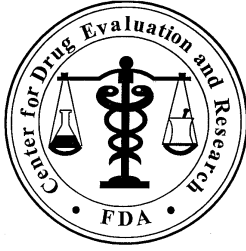


# CENTER FOR DRUG EVALUATION AND RESEARCH

**APPLICATION NUMBER:  
22511Orig1s000**

**OTHER 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 20, 2010

To: Donna Griebel, M.D., Director  
**Division of Gastroenterology Products (DGP)**

Through: Claudia Karwoski, PharmD, Director  
**Division of Risk Management (DRISK)**  
Sharon Mills, RN, BSN, CCRP  
Senior Patient Labeling Reviewer, Acting Team Leader  
**Division of Risk Management (DRISK)**

From: Jessica Diaz, RN, BSN  
Patient Labeling Reviewer  
**Division of Risk Management (DRISK)**

Subject: DRISK Review of Patient Labeling (Medication Guide)

Drug Name(s): VIMOVO (naproxen and esomeprazole magnesium)  
Delayed Release Tablets

Application Type/Number: NDA 22-511

Applicant/sponsor: Pozen, Inc.

OSE RCM #: 2009-1607

## 1 INTRODUCTION

This memorandum is in response to a request by the Division of Gastroenterology Products (DGP) for the Division of Risk Management (DRISK) to review the Medication Guide for VIMOVO (naproxen and esomeprazole magnesium) Delayed Release Tablets.

On June 30, 2009, Pozen, Inc in collaboration with Astra Zeneca submitted New Drug Application (NDA) 22-511 for VIMOVO (naproxen and esomeprazole magnesium) Delayed Release Tablets. The proposed indication for VIMOVO (naproxen and esomeprazole magnesium) Delayed Release Tablets is for relief of signs and symptoms of osteoarthritis, rheumatoid arthritis, and ankylosing spondylitis and to decrease the risk of developing gastric ulcers in patients at risk for developing NSAID-associated gastric ulcers.

Please let us know if DGP would like a meeting to discuss this review or any of our changes prior to sending to the Applicant.

## 2 MATERIAL REVIEWED

- Draft VIMOVO (naproxen and esomeprazole magnesium) Tablets Prescribing Information (PI) submitted June 30, 2009, and revised by the review division throughout the review cycle.
- Draft VIMOVO (naproxen and esomeprazole magnesium) Delayed Release Tablets PI with Medication Guide submitted November 11, 2009 and revised by the review division throughout the review cycle and provided to DRISK on April 13, 2010

## 3 RESULTS OF REVIEW

**In our review of the Medication Guide, we have:**

- simplified wording and clarified concepts where possible
- ensured that the MG is consistent with the PI
- removed unnecessary or redundant information
- ensured that the MG meets the Regulations as specified in 21 CFR 208.24
- ensured that the MG meets the criteria as specified in FDA's Guidance Useful Written Consumer Medication Information (published July 2006)
- ensured that the Vimovo MG is consistent with the currently approved NSAID MG template
- added information after the required NSAID language about the esomeprazole magnesium component of the product, and general information about Vimovo

Our annotated MG is appended to this memo. Any additional revisions to the PI should be reflected in the MG.

Please let us know if you have any questions.

21 Pages of Draft Labeling have been Withheld in Full as b4 (CCI/TS) immediately

Application Type/Number	Submission Type/Number	Submitter Name	Product Name
NDA-22511	ORIG-1	POZEN INC	PN 400 NAPROXEN/ESOMEPRAZOLE MAGNESIUM

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

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/s/

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JESSICA M DIAZ  
04/20/2010

CLAUDIA B KARWOSKI  
04/20/2010  
concur

**RPM FILING REVIEW**  
(Including Memo of Filing Meeting)

**To be completed for all new NDAs, BLAs, and Efficacy Supplements (except SE8 and SE9)**

<b>Application Information</b>		
NDA # 22-511 BLA#	NDA Supplement #:S- BLA STN #	Efficacy Supplement Type SE-
Proprietary Name: Vimovo Established/Proper Name: naproxen and esomeprazole magnesium Dosage Form: Tablets Strengths: 375mg/20mg and 500mg/20mg		
Applicant: Pozen Agent for Applicant (if applicable):		
Date of Application: 30 JUN 2009 Date of Receipt: 30 JUN 2009 Date clock started after UN:		
PDUFA Goal Date: 30 APR 2010		Action Goal Date (if different):
Filing Date: 29 AUG 2009		Date of Filing Meeting: 19 AUG 2009
Chemical Classification: (1,2,3 etc.) (original NDAs only) Type 4		
Proposed indication(s)/Proposed change(s): Signs and symptoms of osteoarthritis, rheumatoid arthritis, and ankylosing spondylitis in patients at risk of developing NSAID associated gastric ulcers		
Type of Original NDA: AND (if applicable) Type of NDA Supplement:		<input type="checkbox"/> 505(b)(1) <input checked="" type="checkbox"/> 505(b)(2) <input type="checkbox"/> 505(b)(1) <input type="checkbox"/> 505(b)(2)
<i>If 505(b)(2): Draft the "505(b)(2) Assessment" form found at: <a href="http://inside.fda.gov:9003/CDER/OfficeofNewDrugs/ImmediateOffice/ucm027499.html">http://inside.fda.gov:9003/CDER/OfficeofNewDrugs/ImmediateOffice/ucm027499.html</a> and refer to Appendix A for further information.</i>		
Review Classification:  <i>If the application includes a complete response to pediatric WR, review classification is Priority.</i>  <i>If a tropical disease priority review voucher was submitted, review classification is Priority.</i>		<input checked="" type="checkbox"/> Standard <input type="checkbox"/> Priority  <input type="checkbox"/> Tropical Disease Priority Review Voucher submitted
Resubmission after withdrawal? <input type="checkbox"/>		Resubmission after refuse to file? <input type="checkbox"/>
Part 3 Combination Product? <input type="checkbox"/> <i>If yes, contact the Office of Combination Products (OCP) and copy them on all Inter-Center consults</i>	<input type="checkbox"/> Drug/Biologic <input type="checkbox"/> Drug/Device <input type="checkbox"/> Biologic/Device	
<input type="checkbox"/> Fast Track <input type="checkbox"/> Rolling Review <input type="checkbox"/> Orphan Designation  <input type="checkbox"/> Rx-to-OTC switch, Full <input type="checkbox"/> Rx-to-OTC switch, Partial <input type="checkbox"/> Direct-to-OTC  Other:	<input type="checkbox"/> PMC response <input type="checkbox"/> PMR response: <input type="checkbox"/> FDAAA [505(o)] <input type="checkbox"/> PREA deferred pediatric studies [21 CFR 314.55(b)/21 CFR 601.27(b)] <input type="checkbox"/> Accelerated approval confirmatory studies (21 CFR 314.510/21 CFR 601.41) <input type="checkbox"/> Animal rule postmarketing studies to verify clinical	

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