CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

208383Orig1s000

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:	June 13, 2017
Application Type and Number:	NDA 208383
Product Name and Strength:	Bevyxxa (betrixaban) capsule, 40 mg, 80 mg
Product Type:	Single Ingredient Product
Rx or OTC:	Rx
Applicant/Sponsor Name:	Portola Pharmaceuticals Inc.
Panorama #:	2017-14274608
DMEPA Primary Reviewer:	Nicole Garrison, PharmD, BCPS
DMEPA Team Leader:	Hina Mehta, PharmD

1 INTRODUCTION

This memorandum is to reassess the proposed proprietary name, Bevyxxa, which was found unacceptable under NDA 208383 on February 15, 2017.[a] The proposed name, Bevyxxa, was found to be vulnerable to medication errors due to confusion with another product, (b) (4) **, under review at the time. Therefore, the ultimate acceptability of the proposed proprietary name, Bevyxxa, was dependent upon which underlying application was approved first.

We note that the goal date for NDA 208383 is June 24, 2017, whereas the underlying application for (b) (4). Therefore, if the proposed proprietary name, Bevyxxa, is granted approval under NDA 208383 on or before June 24, 2017, this application approval will precede approval of the application with the conflicting proposed name, (b) (4) ***. Thus, the Applicant submitted the proposed proprietary name, Bevyxxa, for review.

2 METHODS AND DISCUSSION

2.1 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. Additionally, DMEPA searched the USAN stem list to determine if the name contains any USAN stems as of the last USAN updates. The May 9, 2017 search of USAN stems did not find any USAN stems in the proposed proprietary name.

Since our last review[a], we identified two new names in POCA and determined they will not pose a risk for confusion as described in Appendices F and G. Our evaluation has not altered our previous conclusion regarding the acceptability of the proposed proprietary name.

Finally, DMEPA evaluated the status of the underlying application of the conflicting name, (b) (4) ***, and determined that if NDA 208383 is approved on or before June 24, 2017, this application approval will precede approval of the application with the conflicting proposed name, (b) (4) *** given that the underlying application for (b) (4)

Based upon our safety assessment of the proposed proprietary name, Bevyxxa, the application goal date for NDA 208383, and the status of the underlying application for (b) (4) ***, we find Bevyxxa conditionally acceptable.

3 CONCLUSIONS

We conclude that the proposed proprietary name, Bevyxxa, is acceptable.

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[a] Garrison, N. Proprietary Name Review Memorandum for Bevyxxa (NDA 208383). 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); 2017 FEB 15. Panorama No. 2016-11514658.

If you have any questions or need clarifications, please contact Wana Manitpisitkul, OSE project manager, at 240-402-4156.

3.1 COMMENTS TO THE APPLICANT

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

If any of the proposed product characteristics as stated in your April 6, 2017 submission are altered prior to approval of the marketing application, the name must be resubmitted for review.

If your application receives a complete response, please submit a new request for review of your proposed proprietary name when you respond to the application deficiencies.

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.

2. **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.

APPENDICES

Appendix F: Low Similarity Names (e.g., combined POCA score is ≤54%)

No.	Name	POCA Score (%)
1.	Fenex-PSE	54

Appendix G: Names not likely to be confused or not used in usual practice settings for the reasons described**.**

No.	Name	POCA Score (%)	Failure preventions
1.	(b) (4)	66	(b) (4)

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/s/

NICOLE B GARRISON
06/13/2017

HINA S MEHTA
06/13/2017

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)

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Date of This Review:	February 15, 2017
Application Type and Number:	NDA 208383
Product Name and Strength:	Bevyxxa (betrixaban) capsule, 40 mg, 80 mg
Product Type:	Single-Ingredient Product
Rx or OTC:	Rx
Applicant/Sponsor Name:	Portola Pharmaceuticals Inc.
Panorama #:	2016-11514658
DMEPA Primary Reviewer:	Nicole Garrison, PharmD, BCPS
DMEPA Team Leader:	Hina Mehta, PharmD
DMEPA Acting Associate Director:	Mishale Mistry, PharmD, MPH
DMEPA Division Director:	Todd Bridges, Rph

1 INTRODUCTION

This memorandum is to reassess the proposed proprietary name, Bevyxxa, which was found conditionally acceptable under IND 072679 on February 11, 2016.[a] The Applicant submitted an external name study, conducted by (b) (4) for this product, which was analyzed during the last review of the proprietary name.

We note that there is a change in proposed indication, duration of treatment, dosing in renal impairment, and coadministration with strong P-gp inhibitors for NDA 208383. All other product characteristics remain the same.

Table 1. Comparison of Dosage and Administration between IND and NDA

	IND 072679	**NDA 208383**
Proposed Indication of Use	Prevention of venous thromboembolism (in acutely ill medical patients)	Extended prophylaxis of venous thromboembolism (VTE) in the acutely ill medical population with risk factors for VTE
Duration of treatment	N/A	The recommended duration of treatment is 35 to 42 days.
Dosing and frequency	The recommended dose is an initial loading dose of two 80 mg capsules (160 mg), followed by one 80 mg capsule daily.	The recommended dose is an initial single dose of 160 mg, followed by 80 mg once daily, taken at the same time each day with food.
Dosing in renal impairment	For patients with severe renal impairment (CrCl 15-30 mL/min), the recommended dose is an initial loading dose of two 40 mg capsules, followed by one 40 mg capsule daily. The dose of betrixaban should be reduced (to half) for patients with severe renal impairment (CrCl > 15 < mL/min)	No dose adjustment is needed for mild, moderate (b) (4) renal impairment (CrCl greater than 15 mL/min). (b) (4)
Dosing for coadministration with strong P-gp inhibitors	The recommended dose is an initial loading dose of two 40 mg capsules, followed by one 40 mg capsule daily.	The dose of betrixaban should be reduced to an initial loading dose of 80 mg followed by 40 mg per day

[a] Garrison, N. Proprietary Name Review for Bevyxxa (072679). 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); 2016 FEB 11. Panorama No. 2015-1780602.

		when co-administered with the P-gp inhibitors (b) (4) (b) (4)

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 Hematology Products (DHP) 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. Since that time, we have identified a conflict with another pending proposed proprietary name that is currently under review. The proposed name, Bevyxxa, could result in medication errors due to confusion with (b) (4) ***. Our evaluation of this name pair has altered our previous conclusion regarding the acceptability of the proposed proprietary name. The rationale for the risk of confusion is described below:

We have completed our review of the proposed proprietary name, Bevyxxa, and have concluded that this name is unacceptable for the following reasons.

(b) (4)

After considering the totality of the information above, we conclude there is a risk for name confusion between, Bevyxxa and (b) (4)**** that can result in wrong drug errors.

We acknowledge that our conclusion differs from that of the (b) (4) external study submitted in support of the proposed proprietary name. However, (b) (4) did not identify (b) (4)*** because (b) (4)*** is a proprietary name that is currently under review.

3 CONCLUSIONS

Our re-assessment determined that the proposed proprietary name is not acceptable from a safety perspective. The proposed name is vulnerable to name confusion with (b) (4)***. Therefore, the decision to deny the name will be communicated to the Applicant/Sponsor via letter (See ***Section 3.1).***

If you have any questions or need clarifications, please contact Latonia Ford, OSE project manager, at 301-796-4901.

3.1 COMMENTS TO THE APPLICANT

We have completed our review of the proposed proprietary name, Bevyxxa, and conclude that this name could result in medication errors due to confusion with another product that is also under review. Therefore, the ultimate acceptability of your proposed proprietary name, Bevyxxa, is dependent upon which underlying application is approved first. If another product is approved prior to your product, with a name that would be confused with your proposed proprietary name of Bevyxxa, you will be requested to submit another name.

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)**

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/s/

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02/15/2017

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