

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:

209089Orig1s000

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PROPRIETARY NAME REVIEW(S)

PROPRIETARY NAME MEMORANDUM

Division of Medication Error Prevention and Analysis (DMEPA)
Office of Medication Error Prevention and Risk Management (OMEPRM)
Office of Surveillance and Epidemiology (OSE)
Center for Drug Evaluation and Research (CDER)

***** This document contains proprietary information that cannot be released to the public*****

Date of This Review: May 26, 2016
Application Type and Number: NDA 209089
Product Name and Strength: Xyzal Allergy 24HR (levocetirizine dihydrochloride)
Tablets, 5 mg
Product Type: Single-Ingredient Product
Rx or OTC: OTC
Applicant/Sponsor Name: Sanofi US Services Inc.
Panorama #: 2016-3246951
DMEPA Primary Reviewer: Grace P. Jones, PharmD, BCPS
DMEPA Team Leader: Chi-Ming (Alice) Tu, PharmD

1 INTRODUCTION

This memorandum is to reassess the proposed proprietary name, Xyzal Allergy 24HR, which was found conditionally acceptable under IND 126506 and IND 126507 on March 14, 2016.¹ We note that all product characteristics remain the same.

2 METHODS AND DISCUSSION

The Applicant is proposing a partial Rx-to-OTC switch providing for the OTC use for the treatment of symptoms due to seasonal and perennial allergic rhinitis in children ages 2 years and older and adults up to 65 years of age. The Applicant currently is not seeking OTC use for the hives indication. For re-assessment of the proposed proprietary name, DMEPA considered any lessons learned from recent post-marketing experience, which may have altered our previous conclusion regarding the acceptability of the proposed proprietary name, and conducted a gap FDA Adverse Event Reporting System (FAERS) database search on May 17, 2016 to identify any new medication error reports for product name confusion related to the root name Xyzal, which retrieved no cases. Additionally, DMEPA searched the USAN stem list to determine if the name contains any USAN stems as of the last USAN updates. The May 9, 2016 search of USAN stems did not find any USAN stems in the proposed proprietary name.

2.1 MISBRANDING ASSESSMENT

The Division of Nonprescription Drug Products (DNPD) determined that the proposed name would not misbrand the proposed product. DMEPA concurred with DNPD's assessment of the proposed name.

3 CONCLUSIONS

Our re-assessment did not identify any concerns that represent a potential source of drug name confusion. Therefore, we maintain that the proposed proprietary name is acceptable.

If you have any questions or need clarifications, please contact Abiola Olagundoye-Alawode, OSE project manager, at 301-796-3982.

3.1 COMMENTS TO THE APPLICANT

We have completed our review of the proposed proprietary name, Xyzal Allergy 24HR, and have concluded that this name is acceptable.

If any of the proposed product characteristics as stated in your March 31, 2016 submission are altered prior to approval of the marketing application, the name must be resubmitted for review.

¹ Jones, G. Proprietary Name Review for Xyzal Allergy 24HR (IND 126506 and IND 126507). Silver Spring (MD): Food and Drug Administration, Center for Drug Evaluation and Research, Office of Surveillance and Epidemiology, Division of Medication Error Prevention and Analysis (US); 2016 MAR 14. Panorama No. 2015-1541618, 2015-1541620.

4 REFERENCES

1. **USAN Stems** (<http://www.ama-assn.org/ama/pub/physician-resources/medical-science/united-states-adopted-names-council/naming-guidelines/approved-stems.page>)

USAN Stems List contains all the recognized USAN stems.

2. **Description of FAERS**

The FDA Adverse Event Reporting System (FAERS) is a database that contains information on adverse event and medication error reports submitted to FDA. The database is designed to support the FDA's postmarket safety surveillance program for drug and therapeutic biologic products. The informatic structure of the FAERS database adheres to the international safety reporting guidance issued by the International Conference on Harmonisation. FDA's Office of Surveillance and Epidemiology codes adverse events and medication errors to terms in the Medical Dictionary for Regulatory Activities (MedDRA) terminology. Product names are coded using the FAERS Product Dictionary. More information about FAERS can be found at:

<http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Surveillance/AdverseDrugEffects/default.htm>.

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/s/

GRACE JONES
05/26/2016

CHI-MING TU
05/26/2016

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Date of This Review: May 26, 2016
Application Type and Number: NDA 209090
Product Name and Strength: Children's Xyzal Allergy 24HR (levocetirizine dihydrochloride) Oral Solution, 2.5 mg/5 mL
Product Type: Single-Ingredient Product
Rx or OTC: OTC
Applicant/Sponsor Name: Sanofi US Services Inc.
Panorama #: 2016-3246956
DMEPA Primary Reviewer: Grace P. Jones, PharmD, BCPS
DMEPA Team Leader: Chi-Ming (Alice) Tu, PharmD

1 INTRODUCTION

This memorandum evaluates the proposed proprietary name, Children’s Xyzal Allergy 24HR, from a safety and misbranding perspective.

We previously reviewed the proposed proprietary name, Xyzal Allergy 24HR, for levocetirizine dihydrochloride tablets, 5 mg, and oral solution, 2.5 mg/5 mL, which was found conditionally acceptable under IND 126506 and IND 126507 on March 14, 2016.¹ Upon NDA 209090 submission, Sanofi clarified that the oral solution dosage form will only be marketed as a “Children’s” OTC product. The proposed container labels and carton labeling utilized “Children’s Xyzal Allergy 24HR” as the proprietary name. Based on DMEPA’s feedback, Sanofi submitted the proposed proprietary name, Children’s Xyzal Allergy 24HR, for levocetirizine dihydrochloride oral solution, 2.5 mg/5 mL.

2 METHODS AND DISCUSSION

The Applicant is proposing a partial Rx-to-OTC switch providing for the OTC use for the treatment of symptoms due to seasonal and perennial allergic rhinitis in children ages 2 years and older and adults up to 65 years of age. The Applicant currently is not seeking OTC use for the hives indication. For assessment of the proposed proprietary name, DMEPA considered any lessons learned from recent post-marketing experience, which may have altered our previous conclusion regarding the acceptability of the proposed proprietary name, and conducted a gap FDA Adverse Event Reporting System (FAERS) database search on May 17, 2016 to identify any new medication error reports for product name confusion related to the root name Xyzal, which retrieved no cases. Additionally, DMEPA searched the USAN stem list to determine if the name contains any USAN stems as of the last USAN updates. The May 9, 2016 search of USAN stems did not find any USAN stems in the proposed proprietary name.

Additionally, the Applicant intends to market Children’s Xyzal Allergy 24HR (levocetirizine dihydrochloride oral solution) for the same OTC use as the Xyzal Allergy 24HR, for the temporary relief of symptoms due to hay fever or other respiratory allergies (runny nose, sneezing, itchy, watery eyes, and itching of the nose or throat) in adults and children ages 2 years and older, as pediatric SKU. The Drug Facts Label (DFL) is the same for the proposed Children’s Xyzal Allergy 24HR and the proposed Xyzal Allergy 24Hr, except for the directions for the Children’s Xyzal Allergy 24HR which contains directions for use in children 2 years of age and older. We note this naming convention of adding “Children’s” to OTC products for a pediatric SKU is common among existing OTC products marketed under an application. The DFL of these OTC products are also the same with directions for both adults and children (i.e. Zyrtec Allergy and Children’s Zyrtec Allergy; and Claritin and Children’s Claritin). We are unaware of post-marketing medication errors associated with this naming convention.

¹ Jones, G. Proprietary Name Review for Xyzal Allergy 24HR (IND 126506 and IND 126507). Silver Spring (MD): Food and Drug Administration, Center for Drug Evaluation and Research, Office of Surveillance and Epidemiology, Division of Medication Error Prevention and Analysis (US); 2016 MAR 14. Panorama No. 2015-1541618, 2015-1541620.

3 CONCLUSIONS

Our assessment did not identify any concerns that represent a potential source of drug name confusion. Therefore, we find the proposed proprietary name Children's Xyzal Allergy 24HR, acceptable for this product.

If you have any questions or need clarifications, please contact Abiola Olagundoye-Alawode, OSE project manager, at 301-796-3982.

3.1 COMMENTS TO THE APPLICANT

We have completed our review of the proposed proprietary name, Children's Xyzal Allergy 24HR, and have concluded that this name is acceptable.

If any of the proposed product characteristics as stated in your April 27, 2016 submission are altered prior to approval of the marketing application, the name must be resubmitted for review.

4 REFERENCES

1. **USAN Stems** (<http://www.ama-assn.org/ama/pub/physician-resources/medical-science/united-states-adopted-names-council/naming-guidelines/approved-stems.page>)

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