

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:

206030Orig1s000

PROPRIETARY NAME REVIEW(S)

**Proprietary Name
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:	May 17, 2016
Application Type and Number:	NDA 206030
Product Name and Strength:	Carnexiv*** (carbamazepine injection) 10 mg/ mL
Total Product Strength:	200 mg / 20 mL
Product Type:	Single-Ingredient Product
Rx or OTC:	Rx
Applicant/Sponsor Name:	Lundbeck
Panorama #:	2016-7786445
DMEPA Primary Reviewer:	Lolita White, PharmD
DMEPA Team Leader:	Danielle Harris, PharmD, BCPS

1 INTRODUCTION

This memorandum is to re-assess the proposed proprietary name, Carnexiv*** under NDA 206030, which was found acceptable in a previous review RCM No. 2015-992878.¹ We note that there is no change in product characteristics.

2 METHODS AND DISCUSSION

For re-assessment of the proposed proprietary name, the Division of Medication Error Prevention and Analysis (DMEPA) evaluated the previously identified names of concern considering any lessons learned from recent post-marketing experience, which may have altered our previous conclusion regarding the acceptability of the proposed proprietary name. Additionally, DMEPA searched the USAN stem list to determine if the name contains any USAN stems as of the last USAN updates. The April 28, 2016 search of USAN stems did not find any USAN stems in the proposed proprietary name.

2.1 MISBRANDING ASSESSMENT

The Office of Prescription Drug Promotion (OPDP) determined that the proposed name would not misbrand the proposed product. DMEPA and the Division of Neurology Products (DNP) concurred with the findings of OPDP's assessment of the proposed name.

3 CONCLUSIONS

Our re-assessment did not identify any names that represent a potential source of drug name confusion. Therefore, we maintain that the proposed proprietary name is acceptable.

If you have any questions or need clarifications, please contact CDR Corwin Howard, OSE project manager, at 240-402-8654.

3.1 COMMENTS TO THE APPLICANT

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

If any of the proposed product characteristics as stated in your April 21, 2016 submission are altered prior to approval of the marketing application, the name must be resubmitted for review.

4 REFERENCES

1. *USAN Stems* (<http://www.ama-assn.org/ama/pub/physician-resources/medical-science/united-states-adopted-names-council/naming-guidelines/approved-stems.page>)

USAN Stems List contains all the recognized USAN stems.

¹ White, L. Proprietary Name Review for Carnexiv IND 073686. Silver Spring (MD): FDA, CDER, OSE, DMEPA (US); 2015NOV12. RCM No.: 2015-992878

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/s/

LOLITA G WHITE
05/17/2016

DANIELLE M HARRIS
05/17/2016

**Department of Health and Human Services
Public Health Service
Food and Drug Administration
Center for Drug Evaluation and Research
Office of Surveillance and Epidemiology
Office of Medication Error Prevention and Risk Management**

Proprietary Name Memorandum

Date: January 30, 2014

Reviewer: Jacqueline Sheppard, PharmD
Division of Medication Error Prevention and Analysis

Acting Team Leader: Julie Neshiewat, PharmD, BCPS
Division of Medication Error Prevention and Analysis

Drug Name and Strength: Carbella (Carbamazepine) Injection
200 mg per 20 ml (10 mg/ml)

Application Type/Number: NDA 206030

Applicant/Sponsor: Lundbeck

OSE RCM #: 2014-16825

*** This document contains proprietary and confidential information that should not be released to the public.***

1 INTRODUCTION

The proposed proprietary name, Carbella, was found acceptable in OSE Review # 2013-555, dated July 26, 2013 under IND 073686. This memorandum is to communicate that DMEPA maintains the proposed proprietary name, Carbella, is acceptable from both a promotional and safety perspective under the NDA 206030.

If you have further questions or need clarifications, please contact Ermias Zerislassie, OSE project manager, at 301-796-0097.

1.1 COMMENTS TO THE APPLICANT

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

If any of the proposed product characteristics as stated in your January 16, 2014 submission are altered, the name must be resubmitted for review.

2 REFERENCES

1. OSE Review # 2013-555: Proprietary Name Review for Carbella (Carbamazepine) Injection, July 26, 2013.

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/s/

JACQUELINE E SHEPPARD
01/30/2014

JULIE V NESHIEWAT
01/30/2014