

CENTER FOR DRUG EVALUATION AND RESEARCH

Approval Package for:

APPLICATION NUMBER:

205625Orig1s000

Trade Name: Arnuity Ellipta 100 mcg and 200 mcg

Generic Name: fluticasone furoate inhalation powder

Sponsor: GlaxoSmithKline

Approval Date: August 20, 2014

Indication: For the maintenance treatment of asthma as prophylactic therapy in patients aged 12 years and older.

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APPROVAL LETTER



NDA 205625

NDA APPROVAL

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

Attention: Christopher J. Stotka, Pharm.D.
Director, Global Regulatory Affairs

Dear Dr. Stotka:

Please refer to your New Drug Application (NDA) dated October 22, 2013, received October 22, 2013, 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 amendments dated November 25 and December 19, 2013, and January 16, February 20 and 24, April 9, 17, and 25, May 15 and 23, June 26, and August 1, 4, 8, 13, 14, and 18, 2014.

This new drug application provides for the use of Arnuity Ellipta (fluticasone furoate inhalation powder) 100 mcg and 200 mcg for the maintenance treatment of asthma as prophylactic therapy in patients aged 12 years and older.

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.

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, text for instructions for use). Information on submitting SPL files using eLIST may be found in the guidance for industry *SPL Standard for Content of Labeling Technical Qs and As*, available at <http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM072392.pdf>.

The SPL will be accessible via publicly available labeling repositories.

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 *Providing Regulatory Submissions in Electronic Format – Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications (June 2008)*. 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 205625.**” Approval of this submission by FDA is not required before the labeling is used.

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

EXPIRATION DATING PERIOD

A 30-month expiry dating period is granted for Arnuity Ellipta (fluticasone furoate inhalation powder) when stored at controlled room temperature between 20°C and 25°C (68°F and 77°F) with excursions permitted from 15°C and 30°C (59°F and 86°F).

ADVISORY COMMITTEE

Your application for Arnuity Ellipta was not referred to an FDA advisory committee because this drug is not the first in its class.

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.

We are waiving the pediatric study requirement for patients less than 5 years of age because necessary studies are impossible or highly impracticable to perform.

We are deferring submission of your pediatric studies for ages 5 to 11 years because this product is ready for approval for use in adults and the pediatric studies have not been completed.

Your deferred pediatric studies required by section 505B(a) of the FDCA are required postmarketing studies. The status of these postmarketing studies must be reported annually according to 21 CFR 314.81 and section 505B(a)(3)(B) of the FDCA. These required studies are listed below.

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 a 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

2765-3: 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.

Final Protocol Submission: October 2016
Study Completion: October 2021
Final Report Submission: June 2022

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

Submit the protocols to your IND 070297, with a cross-reference letter to this NDA.

Reports of these required pediatric postmarketing studies must be submitted as a new drug application (NDA) or as a supplement to your approved NDA with the proposed labeling changes you believe are warranted based on the data derived from these studies. When submitting the reports, please clearly mark your submission "**SUBMISSION OF REQUIRED PEDIATRIC ASSESSMENTS**" in large font, bolded type at the beginning of the cover letter of the submission.

We note that you have fulfilled the pediatric studies requirement for ages 12 to 17 years for this application.

PROMOTIONAL MATERIALS

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

Food and Drug Administration
Center for Drug Evaluation and Research
Office of Prescription Drug Promotion
5901-B Ammendale Road
Beltsville, MD 20705-1266

As required under 21 CFR 314.81(b)(3)(i), you must submit final promotional materials, and the package insert, at the time of initial dissemination or publication, accompanied by a Form FDA 2253. 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 Nina Ton, Regulatory Project Manager, at (301) 796-1648.

Sincerely,

{See appended electronic signature page}

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

Enclosures:

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/

BADRUL A CHOWDHURY
08/20/2014