CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

209089Orig1s000
209090Orig1s000

PROPRIETARY NAME REVIEW(S)

DOCKET ALARM
Find authenticated court documents without watermarks at docketalarm.com.

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

DOCKET ALARM
Find authenticated court documents without watermarks at docketalarm.com.

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 (DNDP) determined that the proposed name would not misbrand the proposed product. DMEPA concurred with DNDP'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.

DOCKET ALARM
Find authenticated court documents without watermarks at docketalarm.com.

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.

DOCKET ALARM
Find authenticated court documents without watermarks at docketalarm.com.

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

/s/

GRACE JONES
05/26/2016

CHI-MING TU
05/26/2016

DOCKET ALARM

Find authenticated court documents without watermarks at docketalarm.com.

DOCKET ALARM

Explore Litigation Insights

Docket Alarm provides insights to develop a more informed litigation strategy and the peace of mind of knowing you're on top of things.

Real-Time Litigation Alerts

Keep your litigation team up-to-date with **real-time alerts** and advanced team management tools built for the enterprise, all while greatly reducing PACER spend.

Our comprehensive service means we can handle Federal, State, and Administrative courts across the country.

Advanced Docket Research

With over 230 million records, Docket Alarm's cloud-native docket research platform finds what other services can't. Coverage includes Federal, State, plus PTAB, TTAB, ITC and NLRB decisions, all in one place.

Identify arguments that have been successful in the past with full text, pinpoint searching. Link to case law cited within any court document via Fastcase.

Analytics At Your Fingertips

Learn what happened the last time a particular judge, opposing counsel or company faced cases similar to yours.

Advanced out-of-the-box PTAB and TTAB analytics are always at your fingertips.

API

Docket Alarm offers a powerful API (application programming interface) to developers that want to integrate case filings into their apps.

LAW FIRMS
Build custom dashboards for your attorneys and clients with live data direct from the court.

Automate many repetitive legal tasks like conflict checks, document management, and marketing.

FINANCIAL INSTITUTIONS
Litigation and bankruptcy checks for companies and debtors.

E-DISCOVERY AND LEGAL VENDORS
Sync your system to PACER to automate legal marketing.