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New Drug Application (NDA): 209482

Company: GLAXOSMITHKLINE

 [EMAIL \(MAILTO:?SUBJECT=DRUGS@FDA: FDA APPROVED DRUG PRODUCTS&BODY=HTTP://WWW.ACCESSDATA.FDA.GOV/SCRIPTS/CDER/DAF/INDEX.CFM?EVENT=OVERVIEW.PROCESS%26VARAPPLNO=209482\)](mailto:?subject=Drugs@FDA: FDA Approved Drug Products&body=http://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process%26varapplno=209482)

• [Medication Guide](#)

https://www.accessdata.fda.gov/drugsatfda_docs/label/2017/209482s000lbl.pdf#page=33

Products on NDA 209482

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Drug Name	Active Ingredients	Strength	Dosage Form/Route	Marketing Status	TE Code	RLD	RS
TRELEGY ELLIPTA	FLUTICASONE FUROATE; UMECLIDINIUM BROMIDE; VILANTEROL TRIFENATATE	0.1MG/INH;EQ 0.0625MG BASE/INH;EQ 0.025MG BASE/INH	POWDER;INHALATION	Prescription	None	Yes	Yes

Drug Name	Active Ingredients	Strength	Dosage Form/Route	Marketing Status	TE Code	RLD	RS
TRELEGY ELLIPTA	FLUTICASONE FUROATE; UMECLIDINIUM BROMIDE; VILANTEROL TRIFENATATE	0.2MG/INH;EQ 0.0625MG BASE/INH;EQ 0.025MG BASE/INH	POWDER;INHALATION	Prescription	None	Yes	Yes

Showing 1 to 2 of 2 entries

Approval Date(s) and History, Letters, Labels, Reviews for NDA 209482**Original Approvals or Tentative Approvals**

CSV

Excel

Print

Action Date	Submission	Action Type	Submission Classification	Review Priority; Orphan Status	Letters, Reviews, Labels, Pati
09/18/2017	ORIG-1	Approval	Type 5 - New Formulation or New Manufacturer	STANDARD	Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2017/018882Orig1s001.pdf) Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/applletter/2017/018882Orig1s001ltr.pdf) Review (https://www.accessdata.fda.gov/drugsatfda_docs/nda/2017/018882Orig1s001.pdf)

Showing 1 to 1 of 1 entries

Supplements

CSV

Excel

Print

Action Date	Submission	Supplement Categories or Approval Type	Letters, Reviews, Labels, Patient Package Insert
09/09/2020	SUPPL-11	Labeling- Package Insert	Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2020/209482Orig1s011.pdf) Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/applletter/2020/209482Orig1s011ltr.pdf)

Action Date	Submission	Supplement Categories or Approval Type	Letters, Reviews, Labels, Patient Package Insert
09/09/2020	SUPPL-10	Efficacy-New Indication	Label (PDF) https://www.accessdata.fda.gov/drugsatfda_docs/label/2020/209 Letter (PDF) https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2020/s011ltr.pdf
05/15/2019	SUPPL-5	Labeling- Package Insert	Label (PDF) https://www.accessdata.fda.gov/drugsatfda_docs/label/2019/209 Letter (PDF) https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2019/
01/07/2019	SUPPL-3	Labeling- Package Insert	Label (PDF) https://www.accessdata.fda.gov/drugsatfda_docs/label/2019/209 Letter (PDF) https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2019/
01/07/2019	SUPPL-2		Label (PDF) https://www.accessdata.fda.gov/drugsatfda_docs/label/2019/209
04/24/2018	SUPPL-1	Efficacy-Labeling Change With Clinical Data	Label (PDF) https://www.accessdata.fda.gov/drugsatfda_docs/label/2018/209 Letter (PDF) https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2018/

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Labels for NDA 209482



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 209482/S-001

SUPPLEMENT APPROVAL

GlaxoSmithKline
Five Moore Drive
PO Box 13398
Research Triangle Park, NC 27709-3398

Attention: Mary V. Sides
Director, Global Regulatory Affairs

Dear Ms. Sides:

Please refer to your Supplemental New Drug Application (sNDA) dated November 20, 2017, received November 21, 2017, and your amendments, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Trelegy Ellipta (fluticasone furoate, 100 mcg, umeclidinium 62.5 mcg, and vilanterol 25 mcg inhalation powder).

This Prior Approval supplemental new drug application proposes to revise the indication to state the following: TRELEGY ELLIPTA is a combination of fluticasone furoate, an inhaled corticosteroid (ICS); umeclidinium, an anticholinergic; and vilanterol, a long acting beta2-adrenergic agonist (LABA), indicated for the long-term, once-daily, maintenance treatment of airflow obstruction in patients with chronic obstructive pulmonary disease (COPD). TRELEGY ELLIPTA is also indicated to reduce exacerbations of COPD in patients with a history of exacerbations.

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

Please note that we have previously granted a waiver of the requirements of 21 CFR 201.57(d)(8) regarding the length of Highlights of prescribing information.

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, , Medication Guide, Instructions for Use), with the addition of any labeling changes in pending “Changes Being Effectuated” (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 (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.

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

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 LeAnn Brodhead, Regulatory Project Manager, at (240) 402-2605.

Sincerely,

{See appended electronic signature page}

Lydia Gilbert-McClain, M.D.
Deputy Director
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/

LEANN D BRODHEAD
04/24/2018

LYDIA I GILBERT MCCLAIN
04/24/2018