



NDA 205625/S-005

**SUPPLEMENT APPROVAL
FULFILLMENT OF POSTMARKETING REQUIREMENT**

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

Attention: Christopher J. Stotka, PharmD
Director, Global Regulatory Affairs

Dear Dr. Stotka:

Please refer to your Supplemental New Drug Application (sNDA) dated July 21, 2017, received July 21, 2017, and your amendments, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Arnuity Ellipta (fluticasone furoate) Inhalation Powder, 50 mcg.

This Prior Approval supplemental new drug application provides for the use of Arnuity Ellipta 50 mcg for the maintenance treatment of asthma in pediatric patients ages 5 through 11 years of age.

APPROVAL & LABELING

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.

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 package insert, and text of 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).

CARTON AND IMMEDIATE CONTAINER LABELS

Submit final printed carton and immediate container labels that are identical to the enclosed carton and immediate container labels, 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 — Certain Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications (May 2015, Revision 3)*. For administrative purposes, designate this submission “**Final Printed Carton and Container Labels for approved NDA 205625/S-005.**” Approval of this submission by FDA is not required before the labeling is used.

REQUIRED PEDIATRIC ASSESSMENTS

Under the Pediatric Research Equity Act (PREA) (21 U.S.C. 355c), all applications for new active ingredients (which includes new salts and new fixed combinations), 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 in pediatric patients unless this requirement is waived, deferred, or inapplicable.

We note that we waived the pediatric study requirement in children younger than 5 years of age in the approval letter dated August 20, 2014, because necessary studies are impossible or highly impractical to perform.

We also note that you have the following deferred pediatric study listed in the August 20, 2014, approval letter.

2765-3 Conduct a 52-week, randomized, double-blind, parallel group, active controlled, growth study in females 5-<8 years of age and males 5-<9 years of age with asthma.

Study Completion: October 2021
Final Report Submission: June 2022

FULFILLMENT OF POSTMARKETING REQUIREMENTS

We have received your submission dated July 21, 2017, containing the final reports for the following postmarketing requirements listed in the August 20, 2014, approval letter.

2765-1 Conduct a 12-week, randomized, double-blind, double-dummy, parallel group, placebo-controlled, dose-ranging, efficacy, and safety study in children 5-11 years of age with asthma. The final study report will be submitted as a supplement with the results of the knemometry and HPA axis studies.

Final Protocol Submission: February 2012
Study Completion: September 2014
Final Report Submission: June 2017

2765-2 Conduct 2-week randomized, double-blind, placebo-controlled, 2-way crossover, knemometry growth rate study in children 5-11 years of age with asthma.

Final Protocol Submission: September 2015
Study Completion: March 2016
Final Report Submission: June 2017

2765-4 Conduct a 6-week, randomized, double-blind, parallel group, placebo-controlled, HPA-axis study in children 5-11 years of age with asthma.

Final Protocol Submission: September 2015
Study Completion: November 2016
Final Report Submission: June 2017

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

We remind you that there is one postmarketing requirement listed in the August 20, 2014, approval letter that is still open.

PROMOTIONAL MATERIALS

You may request advisory comments on proposed introductory advertising and promotional labeling. To do so, submit the following, in triplicate, (1) a cover letter requesting advisory comments, (2) the proposed materials in draft or mock-up form with annotated references, and (3) the package insert(s) to:

OPDP Regulatory Project Manager
Food and Drug Administration
Center for Drug Evaluation and Research
Office of Prescription Drug Promotion (OPDP)
5901-B Ammendale Road
Beltsville, MD 20705-1266

Alternatively, you may submit a request for advisory comments electronically in eCTD format. For more information about submitting promotional materials in eCTD format, see the draft Guidance for Industry (available at: <http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM443702.pdf>).

You must submit final promotional materials and package insert(s), accompanied by a Form FDA 2253, at the time of initial dissemination or publication [21 CFR 314.81(b)(3)(i)]. Form FDA 2253 is available at <http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM083570.pdf>. Information and Instructions for completing the form can be found at <http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM375154.pdf>. For more information about submission of promotional materials to the Office of Prescription Drug Promotion (OPDP), see <http://www.fda.gov/AboutFDA/CentersOffices/CDER/ucm090142.htm>.

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 Ngoc-Linh Do, Regulatory Project Manager, at (301) 348-1896.

Sincerely,

{See appended electronic signature page}

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

ENCLOSURE(S):

Content of Labeling

Carton and Container 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
05/17/2018