DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 21254/S-007 **SUPPLEMENT APPROVAL**

GlaxoSmithKline
Five Moore Drive
P.O. Box 13396
Research Triangle Park, NC 27709

Attention: Purnima K. Narang
Assistant Director, CMC Regulatory Affairs

Dear Ms. Narang:

Please refer to your supplemental new drug application dated September 19, 2008, received on September 19, 2008 submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Advair HFA (fluticasone propionate/salmeterol) Inhalation Aerosol 45/21, 115/21, and 230/21 mcg.

We acknowledge receipt of your submissions dated May 15, and September 9 and 14, 2009. Your submission of May 15, 2009 constituted a complete response to our January 15, 2009, action letter.

This Prior Approval supplemental new drug application provides for a 60 actuation sample pack, revisions to the labeling (package insert and Medication Guide), a proposed modification to the approved, Risk Evaluation and Mitigation Strategy (REMS), and a REMS assessment.

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

RISK EVALUATION AND MITIGATION STRATEGY REQUIREMENTS

On September 9, 2009, you submitted a proposed modification and an assessment of your Risk Evaluation and Mitigation Strategy (REMS), originally approved on July 31, 2008. The proposed modified REMS contains a modified Medication Guide reflecting availability of the 60 actuation sample pack and clarified language regarding proper use of Advair HFA, and the same timetable for submission of assessments as the original REMS approved on July 31, 2008.

After consultation between the Office of Surveillance and Epidemiology and the Office of New Drugs, your proposed modified REMS is approved and is appended to this letter. The timetable for submission of assessment will remain the same as that approved on July 31, 2008, with the original approval of the REMS.

Prominently identify submissions containing the REMS assessments or proposed modifications of the REMS with the following wording in bold capital letters at the top of the first page of the submission:

NDA 21-254 REMS ASSESSMENT

NEW SUPPLEMENT FOR NDA 21-254
PROPOSED REMS MODIFICATION
REMS ASSESSMENT

NEW SUPPLEMENT (NEW INDICATION FOR USE)
FOR NDA 21-254
REMS ASSESSMENT
PROPOSED REMS MODIFICATION (if included)

If you do not submit electronically, please send 5 copies of REMS-related submissions.

CONTENT OF LABELING

As soon as possible, but no later than 14 days from the date of this letter, please submit the content of labeling [21 CFR 314.50(l)(1)(i)] in structured product labeling (SPL) format as described at http://www.fda.gov/oc/datacouncil/spl.html that is identical to the Package Insert submitted September 10 ,2009 and Medication guide submitted May 15, 2009 (copy enclosed). Upon receipt, we will transmit that version to the National Library of Medicine for public dissemination. For administrative purposes, please designate this submission, "**SPL for approved NDA 21254/S-007**."

We request that the revised labeling approved today be available on your website within 10 days of receipt of this letter.

CARTON AND IMMEDIATE CONTAINER LABELS

Submit final printed carton and container labels that are identical to the enclosed carton and immediate container labels (submitted May 15, 2009) as soon as they are available, but no more than 30 days after they are printed. Please submit these labels electronically according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format – Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications (October 2005)*. Alternatively, you may submit 12 paper copies, with 6 of the copies individually mounted on heavy-weight paper or similar material. For administrative purposes, designate this submission "Final Printed Carton and Container Labels for approved NDA 21254/S-007." Approval of this submission by FDA is not required before the labeling is used.

Marketing the product with FPL that is not identical to the approved labeling text may render the product misbranded and an unapproved new drug.

If you issue a letter communicating important safety related information about this drug product (i.e., a "Dear Health Care Professional" letter), we request that you submit an electronic copy of the letter to both this NDA and to the following address:

MedWatch
Food and Drug Administration
5600 Fishers Lane, Room 12B05
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 Carol Hill, Regulatory Health Project Manager, at (301) 796-1226.

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
Content of Labeling
Carton and Container Labeling
REMS

Application Type/Number	Submission Type/Number	Submitter Name	Product Name
NDA-21254	SUPPL-7	GLAXOSMITHKLINE	ADVAIR HFA(FLUTICASONE PROPIONATE/SALMET

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

/s/

LYDIA I GILBERT MCCLAIN
09/15/2009