CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

761364Orig1s000

PROPRIETARY NAME REVIEW(S)

SUFFIX REVIEW FOR NONPROPRIETARY NAME

Division of Medication Error Prevention and Analysis 1 (DMEPA 1)

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:	7/11/2024
Responsible OND Division:	Division of Dermatology and Dentistry (DDD)
Application Type and Number:	BLA 761364
Product Name and Strength:	Imuldosa (ustekinumab-srlf) injection Pre-filled syringe: 45 mg/0.5 mL and 90 mg/mL Vial: 130 mg/26 mL (5 mg/mL)
Product Type:	Combination Product (Biologic-Device)
Applicant/Sponsor Name:	Accord BioPharma Inc. (Accord)
FDA Received Date:	February 27, 2023
Nexus NPNS ID #:	2023-207
DMEPA 2 Biologics Suffix Specialist:	Carlos M Mena-Grillasca, BS Pharm
DMEPA 1 Director:	Mishale Mistry, PharmD, MPH

1 PURPOSE OF REVIEW

This review summarizes our evaluation of the four-letter suffixes proposed by Accord for inclusion in the nonproprietary name and communicates our recommendation for the nonproprietary name for BLA 761364.

2 ASSESSMENT OF THE NONPROPRIETARY NAME

On February 27, 2023, Accord submitted a list of eight suffixes, in their order of preference, to be used in the nonproprietary name of their product[a]. Accord also provided findings from an external study conducted by the (b) (4), evaluating the proposed four-letter suffixes in conjunction with the nonproprietary name, for our consideration. Table 1 presents a list of suffixes submitted by Accord:

Table 1. Suffixes submitted by Accord*

1.	srlf
2.	(b) (4)
3.	
4.	
5.	
6.	
7.	
8.	

We reviewed Accord's proposed suffixes in the order of preference listed by Accord, along with the supporting data they submitted, using the principles described in the applicable guidance.[c]

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[a] Cover Letter – Request for Review of Proposed Suffixes BLA 761364. Durham (NC): Accord BioPharma Inc.; 2023 Feb 27. Available from: \\CDSESUB1\EVSPROD\bla761364\0001\m1\us\12-cover-letter-suffix.pdf

[b] Nonproprietary Name Suffix Report BLA 761364. (b) (4) 2023 Jan 10. Available from: \\CDSESUB1\EVSPROD\bla761364\0001\m1\us\1124-non-proprietary-name-suffix-report.pdf

[c] Guidance for Industry: Nonproprietary Naming of Biological Products. 2017. Available from: http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM459987.pdf

2.1 ustekinumab-srlf

Accord's first proposed suffix, -srlf, is comprised of four distinct letters.

We determined that the proposed suffix -srlf, 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.

3 COMMUNICATION OF DMEPA 1 ANALYSIS

These findings were shared with OPDP. On July 3, 2024, OPDP did not identify any concerns that would render this proposed suffix unacceptable. DMEPA 1 also communicated our findings to the Division of Dermatology and Dentistry (DDD) on July 11, 2024.

4 CONCLUSION

We find Accord's proposed suffix -srlf acceptable and recommend the nonproprietary name be revised throughout the draft labels and labeling to ustekinumab-srlf. DMEPA 1 will communicate our findings to the Applicant via letter.

4.1 Recommendations for Accord BioPharma Inc.

We find the nonproprietary name, ustekinumab-srlf, conditionally acceptable for your proposed product. Should your 351(k) BLA be approved during this review cycle, ustekinumab-srlf 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 your proposed suffix will be re-evaluated when you respond to the deficiencies. If we find your suffix unacceptable upon our re-evaluation, we will inform you of our findings.

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/s/

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07/12/2024 12:05:24 PM

PROPRIETARY NAME MEMORANDUM

Division of Medication Error Prevention and Analysis 1 (DMEPA 1)
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:	December 21, 2023
Application Type and Number:	BLA 761364
Product Name and Strength:	Imuldosa (ustekinumab-xxxx)[a] injection, 45 mg/0.5 mL and 90 mg/mL prefilled syringe, 130 mg/26 mL (5 mg/mL) vial
Product Type:	Combination Product (Biologic-Device)
Rx or OTC:	Prescription (Rx)
Applicant/Sponsor Name:	Accord BioPharma Inc (Accord)
PNR ID #:	2023-1044725398
DMEPA 1 Safety Evaluator:	Madhuri R. Patel, PharmD
DMEPA 1 Team Leader:	Yevgeniya Kogan, PharmD, BCSCP
DMEPA 1 Director:	Mishale Mistry, PharmD, MPH

[a] The proposed nonproprietary name has not yet been conditionally accepted. We therefore refer to the proposed product as "ustekinumab-xxxx" throughout this review in place of the nonproprietary name for this product.

1 INTRODUCTION

This memorandum is to reassess the proposed proprietary name, Imuldosa, which was found conditionally acceptable under IND 141843 on September 19, 2023.[b]

Thus, Accord submitted the name, Imuldosa, under BLA 761364 for re-review on October 10, 2023. We note that under BLA 761364, there is a change in dosing for pediatric patients with psoriatic arthritis from (b) (4) to '45 mg for weight range of 60 kg or more and 90 mg for weight range greater than 100 kg with co-existent moderate-to-severe plaque psoriasis'. All other product characteristics remain the same.

2 METHODS AND DISCUSSION

2.1 MISBRANDING ASSESSMENT

The Office of Prescription Drug Promotion (OPDP) determined that Imuldosa would not misbrand the proposed product. The Division of Medication Error Prevention and Analysis 1 (DMEPA 1) concurred with the findings of OPDP's assessment for Imuldosa. The Division of Dermatology and Dentistry (DDD) concurred with the findings of OPDP's assessment for Imuldosa.

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. We also evaluated previously identified names taking into account the change in dosing for pediatric patients with psoriatic arthritis from (b) (4) to '45 mg for weight range of 60 kg or more and 90 mg for weight range greater than 100 kg with co-existent moderate-to-severe plaque psoriasis'. Our evaluation has not altered our previous conclusion regarding the acceptability of the proposed proprietary name, Imuldosa.

Additionally, we searched the USAN stem list to determine if the proposed proprietary name contains any USAN stems as of the last USAN updates. The December 5, 2023 search of USAN stems did not find any USAN stems in the proposed proprietary name, Imuldosa.

2.3 COMMUNICATION OF DMEPA'S DETERMINATION

On December 21, 2023, we communicated our determination to the Division of Dermatology and Dentistry (DDD).

[b] Patel, M. Proprietary Name Review for Imuldosa*** (IND 141843). Silver Spring (MD): FDA, CDER, OSE, DMEPA 1 (US); 2023 SEP 19. PNR ID No. 2023-1044725074.

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, Imuldosa, is conditionally acceptable.

If you have any questions or need clarifications, please contact Wana Manitpisitkul, OSE project manager, at 240-402-4156.

3.1 COMMENTS TO ACCORD BIOPHARMA INC

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

If any of the proposed product characteristics as stated in your submission, received on October 10, 2023, 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.

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/s/

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