CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

206439Orig1s000

PROPRIETARY NAME REVIEW(S)

PROPRIETARY NAME REVIEW

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:	May 15, 2014
Application Type and Number:	NDA 206439
Product Name and Strength:	Namzaric (Memantine and Donepezil) extended-release capsules 14 mg/10 mg, 28mg/10 mg
Product Type:	Multi-ingredient
Rx or OTC:	Rx
Applicant/Sponsor Name:	Forest Research Institute, Inc.
Submission Date:	February 27, 2014
Panorama #:	2014-17012
DMEPA Primary Reviewer:	Justine Harris, RPh
DMEPA Acting Team Leader:	Julie Villanueva Neshiewat, PharmD, BCPS
DMEPA Acting Team Leader:	Tingting Gao, PharmD
DMEPA Deputy Director	Kellie A. Taylor, Pharm.D., MPH

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1 INTRODUCTION

This review evaluates the proposed proprietary name, Namzaric, from a safety and promotional perspective. The sources and methods used to evaluate the proposed name are outlined in the reference section and Appendix A respectively. The Applicant submitted an external name study, conducted by (b) (4) for this product.

1.1 PRODUCT INFORMATION

The following product information is provided in the February 27, 2014 proprietary name submission.

- Intended Pronunciation: nam-ZAIR-ick
- Active Ingredients: memantine HCl /donepezil HCl
- Indication of Use: Treatment of moderate to severe dementia of the Alzheimer's type
- Route of Administration: Oral
- Dosage Form: extended-release capsules[1]
- Strengths:
  - 14 mg memantine/10 mg donepezil HCl
  - 28 mg memantine/10 mg donepezil HCl
- Dose and Frequency: The usual dosage is 28 mg/10 mg once daily. The maximum daily dose is 28 mg/10 mg. For patients with severe renal impairment a dose of 14 mg/10 mg once daily is recommended.
- How Supplied:
  - The 14 mg/10 mg capsule product will be available in 30-count bottle, 90 count bottle, (b) (4)
  - The 28 mg/10 mg capsule product will be available in 30-count bottle, 90-count bottle, (b) (4)
- Storage: This product should be stored at 25° C (77°F); excursions permitted between 15°C - 30° C (59°F - 86°F). (b) (4)

2 RESULTS

The following sections provide information obtained and considered in the overall evaluation of the proposed proprietary name.

[1] Chemistry, Manufacturing, and Controls (CMC) has determined this dosage form will be designated as extended-release capsules

2.1 PROMOTIONAL ASSESSMENT

The Office of Prescription Drug Promotion (OPDP) determined the proposed name is acceptable from a promotional perspective. DMEPA and the Division of Neurology Products (DNP) concurred with the findings of OPDP's promotional assessment of the proposed name.

2.2 SAFETY ASSESSMENT

The following aspects were considered in the safety evaluation of the name.

2.2.1 United States Adopted Names (USAN) Search

There is no USAN stem present in the proprietary name[2].

2.2.2 Components of the Proposed Proprietary Name

The Applicant indicated in their submission that the proposed name, Namzaric, is derived from Namenda and Aricept. This proprietary name is comprised of a single word that does not contain any components (i.e. a modifier, route of administration, dosage form, etc.) that are misleading or can contribute to medication error. Since this product will be designated as an extended-release capsule, we considered if a modifier was needed to convey its extended-release properties (See Discussion, Section 3).

2.2.3 FDA Name Simulation Studies

One hundred and fourteen practitioners participated in DMEPA's prescription studies. The interpretations did not overlap with any currently marketed products nor did the misinterpretations sound or look similar to any currently marketed products or any products in the pipeline.

Twenty-one (26%) participants correctly interpreted the name, Namzaric, in the written prescription studies, and one participant in the verbal study. Nine participants (27%) in the verbal prescription study misinterpreted the letter 'a' in the letter string 'Nam' as an 'e' and seven participants in the written studies interpreted this 'a' as 'u'. Thirty-six participants (45%) misinterpreted the ending letter string '-zaric' as '-zani' and fifteen (19%) misinterpreted this letter string as '-raric' in the written studies. Eleven participants (32%) misinterpreted the 'c' for a 'k' in the verbal prescription study. Appendix B contains the results from the verbal and written prescription studies.

2.2.4 Comments from Other Review Disciplines at Initial Review

In response to the OSE, March 14, 2014 e-mail, the Division of Neurology Products (DNP) did not forward any comments or concerns relating to the proposed proprietary name at the initial phase of the review.

[2]USAN stem search conducted on March 14, 2014.

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