

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:

211882Orig1s000

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:	May 15, 2019
Application Type and Number:	NDA 211882
Product Name and Strength:	Arazlo (tazarotene) lotion, 0.045%
Product Type:	Single Ingredient Product
Rx or OTC:	Prescription (Rx)
Applicant/Sponsor Name:	Bausch Health US, LLC
Panorama #:	2019-29566961
DMEPA Safety Evaluator:	Madhuri R. Patel, PharmD
DMEPA Team Leader:	Sevan Kolejian, PharmD, MBA

1 INTRODUCTION

This memorandum is to reassess the proposed proprietary name, Arazlo, which was found conditionally acceptable under IND (b) (4) on February 20, 2019.^a

We note that there is a change in the dose for NDA 211882 (b) (4) to the newly proposed dose of apply a thin layer to affected areas once daily^b). All other product characteristics remain the same.

2 METHODS AND DISCUSSION

2.1 MISBRANDING ASSESSMENT

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

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 taking into account the change in dose to apply a thin layer. Our evaluation has not altered our previous conclusion regarding the acceptability of the proposed proprietary name, Arazlo.

Additionally, DMEPA searched the USAN stem list to determine if the proposed proprietary name contains any USAN stems as of the last USAN updates. The February 27, 2019 search of USAN stems did not find any USAN stems in the proposed proprietary name, Arazlo.

2.3 COMMUNICATION OF DMEPA'S ANALYSIS AT MIDPOINT OF REVIEW

DMEPA communicated our findings to the Division of Dermatology and Dental Products (DDDP) via e-mail on May 10, 2019. At that time we also requested additional information or concerns that could inform our review. Per e-mail correspondence from the Division of Dermatology and Dental Products (DDDP) on May 10, 2019, they stated no additional concerns with the proposed proprietary name, Arazlo.

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, Arazlo, is acceptable.

^a Patel, M. Proprietary Name Review for Arazlo (tazarotene) (IND 126277). Silver Spring (MD): FDA, CDER, OSE, DMEPA (US); 2019 FEB 20. Panorama No.: 2018-25544247.

^b Proposed Prescribing Information for Arazlo. Laval (Quebec, Canada): Bausch Health Companies Inc. 2019 Feb 22. Available from: \\cdsesub1\evsprod\nda211882\0001\m1\us\draft-labeling-text-pi-clean.pdf

If you have any questions or need clarifications, please contact Tri Minh Bui-Nguyen, OSE project manager, at 240-402-3726.

3.1 COMMENTS TO BAUSCH HEALTH US, LLC

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

If any of the proposed product characteristics as stated in your submission, received on February 22, 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/

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05/15/2019 12:06:32 PM

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05/15/2019 02:29:50 PM