NDA 208798/S-008

SUPPLEMENT APPROVAL
FULLFILLMENT OF POSTMARKETING REQUIREMENT

Teva Pharmaceutical Industries Ltd.
c/o: Teva Branded Pharmaceutical Products R&D Inc.
145 Brandywine Parkway
Building 300
West Chester, PA 19380

Attention: Richard Jiang
Director, Regulatory Affairs

Dear Mr. Jiang:

Please refer to your supplemental new drug application (sNDA) dated December 21, 2020, received December 21, 2020, and your amendments, submitted pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act (FDCA) for ArmonAir RespiClick (fluticasone propionate) inhalation powder, 30 mcg, 55 mcg.

This Prior Approval supplemental new drug application provides for the use of ArmonAir Respiclick for the maintenance treatment of asthma as prophylactic therapy in pediatric patients aged 4 to 11 years.

APPROVAL & LABELING

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.

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.

[1] http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm

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 208798/S-008**." 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 also note that you have fulfilled the pediatric studies requirement for ages 4 to less than12 years for this application.

FULFILLMENT OF POSTMARKETING REQUIREMENT

We have received your submission dated December 21, 2020, containing the final

[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.

reports for the following postmarketing requirements listed in the January 27, 2017, approval letter.

3154-1 Conduct a double-blind (incorporating an open-label comparator), 3-period, crossover study to determine the pharmacokinetic profile and tolerability of single doses of fluticasone propionate inhalation powder multi-dose dry powder inhaler (MDPI) and fluticasone propionate/salmeterol xinafoate inhalation powder MDPI compared to Advair Diskus in patients with persistent asthma 4 through 11 years of age.

Final Protocol Submission:	March 2016
Study Completion:	June 2016
Final Report Submission:	December 2020

3154-2 Conduct a 12-week, randomized, double-blind, placebo-controlled, efficacy and safety study of fluticasone propionate inhalation powder multi-dose dry powder inhaler (MDPI) compared with fluticasone propionate/salmeterol xinafoate inhalation powder MDPI in patients with persistent asthma 4 through 11 years of age.

Final Protocol Submission:	June 2018
Study Completion:	April 2019
Final Report Submission:	December 2020

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

This completes all of your postmarketing requirements and postmarketing commitments acknowledged in our January 27, 2017, letter.

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]

[3] For the most recent version of a guidance, check the FDA guidance web page at https://www.fda.gov/media/128163/download.

U.S. Food and Drug Administration
Silver Spring, MD 20993
www.fda.gov

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

Sincerely,

{See appended electronic signature page}

Banu Karimi-Shah, MD
Deputy 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
  - Patient Package Insert
  - Instructions for Use
- Carton and Container Labeling

[4] http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM083570.pdf
[5] http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM375154.pdf

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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/

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