

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:

206544Orig1s000

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*****

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| Date of This Review: | March 16, 2015 |
| Application Type and Number: | NDA 206544 |
| Product Name and Strength: | Morphabond (morphine sulfate) Extended-release Tablets 15 mg, 30 mg, 60 mg, 100 mg |
| Product Type: | Single Ingredient |
| Rx or OTC: | Rx |
| Applicant/Sponsor Name: | Inspirion |
| Submission Date: | January 29, 2015 |
| Panorama #: | 2015-48327 |
| DMEPA Primary Reviewer: | James Schlick, RPh, MBA |
| DMEPA Acting Team Leader: | Vicky Borders-Hemphill, PharmD |
| DMEPA Associate Director: | Irene Z. Chan, PharmD, BCPS |

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1 INTRODUCTION

This memorandum is to reassess the proposed proprietary name, Morphabond. DMEPA previously found the name acceptable in OSE Review No. 2014-25472¹, dated November 13, 2014.

1.1 PRODUCT INFORMATION

The following product information is provided in the January 29, 2015 proprietary name submission.

- Intended Pronunciation: \ˈmôr-ˈfa-ˈbänd\.
- Active Ingredient: Morphine sulfate
- Indication of Use: Management of moderate to severe pain when a continuous, around-the-clock opioid analgesic is needed for an extended period of time.
- Route of Administration: Oral
- Dosage Form: Extended-release tablets
- Strength: 15 mg, 30 mg, 60 mg, 100 mg
- Dose and Frequency: 15 mg to 100 mg orally every (b) (4) 12 hours
- How Supplied/Container Closure: Supplied in 100-count bottles that consist of a 100-cc (b) (4), high-density polyethylene bottle, a (b) (4) (b) (4) (b) (4) (b) (4) and a (b) (4) child-resistant cap with a (b) (4).
- Storage: Room temperature

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.

¹ Schlick, J. Proprietary Name Review for Morphabond (IND 115822). 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 November 13, 28 p. OSE RCM No. 2014-25472.

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 #2014-25472 that have orthographic and phonetic similarities to the proposed name Morphabond. 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 February 19, 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.

Assessment of Omitted Modifier

We previously found the name, Morphabond, acceptable in OSE review# 2014-25472. However, our previous safety analysis recommended that Inspirion consider a modifier as an additional safety measure to differentiate between their extended –release morphine and currently marketed immediate-release morphine products.

The use of an appropriate modifier with your proposed proprietary name to convey the extended-release nature of your product may help distinguish this extended-release product from currently marketed immediate-release morphine products. Morphabond has overlapping strengths with currently marketed immediate-release morphine sulfate tablets and capsules, which may increase the risk of your product being confused as an immediate-release product. The addition of a modifier to your proprietary name may provide an additional measure to emphasize the extended-release nature of your product, and highlight a difference between your extended-release morphine sulfate product and the currently marketed immediate-release morphine products. For these reasons, when you submit your request for proprietary name review at the time you file your NDA, we recommend that you consider proposing a modifier as part your proposed proprietary name in order to reduce the potential for confusion between the currently marketed immediate-release morphine products and your proposed product.

Inspirion considered the addition of a modifier to the root name, Morphabond, in their January 29, 2015 submission and provided the following rationale for not including a modifier:

Inspirion has considered the comments of DMEPA and believes that the descriptor following MorphaBond, (ie, morphine sulfate ER tablets) is sufficient to distinguish Inspirion's ER product from currently marketed IR morphine products.

We considered Inspirion's rationale of the inclusion of the dosage form description as part of the established name in the overall safety evaluation of the proposed proprietary name. We determined that the dosage form description can provide an additional cue that

the product is an extended-release product. In our previous safety analysis we identified cases where extended-release products were given at intervals more frequent than labeled and included products that had overlapping product strengths with immediate-release formulations. While we still have a concern about the potential for confusion between immediate and extended-release formulations resulting in wrong frequency errors, we looked at other currently marketed morphine extended-release oral dosage forms marketed without a modifier in the proprietary name, and we did not identify any wrong frequency error or wrong technique error cases for these products in the FDA Adverse Event Reporting System (FAERS).

Based on the consideration of the additional information, we maintain that the name Morphabond, without the addition of a modifier, is acceptable. However, we will monitor for any errors in our postmarketing surveillance, and if any confusion related to the name Morphabond arises, then additional regulatory action may be considered.

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, Morphabond, and have concluded that this name is acceptable.

3 REFERENCES

1. Schlick, J. Proprietary Name Review for Morphabond (IND 115822). 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 November 13, 28 p. OSE RCM No. 2014-25472.
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.

4. *Description of FAERS*

The FDA Adverse Event Reporting System (FAERS) is a database that contains information on adverse event and medication error reports submitted to FDA. The database is designed to support the FDA's postmarket safety surveillance program for drug and therapeutic biologic products. The informatic structure of the FAERS database adheres to the international safety reporting guidance issued by the International Conference on Harmonisation. FDA's Office of Surveillance and Epidemiology codes adverse events and medication errors to terms in the Medical Dictionary for Regulatory Activities (MedDRA) terminology. Product names are coded using the FAERS Product Dictionary. More information about FAERS can be found at: <http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Surveillance/AdverseDrugEffects/default.htm>.

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/s/

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