

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:

210455Orig1s000

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:	December 04, 2017
Application Type and Number:	NDA 210455
Product Name and Strength:	Symtuza (darunavir, cobicistat, emtricitabine, and tenofovir alafenamide) Tablets, 800 mg/150 mg/200 mg/10 mg
Product Type:	Multi-Ingredient Product
Rx or OTC:	Rx
Applicant/Sponsor Name:	Janssen Research & Development, LLC
Panorama #:	2017-17789081
DMEPA Safety Evaluator:	Valerie S. Wilson, PharmD
DMEPA Team Leader:	Otto L. Townsend, PharmD

1 INTRODUCTION

This memorandum is to reassess the proposed proprietary name, Symtuza, which was found conditionally acceptable under IND 113456 on April 21, 2017.^a 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 the proposed name would not misbrand the proposed product. DMEPA and the Division of Antiviral Products (DAVP) 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 5, 2017 search of USAN stems did not find any USAN stems in the proposed proprietary name.

2.3 COMMUNICATION OF DMEPA'S ANALYSIS AT MIDPOINT OF REVIEW

DMEPA communicated our findings to the Division of Division of Antiviral Products (DAVP) via e-mail on November 8, 2017. At that time, we also requested additional information or concerns that could inform our review. Per e-mail correspondence from the DAVP on November 15, 2017, they stated concern for name confusion between the proposed proprietary names, Cimduo*** and Symtuza.

We evaluated the name pair further to determine if there is sufficient orthographic, phonetic, and product characteristic differences to mitigate the risk of name confusion.

Phonetically, the third syllables of this name pair (i.e. -zah and -oh) sound different. We acknowledge that the 2nd syllables of this name pair (i.e. -toó-and -DEW-) could sound similar when spoken; however, we note that during the verbal DMPEA prescription studies, there was no misinterpretation of the /t/ sound for the /d/ sound in Symtuza. Likewise, during the verbal DMEPA prescription studies for Cimduo***, there was no misinterpretation of the /d/sound for the /t/sound.

Orthographically, Symtuza begins with the letter "S" that when scripted looks different from the beginning letter "C" in Cimduo***. Symtuza*** contains the down-stroke letter "y" in its prefix and the cross-stroke letter "t" in its suffix which is not contained in Cimduo***. The letter "z" in Symtuza*** affords an additional orthographic difference whether scripted as a down-stroke or scripted without a downstroke.

^a Roosta, N. Proprietary Name Review for Symtuza IND 113456 Silver Spring (MD): FDA, CDER, OSE, DMEPA (US); 2017 APR 21. Panorama No. 2016-12078665.

Additionally, there is no numerical similarity or numerical overlap between the strengths of these two products.

Based on the above, we find there is a sufficient combination of orthographic, phonetic, and product characteristic differences to mitigate confusion between this name pair. This is further supported by a combined POCA score of 48%, which indicates this name pair has low similarity.

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 Danyal Chaudhry, OSE project manager, at 301-796-3813.

3.1 COMMENTS TO THE APPLICANT

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

If any of the proposed product characteristics as stated in your September 22, 2017 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/

VALERIE S WILSON
12/04/2017

OTTO L TOWNSEND
12/04/2017