CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

207932Orig1s000

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:	January 30, 2015
Application Type and Number:	NDA 207932
Product Name and Strength:	Belbuca (buprenorphine HCl) buccal film 75 mcg, 150 mcg, 300 mcg, 450 mcg, 600 mcg, 750 mcg and 900 mcg
Product Type:	Single
Rx or OTC:	Rx
Applicant/Sponsor Name:	Endo Pharmaceuticals
Submission Date:	December 23, 2014
Panorama #:	2014-46342
DMEPA Primary Reviewer:	James Schlick, RPh, MBA
DMEPA Acting Team Leader:	Vicky Borders-Hemphill, PharmD

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1 INTRODUCTION

This memorandum is to reassess the proposed proprietary name, Belbuca. DMEPA previously found the name acceptable in OSE Review No. 2014-17155[1], dated June 20, 2014.

1.1 PRODUCT INFORMATION

The following product information is provided in the December 23, 2014 proprietary name submission.

- Intended Pronunciation: bel-BUE-kuh
- Active Ingredient: buprenorphine
- Indication of Use: for the management of (b) (4) severe pain (b) (4)
- Route of Administration: buccal
- Dosage Form: buccal soluble films
- Strength: 75 mcg, 150 mcg, 300 mcg, 450 mcg, 600 mcg, 750 mcg and 900 mcg
- Dose and Frequency: twice daily
- How Supplied: Cartons containing 60 individually wrapped films
- Storage: 15°C to 30°C (59°F-86°F)
- Container and Closure Systems: (b) (4), child- resistant, foil packages

1.2 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 Analgesia, Anesthesia, and Addiction Products (DAAAP) concurred with the findings of OPDP's assessment of the proposed name.

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[1] Borders-Hemphill, V. Proprietary Name Review for Belbuca (IND 072428). 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); 2014 June 20 22p. OSE RCM No. 2014-17155.

1.3 SAFETY ASSESSMENT

To reassess the proposed proprietary name, DMEPA searched the POCA database (see Section 3) and conducted a gap analysis to identify names approved since the previous OSE Proprietary Name Review #2014-17155 that have orthographic and phonetic similarities to the proposed name Belbuca. Our POCA search did not identify any new names that represent a potential source of drug name confusion.

We re- 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. Furthermore, DMEPA searched the USAN stem list to determine if the name contains any USAN stems as of the last USAN updates. The January, 29, 2015 search of USAN stems did not find any USAN stems in the proposed proprietary name.

Lastly, we reviewed the product characteristics in the current proprietary name submission and compared them to the product characteristics in the previous proprietary name review. We determined that none of the product characteristics have changed since the last proprietary name review.

As a result, we maintain that the name, Belbuca, is acceptable.

2 CONCLUSIONS

The proposed proprietary name is acceptable.

If you have further questions or need clarifications, please contact Vaishali Jarral, OSE project manager, at 301-796-4248.

2.1 COMMENTS TO THE APPLICANT

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

3 REFERENCES

1. Borders-Hemphill, V. Proprietary Name Review for Belbuca (IND 072428). 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); 2014 June 20 22p. OSE RCM No. 2014-17155.

2. ***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.

3. Phonetic and Orthographic Computer Analysis (POCA)

POCA is a system that FDA designed. As part of the name similarity assessment, POCA is used to evaluate proposed names via a phonetic and orthographic algorithm. The proposed proprietary name is converted into its phonemic representation before it runs through the phonetic algorithm. Likewise, an orthographic algorithm exists that operates in a similar fashion. POCA is publicly accessible.

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

/s/

JAMES H SCHLICK
01/30/2015

BRENDA V BORDERS-HEMPHILL
01/30/2015