this issue, since the performance of the drug product is dependent upon temperature and humidity conditions.

2. Increase the prominence of the established name on your carton and container labels such that it is commensurate with the prominence of the proprietary name, in accordance with 21 CFR 201.10(g)(2).

Be advised that, as of April 1, 1999, all applications for new active ingredients, new dosage forms, new indications, new routes of administration, and new dosing regimens are required to contain an assessment of the safety and effectiveness of the product in pediatric patients unless this requirement is waived or deferred (63 *FR* 66632). We are waiving the pediatric study requirement for this action on this application.

In addition, please submit three copies of the introductory promotional materials that you propose to use for this product. All proposed materials should be submitted in draft or mock-up form, not final print. Please submit one copy to this Division and two copies of both the promotional materials and the package insert directly to:

Division of Drug Marketing, Advertising, and Communications, HFD-42
Food and Drug Administration
5600 Fishers Lane
Rockville, Maryland 20857

If a letter communicating important information about this drug product (i.e., a "Dear Health Care Professional" letter) is issued to physicians and others responsible for patient care, 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

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

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 Dr. Craig Ostroff, Regulatory Management Officer, at (301) 827-1050.

Sincerely,

{See appended electronic signature page}

Robert J. Meyer, M.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/

Robert Meyer

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