CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

761063Orig1s000

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:	December 4, 2017
Application Type and Number:	BLA 761063
Product Name and Strength:	Emgality (galcanezumab) injection 120 mg/mL
Product Type:	Single ingredient, combination product
Rx or OTC:	Rx
Applicant/Sponsor Name:	Eli Lilly and Company
Panorama #:	2017-17802109
DMEPA Safety Evaluator:	Chad Morris, PharmD, MPH
DMEPA Team Leader:	Lolita White, PharmD

1 INTRODUCTION

This memorandum is to reassess the proposed proprietary name, Emgality, which was found conditionally acceptable under IND 111295 on May 24 2017.[a]

We note that there is a change in dosing regimen for BLA 761063. All other product characteristics remain the same.

2 METHODS AND DISCUSSION

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.

2.2 SAFETY ASSESSMENT

For re-assessment of the proposed proprietary name, 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. We also evaluated previously identified names taking into account the change in dosing regimen (previous submission: (b) (4) current submission: 240 mg once followed by 120 mg monthly) . Our evaluation has not 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 October 3, 2017 search of USAN stems did not find any USAN stems in the proposed proprietary name.

2.3 COMMUNICATION OF DMEPA'S ANALYSIS AT MIDPOINT OF REVIEW

DMEPA communicated our findings to the Division of Neurology Products (DNP) via e-mail on November 16, 2017. At that time we also requested additional information or concerns that could inform our review. Per e-mail correspondence from the DNP on November 29, 2017, they stated no additional concerns with the proposed proprietary name, Emgality.

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 Corwin Howard, OSE project manager, at 240-402-8654.

[a] Morris, C. Proprietary Name Review for Emgality (IND 111295). Silver Spring (MD): FDA, CDER, OSE, DMEPA (US); 2017 MAY 24. Panorama No. 2017-12897904.

3.1 COMMENTS TO THE APPLICANT

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

If any of the proposed product characteristics as stated in your September 26, 2017 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.

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

/s/

JOHN C MORRIS
12/04/2017

LOLITA G WHITE
12/04/2017