

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:

761035Orig1s000

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 15, 2015

Application Type and Number: BLA 761035

Product Name and Strength: Empliciti (Elotuzumab) for Injection
300 mg/vial, 400 mg/vial

Product Type: Single Ingredient

Rx or OTC: Rx

Applicant/Sponsor Name: Bristol Myers Squibb

Panorama #: 2015-905056

DMEPA Primary Reviewer: Michelle Rutledge, PharmD

DMEPA Team Leader: Yelena Maslov, PharmD

DMEPA Associate Director: Lubna Merchant, PharmD, MS

1. INTRODUCTION

This memorandum is to re-assess the proposed proprietary name, Empliciti under BLA 761035, which was found conditionally acceptable under IND 100043, dated November 26, 2014¹. We note the addition of a 300 mg/vial strength for this proposed product. However, the addition of the new strength does not change our recommendation that the proposed proprietary name is still acceptable based on POCA results¹.

2. DISCUSSION

- During evaluation of the proposed proprietary name, Empliciti, in an August 10, 2015 meeting, the Division of Hematology Products (DHP) objected to the proposed name, Empliciti, from a misbranding perspective. DHP stated “Empliciti” can be defined as with no qualification or question; absolute. DHP also, stated that the proposed proprietary name, Empliciti, may also evoke “simplicity” meaning this product is simple to use.
- OPDP re-evaluated the name in light of DHP’s concerns and continued to maintain their non-objection to the proposed proprietary name, Empliciti.
- In a meeting dated September 9, 2015, OPDP, DHP and DMEPA discussed the proprietary name Empliciti, DHP expressed their concerns with the name. OPDP acknowledged and agreed with DHP’s concerns. However, OPDP stated that there is no data that supports the rationale that consumers or prescribers will make the connection between Empliciti and implicit or simplicity. OPDP’s current thinking is a proprietary name must imply a claim of superiority within the role of therapy.
- DHP stated their continued concerns but deferred to DMEPA to determine the final acceptability of the name.

3. CONCLUSIONS

DMEPA maintains the proposed proprietary name, Empliciti, is acceptable from both a misbranding and safety perspective under BLA 761035.

If you have further questions or need clarifications, please contact Kevin Wright, OSE Project Manager, at (301) 796-3621.

4. COMMENTS TO THE APPLICANT

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

¹ Vora, Neil. Proprietary Name Review for Empliciti (IND 100043). 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 Nov 26. OSE RCM No.: 2014-25812.

If any of the proposed product characteristics as stated in your June 29, 2015 submission are altered, the name must be resubmitted for review.

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

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09/15/2015

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09/15/2015

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