

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:

219304Orig1s000

PROPRIETARY NAME REVIEW(S)

PROPRIETARY NAME MEMORANDUM

Division of Medication Error Prevention and Analysis 2 (DMEPA 2)
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 15, 2024
Application Type and Number:	NDA 219304
Product Name, Dosage Form, and Strength:	Romvimza (vimseltinib) capsules, 14 mg, 20 mg, and 30 mg
Product Type:	Single Ingredient Product
Rx or OTC:	Prescription (Rx)
Applicant/Sponsor Name:	Deciphera Pharmaceuticals, LLC (Deciphera)
PNR ID #:	2024- 1044725847
DMEPA 2 Safety Evaluator:	Ngoc-Linh Do, PharmD
DMEPA 2 Acting Team Leader:	Tingting Gao, PharmD
DMEPA 2 Deputy Director:	Chi-Ming (Alice) Tu, PharmD, BCPS

1 INTRODUCTION

This memorandum is to reassess the proposed proprietary name, Romvimza, which was found conditionally acceptable under IND 131218 on May 23, 2024.^a Thus, Deciphera submitted the proposed proprietary name, Romvimza, under NDA 219304 for re-review on June 17, 2024.^b We note that Deciphera provided additional dosage information^c regarding dose modifications for adverse reactions for NDA 219304 (see Table 1 below). All other product characteristics remain the same.

Table 1. Recommended Dose Reduction

Dose Reduction	Twice Weekly Dose
First	20 mg
Second	14 mg

2 DISCUSSION

2.1 MISBRANDING ASSESSMENT

The Office of Prescription Drug Promotion (OPDP) determined that Romvimza would not misbrand the proposed product. The Division of Medication Error Prevention and Analysis 2 (DMEPA 2) concurred with the findings of OPDP's assessment for Romvimza. The Division of Oncology 3 (DO3) did not comment on the findings of OPDP's assessment for Romvimza.

2.2 SAFETY ASSESSMENT

For re-assessment of the proposed proprietary name, Romvimza, 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 dosage. Our evaluation has not altered our previous conclusion regarding the acceptability of the proposed proprietary name, Romvimza .

Additionally, we searched the United States Adopted Name (USAN) stem list to determine if the proposed proprietary name contains any USAN stems as of the last USAN updates. The July 30, 2024 search of USAN stems did not find any USAN stems in the proposed proprietary name, Romvimza.

^a Do, N. Proprietary Name Review for Romvimza (IND 131218). Silver Spring (MD): FDA, CDER, OSE, DMEPA 2 (US); 2024 MAY 23. PNR ID No. 2024-1044725556.

^b Proprietary Names (NDA 219304 Romvimza (vimseltinib)). Waltham (MA): Deciphera Pharmaceuticals, LLC; 2024 JUN 17. Available from: [\\CDSESUB1\EVSPROD\nda219304\0002\m1\us\118-prop-names\prop-name-romvimza.pdf](#).

^c Proposed prescribing information for Romvimza. Waltham (MA): Deciphera Pharmaceuticals, LLC; 2024 June 17. Available from: [\\CDSESUB1\EVSPROD\nda219304\0002\m1\us\114-labeling\114a-draft-label\romvimza-uspi-label.docx](#).

2.2.1 COMMUNICATION OF DMEPA'S DETERMINATION

On August 15, 2024, DMEPA 2 communicated our determination to the Division of Oncology 3 (DO3).

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, Romvimza, is conditionally acceptable.

3.1 COMMENTS TO DECIPHERA PHARMACEUTICALS, LLC

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

If any of the proposed product characteristics as stated in your submission, received on June 17, 2024, are altered prior to approval of the marketing application, the proprietary name must be resubmitted for review.

4 REFERENCE

1. *United States Adopted Names (USAN) Stems*

USAN Stems List contains all the recognized USAN stems, available at <https://www.ama-assn.org/about/united-states-adopted-names/united-states-adopted-names-approved-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/

NGOC - LINH DO
08/15/2024 12:52:34 PM

TINGTING GAO
08/19/2024 10:00:25 AM

CHI-MING TU
08/19/2024 11:29:18 AM