CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

215446Orig1s000

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)

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Date of This Review:	February 17, 2022
Application Type and Number:	NDA 215446
Product Name and Strength:	Radicava ORS (edaravone) oral suspension, 105 mg/5 mL
Product Type:	Combination Product (Drug-Device)
Rx or OTC:	Prescription (Rx)
Applicant/Sponsor Name:	Mitsubishi Tanabe Pharma Corporation (Mitsubishi)
PNR ID #:	2021-1044724294
DMEPA 2 Safety Evaluator:	Beverly Weitzman, PharmD
DMEPA 2 Team Leader (Acting):	Stephanie DeGraw, PharmD
DMEPA 2 Director:	Danielle Harris, PharmD

1 INTRODUCTION

This memorandum is to reassess the proposed proprietary name, Radicava ORS, which was found conditionally acceptable under IND 138145 on January 13, 2021.[a] Thus, Mitsubishi submitted the name, Radicava ORS, under NDA 215446 for review on November 19, 2021. However, the Applicant made an error in the Product Profile table such that the information in the table did not correspond with the correct product descriptors (e.g., established name and prescription status). Therefore, Mitsubishi submitted a Proprietary Name Review amendment on November 30, 2021 to revise the Product Profile table to align with the correct corresponding product descriptors. We note that all product characteristics remain the same.

2 METHODS AND DISCUSSION

2.1 MISBRANDING ASSESSMENT

The Office of Prescription Drug Promotion (OPDP) determined that Radicava ORS 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 Radicava ORS. However, the Division of Neurology 1 (DN 1) provided the following comment:

We do not think 'ORS' is a readily recognizable suffix and would prefer a simple distinction [Radicava (edaravone) oral suspension].

Additionally, DN 1 stated that *'ORS' is an abbreviation for oral rehydration solution used in treatment of cholera*. DN 1 previously provided this comment which was noted in our review of Radicava ORS under IND 138145 (see OSE # 2020-40055967 dated January 13, 2021).

We evaluated the ability of health care providers to correctly identify "ORS" as "oral suspension" and the potential for misinterpretation as "oral rehydration solution" in the previous review for Radicava ORS under IND 138145 in Section 2.2.5 "Safety Assessment of the Root Name and Modifier, ORS".[a] We met internally with the OND review team and discussed our previous findings on this matter and the review team aligned with DMEPA findings. Thus, we maintain our conclusion that while there is some residual risk that health care professionals may inaccurately assume that Radicava ORS is an oral rehydration therapy, we expect that market uptake of the new oral suspension formulation will increase health care provider awareness of the intended meaning of the proposed modifier, ORS, and any residual risk can be managed with label and labeling mitigations.

2.2 SAFETY ASSESSMENT

For re-assessment of the proposed proprietary name, we evaluated the previous assessment of the proposed root name "Radicava" and the use of the modifier "ORS" considering any lessons learned from recent post-marketing experience, which may have altered our previous conclusion regarding the acceptability of the proposed proprietary name. Our reassessment did not change our previous conclusion and we agree with the previous assessment of the proposed proprietary

[a] Weitzman, B. Proprietary Name Review for Radicava ORS (IND 138145). Silver Spring (MD): FDA, CDER, OSE, DMEPA 2 (US); 2021 JAN 13. PNR ID No. 2020-40055967.

name, Radicava ORS. 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 January 19, 2022 search of USAN stems did not find any USAN stems in the proposed proprietary name, Radicava ORS.

2.3 COMMUNICATION OF DMEPA'S DETERMINATION

On February 17, 2022, we communicated our determination to the Division of Neurology 1 (DN 1).

3 CONCLUSION

Our re-assessment did not identify any potential source of drug name confusion. Therefore, we maintain that the proposed proprietary name, Radicava ORS, is acceptable.

If you have any questions or need clarifications, please contact Margee Webster, OSE project manager, at 240-402-0012.

3.1 COMMENTS TO MITSUBISHI TANABE PHARMA CORPORATION

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

If any of the proposed product characteristics as stated in your submission, received on November 23, 2021, 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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