CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:
22511Orig1s000

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

Date:	April 14, 2010
To:	Donna Griebel, MD, Director Division of Gastroenterology Products
Through:	Denise P. Toyer, PharmD, Deputy Director Division of Medication Error Prevention and Analysis (DMEPA)
From:	Laura Pincock, Pharm.D., Acting Team Leader Division of Medication Error Prevention and Analysis (DMEPA)
Subject:	Proprietary Name Review
Drug Name(s):	Vimovo (Naproxen and Esomeprazole Magnesium) Tablets 375 mg/20 mg and 500 mg/20 mg
Application Type/Number:	NDA 022511
Applicant:	Pozen, Inc.
OSE RCM #:	2009-1779

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

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1 INTRODUCTION

This re-assessment of the proposed proprietary name Vimovo 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, Vimovo, acceptable in OSE Review # 2009-1244 dated September 10, 2009. In addition, the Division of Drug Marketing, Advertising and Communications (DDMAC) found the name acceptable from a promotional perspective, and the Division of Gastroenterology Products did not have any concerns with the proposed proprietary name, Vimovo, during our initial review.

2 METHODS AND RESULTS

For the proposed proprietary name, DMEPA staff search a standard set of databases and information sources (see Section 4) to identify names with orthographic and/or phonetic similarity to the proposed name that have been approved since the previous proprietary name review. We used the same search criteria previously used in OSE Review #2009-1244. Because none of the proposed product characteristics were altered we did not re-evaluate previous names of concern. Additionally, DMEPA searched the United States Adopted Names (USAN) stem list to determine if the name contains any USAN stems that may have been added during any USAN updates that occur since the initial assessment of the proposed proprietary name. DMEPA bases the overall risk assessment on the findings of a failure mode and effects analysis (FMEA) of the proposed proprietary name, and focuses on the avoidance of medication errors.

The searches of the databases referenced in Section 4 did not yield any new names thought to look or sound similar to Vimovo and represent a potential source of drug name confusion. Likewise, DMEPA staff did not identify any USAN stems in the proposed proprietary name Vimovo as of April 8, 2010. Accordingly, DMEPA finds the proposed proprietary name Vimovo acceptable for this product.

3 CONCLUSIONS AND RECOMMENDATIONS

The proprietary name risk assessment findings indicate that the proposed name Vimovo is not vulnerable to name confusion that could lead to medication errors nor is the name considered promotional. Thus, the Division of Medication Error Prevention and Analysis (DMEPA) has no objection to the proposed proprietary name Vimovo for this product at this time.

DMEPA considers this a final proprietary name review. However, if approval of the NDA is delayed beyond 90 days from the date of this review, DGP should notify DMEPA because the proposed proprietary name must be re-reviewed prior to the new approval date.

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4 REFERENCES

1. OSE Review # 2009-1244 dated September 10, 2009. Proprietary Name Review of Vimovo (Naproxen and Esomeprazole Magnesium) Tablets. Raichell S. Brown, Safety Evaluator.

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/ama1/pub/upload/mm/365/stem-list-cumulative.pdf)***

USAN Stems List contains all the recognized USAN stems.

4. ***CDER Proposed Names List***

CDER Proposed Names List is a compiled list of proposed proprietary names submitted to the Division of Medication Error Prevention and Analysis (DMEPA) for review. The list is updated weekly and maintained by DMEPA.

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