DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 205625/S-001

SUPPLEMENT APPROVAL

GlaxoSmithKline
Five Moore Drive
P.O. 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 October 9, 2014, received October 9, 2014, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Arnuity Ellipta (fluticasone furoate inhalation powder) 100 mcg and 200 mcg.

We acknowledge receipt of your amendment dated December 19, 2014.

This "Changes Being Effected" supplemental new drug application proposes the following changes: 1) revising the carton and container labels for Arnuity Ellipta from Fluticasone Furoate to Fluticasone Furoate and Lactose Monohydrate on both Arnuity Ellipta strengths, 100 mcg and 200 mcg, 2) changing the color of the Arnuity Ellipta 200 mcg strength from green to orange and yellow, and 3) adding several minor editorial changes.

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.

CARTON AND IMMEDIATE CONTAINER LABELS

We acknowledge your October 9, 2014, submission containing final printed carton and container labels.

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.

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 Nina, Regulatory Project Manager, at (301) 796-1648.

Sincerely,

{See appended electronic signature page}

Badrul A. Chowdhury, MD, PhD
Director
Division of Pulmonary, Allergy, and Rheumatology Products
Office of Drug Evaluation II
Center for Drug Evaluation and Research

ENCLOSURE:
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/

BADRUL A CHOWDHURY
03/20/2015