CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

210951Orig1s000

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:	January 3, 2018
Application Type and Number:	NDA 210951
Product Name and Strength:	Erleada (apalutamide) tablets, 60 mg
Product Type:	Single Ingredient Product
Rx or OTC:	Rx
Applicant/Sponsor Name:	Janssen Biotech, Inc.
Panorama #:	2017-18296267
DMEPA Primary Reviewer:	Tingting Gao, PharmD
DMEPA Team Leader:	Chi-Ming (Alice) Tu, PharmD

1 INTRODUCTION

This memorandum is to reassess the proposed proprietary name, Erleada, which was found unacceptable under IND 104676 on March 21, 2017.[a] The proposed proprietary name, Erleada, was found to be vulnerable to medication errors due to confusion with another product, (b) (4) under review at the time (b) (4) Therefore, the ultimate acceptability of the proposed proprietary name, Erleada, was dependent upon which underlying application was approved first.

Since that time, Janssen Biotech, Inc. submitted NDA 210951 for apalutamide under the proposed proprietary name, Erleada. We note that all product characteristics remain the same. The application goal date for NDA 210951 is April 10, 2018, (b) (4) (b) (4). Therefore, if the proposed proprietary name, Erleada, is granted approval under NDA 210951 on or before April 10, 2018, this application approval will precede approval of the application with the conflicting proposed name, (b) (4) Thus, the applicant resubmitted the proposed proprietary name, Erleada, for review.

2 METHODS AND DISCUSSION

2.1 MISBRANDING ASSESSMENT

The Office of Prescription Drug Promotion (OPDP) determined that the proposed name would not misbrand the proposed product. DMEPA and the Division of Oncology Products 1 (DOP1) concurred with the findings of OPDP's assessment of the proposed name.

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. Additionally, DMEPA searched the USAN stem list to determine if the name contains any USAN stems as of the last USAN updates. The October 31, 2017 search of USAN stems did not find any USAN stems in the proposed proprietary name.

Finally, DMEPA evaluated the status of the underlying application of the conflicting name, (b) (4) We determined that the underlying application for (b) (4) Therefore, if NDA 210951 is approved on or before the April 10, 2018 PDUFA goal date for the application, this application approval will precede approval of the underlying application with the conflicting proposed name, (b) (4)

[a] Gao, T. Proprietary Name Review for Erleada (IND 104676). 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); 2017 MAR 21. Panorama No. 2016-11977449.

Based upon our safety assessment of the proposed proprietary name, Erleada, the application goal date for NDA 210951, [redacted] (b) (4) we find Erleada conditionally acceptable.

2.3 COMMUNICATION OF DMEPA'S ANALYSIS

DMEPA communicated our findings to the Division of Division of Oncology Products 1 (DOP1) via e-mail on January 3, 2018. At that time, we also requested additional information or concerns that could inform our review. Per e-mail correspondence from DOP1 on January 3, 2018, they stated no additional concerns with the proposed proprietary name, proposed name.

3 CONCLUSIONS

We conclude that the proposed proprietary name, Erleada, 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 THE APPLICANT

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

If any of the proposed product characteristics as stated in your October 13, 2017 submission are altered prior to approval of the marketing application, the name must be resubmitted for review.

If your application receives a complete response, please submit a new request for review of your proposed proprietary name when you respond to the application deficiencies.

4 REFERENCES

1. **USAN Stems (http://www.ama-assn.org/ama/pub/physician-resources/medical-science/united-states-adopted-names-council/naming-guidelines/approved-stems.page)**
   USAN Stems List contains all the recognized USAN stems.

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

/s/

TINGTING N GAO
01/03/2018

CHI-MING TU
01/03/2018