CENTER FOR DRUG EVALUATION AND RESEARCH

Approval Package for:

APPLICATION NUMBER:

22511Orig1s000

Trade Name:	**Vimovo**
Generic Name:	**naproxen/esomeprazole magnesium, Delayed Release Tablets**
Sponsor:	**Pozen**
Approval Date:	**4/30/2010**
Indications:	**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 of developing Non-Steroidal Anti-inflammatory Drug (NSAID) associated gastric ulcers.**

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CONTENTS

Reviews / Information Included in this NDA Review.	
Approval Letter	x
Other Action Letters	
Labeling	x
REMS	
Summary Review	x
Officer/Employee List	x
Office Director Memo	
Cross Discipline Team Leader Review	
Medical Review(s)	x
Chemistry Review(s)	x
Environmental Assessment	
Pharmacology Review(s)	x
Statistical Review(s)	x
Microbiology Review(s)	
Clinical Pharmacology/Biopharmaceutics Review(s)	x
Other Reviews	x
Risk Assessment and Risk Mitigation Review(s)	
Proprietary Name Review(s)	x
Administrative/Correspondence Document(s)	x

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APPROVAL LETTER

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 022511 **NDA APPROVAL**

Pozen
Attention: Paul A. Ossi
Senior Vice President, Regulatory Affairs
1414 Raleigh Road
Suite 400
Chapel Hill, N.C. 27517

Dear Mr. Ossi:

Please refer to your New Drug Application (NDA), received June 30, 2009, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Vimovo (naproxen/esomeprazole magnesium) Delayed Release Tablets, 375 mg/20 mg and 500 mg/20 mg.

We acknowledge receipt of your submissions dated June 30, 2009; August 6, 2009; October 29, 2009; November 11, 13, 19, and 30, 2009; December 18, 2009; March 4, 9, 24, 25, and 26, 2010 and April 23, 28 and 30, 2010.

This new drug application provides for the use of Vimovo (naproxen/esomeprazole magnesium) Delayed Release Tablets, 375 mg/20 mg and 500 mg/20 mg 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 of developing Non-Steroidal Anti-inflammatory Drug (NSAID) associated gastric ulcers.

In our letter dated October 9, 2009, we notified you that a risk evaluation and mitigation strategy (REMS) was required for Vimovo (naproxen/esomeprazole magnesium) to ensure that the benefits of the drug outweigh the risks of cardiovascular and gastrointestinal adverse events. We indicated that your REMS must include a Medication Guide and a timetable for submission of assessments of the REMS.

After consultations between the Office of New Drugs and the Office of Surveillance and Epidemiology, we have reconsidered the need for a REMS for this product. We believe that a Medication Guide is necessary to inform patients of the serious risks of cardiovascular and gastrointestinal adverse events. However, since other drugs currently approved in the non-steroidal anti-inflammatory drug (NSAID) class have Medication Guides with identical safety information regarding these risks that are not included in a REMS, we will not require a REMS.

We have completed our review of this application, as amended. It is approved, effective on the date of this letter, for use as recommended in the enclosed agreed-upon labeling text.

REQUIRED PEDIATRIC ASSESSMENTS

Under the Pediatric Research Equity Act (PREA) (21 U.S.C. 355c), all applications for new active ingredients, new indications, new dosage forms, new dosing regimens, or new routes of administration are required to contain an assessment of the safety and effectiveness of the product for the claimed indications in pediatric patients unless this requirement is waived, deferred, or inapplicable.

For the indication, relief of signs and symptoms of osteoarthritis (OA) and to decrease the risk of developing gastric ulcers in OA patients at risk of developing NSAID-associated gastric ulcers, we are waiving the pediatric study requirement for ages birth to 16 years, 11 months. OA is one of the "adult-related" conditions that does not occur in pediatrics and qualifies for a waiver because studies would be impossible or highly impractical.

For the indication, relief of signs and symptoms of ankylosing spondylitis (AS) and to decrease the risk of developing gastric ulcers in AS patients at risk of developing NSAID-associated gastric ulcers, we are waiving the pediatric study requirement for ages birth to 16 years, 11 months. Necessary studies are impossible or highly impracticable because there are too few pediatric patients with this disease to study. AS typically presents in young adulthood.

For the indication, relief of signs and symptoms of rheumatoid arthritis (RA) and to decrease the risk of developing gastric ulcers in RA patients at risk of developing NSAID-associated gastric ulcers, we are waiving the pediatric study requirement for ages birth to 1 year, 11 months. Necessary studies for pediatric patients in this age range are impossible or highly impracticable because Juvenile Rheumatoid Arthritis (JRA) does not usually present at birth and fewer than 2% of all pediatric visits to a physician for an NSAID prescription for arthritis and arthropathy occur in this age group.

For the indication, relief of signs and symptoms of rheumatoid arthritis (RA) and to decrease the risk of developing gastric ulcers in RA patients at risk of developing NSAID-associated gastric ulcers, we are deferring submission of your pediatric studies for ages 2 to 16 years, 11 months because this product is ready for approval for use in adults and the pediatric studies have not been completed.

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