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RESEARCH**

APPLICATION NUMBER:

207920Orig1s000

PROPRIETARY NAME REVIEW(S)

PROPRIETARY NAME REVIEW – MEMORANDUM

Division of Medication Error Prevention and Analysis (DMEPA)
Office of Medication Error Prevention and Risk Management (OMEPRM)
Office of Surveillance and Epidemiology (OSE)
Center for Drug Evaluation and Research (CDER)

***** This document contains proprietary information that cannot be released to the public*****

Date of This Review:	April 2, 2015
Application Type and Number:	NDA 207920
Product Name and Strength:	Nexium 24HR (Esomeprazole Magnesium) Delayed-Release Tablets, 22.3 mg
Product Type:	Single Ingredient
Rx or OTC:	OTC
Applicant/Sponsor Name:	Pfizer Inc. (On behalf of AstraZeneca)
Panorama #:	2015-49805
DMEPA Primary Reviewer:	Grace P. Jones, PharmD, BCPS
DMEPA Team Leader:	Chi-Ming (Alice) Tu, PharmD

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1 INTRODUCTION

This review evaluates the proposed proprietary name, Nexium 24HR, from a misbranding and safety perspective.

1.1 REGULATORY HISTORY

We previously found the proprietary name, Nexium 24HR, acceptable for Esomeprazole Capsules, 20 mg (equivalent to 22.3 mg esomeprazole magnesium), under:

- IND 111185 in OSE RCM# 2012-2516 dated April 17, 2013.
- NDA 204655 in OSE RCM# 2013-1565 dated September 13, 2013.

NDA 204655 for Nexium 24HR (Esomeprazole Magnesium) Capsules, 22.3 mg, was approved on March 28, 2014.

In addition, we previously found the proposed proprietary name, Nexium 24HR, acceptable for Esomeprazole Tablets, 20 mg (equivalent to 22.3 mg esomeprazole magnesium), under:

- IND 118964 in OSE RCM# 2013-2458 dated November 4, 2013.

The Applicant now seeks approval of the proposed name, Nexium 24HR, for Esomeprazole Magnesium, 22.3 mg, under NDA 207920.

1.2 PRODUCT INFORMATION

The only difference between the proposed NDA 207920 and the previously reviewed NDA 204655 product is the dosage form (tablets vs. capsules). Because both products otherwise share the same product characteristics (active ingredients, indication of use, strength, route of administration, dose and frequency, etc.), the change in dosage form does not affect the proposed NDA 207920 product's use in the usual clinical setting. We are not aware of any name confusion related to the name Nexium 24HR from our routine post-marketing surveillance for medication errors. Since we have already evaluated and found the proprietary name Nexium 24HR acceptable from a misbranding and safety perspective under NDA 204655 (approved capsules) and IND 118964 (proposed tablets), the proposed name Nexium 24HR is also acceptable for this NDA 207920 product.

1.3 MISBRANDING ASSESSMENT AND COMMENTS AT INITIAL REVIEW

At the initial phase of the review, in response to our initial OSE, March 9, 2015 email, the Division of Nonprescription Drug Products (DNBP) had no concerns regarding the proposed proprietary name, Nexium 24HR. We concur with DNBP's assessment at initial review and conclude that the proposed proprietary name does not misbrand the proposed product.

2 CONCLUSIONS

The proposed proprietary name is acceptable from both a safety and misbranding perspective.

If you have further questions or need clarifications, please contact Abiola Olagundoye-Alawode, OSE project manager, at 301-796-3982.

2.1 COMMENTS TO THE APPLICANT

We have completed our review of the proposed proprietary name, Nexium 24HR, and have concluded that this name is acceptable.

If any of the proposed product characteristics as stated in your February 25, 2015 submission are altered prior to approval of the marketing application, the name must be resubmitted for review.

3 REFERENCES

1. Tu, C. Proprietary Name Review for Nexium 24HR (IND 111185). Silver Spring (MD): Food and Drug Administration, Center for Drug Evaluation and Research, Office of Surveillance and Epidemiology, Division of Medication Error Prevention and Analysis (US); 2013 Apr 17. OSE RCM No.: 2012-2516.
2. Tu, C. Proprietary Name Review for Nexium 24HR (NDA 204655). Silver Spring (MD): Food and Drug Administration, Center for Drug Evaluation and Research, Office of Surveillance and Epidemiology, Division of Medication Error Prevention and Analysis (US); 2013 Sep 13. OSE RCM No.: 2013-1565.
3. Tu, C. Proprietary Name Review for Nexium 24HR (IND 118964). Silver Spring (MD): Food and Drug Administration, Center for Drug Evaluation and Research, Office of Surveillance and Epidemiology, Division of Medication Error Prevention and Analysis (US); 2013 Nov 4. OSE RCM No.: 2013-2458.

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/s/

GRACE JONES
04/02/2015

CHI-MING TU
04/02/2015