

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:

212099Orig1s000

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:	April 11, 2019
Application Type and Number:	NDA 212099
Product Name and Strength:	Nubeqa (darolutamide) tablets, 300 mg
Product Type:	Single Ingredient Product
Rx or OTC:	Prescription (Rx)
Applicant/Sponsor Name:	Bayer HealthCare Pharmaceuticals Inc.
Panorama #:	2019-29780709
DMEPA Safety Evaluator:	Tingting Gao, PharmD
DMEPA Team Leader:	Chi-Ming (Alice) Tu, PharmD

1 INTRODUCTION

This memorandum is to reassess the proposed proprietary name, Nubeqa, which was found conditionally acceptable under IND 114769 on October 18, 2018.^a

We note that there is a change in dose for NDA 212099 since our last review (newly proposed dose modification of 300 mg twice daily for patients who experience a greater than or equal to Grade 3 toxicity or an intolerable adverse reaction^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 Nubeqa would not misbrand the proposed product. The Division of Medication Error Prevention and Analysis (DMEPA) and the Division of Oncology Products 1 (DOP1) concurred with the findings of OPDP's assessment for Nubeqa.

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 newly proposed dose modification of 300 mg twice daily for patients who experience a greater than or equal to Grade 3 toxicity or an intolerable adverse reaction. Our evaluation has not altered our previous conclusion regarding the acceptability of the proposed proprietary name, Nubeqa.

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 March 29, 2019 search of USAN stems did not find any USAN stems in the proposed proprietary name, Nubeqa.

2.3 COMMUNICATION OF DMEPA'S ANALYSIS AT MIDPOINT OF REVIEW

DMEPA communicated our findings to the Division of Oncology Products 1 (DOP1) via e-mail on April 8, 2019. At that time we also requested additional information or concerns that could inform our review. Per e-mail correspondence from the Division of Oncology Products 1 (DOP1) on April 11, 2019, they stated no additional concerns with the proposed proprietary name, Nubeqa.

^a Little, C. Proprietary Name Review for Nubeqa (IND 114769). Silver Spring (MD): FDA, CDER, OSE, DMEPA (US); 2018 Oct 18. Panorama No.: 2018-22709638.

^b Proposed Prescribing Information for Nubeqa. Whippany (NJ): Bayer HealthCare Pharmaceuticals Inc. 2019 Feb 26. Available from: [\\cdsesub1\evsprod\nda212099\0002\m1\us\114-labeling\draft\labeling\uspi-and-ppi.docx](#)

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, Nubeqa, is acceptable.

If you have any questions or need clarifications, please contact Frances Fahnbulleh, OSE project manager, at 301-796- 0942.

3.1 COMMENTS TO BAYER HEALTHCARE PHARMACEUTICALS INC.

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

If any of the proposed product characteristics as stated in your submission, received on March 4, 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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