CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

761047Orig1s000

PROPRIETARY NAME REVIEW(S)

MEMORANDUM
NONPROPRIETARY NAME SUFFIX

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 3, 2017
Requesting Office or Division:	Division of Gastrointestinal and Inborn Errors Products (DGIEP)
Application Type and Number:	BLA 761047
Product Name and Strength:	Mepsevii (vestronidase alfa-vjbk) injection, 2 mg/mL
Total Product Strength:	10 mg/ 5 mL
Product Type:	Single ingredient product
Rx or OTC:	Rx
Applicant/Sponsor Name:	Ultragenyx Pharmaceutical Inc.
Panorama #:	2017-1325
DMEPA Primary Reviewer:	Sherly Abraham, R.Ph.
OMEPRM Deputy Director (Acting):	Lubna Merchant, MS, PharmD

1 PURPOSE OF MEMO

This memorandum summarizes our evaluation of the four-letter suffix for inclusion in the nonproprietary name and communicates our recommendation for the nonproprietary name for BLA 761047.

2 ASSESSMENT OF THE NONPROPRIETARY NAME

Ultragenyx was notified of the Agency's intention to designate a proper name that includes a four-letter distinguishing suffix that is devoid of meaning for its product in an advice letter[a] . At the Mid-Cycle communication teleconference held on June 14, 2017, Ultragenyx requested the Agency designate a FDA-generated a four-letter suffix to be used in the nonproprietary name of its product.

1. vestronidase alfa-vjbk

FDA generated a four letter suffix, -vjbk. This suffix was evaluated against the criteria described in the guidance[b].

We determined that the FDA-generated suffix "-vjbk", is not too similar to any other product's suffix designation, does not look similar to the names of other currently marketed products, that the suffix is devoid of meaning, and does not make any misrepresentations with respect to safety or efficacy of this product.

These findings were shared with the TBBS, ORP, OCC and OPDP. In email correspondence dated August 2, 2017 the workgroup concurred with DMEPA's assessment and conclusion.

3 CONCLUSION

We find the suffix "-vjbk" acceptable and recommend the nonproprietary name be revised throughout the draft labels and labeling to vestronidase alfa-vjbk.

3.1 RECOMMENDATIONS FOR ULTRAGENYX PHARMACEUTICAL INC.

We find the nonproprietary name, vestronidase alfa-vjbk, conditionally acceptable for your proposed product. Should your 351(a) BLA be approved during this review cycle, vestronidase alfa-vjbk will be the proper name designated in the license and you should revise your proposed labels and labeling accordingly. However, please be advised that if your application receives a complete response, the acceptability of the proposed suffix will be re-evaluated when you respond to the deficiencies. If we find the proposal unacceptable upon our re-evaluation, we would inform you of our finding.

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[a] Merchant, L. Advice letter for BLA 761047. Silver Spring (MD): FDA, CDER, OSE, DMEPA (US); 2017 APR 3.

[b] See Section VI which describes that any suffixes should be devoid of meaning in Guidance for Industry: Nonproprietary Naming of Biological Products. 2017. Available from http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM459987.pdf

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/s/

SHERLY ABRAHAM
08/03/2017

LUBNA A MERCHANT
08/03/2017

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:	May 24, 2017
Application Type and Number:	BLA 761047
Product Name and Strength:	Mepsevii (vestronidase alfa) injection 2 mg/mL
Total Product Strength:	10 mg/ 5 mL
Product Type:	Single Ingredient
Rx or OTC:	Rx
Applicant/Sponsor Name:	Ultragenyx Pharmaceutical Inc.
Panorama #:	2017- 13814391
DMEPA Primary Reviewer:	Madhuri R. Patel, PharmD
DMEPA Team Leader (Acting):	Sarah K. Vee, PharmD

1 INTRODUCTION

This memorandum is to reassess the proposed proprietary name, Mepsevii, which was found conditionally acceptable under IND on January 3, 2017.[a] The Applicant re-submitted the name, Mepsevii, for review under BLA 761047 on March 16, 2017. We note that all 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 Gastrointestinal 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 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 4, 2017 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.

If you have any questions or need clarifications, please contact Nicholas Miles, OSE project manager, at 301-796-7025.

3.1 COMMENTS TO THE APPLICANT

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

If any of the proposed product characteristics as stated in your March 16, 2017 submission are altered prior to approval of the marketing application, the name must be resubmitted for review.

[a] Patel M. Proprietary Name Review for Mepsevii. 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 JAN 3. Panorama No. 2016-9273546.

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.

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/s/

MADHURI R PATEL
05/24/2017

SARAH K VEE
05/24/2017