



NDA 208799/S-021

**SUPPLEMENT APPROVAL  
FULFILLMENT 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 AirDuo RespiClick, AirDuo Digihaler (fluticasone propionate/salmeterol xinafoate) inhalation powder).

This Prior Approval supplemental new drug application provides for an update to Section 8.4 Pediatric Use of the labeling for AirDuo Respiclick, AirDuo Digihaler.

**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.<sup>1</sup> 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

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<sup>1</sup> <http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm>

industry *SPL Standard for Content of Labeling Technical Qs and As*.<sup>2</sup>

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).

### **FULLFILLMENT OF POSTMARKETING REQUIREMENTS**

We have received your submission dated December 21, 2020, which contains the final report for the following postmarketing requirement listed in the January 27, 2017, approval letter for NDA 208799.

- 3155-1      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
- 3155-2      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

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<sup>2</sup> 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>.

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*.<sup>3</sup>

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.<sup>4</sup> Information and Instructions for completing the form can be found at FDA.gov.<sup>5</sup>

### **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

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

<sup>4</sup> <http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM083570.pdf>

<sup>5</sup> <http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM375154.pdf>

- Patient Package Insert or Medication Guide
- Instructions for Use

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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.**  
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/s/  
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