

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:

208624Orig1s000

PROPRIETARY NAME REVIEW(S)

PROPRIETARY NAME REVIEW

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:	January 14, 2015
Application Type and Number:	NDA 208624
Product Name and Strength:	Viekira XR (dasabuvir, ombitasvir, paritaprevir, and ritonavir), Extended-release Tablets 200 mg/8.33 mg/50 mg/33.33 mg
Product Type:	Multi-Ingredient Product
Rx or OTC:	Rx
Applicant/Sponsor Name:	Abbvie
Panorama #:	2015-1824913
DMEPA Primary Reviewer:	Mónica Calderón, PharmD, BCPS
DMEPA Team Leader:	Vicky Borders-Hemphill, PharmD

1 INTRODUCTION

The proposed proprietary name, Viekira XR, was found conditionally acceptable in OSE Review # 2015-651595, under IND 122839, dated October 7, 2015. This memorandum is to communicate that DMEPA maintains the proposed proprietary name, Viekira XR, is acceptable from both a misbranding and safety perspective under NDA 208624.

1.1 PRODUCT INFORMATION

The following is a comparison of product characteristics for Viekira Pak and Viekira XR. The product information for Viekira XR was provided in the October 26, 2015 proprietary name submission.

	Viekira Pak (NDA 206619)	Viekira XR (IND 122839)
	Approved December 19, 2014	Proposed
Intended Pronunciation		vee-KEE-rah ex ar
Active Ingredient	Ombitasvir, paritaprevir, and ritonavir; copackaged with dasabuvir	Dasabuvir, ombitasvir, paritaprevir, and ritonavir
Indication of Use	With or without ribavirin is indicated for the treatment of patients with genotype 1 chronic hepatitis C virus (HCV) infection including those with compensated cirrhosis	
Route of Administration	Oral	
Dosage Form	Tablets	
Strength	Ombitasvir, paritaprevir, and ritonavir:12.75 mg/75 mg/50 mg; Dasabuvir: 250 mg	200 mg/8.33 mg/50 mg/33.33 mg
Dose & Frequency	Two ombitasvir, paritaprevir, ritonavir tablets once daily (in the morning) and one dasabuvir tablet twice daily (morning and evening)	Take 3 tablets once daily
How Supplied	Monthly carton for a total of 28 days of therapy. Each monthly carton contains four weekly cartons. Each weekly	Blister package for once-daily administration. Each blister card containing 3 tablets is assembled

	carton contains seven daily dose packs.	on a daily dosing wallet (pack). The daily dosing wallets (packs) are packaged in weekly cartons. Four weekly cartons are supplied in an outer monthly carton providing a 28-day supply.
Storage	At or below 30°C.	

1.2 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 (DAIP) concurred with the findings of OPDP's assessment of the proposed name.

1.3 SAFETY ASSESSMENT

To reassess the proposed proprietary name, we re-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. Furthermore, DMEPA searched the USAN stem list to determine if the name contains any USAN stems as of the last USAN update. The December 10, 2015 search of the USAN stems did not find any USAN stems in the proposed proprietary name.

We note that the product characteristics are the same and the formulation has been determined to be extended-release.

2 CONCLUSIONS

The proposed proprietary name is acceptable.

If you have further questions or need clarifications, please contact Danyal Chaudhry, OSE project manager, at 301-796-3813.

2.1 COMMENTS TO THE APPLICANT

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

REFERENCES

1. Calderon M. Proprietary Name Review for Viekira XR IND 122839. Silver Spring (MD): FDA, CDER, OSE, DMEPA (US); 2015 October 07. RCM No.: 2015-651595.
2. USAN Stems 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.

3. Phonetic and Orthographic Computer Analysis (POCA)

POCA is a system that FDA designed. As part of the name similarity assessment, POCA is used to evaluate proposed names via a phonetic and orthographic algorithm. The proposed proprietary name is converted into its phonemic representation before it runs through the phonetic algorithm. Likewise, an orthographic algorithm exists that operates in a similar fashion. POCA is publicly accessible.

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/s/

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01/14/2016

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01/14/2016