

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:

208447Orig1s000

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)

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Date of This Review:	December 9, 2016
Application Type and Number:	NDA 208447
Product Name and Strength:	Zejula (niraparib) capsules, 100 mg
Product Type:	Single ingredient product
Rx or OTC:	Rx
Applicant/Sponsor Name:	Tesaro, Inc.
Panorama #:	2016-11135884
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, Zejula, which was found conditionally acceptable under IND 100996 on July 6, 2016.^a

We note that there is a change in dose for NDA 208447. IND 100996 submission only proposed a 300 mg/day dose, whereas the NDA 208447 submission proposed additional dose reductions to 200 mg/day and 100 mg/day. All other product characteristics remain the same.

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 reevaluated 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 (see Table 1). Our evaluation has not 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 November 16, 2016 search of USAN stems did not find any USAN stems in the proposed proprietary name.

As a result, we maintain that the proposed proprietary name is acceptable.

Table 1. Comparison of proposed doses between IND and NDA		
Zejula (niraparib) capsules	IND 100996	NDA 208447
Dose and Frequency	<i>Recommended dose:</i> 300 mg once daily There are no dosing adjustments required for specific populations at this time.	<i>Recommended dose:</i> 300 mg once daily <i>Dose adjustment for adverse reactions:</i> Starting dose: 300 mg/day First dose reduction: 200 mg/day Second dose reduction: 100 mg/day

^a Gao, T. Proprietary Name Review for Zejula (IND 100996). 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); 2016 JULY 6. Panorama No. 2016-8194492.

3 CONCLUSIONS

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 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, Zejula, and have concluded that this name is acceptable.

If any of the proposed product characteristics as stated in your November 2, 2016 submission are altered prior to approval of the marketing application, the name must be resubmitted for review.

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
12/09/2016

CHI-MING TU
12/09/2016