CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

761145Orig1s000

PROPRIETARY NAME REVIEW(S)

MEMORANDUM

SUFFIX REVIEW FOR NONPROPRIETARY NAME

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:	March 3, 2020
Responsible OND Division:	Division of Hematologic Malignancies 2
Application Type and Number:	BLA 761145
Product Name and Strength:	Darzalex Faspro (daratumumab and hyaluronidase-fihj) injection, 1,800 mg and 30,000 Units/15 mL
Product Type:	Single Ingredient Product
Applicant/Sponsor Name:	Janssen Biotech, Inc. (Janssen)
OSE RCM #:	2019-1980
DMEPA Primary Reviewer:	Carlos M Mena-Grillasca, BS Pharm
DMEPA Deputy Director:	Danielle Harris, PharmD, BCPS

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 761145.

1.1 Regulatory History

Janssen was notified of the Agency's intention to designate a nonproprietary name that includes a four-letter distinguishing suffix that is devoid of meaning for their product in an Advice Letter[a].

2 ASSESSMENT OF THE NONPROPRIETARY NAME

daratumumab and hyaluronidase-fihj

FDA generated a four-letter suffix, -fihj. This suffix was evaluated using the principles described in the applicable guidance[b].

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

We acknowledge that the proposed product is composed of two active ingredients, 'daratumumab' and 'hyaluronidase'. Since the product contains two active ingredients, the core name for this product is the core names of the two components, daratumumab and hyaluronidase. We considered the placement of the suffix within the nonproprietary name (i.e., after the daratumumab component of the core name vs. after the hyaluronidase component of the core name). We are concerned that placement of the suffix after the daratumumab component could result in misinterpretation of the nonproproprietary name. Since both daratumumab and hyaluronidase are available as individual components, the nonproprietary name, daratumumab-xxxx and hyaluronidase, could be misinterpreted as an order for the individual components versus the proposed fixed-combination product, which may lead to confusion and medication error. Thus, in this case, we determined that the suffix should be attached at the end of the core name of the product (daratumumab and hyaluronidase) with a hyphen, consistent with recommendations provided in the applicable guidance[c]. This placement would also ensure visibility of the suffix within the nonproprietary name. Thus, we determined daratumumab and hyaluronidase-fihj will be the proper name designated in the license.

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[a] Harris, D. General Advice Letter for BLA 761145. Silver Spring (MD): FDA, CDER, OSE, DMEPA (US) 2019 Sep 26.
[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
[c] 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

3 COMMUNICATION OF DMEPA'S ANALYSIS

These findings were shared with OPDP. In email correspondence dated December 4, 2019, OPDP did not identify any concerns that would render this suffix unacceptable. DMEPA also communicated our findings to the Division of Hematologic Malignancies 2 via e-mail on December 5, 2019.

4 CONCLUSION

We find the suffix -fihj acceptable and recommend the nonproprietary name be revised throughout the draft labels and labeling to daratumumab and hyaluronidase-fihj. DMEPA will communicate our findings to the Applicant via letter.

4.1 Recommendation for Janssen Biotech, Inc.

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

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/s/

CARLOS M MENA-GRILLASCA
03/03/2020 12:18:02 PM

DANIELLE M HARRIS
03/04/2020 07:47:29 AM

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:	September 4, 2019
Application Type and Number:	BLA 761145
Product Name and Strength:	Darzalex Faspro (daratumumab and hyaluronidase) injection, 120 mg/mL and 2,000 units/mL
Total Product Strength:	1,800 mg and 30,000 units per 15 mL
Product Type:	Multiple Ingredient Product
Rx or OTC:	Prescription (Rx)
Applicant/Sponsor Name:	Janssen Research & Development, L.L.C (Janssen)
Panorama #:	2019-33353992
DMEPA Safety Evaluator:	Ariane O. Conrad, PharmD, BCACP, CDE
DMEPA Team Leader:	Hina Mehta, PharmD

1 INTRODUCTION

This memorandum is to reassess the proposed proprietary name, Darzalex Faspro, which was found conditionally acceptable under IND 125541 on July 15, 2019.[a] 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 Darzalex Faspro would not misbrand the proposed product per their August 7, 2019 email. The Division of Medication Error Prevention and Analysis (DMEPA) and the Division of Hematology Products (DHP) concurred with the findings of OPDP's assessment for Darzalex Faspro.

2.2 SAFETY ASSESSMENT

For re-assessment of the proposed proprietary name, we 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, we searched the United States Adopted Name (USAN) stem list to determine if the proposed proprietary name contains any USAN stems as of the last USAN updates. The July 30, 2019 search of USAN stems did not find any USAN stems in the proposed proprietary name, Darzalex Faspro.

2.3 COMMUNICATION OF DMEPA'S ANALYSIS AT MIDPOINT OF REVIEW

We communicated our findings to the Division of Hematology Products (DHP) via email on August 29, 2019. At that time, we also requested additional information or concerns that could inform our review. Per email correspondence from the Division of Hematology Products (DHP) on September 4, 2019, they stated no additional concerns with the proposed proprietary name, Darzalex Faspro.

3 CONCLUSION

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, Darzalex Faspro, is acceptable.

If you have any questions or need clarifications, please contact Neil Vora, OSE project manager, at 240-402-4845.

3.1 COMMENTS TO JANSSEN RESEARCH & DEVELOPMENT, L.L.C

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

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[a] Garrison N. Proprietary Name Review for Darzalex Faspro (IND 125541). Silver Spring (MD): FDA, CDER, OSE, DMEPA (US); 2019 Jul 15. Panorama No.: 2019-28736946.

If any of the proposed product characteristics as stated in your submission, received on July 24, 2019, are altered prior to approval of the marketing application, the name must be resubmitted for review.

4 REFERENCE

1. **USAN Stems (https://www.ama-assn.org/about/united-states-adopted-names-approved-stems)**

   USAN Stems List contains all the recognized USAN stems.

This is a representation of an electronic record that was signed electronically. Following this are manifestations of any and all electronic signatures for this electronic record.

/s/

ARIANE O CONRAD
09/04/2019 04:02:37 PM

HINA S MEHTA
09/05/2019 10:38:37 AM