

CENTER FOR DRUG EVALUATION AND RESEARCH

Approval Package for:

APPLICATION NUMBER:

NDA 21153/S-047

Trade Name: **NEXIUM**

Generic Name: **Esomeprazole Magnesium**

Sponsor: **AstraZeneca LP**

Approval Date: 10/04/2013

Indications: NEXIUM is a proton pump inhibitor indicated for the following:

- Treatment of gastroesophageal reflux disease (GERD)
- Risk reduction of NSAID-associated gastric ulcer
- H. pylori eradication to reduce the risk of duodenal ulcer recurrence
- Pathological hypersecretory conditions, including Zollinger-Ellison syndrome

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:
NDA 21153/S-047

CONTENTS

Reviews / Information Included in this NDA Review.

Approval Letter	X
Other Action Letters	
Labeling	
Summary Review	
Officer/Employee List	
Office Director Memo	
Cross Discipline Team Leader Review	
Medical Review(s)	
Chemistry Review(s)	X
Environmental Assessment	
Pharmacology Review(s)	
Statistical Review(s)	
Microbiology Review(s)	
Clinical Pharmacology/Biopharmaceutics Review(s)	
Risk Assessment and Risk Mitigation Review(s)	
Proprietary Name Review(s)	
Other Review(s)	
Administrative/Correspondence Document(s)	

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:
NDA 21153/S-047

APPROVAL LETTER



NDA 21153/S-047

APPROVAL LETTER

AstraZeneca LP
Attention: Judy W. Firor
Regulatory Affairs Director
1800 Concord Pike, P.O. Box 8355
Wilmington, DE 19803

Dear Ms. Firor:

Please refer to your Supplemental New Drug Application (sNDA) dated June 4, 2013, received June 5, 2013, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Nexium® (esomeprazole magnesium) Delayed-Release Capsules.

This "Prior Approval" supplemental new drug application provides for a change to the ink imprint for 20 mg Nexium® (esomeprazole magnesium) Delayed- Release Capsules.

We have completed our review of this supplemental new drug application. This supplement is approved.

We remind you that you must comply with the requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

If you have any questions, call Cathy Tran-Zwanetz, Regulatory Project Manager, at (301) 796-3877.

Sincerely,

{See appended electronic signature page}

Thomas F. Oliver, Ph.D.
Branch Chief, Branch VI
Division of New Drug Quality Assessment II
Office of New Drug Quality Assessment
Center for Drug Evaluation and Research

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

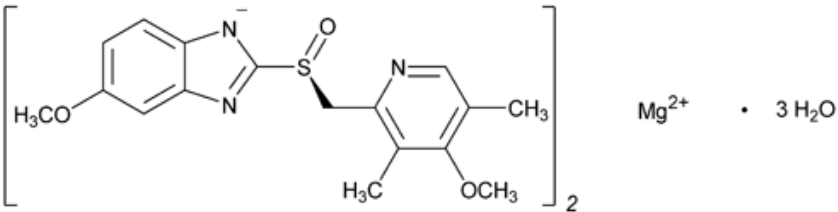
/s/

THOMAS F OLIVER
10/04/2013

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:
NDA 21153/S-047

CHEMISTRY REVIEW(S)

CHEMISTS REVIEW Jeffrey B. Medwid, Ph.D.	1. ORGANIZATION ONDQA Div II, Branch VI and CDER/ODEIII/DGIEP	2. NDA NUMBER 21-153
3. NAME AND ADDRESS OF APPLICANT ASTRAZENECA LP 1800 CONCORD PIKE PO BOX 8355 WILMINGTON, DELAWARE 198038355 UNITED STATES		4. COMMUNICATION, DATE S-047; PAS Letter Date: June 5, 2013 Received Date: June 5, 2013 PDUFA DATE: October 5, 2013
5. PROPRIETARY NAME Nexium 20/40 DRC Capsules	6. NAME OF THE DRUG Esomeprazole magnesium	7. AMENDMENTS, REPORT, DATE None
8. CBE-0 SUPPLEMENT PROVIDES FOR: a change in the ink imprint for 20 mg Nexium Delayed Release Capsules		
9. PHARMACOLOGICAL CATEGORY <i>Gastric acid secretion inhibitor</i>	10. HOW DISPENSED Rx	11. RELATED IND, NDA, DMF & CONSULT REVIEWS
12. DOSAGE FORM Capsules	13. POTENCY 20 mg	
14. CHEMICAL NAME AND STRUCTURE		
NEXIUM® 5-Methoxy-2-[(S)-[(4-methoxy-3,5-dimethyl-2-pyridyl)methyl]sulfinyl]benzimidazole, magnesium salt (2:1), trihydrate $C_{34}H_{36}MgN_6O_6S_2 \cdot 3H_2O$. 767.17. 		
15. COMMENTS <p>This PA: provides for a change in the ink imprint for 20 mg Nexium Delayed Release Capsules</p> <p>In accordance with 21 CFR 314.70, AstraZeneca LP (AstraZeneca) is submitting this supplement to provide for a change to the ink imprint for 20 mg NEXIUM® delayed release capsules. <i>The imprint is currently on two lines but will be changed to one line!</i></p> <p>This submission includes two key issues supporting the change to the ink imprint:</p> <p>1.11.1 Quality Information Amendment, providing justification information for the submission. See <i>Attachment 1</i> of this review for Justification information and <i>Reviewer Comments: ACCEPTABLE</i></p> <p>1.12.14 Environmental Analysis - Assessment Statement. See <i>Attachment 2</i> of this review for EA information and <i>Reviewer Comments: ACCEPTABLE</i></p>		

Based on the [acceptable](#) recommendation by this reviewer on both key issues to this review this supplement is recommended for approval from a CMC point of view.

16. CONCLUSION AND RECOMMENDATION

This supplement is recommended for approval from a CMC perspective.

17. NAME	18. REVIEWERS SIGNATURE	19. DATE COMPLETED
Jeffrey B. Medwid	See appended electronic signature sheet	October 1, 2013

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

/s/

JEFFREY B MEDWID
10/01/2013

THOMAS F OLIVER
10/04/2013