

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:

207233Orig1s000

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:	January 30, 2015
Application Type and Number:	NDA 207233
Product Name and Strength:	Vivlodex (meloxicam) capsules 5 mg and 10 mg
Product Type:	Single
Rx or OTC:	Rx
Applicant/Sponsor Name:	Iroko Pharmaceuticals
Submission Date:	December 29, 2014
Panorama #:	2014-46402
DMEPA Primary Reviewer:	James Schlick, RPh, MBA
DMEPA Acting Team Leader:	Vicky Borders-Hemphill, PharmD

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1 INTRODUCTION

This memorandum is to reassess the proposed proprietary name, Vivlodex. DMEPA previously found the name acceptable in OSE Review No. 2014-17040¹, dated June 18, 2014.

1.1 PRODUCT INFORMATION

The following product information is provided in the December 29, 2014 proprietary name submission.

- Intended Pronunciation: Viv' loe dex
- Active Ingredient: meloxicam
- Indication of Use: osteoarthritis pain
- Route of Administration: oral
- Dosage Form: capsule
- Strength: 5 mg and 10 mg
- Dose and Frequency: once daily; max 10 mg daily
- How Supplied: bottles of 30 and 90 capsules
- Storage: Room temperature
- Container and Closure Systems: bottles

1.2 MISBRANDING ASSESSMENT

The Office of Prescription Drug Promotion (OPDP) determined that the proposed name would not misbrand the proposed product. DMEPA and the Division of Analgesia, Anesthesia, and Addiction Products (DAAAP) concurred with the findings of OPDP's assessment of the proposed name.

1.3 SAFETY ASSESSMENT

To reassess the proposed proprietary name, DMEPA searched the POCA database (see Section 3) and conducted a gap analysis to identify names approved since the previous OSE Proprietary Name Review #2014-17040 that have orthographic and phonetic similarities to the proposed name Vivlodex. Our POCA search did not identify any new names that represent a potential source of drug name confusion.

We re- evaluated the previously identified names of concern considering any lessons learned from recent post-marketing experience, which may have altered our previous

¹ Borders-Hemphill, V. Proprietary Name Review for Vivlodex (IND 114045). 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); 2014 June 18. 29p. OSE RCM No. 2014-17040.

conclusion regarding the acceptability of the proposed proprietary name. Furthermore, DMEPA searched the USAN stem list to determine if the name contains any USAN stems as of the last USAN updates. The January 29, 2015 search of USAN stems did not find any USAN stems in the proposed proprietary name.

Lastly, we reviewed the product characteristics in the current proprietary name submission and compared them to the product characteristics in the previous proprietary name review. We determined that none of the product characteristics have changed since the last proprietary name review.

As a result, we maintain that the name, Vivlodex, is acceptable.

2 CONCLUSIONS

The proposed proprietary name is acceptable.

If you have further questions or need clarifications, please contact Lisa Skarupa, OSE project manager, at 301-796-2219.

2.1 COMMENTS TO THE APPLICANT

We have completed our review of the proposed proprietary name, Vivlodex, and have concluded that this name is acceptable.

3 REFERENCES

1. Borders-Hemphill, V. Proprietary Name Review for Vivlodex (IND 114045). 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); 2014 June 18. 29p. OSE RCM No. 2014-17040.
2. *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.

3. *Phonetic and Orthographic Computer Analysis (POCA)*

POCA is a system that FDA designed. As part of the name similarity assessment, POCA is used to evaluate proposed names via a phonetic and orthographic algorithm. The proposed proprietary name is converted into its phonemic representation before it runs through the phonetic algorithm. Likewise, an orthographic algorithm exists that operates in a similar fashion. POCA is publicly accessible.

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

/s/

JAMES H SCHLICK
01/30/2015

BRENDA V BORDERS-HEMPHILL
01/30/2015