NDA 209482/S-010
NDA 209482/S-011

SUPPLEMENT APPROVAL

GlaxoSmithKline Intellectual Property Development Ltd. England
1250 S. Collegeville Road
Collegeville, PA 19426-0989

Attention: Ron Chamrin
Manager, Global Regulatory Affairs

Dear Mr. Chamrin:

Please refer to your supplemental new drug applications NDA 209482/S-010, dated and received on September 26, 2019, and NDA 209482/S-011, dated and received on February 10, 2020, and your amendments, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Trelegy Ellipta (Fluticasone Furoate/Umeclidinium/Vilanterol 100 mcg/62.5 mcg/25 mcg) inhalation powder.

Prior Approval supplemental new drug application NDA 209482/S-010 provides for the addition of the indication of maintenance treatment of asthma in patients aged 18 years and older, and the addition of a new dose option (Fluticasone Furoate/Umeclidinium/Vilanterol 200 mcg/62.5 mcg/25 mcg).

Prior Approval supplemental new drug application NDA 209482/S-011 provides for updating of the labeling with the addition of Section 6.2 Postmarketing Experience.

APPROVAL & LABELING

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

WAIVER OF ½ PAGE LENGTH REQUIREMENT FOR HIGHLIGHTS

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 FDA.gov.[1] Content of labeling must be identical to the enclosed labeling (text for the Prescribing Information, Patient Package Insert, and 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 *SPL Standard for Content of Labeling Technical Qs and As*.[2]

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 Microsoft Word format, that includes the changes approved in this supplemental application, as well as annual reportable changes. To facilitate review of your submission(s), 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 CONTAINER LABELING

Submit final printed carton and container labeling that are identical to the enclosed carton and container labeling, as soon as they are available, but no more than 30 days after they are printed. Please submit these labeling electronically according to the guidance for industry *Providing Regulatory Submissions in Electronic Format — Certain Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications*. For administrative purposes, designate this submission "**Final Printed Carton and Container Labeling for approved NDA 209482/S-010 and NDA 209482/S-011**." Approval of this submission by FDA is not required before the labeling is used.

[1] http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm
[2] We update guidances periodically. For the most recent version of a guidance, check the FDA Guidance Documents Database https://www.fda.gov/RegulatoryInformation/Guidances/default.htm.

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 are waiving the pediatric study requirement for ages younger than 4 years because necessary studies are impossible or highly impracticable.

We are deferring submission of your pediatric study for ages 5 to 17 years for this application because this product is ready for approval for use in adults and the pediatric study have not been completed.

Your deferred pediatric studies required by section 505B(a) of the Federal Food, Drug, and Cosmetic Act/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)(4)(C) of the Federal Food, Drug, and Cosmetic Act/FDCA. These required studies are listed below.

3935-1 Conduct a 24-week, randomized, double-blind, parallel-group, active-controlled, efficacy and safety study of fluticasone furoate/umeclidinium/vilanterol inhalation powder via the Ellipta device in children 12-17 years of age with asthma.

Final Protocol Submission:	11/2023
Study Completion:	10/2027
Final Report Submission:	04/2028

3935-2 Conduct a 4-week randomized, double-blind, parallel-group, active-controlled dose-ranging trial with at least two doses of umeclidinium inhalation powder via the Ellipta device in children 5 to 11 years of age with asthma.

Final Protocol Submission:	08/2028
Study Completion:	12/2029
Final Report Submission:	06/2030

3935-3 Conduct a 24-week, randomized, double-blind, parallel-group, active-controlled, efficacy and safety study of fluticasone furoate/ umeclidinium/vilanterol inhalation powder via the Ellipta device in children 5 to 11 years of age with asthma.

Final Protocol Submission:	10/2030
Study Completion:	04/2033
Final Report Submission:	10/2033

PROMOTIONAL MATERIALS

You may request advisory comments on proposed introductory advertising and promotional labeling. For information about submitting promotional materials, see the final guidance for industry *Providing Regulatory Submissions in Electronic and Non-Electronic Format-Promotional Labeling and Advertising Materials for Human Prescription Drugs.*[3]

You must submit final promotional materials and Prescribing Information, 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 FDA.gov.[4] Information and Instructions for completing the form can be found at FDA.gov.[5]

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 Elaine Sit, Regulatory Project Manager, at (301) 796-5073.

Sincerely,

{See appended electronic signature page}

Sally Seymour, MD
Director
Division of Pulmonology, Allergy, and Critical Care
Office of Immunology and Inflammation
Center for Drug Evaluation and Research

ENCLOSURE(S):

- Content of Labeling
    - Prescribing Information

[3] For the most recent version of a guidance, check the FDA guidance web page at https://www.fda.gov/media/128163/download.
[4] http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM083570.pdf
[5] http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM375154.pdf

  - Patient Package Insert
  - Instructions for Use
- Carton and Container Labeling

This is a representation of an electronic record that was signed electronically. Following this are manifestations of any and all electronic signatures for this electronic record.

/s/

BANU A KARIMI SHAH
09/09/2020 02:22:29 PM
signing with the delegated authority of Dr. Sally Seymour, Division Director, DPACC