CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

761024Orig1s000

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 11, 2016
Application Type and Number:	BLA 761024
Product Name and Strength:	Amjevita (ABP-501*) Injection 20 mg/0.4 mL, 40 mg/0.8 mL
Product Type:	Combination Product
Rx or OTC:	Rx
Applicant/Sponsor Name:	Amgen
Panorama #:	2016-9120406
DMEPA Primary Reviewer:	Teresa McMillan, PharmD
DMEPA Team Leader:	Mishale Mistry, PharmD, MPH
DMEPA Deputy Director:	Lubna Merchant, MS, PharmD

1 INTRODUCTION

This memorandum is to reassess the proposed proprietary name, Amjevita, which was found conditionally acceptable under IND 111714 on June 22, 2016.[a] (b) (4)

*Amjevita has been developed as a proposed biosimilar to US-licensed Humira (adalimumab). Since the proper name for Amjevita has not yet been determined, ABP-501 is used throughout this review as the proper name for this product.

(b) (4)

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 Pulmonary, Allergy, and Rheumatology Products (DPARP) 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. We also evaluated previously identified names (b) (4) 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 August 10, 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 Michael Sinks, OSE project manager, at 240-402-2684.

3.1 COMMENTS TO THE APPLICANT

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

If any of the proposed product characteristics as stated in your July 14, 2016 submission are altered prior to approval of the marketing application, the name must be resubmitted for review.

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[a] McMillan, T. Proprietary Name Review for Amjevita (IND 111714). 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 JUN 22]. Panorama No. 2016-2706213.

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/

TERESA S MCMILLAN
08/11/2016

MISHALE P MISTRY
08/15/2016

LUBNA A MERCHANT
08/15/2016