19 February 2020

Sally Seymour, MD
Director, Division of Pulmonary, Allergy and Rheumatology Products
Food and Drug Administration
Center for Drug Evaluation and Research
Central Document Room
5901-B Ammendale Road
Beltsville, MD 20705

NDA 208798, Sequence No. 0099
ARMONAIR® (fluticasone propionate) Inhalation Powder
NDA 208799, Sequence No. 0204
AIRDUO® (fluticasone propionate/salmeterol) Inhalation Powder

RE: DEFERRAL EXTENSION REQUEST
RESPONSE TO PREA NON-COMPLIANCE LETTER

Dear Dr. Seymour,

Reference is made to Teva's New Drug Application (NDA) 208798 for ARMONAIR® (fluticasone propionate) inhalation powder for the maintenance treatment of asthma as prophylactic therapy, and NDA 208799 for AIRDUO® (fluticasone propionate/salmeterol) inhalation powder for the treatment of asthma.

Cross-reference is made to Investigational New Drug application (IND) 108838 for Fluticasone Propionate Inhalation Powder, and to IND 072240 for Fluticasone Propionate/Salmeterol Xinafoate Inhalation Powder, which support the development programs for the two NDAs.

On 27 January 2017, the NDAs were approved for use in patients aged 12 years and older. The Approval Letter for both NDAs included Post Marketing Requirements (PMRs) 3155-1 and 3155-2, which deferred studies in children 4-11 years of age (a pharmacokinetic and tolerability study, and a safety and efficacy study) and required final reports by 31 December 2019.

On 17 November 2017, the FDA issued a Written Request (WR) for a pediatric study for these two products that added conditions to PMR 3155-2. In the FDA's Written Request-Amendment 2, the timeframe for submitting the study report was extended to 29 May 2020.

Subsequently, as described in submissions on 13 February 2020 (NDA 208798, Seq. 0098, and NDA 208799, Seq. 0203), and consistent with the recommendations in the FDA Minutes of the 15 October 2019 (b) (4) Meeting, to accommodate the generation and reporting of CMC data needed for the pediatric use (b) (4), Teva requested an extension of the reporting date for the study required in the PWR to 31 December 2020.

The purpose of this submission is to request that the date for submitting the Final Report of the Deferred Pediatric Assessments mandated by the PMRs be extended to 31 December 2020, consistent with the FDA's (b) (4) Meeting advice and the proposed PWR reporting date.

This Deferral Extension Request is also intended to address the FDA's Notification Letter dated 31 January 2020 which requested an explanation of the delay in submission of the two PMA assessment reports required under PREA, and to identify the planned assessment report date.

Note that studies FSS-PK-10007 and FSS-AS-30003 were designed and performed to address PMR 3155-1 and 3155-2, respectively:

- Study FSS-PK-10007: "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 Multidose Dry Powder Inhaler and Fluticasone Propionate/Salmeterol Multidose Dry Powder Inhaler Compared to ADVAIR® DISKUS® in Patients with Persistent Asthma 4 through 11 Years of Age."
- Study FSS-AS-30003: "A 12-week, Randomized, Double- Blind, Placebo-Controlled, Efficacy and Safety Study of Fluticasone Propionate Multidose Dry Powder Inhaler Compared with Fluticasone Propionate/Salmeterol Multidose Dry Powder Inhaler in Patients Aged 4 Through 11 Years with Persistent Asthma."

The clinical study report (CSR) for Study FSS-PK-10007 was submitted on 21 February 2017 (IND 108838, Seq. 0106; IND 072240, Seq. 0082), and the CSR for Study FSS-AS-30003 was submitted on 06 Feb 2020 (IND 108838, Seq. 0135; IND 072240, Seq.0116).

Teva respectfully requests the Agency to grant this PMR Deferral Extension Request, and plans to submit these two CSRs, relevant CMC information, Module 2 Summaries, and other information and data needed (b) (4) no later than 31 December 2020.

Teva Branded Pharmaceutical Products R&D, Inc., requests that all information in this file be treated as confidential within the meaning of 21 CFR §312.130, and that no information from the file be made public without our written consent to an authorized member of your office.

This eCTD submission is being submitted via the FDA Electronic Submission Gateway (ESG). The contents of this submission are verified to be virus free using Trend Micro OfficeScan, Version 12.0.1855, on the date of this letter. If there are any technical questions regarding this submission, please contact Apurva Pandya at apurva.pandya@tevapharm.com or 973-658-1786.

This information is submitted for your review and retention in your files. Should there be any questions regarding the information contained herein, please do not hesitate to contact me by phone: 610-883-5752 or email: michael.spitz@tevapharm.com.

Sincerely,

Michael S. Spitz, MS, RAC
Sr. Director, Global Specialty Regulatory Affairs
Teva Branded Pharmaceutical Products R&D, Inc.