

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:

214096Orig1s000

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:	August 31, 2020
Application Type and Number:	NDA 214096
Product Name and Strength:	Tepmetko (tepotinib) Tablets, 225 mg
Product Type:	Single Ingredient Product
Rx or OTC:	Prescription (Rx)
Applicant/Sponsor Name:	EMD Serono Research and Development Institute Inc (EMD Serono)
Panorama #:	2020-40745146
DMEPA Safety Evaluator:	Janine Stewart, PharmD
DMEPA Team Leader (Acting):	Ashleigh Lowery, PharmD, BCCCP

1 INTRODUCTION

This memorandum is to reassess the proposed proprietary name, Tepmetko, which was found conditionally acceptable under IND 128073 on April 1, 2020.^a

Thus, EMD Serono submitted the name, Tepmetko, under NDA 214096 for re-review on June 29, 2020. We note that there is a change in the strength expression from 250 mg to 225 mg (equivalent to 250 mg tepotinib hydrochloride hydrate), a change in the dose from 500 mg to 450 mg, and a newly proposed dose reduction to 225 mg for adverse reactions for NDA 214096. All other product characteristics remain the same.

2 METHODS AND DISCUSSION

2.1 MISBRANDING ASSESSMENT

The Office of Prescription Drug Promotion (OPDP) determined that Tepmetko would not misbrand the proposed product. The Division of Medication Error Prevention and Analysis (DMEPA) and the Division of Oncology 2 (DO2) concurred with the findings of OPDP's assessment for Tepmetko.

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 the strength expression from 250 mg to 225 mg (equivalent to 250 mg tepotinib hydrochloride hydrate), the change in the dose from 500 mg to 450 mg, and the newly proposed dose reduction to 225 mg for adverse reactions. Our evaluation has not altered our previous conclusion regarding the acceptability of the proposed proprietary name, Tepmetko.

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 July 28, 2020 search of USAN stems did not find any USAN stems in the proposed proprietary name, Tepmetko.

2.3 COMMUNICATION OF DMEPA'S ANALYSIS AT MIDPOINT OF REVIEW

We communicated our findings to the Division of Oncology 2 (DO2) via e-mail on August 20, 2020. At that time we also requested additional information or concerns that could inform our review. Per e-mail correspondence from the Division of Oncology 2 (DO2) on August 31, 2020, they stated no additional concerns with the proposed proprietary name, Tepmetko.

^a Stewart, J. Proprietary Name Review for Tepmetko (IND 128073). Silver Spring (MD): FDA, CDER, OSE, DMEPA (US); 2020 APR 01. Panorama No.: 2019-35621050.

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, Tepmetko, is acceptable.

If you have any questions or need clarifications, please contact Latonia Ford, OSE project manager, at 301-796-4901.

3.1 COMMENTS TO EMD SERONO RESEARCH AND DEVELOPMENT INSTITUTE INC

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

If any of the proposed product characteristics as stated in your submission, received on June 29, 2020, 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/

JANINE A STEWART
08/31/2020 05:10:47 PM

ASHLEIGH V LOWERY
09/01/2020 04:28:02 PM