DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 20-983/S-009

GlaxoSmithKline
P.O. Box 13398
Five Moore Drive
Research Triangle Park
North Carolina 27709-3398

Attention: Robert J. Bohinski
Associate Director, Respiratory US Regulatory Affairs

Dear Mr. Bohinski:

Please refer to your supplemental new drug application dated December 17, 2004, received December 20, 2005, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Ventolin HFA (albuterol sulfate) Inhalation Aerosol.

We acknowledge receipt of your submissions dated December 21, 2004, February 23, March 18, and 25, and April 8, and 13, 2005.

This supplemental new drug application provides for Ventolin HFA MDI with dose counter.

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.

The final printed labeling (FPL) must be identical to the enclosed labeling (package insert, patient instructions for use, and immediate container and carton labels submitted April 13, 2005).

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 this submission "**FPL for approved supplement NDA 20-983/S-009**." Approval of this submission 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 this product. Submit all proposed materials in draft or mock-up form, not final print. Send one copy to the Division of Pulmonary and Allergy Drug Products and two copies of both the promotional materials and the package insert(s) directly to:

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

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

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).

We remind you of your agreement listed in your amendment dated March 25, 2005, to complete the following within 18 months of approval:

Conduct a comprehensive and well-designed study of the dosing behavior of the Ventolin HFA product to fully characterize the observed high initial doses obtained during the priming actuations. The study should also address the impact of storage time (e.g., up to 9 months) and orientation on the dosing behavior during priming.

If you have any questions, call Akilah Green, Regulatory Project Manager, at (301) 827-5585.

Sincerely,

Richard Lostitto, 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

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

Richard Lostritto

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