CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

206488Orig1s000

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:	September 30, 2015
Application Type and Number:	NDA 206488
Product Name and Strength:	Exondys 51 (eteplirsen) injection, 50 mg/mL
Total Product Strength:	100 mg/2 mL and 500 mg/10 mL
Product Type:	Single ingredient
Rx or OTC:	Rx
Applicant/Sponsor Name:	Sarepta Therapeutics
Panorama #:	2015-1341038
DMEPA Primary Reviewer:	Justine Harris, RPh
DMEPA Team Leader:	Danielle Harris, PharmD, BCPS

Reference ID: 3827097

1 INTRODUCTION

The proposed proprietary name, Exondys 51, was reviewed by DMEPA on October 29, 2014 under IND 077429 and was found conditionally acceptable.[1] We note that the product characteristics are the same. This memorandum is to communicate that DMEPA maintains the proposed proprietary name, Exondys 51, is acceptable from both a misbranding and safety perspective under the NDA 206488.

2 METHODS AND DISCUSSION

For re-assessment of the proposed proprietary name, DMEPA searched the POCA databases to identify new names with orthographic and phonetic similarity not identified in the previous OSE proprietary name review. Additionally, we searched the USAN stem list to determine if the name contains any USAN stems as of the last USAN update.[2]

Our re-assessment identified one new name that represents a potential source of drug name confusion. However, this name does not pose a risk for confusion as described in Appendices A. Finally, the September 1, 2015, search of the USAN stems did not find any USAN stems in the proposed proprietary name.

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 Neurology Products (DNP) concurred with the findings of OPDP's assessment of the proposed name.

3 CONCLUSIONS

The proposed proprietary name is acceptable.

If you have further questions or need clarifications, please contact Ermias Zerislassie OSE project manager at 301-496-0097.

3.1 COMMENTS TO THE APPLICANT

We have completed our review of the proposed proprietary name, Exondys 51, and have concluded that this name is acceptable.

If any of the proposed product characteristics as stated in your August 28, 2015 submission are altered, the name must be resubmitted for review.

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[1] Harris, J. Proprietary Name Review for Exondys 51 (eteplirsen), (IND 077429). 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 OCT 29. Panorama No. . 2014-25473: 2014 OCT 29.

[2] USAN stem search conducted on September 1, 2015

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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 A: Moderately Similar Names (e.g., combined POCA score is ≥50% to ≤69%) with overlap or numerical similarity in Strength and/or Dose

No.	**Proposed name: Exondys 51** **Strength(s): 50 mg/mL** **Usual Dose: 30 mg/kg once weekly as an IV infusion over 60 minutes.**	**POCA Score (%)**	**Prevention of Failure Mode** **In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names**
1.	Yondelis***	50	The prefix and suffix of this name pair have sufficient orthographic differences. The first and second syllable of this name pair sound different. The modifier, '51', if included, further differentiates the name pair orthographically and phonetically.

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/s/

JUSTINE HARRIS
09/30/2015

DANIELLE M HARRIS
09/30/2015