DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 020786/S-033
NDA 021704/S-017

SUPPLEMENT APPROVAL

sanofi-aventis US LLC
Attention: Mridul Shah, MS
Associate Director, Global Regulatory Affairs
55 Corporate Drive
Bridgewater, NJ 08807

Dear Ms. Shah:

Please refer to your Supplemental New Drug Applications submitted pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act (FDCA) for the following:

NDA NUMBER:	020786	021704
SUPPLEMENT NUMBER:	33	17
PRODUCT NAME:	Allegra-D Allergy and Congestion (fexofenadine hydrochloride 60 mg and pseudoephedrine hydrochloride 120 mg) tablets	Allegra-D Allergy and Congestion (fexofenadine hydrochloride 180 mg and pseudoephedrine hydrochloride 240 mg) tablets
DATE OF SUBMISSION:	August 8, 2014	
DATE OF RECEIPT:	August 8, 2014	

We acknowledge receipt of your amendments to NDA 020786/S-033 dated August 11 and 28, 2014; January 21 and 30, February 9, March 24, April 10, 13, and 15, 2015.

We acknowledge receipt of your amendments to NDA 021704/S-017 dated August 11 and 28, 2014; January 21 and 30, February 9, March 24 and March 27, 2015.

These “Prior Approval” supplemental new drug applications provide for a modification of the “Uses” section of the Drug Facts Label (DFL) to include “relief of nasal congestion due to the common cold.”

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 agreed-upon labeling text.

LABELING

Submit final printed labeling (FPL), as soon as they are available, but no more than 30 days after they are printed. The FPL must be in the "Drug Facts" format (21 CFR 201.66), where applicable, and identical to the enclosed labeling for the following:

NDA 020786/S-033 Allegra-D Allergy and Congestion Tablets (fexofenadine hydrochloride 60 mg and pseudoephedrine hydrochloride 120 mg)	• 10-count immediate container (blister pack) • 10-count outer carton (France sourced product and U.S. sourced product) • 20-count outer carton (France sourced product and U.S. sourced product • 30-count outer carton (France sourced product and U.S. sourced product
NDA 021704/S-017 Allegra-D Allergy and Congestion Tablets (fexofenadine hydrochloride 180 mg and pseudoephedrine hydrochloride 240 mg)	• 5-count immediate container (blister pack) • 5-count outer carton (France sourced product and U.S. sourced product) • 10-count outer carton (France sourced product and U.S. sourced product) • 15-count outer carton (France sourced product and U.S. sourced product)

The FPL should be submitted electronically according to the guidance for industry titled "Providing Regulatory Submissions in Electronic Format – Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications (June 2008)." Alternatively, you may submit 12 paper copies, with 6 of the copies individually mounted on heavy-weight paper or similar material. For administrative purposes, designate this submission "**Final Printed Labeling for approved NDA 020786/S-033" and "Final Printed Labeling for NDA 021704/S-017"**, as appropriate. Approval of these submissions by FDA are not required before the labeling is used.

DRUG REGISTRATION AND LISTING

All drug establishment registration and drug listing information is to be submitted to FDA electronically, via the FDA automated system for processing structured product labeling (SPL) files (eLIST). At the time that you submit your final printed labeling (FPL), the content of labeling (Drug Facts) should be submitted in SPL format as described at http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm. Information on submitting SPL files using eLIST may be found in the guidance for industry titled "SPL Standard for Content of Labeling Technical Qs and As" at http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM072392.pdf. In addition, representative container or carton labeling, whichever includes Drug Facts, (where differences exist only in the quantity of contents statement) should be submitted as a JPG file.

REQUIRED PEDIATRIC ASSESSMENTS

Under the Pediatric Research Equity Act (PREA) (21 U.S.C. 355c), all applications for new active ingredients, 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(s) in pediatric patients unless this requirement is waived, deferred, or inapplicable.

We are waiving the pediatric study requirements for ages 0 months to 1 year and 11 months because there is evidence strongly suggesting that these drug products would be unsafe in this pediatric group.

We are deferring submission of your pediatric studies for ages 2 years to less than 12 years for these applications because these products are ready for approval for use in adults and the pediatric studies have not been completed.

Your deferred pediatric studies required by section 505B(a) of the 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)(3)(B) of the FDCA. These required studies are listed below.

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.

Final Protocol Submission:	05/2020
Study Completion:	11/2020
Final Report Submission:	05/2021

2916-2 Conduct a study in children 6 to less than 12 years of age to evaluate the efficacy and safety of the pseudoephedrine component, in your combination product, for temporary relief of nasal congestion due to the common cold.

Final Protocol Submission:	10/2021
Study Completion:	01/2023
Final Report Submission:	06/2023

2916-3 If the studies conducted in children 6 to less than 12 years of age demonstrate safety and efficacy for the intended claim, conduct a study to determine an appropriate dose and dosing interval for use in children, 2 to less than 6 years of age, who may benefit from the pseudoephedrine component of the drug product (i.e., not in otherwise healthy pediatric volunteers) to relieve nasal congestion due to the common cold.

Final Protocol Submission:	05/2023
Study Completion:	01/2024
Final Report Submission:	06/2024

2916-4 If the studies conducted in children 6 to less than 12 years of age demonstrate safety and efficacy for the intended claim, conduct a study to evaluate the safety of the pseudoephedrine component, in your combination product, for temporary relief of nasal congestion due to the common cold in children 2 to less than 6 years of age. Efficacy of fexofenadine and pseudoephedrine for the age group 2 to less than 6 years may be extrapolated from data in the older age group.

Final Protocol Submission:	10/2024
Study Completion:	01/2026
Final Report Submission:	06/2026

Submit the protocols to your IND 48486 and IND 66289 with a cross-reference letter to the respective NDAs.

Reports of these required pediatric postmarketing studies must be submitted as new drug applications (NDAs) or as supplements to your approved NDAs with the proposed labeling changes you believe are warranted based on the data derived from these studies. When submitting the reports, please clearly mark your submission "**SUBMISSION OF REQUIRED PEDIATRIC ASSESSMENTS**" in large font, bolded type at the beginning of the cover letters of the submissions.

These products are appropriately labeled for use in ages 12 to less than 18 years for this indication. Therefore, no additional studies are needed in this pediatric group.

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 Sherry Stewart, Regulatory Project Manager, at (301) 796-9618.

Sincerely,

{See appended electronic signature page}

Theresa Michele, MD
Director
Division of Nonprescription Drug Products
Office of Drug Evaluation IV
Center for Drug Evaluation and Research

ENCLOSURES:
Carton and Container Labeling

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

THERESA M MICHELE
06/08/2015