DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 21254/S-009

SUPPLEMENT APPROVAL
FULFILLMENT OF POSTMARKETING COMMITMENT

GlaxoSmithKline
5 Moore Drive
Research Triangle Park, NC 27709-3398

Attention: Kevin Fitzgerald, R.Ph.
Senior Director, Global Regulatory Affairs

Dear Mr. Fitzgerald:

Please refer to your Supplemental New Drug Application (sNDA) dated June 25, 2009, received June 26, 2009, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Advair HFA (fluticasone propionate/salmeterol xinafoate) Inhalation Aerosol 45 mcg/21 mcg, 115 mcg/21 mcg, and 230 mcg/21mcg.

We have received your submission dated January 23, 2009, containing the final report for the following postmarketing commitment listed in the June 8, 2006, approval letter.

1. To conduct a study for the treatment of asthma in pediatric patients ages greater than 4 and less than 12 years of age.

We have reviewed your submission and conclude that the above commitment has been fulfilled.

We also acknowledge receipt of your amendments dated November 5, 2009, July 9,and October 22, 2010, January 31, July 26 and August 10, 2011, and October 22, November 9, and December 17, 2012.

This Prior Approval supplemental new drug application provides for revisions to Section 8: Use in Special Population , Pediatric Use and conversion of the label to the Physician's Label Rule (PLR) format as defined in 21 CFR 201.56(d) and 21 CFR 201.57.

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

We acknowledge your request dated November 9, 2012 to waive the requirements of 21 CFR 201.57 (d)(8) regarding the length of Highlights. This waiver applies to all future supplements containing revised labeling unless we notify you otherwise.

CONTENT OF LABELING

As soon as possible, but no later than 14 days from the date of this letter, submit the content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format using the FDA automated drug registration and listing system (eLIST), as described at http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm. Content of labeling must be identical to the enclosed labeling text for the package insert and text for the Medication Guide with the addition of any labeling changes in pending "Changes Being Effected" (CBE) supplements, as well as annual reportable changes not included in the enclosed labeling.

Information on submitting SPL files using eLIST may be found in the guidance for industry titled "SPL Standard for Content of Labeling Technical Qs and As" at http://www.fda.gov/downloads/DrugsGuidanceComplianceRegulatoryInformation/Guidances/UCM072392.pdf.

The SPL will be accessible from publicly available labeling repositories.

Also within 14 days, amend all pending supplemental applications for this NDA, including CBE supplements for which FDA has not yet issued an action letter, with the content of labeling [21 CFR 314.50(l)(1)(i)] in MS Word format, that includes the changes approved in this supplemental application, as well as annual reportable changes and annotate each change. To facilitate review of your submission, provide a highlighted or marked-up copy that shows all changes, as well as a clean Microsoft Word version. The marked-up copy should provide appropriate annotations, including supplement number(s) and annual report date(s).

REPORTING REQUIREMENTS

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 F. Hill, Senior Regulatory Health Project Manager, at (301) 796-1226.

Sincerely,

{See appended electronic signature page}

Sally Seymour, M.D.
Deputy Director for Safety
Division of Pulmonary, Allergy, and Rheumatology Products
Office of Drug Evaluation II
Center for Drug Evaluation and Research

Enclosure:
Content of Labeling

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

/s/

SALLY M SEYMOUR
12/19/2012