CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

204592Orig1s000

PROPRIETARY NAME REVIEW(S)

Department of Health and Human Services
Public Health Service
Food and Drug Administration
Center for Drug Evaluation and Research
Office of Surveillance and Epidemiology
Office of Medication Error Prevention and Risk Management

Proprietary Name Review--Final

Date:	September 5, 2013
Reviewer(s):	Vicky Borders-Hemphill, Pharm.D. Division of Medication Error Prevention and Analysis
Team Leader	Jamie Wilkins Parker, Pharm.D. Division of Medication Error Prevention and Analysis
Drug Name and Strength(s):	Zorvolex (Diclofenac acid) Capsules, 18 mg and 35 mg
Application Type/Number:	NDA 204592
Applicant/Sponsor:	Iroko Pharmaceuticals, LLC
OSE RCM #:	2013-1067

*** This document contains proprietary and confidential information that should not be released to the public.***

CONTENTS

1 INTRODUCTION

This re-assessment of the proposed proprietary name, Zorvolex is written in response to the anticipated approval of this NDA within 90 days from the date of this review. DMEPA found the proposed name, Zorvolex, acceptable in OSE Review #2013-343 dated April 26, 2013.

2 METHODS AND DISCUSSION

For re-assessments of proposed proprietary names, DMEPA searches a standard set of databases and information sources (see section 4) to identify names with orthographic and phonetic similarity to the proposed name that have been approved since the previous OSE proprietary name review. For this review we used the same search criteria described in OSE Review #2013-343. We note that none of the proposed product characteristics were altered. However, we evaluated the previously identified names of concern considering any lessons learned from recent post-marketing experience, which may have altered our previous conclusion regarding the acceptability of the proposed proprietary name. The searches of the databases yielded no new names, thought to look or sound similar to Zorvolex and represent a potential source of drug name confusion

Additionally, DMEPA searched the United States Adopted Names (USAN) list to determine if the name contains any USAN stems as of the last USAN updates. The Safety Evaluator did not identify any USAN stems in the proposed proprietary name, as of September 5, 2013.

3 CONCLUSIONS

The re-evaluation of the proposed proprietary name, Zorvolex, did not identify any vulnerabilities that would result in medication errors with any additional names. Thus, DMEPA has no objection to the proprietary name, Zorvolex, for this product at this time.

DMEPA considers this a final review; however, if approval of the NDA is delayed beyond 90 days from the date of this review, then the Division of Analgesia, Anesthesia, and Addiction Products should notify DMEPA because the proprietary name must be re-reviewed prior to the new approval date.

If you have further questions or need clarifications, please contact Vaishali Jarral, OSE project manager, at 301-796-4248.

4 REFERENCES

1. **OSE Reviews**

2. ***Drugs@FDA (http://www.accessdata.fda.gov/scripts/cder/drugsatfda/index.cfm)***

   Drugs@FDA contains most of the drug products approved since 1939. The majority of labels, approval letters, reviews, and other information are available for drug products approved from 1998 to the present. Drugs@FDA contains official information about FDA approved brand name, generic drugs, therapeutic biological products, prescription and over-the-counter human drugs and discontinued drugs and "Chemical Type 6" approvals.

3. ***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.

4. ***Division of Medication Error Prevention and Analysis Proprietary Name Consultation Request***

   Compiled list of proposed proprietary names submitted to the Division of Medication Error Prevention and Analysis for review. The list is generated on a weekly basis from the Access database/tracking system.

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