DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 21077/S-056 and S-057

SUPPLEMENT APPROVAL
FULFILLMENT OF POSTMARKETING REQUIREMENT

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

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

Dear Mr. Fitzgerald:

Please refer to your Supplemental New Drug Applications (sNDAs) dated October 3, 2016, and your amendments, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Advair Diskus (fluticasone propionate/salmeterol xinafoate) Inhalation Powder, 100 mcg/50 mcg, 250 mcg/50 mcg and 500 mcg/50 mcg.

We acknowledge receipt of your major amendment dated July 13, 2017, which extended the goal date by three months.

These Prior Approval supplemental new drug applications provide for changes to the prescribing information to incorporate the results of the required safety trials with Advair Diskus and revised class labeling for inhaled corticosteroid/long-acting beta agonist combination products, including removal of the Boxed Warning for asthma-related death. These supplements also provide for replacement of the Medication Guide with the Patient Information leaflet and revised labeling in accordance with the Pregnancy and Lactation Labeling Rule (PLLR).

APPROVAL & LABELING

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

WAIVER OF HIGHLIGHTS SECTION

We are waiving the requirements of 21 CFR 201.57(d)(8) regarding the length of Highlights of prescribing information. 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, text for the patient information leaflet, and text for the instructions for use, 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 that include labeling changes 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).

REQUIRED PEDIATRIC ASSESSMENTS

Under the Pediatric Research Equity Act (PREA) (21 U.S.C. 355c), all applications for new active ingredients, new indications, new dosage forms, new dosing regimens, or new routes of administration are required to contain an assessment of the safety and effectiveness of the product for the claimed indication(s) in pediatric patients unless this requirement is waived, deferred, or inapplicable.

Because none of these criteria apply to your application, you are exempt from this requirement.

FULFULLMENT OF POSTMARKETING COMMITMENT

We have received your submissions dated January 15 and May 19, 2016, containing the final reports for the following postmarketing requirements listed in the April 14, 2011 postapproval postmarketing requirement letter.

1750-1 A randomized, double-blind, 26-week, active controlled clinical trial comparing

Advair Diskus (fluticasone propionate and salmeterol xinafoate inhalation powder) and fluticasone propionate inhalation powder to evaluate the risk of serious asthma outcomes (hospitalizations, intubation, death) in 11,700 adult and adolescent patients 12 years of age and older with persistent asthma.

Final Protocol Submission:	May 2011
Trial Completion:	February 2017
Final Report Submission:	June 2017

1750-2 A randomized, double-blind, 26-week, active controlled clinical trial comparing Advair Diskus (fluticasone propionate and salmeterol xinafoate inhalation powder) and Flovent Diskus (fluticasone propionate inhalation powder) to evaluate the risk of serious asthma outcomes (hospitalizations, intubation, death) in 6200 pediatric patients 4 to 11 years of age with persistent asthma.

Final Protocol Submission:	May 2011
Trial Completion:	February 2017
Final Report Submission:	June 2017

We have reviewed your submissions and conclude that the above requirements were fulfilled.

This completes all your postmarketing requirements acknowledged in our April 14, 2011, letter.

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 for Safety, at (301) 796-1226.

Sincerely,

{See appended electronic signature page}

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

ENCLOSURE(S):
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
12/20/2017