August 4th, 2021

Nushin Todd, MD, PhD, Director (Acting)
Division of Nonprescription Drugs I
Center for Drug Evaluation and Research
Food and Drug Administration
Central Document Room
5901-B Ammendale Rd
Beltsville, MD 20705-1266

NDA 020786; Sequence 0110
Allegra-D Allergy and Congestion (fexofenadine hydrochloride 60 mg and pseudoephedrine hydrochloride 120 mg) tablets
NDA 021704: Sequence 0116
Allegra-D Allergy and Congestion (fexofenadine hydrochloride 180 mg and pseudoephedrine hydrochloride 240 mg) tablets

IND (b) (4) Allegra-D 12 Hour Allergy and Congestion Sequence 0055
IND Allegra-D 24 Hour Allergy and Congestion Sequence 0023

RE: RESPONSE TO PREA NON-COMPLIANCE LETTER

Dear Dr. Todd:

Reference is made to Sanofi's New Drug Application (NDA) 020786 for Allegra-D Allergy and Congestion (fexofenadine hydrochloride 60 mg and pseudoephedrine hydrochloride 120 mg) tablets and NDA 021704 Allegra-D Allergy and Congestion (fexofenadine hydrochloride 180 mg and pseudoephedrine hydrochloride 240 mg) tablets for the temporary relief of symptoms due to hay fever or other upper respiratory allergies: runny nose, sneezing, itchy, watery eyes and itching of the nose and throat, the reduction of swelling of the nasal passages, the temporary relief of sinus congestion and pressure, and the temporary restoration of freer breathing through the nose in adults and children 12 years of age and older.

Reference is also made to the 8 June 2015 approval of supplement S-033 and S-017 to the respective NDAs for the inclusion of "relief of nasal congestion due to the common cold" to the "Uses" section of the Drug Facts Label (DFL). The approval letter for both NDAs included Post-marketing Requirements (PMRs). PMR 2916-1 deferred studies in children 6 to less than 12 years of age (dose and dosing interval study) and required a final report by 31 May 2021.

This submission includes our formal response to the Pediatric Research Equity Act (PREA) Non-Compliance Letter dated 21 June 2021.

BACKGROUND

1. On June 8, 2015, Sanofi-Aventis LLC received approval from FDA to add the indication "relief of nasal congestion due to the common cold" for adults and children aged 12 years and older to the "Uses" section of the Drug Facts label for NDAs 20786 and 21704. With this approval, Sanofi was required to assess the safety and effectiveness of the drug product for the claimed indication in pediatric patients ages 2 years to less than 12 years under the Pediatric Research Equity Act (PREA). Reference is made to the first PMR as under:

2916-1: *Conduct a study to determine an appropriate dose and dosing interval for fexofenadine and pseudoephedrine in children, 6 to less than 12 years of age, who may benefit from the pseudoephedrine component of the drug product (i.e., not in otherwise healthy pediatric volunteers) for temporary relief of nasal congestion due to the common cold.*

- Subsequently, Sanofi-Aventis US LLC had a teleconference with the Agency on 07 March 2019 to discuss proposals to satisfy the data requirements for the PMRs.

- Following the teleconference noted above, Sanofi-Aventis LLC requested a Type C meeting on 17 April 2020 to discuss our follow up proposals and alignment on next steps for addressing the PMRs and thereafter received a written response from the Agency on 08 October 2020.

We are continuing to work to address the Agency's feedback from both the 07 March 2019 and 08 October 2020. We sincerely apologize for the delay in submission of the final report and remain committed to fulfill the post marketing requirements under PREA.

The purpose of this submission is to confirm that Sanofi-Aventis US LLC will submit the Final Report of the Deferred Pediatric Assessment mandated by the PMR by 01 October 2021.

Sanofi 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. A version of this containing the proposed redactions is attached with the submission.

Sanofi is a Transaction Partner; accordingly, the subject information is being submitted via the FDA Electronic Submissions Gateway (ESG). All files were verified to be free of viruses. Please contact Paulina Roitman by telephone: 416-667-2966 or by email: Paulina.roitman@sanofi.com for any ESG questions or concerns.

Should you have any questions, or require additional information related to this request, please contact me by phone at 423-599-5500 or annelies.verbeek@sanofi.com.

Sincerely,

Annelies Verbeek, MD
CHC US Head Scientific Affairs