CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

761052Orig1s000

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:	August 5, 2016
Application Type and Number:	BLA 761052
Product Name and Strength:	Brineura (cerliponase alfa) Injection 30 mg/mL
Total Product Strength:	150 mg/5 mL
Product Type:	Single Ingredient
Rx or OTC:	Rx
Applicant/Sponsor Name:	BioMarin Pharmaceutical, Inc.
Panorama #:	2016- 8279583
DMEPA Primary Reviewer:	Sherly Abraham, R.Ph.
DMEPA Team Leader:	Mishale Mistry, Pharm.D., MPH

1 INTRODUCTION

This memorandum is to reassess the proposed proprietary name, Brineura, which was found conditionally acceptable under IND 122472 on October 28, 2015.[1] The previous review evaluated the [redacted] (b) (4) (30 mg/mL). In the Applicant's BLA submission, we note that the product will be packaged in two single-dose vials of 150 mg/5 mL (30 mg/mL). 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 the Division of Gastroenterology and Inborn Errors Products (DGIEP) concurred with the findings of OPDP's assessment of the proposed name.

2.2 SAFETY ASSESSMENT

For re-assessment of the proposed proprietary of 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 product strength due to product packaging. 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 July 29, 2016, search of USAN stems did not find any USAN stems in the proposed proprietary 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 from a promotional and safety perspective.

If you have any questions or need clarifications, please contact Alek Winiarski, OSE project manager, at 301-796-5295.

3.1 COMMENTS TO THE APPLICANT

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

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[1]Barlow, Matt. Proprietary Name Review for Brineura (IND 122472). 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); 2015 10 28, Panorama No. 370321

If any of the proposed product characteristics as stated in your May 27, 2016, submission are altered prior to approval of the marketing application, the name must be resubmitted for review.

APPEARS THIS WAY ON ORIGINAL

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/

SHERLY ABRAHAM
08/09/2016

MISHALE P MISTRY
08/10/2016