CENTER FOR DRUG EVALUATION AND RESEARCH

Approval Package for:

APPLICATION NUMBER:

209089Orig1s000
209090Orig1s000

Trade Name:	Xyzal Allergy 24HR
Generic or Proper Name:	levocetirizine dihydrochloride
Sponsor:	Sanofi-aventis U.S. LLC
Approval Date:	January 26, 2017
Indication:	Temporarily relieves these symptoms due to hay fever or other upper respiratory allergies: runny nose sneezing itchy,watery eyes itching of the nose or throat

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209089Orig1s000
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CONTENTS

Reviews / Information Included in this NDA Review.

Approval Letter	**X**
Other Action Letters	
Labeling	**X**
REMS	
Summary Review	**X**
Officer/Employee List	**X**
Office Director Memo	
Cross Discipline Team Leader Review	**X**
Clinical Review(s)	**X**
Product Quality Review(s)	**X**
Non-Clinical Review(s)	**X**
Statistical Review(s)	**X**
Clinical Microbiology / Virology Review(s)	
Clinical Pharmacology Review(s)	**X**
Other Reviews	**X**
Risk Assessment and Risk Mitigation Review(s)	
Proprietary Name Review(s)	**X**
Administrative/Correspondence Document(s)	**X**

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APPROVAL LETTER

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 209089
NDA 209090

NDA APPROVAL

sanofi-aventis U.S. LLC
Attention: Cynthia Psaras, PhD
Director, Global Regulatory Affairs
55 Corporate Drive
Mail Stop 55D-225A
Bridgewater, NJ 08807

Dear Dr. Psaras:

Please refer to your New Drug Applications (NDAs) dated and received March 31, 2016, and your amendments, submitted pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act (FDCA) for the following NDAs:

- NDA 209089: Xyzal Allergy 24HR (levocetirizine dihydrochloride) tablets, 5 mg
- NDA 209090: Xyzal Allergy 24HR (levocetirizine dihydrochloride) oral solution, 2.5 mg per 5 mL (0.5 mg per mL).

These NDAs for the use of Xyzal Allergy 24HR (levocetirizine dihydrochloride) tablets, 5 mg and Xyzal Allergy 24HR (levocetirizine dihydrochloride) oral solution, 2.5 mg per 5 mL (0.5 mg per mL) provide for the following indication:

Temporarily relieves these symptoms due to hay fever or other upper respiratory allergies:

- runny nose
- sneezing
- itchy, watery eyes
- itching of the nose or throat

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 for NDA 209089 must be identical to the 10-count carton (blister), 10-count immediate container (blister), 35-count carton (bottle), 35-count immediate container (bottle), 45-count carton *Bonus* (bottle), 45-immediate container *Bonus* (bottle), 55-count carton (bottle), 55-count immediate container (bottle), 80-count carton (bottle), 80-count immediate container (bottle), and 110-count club pack (bottle) labeling submitted on January 9, 2017, and

bottle seal label submitted on March 31, 2016, and must be in the "Drug Facts" format (21 CFR 201.66), where applicable.

The FPL for NDA 209090 must be identical to the 5 fluid ounce (fl. oz.) carton (bottle) *Children's Tutti-Frutti Flavor*, 5 fluid ounce (fl. oz.) immediate container (bottle) labeling and Oral Solution Dosing Cup labeling representation submitted on January 9, 2017 and bottle seal label submitted on March 31, 2016 and must be in the "Drug Facts" format (21 CFR 201.66), where applicable.

The FPL should be submitted electronically according to the guidance for industry titled "Providing Regulatory Submissions in Electronic Format — Certain Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications (May 2015, Revision 3)." For administrative purposes, designate this submission "**Final Printed Labeling for approved NDA 209089**" or **"Final Printed labeling for approved NDA 209090"** 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.

Because none of these criteria apply to your applications, you are exempt from this requirement.

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