

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:

206619Orig1s000

PROPRIETARY NAME REVIEW(S)

ADDENDUM

REVIEW OF PROPRIETARY NAME

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)

Date of This Memorandum: November 10, 2014
Requesting Office or Division: Division of Antiviral Products (DAVP)
Application Type and Number: NDA 206619
Product Name and Strength: Viekira Pak (ombitasvir, paritaprevir, ritonavir copackaged dasbuvir) Tablets, 12.5 mg/75 mg/50 mg
Submission Date: October 22, 2014
Applicant/Sponsor Name: Abbvie
OSE RCM #: 2014-26044-1
DMEPA Primary Reviewer: Mónica Calderón, PharmD, BCPS
DMEPA Acting Team Leader: Vicky Borders-Hemphill, PharmD
DMEPA Associate Director: Irene Chan, PharmD, BCPS

1 PURPOSE OF ADDENDUM

DMEPA previously completed a review which found the proposed proprietary name, Viekira Pak, conditionally acceptable.¹ On October 22, 2014, Gilead Sciences, Inc. submitted a letter objecting to the proposed proprietary name, Viekira Pak, stating that the proposed name is

(b) (4)

(see Appendix).

Upon receipt of the objection, DMEPA requested input regarding the new information from the Office of Prescription Drug Promotion (OPDP) and the Division of Antiviral Products (DAVP). After consideration of the information presented by Gilead, OPDP and DAVP maintain their

¹ Calderon, M. Proprietary name review (NDA 206619). Silver Spring (MD): Food and Drug Administration, Center for Drug Evaluation and Research, Office of Surveillance and Epidemiology, Division of Medication Error Prevention and Analysis (US); 2014 Aug 19. 32 p. OSE RCM No.: 2014-26044.

non-objection to the proposed proprietary name, Viekira Pak. DMEPA also maintains our position in finding the proposed proprietary name, Viekira Pak, acceptable.

2 CONCLUSIONS

DMEPA maintains that the proposed proprietary name, Viekira Pak, is acceptable. We have no additional concerns at this time.

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/s/

MONICA M CALDERON
11/10/2014

BRENDA V BORDERS-HEMPHILL
11/10/2014

IRENE Z CHAN
11/12/2014

PROPRIETARY NAME REVIEW 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)

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Date of This Review:	August 19, 2014
Application Type and Number:	NDA 206619
Product Name and Strength:	Viekira Pak (ombitasvir, paritaprevir, ritonavir copackaged with dasabuvir) Tablets, 12.5 mg/75 mg/50 mg and 250 mg
Product Type:	Multiple Ingredient Product
Rx or OTC:	Rx
Applicant/Sponsor Name:	Abbvie, Inc.
Submission Date:	August 6, 2014
Panorama #:	2014-26044
DMEPA Primary Reviewer:	Mónica Calderón, PharmD, BCPS
DMEPA Associate Director:	Irene Chan, PharmD, BCPS

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1 INTRODUCTION

The proposed proprietary name, Viekira Pak, was found acceptable in OSE Review# 2014-16795, 2014-16796, 2014-16797, 2014-17242, dated April 29, 2014 under IND 101636, IND 103526, IND 108434, and NDA 206619. The name has been resubmitted for review due to adoption of the new established name, paritaprevir, for ABT-450 in place of the original established name, veruprevir. No other product characteristics have been altered. This memorandum is to communicate that DMEPA maintains the proposed proprietary name, Viekira Pak, is acceptable from both a promotional and safety perspective under the NDA (b) (4)

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

1.1 COMMENTS TO THE APPLICANT

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

If any of the proposed product characteristics as stated in your August 4, 2014 submission are altered, the name must be resubmitted for review.

2 REFERENCES

OSE Review# OSE Review# 2014-16795, 2014-16796, 2014-16797, 2014-17242: Proprietary Name Review for Viekira Pak (ombatisvir, veruprevir, ritonavir copackaged with dasabuvir), April 29, 2014.

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/s/

MONICA M CALDERON
08/19/2014

IRENE Z CHAN
08/20/2014

**Department of Health and Human Services
Public Health Service
Food and Drug Administration
Center for Drug Evaluation and Research
Office of Surveillance and Epidemiology
Office of Medication Error Prevention and Risk Management**

Proprietary Name Review

Date: April 29, 2014

Reviewer: James Schlick, RPH, MBA
Division of Medication Error Prevention and Analysis

Team Leader and Associate Director: Irene Z. Chan, PharmD, BCPS
Division of Medication Error Prevention and Analysis

Acting Division Director: Kellie Taylor, PharmD, MPH
Division of Medication Error Prevention and Analysis

Drug Name and Strengths: Viekira Pak (Dasabuvir: 250 mg Tablets, Veruprivir 75 mg Tablets, Ritonavir 50 mg Tablets, Ombitasvir 12.5 mg Tablets)

Application Type/Number: IND 101636, IND 103526, IND 108434
NDA 206619

Applicant: Abbvie, Inc.

OSE RCM #: IND: 2014-16795, 2014-16796, 2014-16797
NDA: 2014-17242

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1 INTRODUCTION

This review evaluates the proposed proprietary name, Viekira Pak, from a safety and promotional perspective. The sources and methods used to evaluate the proposed name are outlined in the reference section and Appendix A respectively.

1.1 REGULATORY HISTORY

During the preliminary assessment for the proposed name Viekira, we noted the proposed product was packaged in a daily blister card containing two different tablets, each with different active ingredients. DMEPA communicated this information in a teleconference¹ on December 30, 2013, and recommended adding the modifier 'Pak' to alert health care practitioners that Viekira is a packaged product that combines tablets with different active ingredients. Abbvie withdrew the proposed proprietary name, Viekira, and submitted the current name under review, Viekira Pak.

1.2 PRODUCT INFORMATION

The following product information is provided in the January 10, 2014 and April 21, 2014 proprietary name submission.

- Active Ingredient: Dasabuvir and Veruprivir/ Ritonavir/Ombitasvir
- Indication of Use: Chronic hepatitis C viral infection
- Route of Administration: oral
- Dosage Form: Tablets
- Strength: Tablet A- Dasabuvir 250 mg
Tablet B- Veruprivir 75 mg; Ritonavir 50 mg; Ombitasvir 12.5 mg
- Dose and Frequency: Take one Dasabuvir (tablet A) orally twice daily- once in the morning and once in the evening. Take two Veruprivir/ Ritonavir/Ombitasvir (tablet B) orally once daily in the morning.
- How Supplied: Co-packaged in a blister pack. Each blister pack contains 2 dasabuvir tablets and 2 Veruprivir/ Ritonavir/Ombitasvir tablets.
- Storage: (b) (4)

2 RESULTS

The following sections provide information obtained and considered in the overall evaluation of the proposed proprietary name.

¹ Memorandum of Teleconference submitted in DARRTS on December 31, 2013

2.1 PROMOTIONAL ASSESSMENT

The Office of Prescription Drug Promotion (OPDP) determined the proposed name is acceptable from a promotional perspective. DMEPA and the Division of Antiviral Products (DAVP) concurred with the findings of OPDP's promotional assessment of the proposed name.

2.2 SAFETY ASSESSMENT

The following aspects were considered in the safety evaluation of the name.

2.2.1 United States Adopted Names (USAN) SEARCH

There is no USAN stem present in the proposed proprietary name.²

2.2.2 Components of the Proposed Proprietary Name

The Applicant indicated in their submission that the proposed name, Viekira Pak, has no intended meaning. This proprietary name is comprised of a root name, Viekira, and a modifier. The modifier 'Pak' represents a pack or a package. We find the modifier acceptable since the product is comprised of a daily blister pack containing the proposed daily dosing regimen. Additionally, this modifier was recommended by DMEPA in a previous teleconference with the Sponsor³.

2.2.3 FDA Name Simulation Studies

Eighty-five practitioners participated in DMEPA's prescription studies. One interpretation overlapped with the currently marketed product, Vicodin. This misinterpretation is evaluated as part of our overall Failure Modes and Effects Analysis (FMEA) in section 2.2.5.

None of the other interpretations overlapped with any currently marketed products nor did the misinterpretations sound or look similar to any currently marketed products or any products in the pipeline. The name, Viekira Pak, was correctly interpreted by 45 participants (53%). The modifier 'Pak' was not included in 4 responses. In the verbal prescription study, the letter string 'Viek' was misinterpreted as 'Vic' by 14 participants. In the written prescription study, the letter 'a' was misinterpreted as the letter 'n' by 7 participants. We have considered these variations in our look-alike and sound-alike searches and analysis (see Appendix B). Appendix C contains the results from the verbal and written prescription studies.

2.2.4 Comments from Other Review Disciplines at Initial Review

In response to the OSE, January 27, 2014 e-mail, the Division of Antiviral Products (DAVP) did not forward any comments or concerns relating to the proposed proprietary name at the initial phase of the review.

² USAN stem list searched February 1, 2014.

³ See footnote #1

2.2.5 Failure Mode and Effects Analysis of Similar Names

Appendix B lists possible orthographic and phonetic misinterpretations of the letters appearing in the proposed proprietary name, Viekira Pak. Table 1 lists the names with orthographic, phonetic, or spelling similarity to the proposed proprietary name, Viekira Pak, identified by the primary reviewer, the Expert Panel Discussion (EPD), the Phonetic and Orthographic Computer Analysis software program (POCA), and other review disciplines. Table 1 also includes the names identified by (b) (4) not identified by DMEPA that require further evaluation.

Table 1: Collective List of Potentially Similar Names (DMEPA, EPD and Other Disciplines)

Look Similar to Viekira (n=24)					
Name	Source	Name	Source	Name	Source
Verdeso	FDA	Xalkori	FDA	(b) (4)	FDA
Viadur	FDA	Exuberata	FDA	(b) (4)	FDA
Viatro	FDA	Rezira	FDA	(b) (4)	FDA
Veletri	FDA	Vestura	FDA	(b) (4)	FDA
Victoza	Both	(b) (4)	FDA	Leukine	FDA
Viactiv	FDA	(b) (4)	FDA	Vidaza	FDA
Verluma	FDA	Voltaren	External	Viadent	FDA
Videx	FDA	Anakinra	External	Lyrice	External
Look and Sound Similar to Viekira (n=14)					
Name	Source	Name	Source	Name	Source
(b) (4)	FDA	Viramune	External	Viokase	Both
Kira	Both	Vistra 650	FDA	Viokace	Both
Lexiva	External	(b) (4)	FDA	(b) (4)	FDA
Vicodin	External and FDA Rx Study	Visken	Both	Viekira***	FDA
Viracept	External	Viagra	Both		

We evaluated the potential for confusion between Vicodin and Viekira Pak in detail due to the misinterpretation in the FDA prescription study (see section 2.2.3 and Appendix C).

The proposed name, Viekira Pak, includes the modifier ‘Pak’. If the modifier is included on a prescription, it provides orthographic differentiation from Vicodin. The Phonetic and Orthographic Computer Analysis (POCA) software program identified the name pair with a combined score of less than 50, indicating low similarity between the names. Additionally, Vicodin is a class 3 controlled substance. Under DEA requirements, specific information, including strength and frequency of administration, is required on a prescription for a controlled substance⁴. The usual frequency of Vicodin is “every 4 to 6

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⁴ Code of Federal Regulations- 21 CFR 1306.05

hours”, which differs from Viekira Pak’s frequency of “daily” and “twice daily”. Alternatively, Viekira Pak may be prescribed with instructions to use as directed without specifying frequency, which is not allowable for a Vicodin prescription since it is a controlled substance.

The strength of Vicodin can also provide differentiation. Even though Vicodin is a single strength product, Vicodin ES and Vicodin HP are also on the market. Postmarket evidence indicates that modifiers are often dropped from prescriptions; however, even if the modifier is dropped, the strength is still required, and there are no overlaps in strengths between the two products.

(b) (4) conducted an external name study on the proposed root name, Viekira, in August 2013, and their safety survey also identified Vicodin as a similar name. (b) (4) analysis of the name pair noted that they share overlapping dosage form, route of administration, and single strength. However, (b) (4) also noted that the frequency of administration and usual dose are significantly different. Additionally, (b) (4) noted that Viekira could simply be ordered as “UAD” or “Use as directed” where Vicodin would contain instructions for use that are significantly different. (b) (4) also determined there were orthographic and phonetic differences between the letter strings ‘codin’ and ‘ekira’. Thus, (b) (4) conclusion is similar to our own conclusion regarding the risk for confusion between Viekira and Vicodin.

Based on these factors, the risk for confusion between Vicodin and Viekira Pak is minimized, thus we believe both proprietary names can safely co-exist in the market.

Our analysis of the 38 names contained in Table 1 determined all 38 names will not pose a risk for confusion as described in Appendices D through E.

2.2.6 Communication of DMEPA’s Analysis at Midpoint of Review

DMEPA communicated our findings to the Division of Antiviral Products (DAVP) via e-mail on March 12, 2013. At that time we also requested additional information or concerns that could inform our review. Per e-mail correspondence from the Division of Antiviral Products on March 13, 2014, they stated no additional concerns with the proposed proprietary name, Viekira Pak.

3 CONCLUSIONS

The proposed proprietary name is acceptable from both a promotional and safety perspective.

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

4 REFERENCES

1. Micromedex Integrated Index (<http://csi.micromedex.com>)

Micromedex contains a variety of databases covering pharmacology, therapeutics, toxicology and diagnostics.

2. ***Phonetic and Orthographic Computer Analysis (POCA)***

POCA is a database which was created for the Division of Medication Error Prevention and Analysis, FDA. As part of the name similarity assessment, proposed names are evaluated via a phonetic/orthographic algorithm. The proposed proprietary name is converted into its phonemic representation before it runs through the phonetic algorithm. Likewise, an orthographic algorithm exists which operates in a similar fashion.

3. Drug Facts and Comparisons, online version, St. Louis, MO
(<http://factsandcomparisons.com>)

Drug Facts and Comparisons is a compendium organized by therapeutic course; it contains monographs on prescription and OTC drugs, with charts comparing similar products. This database also lists the orphan drugs.

4. ***FDA Document Archiving, Reporting & Regulatory Tracking System [DARRTS]***

DARRTS is a government database used to organize Applicant and Sponsor submissions as well as to store and organize assignments, reviews, and communications from the review divisions.

5. ***Division of Medication Errors Prevention and Analysis proprietary name consultation requests***

This is a list of proposed and pending names that is generated by the Division of Medication Error Prevention and Analysis from the Access database/tracking system.

6. Drugs@FDA (<http://www.accessdata.fda.gov/scripts/cder/drugsatfda/index.cfm>)

Drugs@FDA contains most of the drug products approved since 1939. The majority of labels, approval letters, reviews, and other information are available for drug products approved from 1998 to the present. Drugs@FDA contains official information about FDA approved brand name, generic drugs, therapeutic biological products, prescription and over-the-counter human drugs and discontinued drugs and “Chemical Type 6” approvals.

7. ***U.S. Patent and Trademark Office*** (<http://www.uspto.gov>)

USPTO provides information regarding patent and trademarks.

8. ***Clinical Pharmacology Online*** (www.clinicalpharmacology-ip.com)

Clinical Pharmacology contains full monographs for the most common drugs in clinical use, plus mini monographs covering investigational, less common,

combination, nutraceutical and nutritional products. It also provides a keyword search engine.

9. *Natural Medicines Comprehensive Databases* (www.naturaldatabase.com)

Natural Medicines contains up-to-date clinical data on the natural medicines, herbal medicines, and dietary supplements used in the western world.

10. *Access Medicine* (www.accessmedicine.com)

Access Medicine® from McGraw-Hill contains full-text information from approximately 60 titles; it includes tables and references. Among the titles are: Harrison's Principles of Internal Medicine, Basic & Clinical Pharmacology, and Goodman and Gilman's The Pharmacologic Basis of Therapeutics.

11. *USAN Stems* (<http://www.ama-assn.org/ama/pub/about-ama/our-people/coalitions-consortiums/united-states-adopted-names-council/naming-guidelines/approved-stems.shtml>)

USAN Stems List contains all the recognized USAN stems.

12. *Red Book* (www.thomsonhc.com/home/dispatch)

Red Book contains prices and product information for prescription, over-the-counter drugs, medical devices, and accessories.

13. *Lexi-Comp* (www.lexi.com)

Lexi-Comp is a web-based searchable version of the Drug Information Handbook.

14. *Medical Abbreviations* (www.medilexicon.com)

Medical Abbreviations dictionary contains commonly used medical abbreviations and their definitions.

15. *CVS/Pharmacy* (www.CVS.com)

This database contains commonly used over the counter products not usually identified in other databases.

16. *Walgreens* (www.walgreens.com)

This database contains commonly used over the counter products not usually identified in other databases.

17. *Rx List* (www.rxlist.com)

RxList is an online medical resource dedicated to offering detailed and current pharmaceutical information on brand and generic drugs.

18. Dogpile (www.dogpile.com)

Dogpile is a [Metasearch](#) engine that searches multiple search engines including Google, Yahoo! and Bing, and returns the most relevant results to the search.

19. Natural Standard (<http://www.naturalstandard.com>)

Natural Standard is a resource that aggregates and synthesizes data on complementary and alternative medicine.

APPENDICES

Appendix A

FDA's Proprietary Name Risk Assessment considers the promotional and safety aspects of a proposed proprietary name. The promotional review of the proposed name is conducted by OPDP. OPDP evaluates proposed proprietary names to determine if they are overly fanciful, so as to misleadingly imply unique effectiveness or composition, as well as to assess whether they contribute to overstatement of product efficacy, minimization of risk, broadening of product indications, or making of unsubstantiated superiority claims. OPDP provides their opinion to DMEPA for consideration in the overall acceptability of the proposed proprietary name.

The safety assessment is conducted by DMEPA. DMEPA staff search a standard set of databases and information sources to identify names that are similar in pronunciation, spelling, and orthographically similar when scripted to the proposed proprietary name. Additionally, we consider inclusion of USAN stems or other characteristics that when incorporated into a proprietary name may cause or contribute to medication errors (i.e., dosing interval, dosage form/route of administration, medical or product name abbreviations, names that include or suggest the composition of the drug product, etc.). DMEPA defines a medication error as any preventable event that may cause or lead to inappropriate medication use or patient harm while the medication is in the control of the health care professional, patient, or consumer.⁵

Following the preliminary screening of the proposed proprietary name, DMEPA gathers to discuss their professional opinions on the safety of the proposed proprietary name. This meeting is commonly referred to the Center for Drug Evaluation and Research (CDER) Expert Panel discussion. DMEPA also considers other aspects of the name that may be misleading from a safety perspective. DMEPA staff conducts a prescription simulation studies using FDA health care professionals. When provided, DMEPA considers external proprietary name studies conducted by or for the Applicant/Sponsor and incorporates the findings of these studies into the overall risk assessment.

The DMEPA primary reviewer assigned to evaluate the proposed proprietary name is responsible for considering the collective findings, and provides an overall risk assessment of the proposed proprietary name. DMEPA bases the overall risk assessment on the findings of a Failure Mode and Effects Analysis (FMEA) of the proprietary name and misleading nature of the proposed proprietary name with a focus on the avoidance of medication errors.

DMEPA uses the clinical expertise of its staff to anticipate the conditions of the clinical setting where the product is likely to be used based on the characteristics of the proposed product. DMEPA considers the product characteristics associated with the proposed product throughout the risk assessment because the product characteristics of the proposed may provide a context for communication of the drug name and ultimately determine the use of the product in the *usual* clinical practice setting.

⁵ National Coordinating Council for Medication Error Reporting and Prevention. <http://www.nccmerp.org/about/MedErrors.html>. Last accessed 10/11/2007.

Typical product characteristics considered when identifying drug names that could potentially be confused with the proposed proprietary name include, but are not limited to; established name of the proposed product, proposed indication of use, dosage form, route of administration, strength, unit of measure, dosage units, recommended dose, typical quantity or volume, frequency of administration, product packaging, storage conditions, patient population, and prescriber population. DMEPA considers how these product characteristics may or may not be present in communicating a product name throughout the medication use system. Because drug name confusion can occur at any point in the medication use process, DMEPA considers the potential for confusion throughout the entire U.S. medication use process, including drug procurement, prescribing and ordering, dispensing, administration, and monitoring the impact of the medication.⁶

The DMEPA considers the spelling of the name, pronunciation of the name when spoken, and appearance of the name when scripted. DMEPA compares the proposed proprietary name with the proprietary and established name of existing and proposed drug products and names currently under review at the FDA. DMEPA compares the pronunciation of the proposed proprietary name with the pronunciation of other drug names because verbal communication of medication names is common in clinical settings. DMEPA examines the phonetic similarity using patterns of speech. If provided, DMEPA will consider the Sponsor's intended pronunciation of the proprietary name. However, DMEPA also considers a variety of pronunciations that could occur in the English language because the Sponsor has little control over how the name will be spoken in clinical practice. The orthographic appearance of the proposed name is evaluated using a number of different handwriting samples. DMEPA applies expertise gained from root-cause analysis of postmarketing medication errors to identify sources of ambiguity within the name that could be introduced when scripting (e.g., "T" may look like "F," lower case 'a' looks like a lower case 'u,' etc). Additionally, other orthographic attributes that determine the overall appearance of the drug name when scripted (see Table 1 below for details).

⁶ Institute of Medicine. Preventing Medication Errors. The National Academies Press: Washington DC. 2006.

Table 1. Criteria Used to Identify Drug Names that Look- or Sound-Similar to a Proposed Proprietary Name.

Type of Similarity	Considerations when Searching the Databases		
	<i>Potential Causes of Drug Name Similarity</i>	<i>Attributes Examined to Identify Similar Drug Names</i>	<i>Potential Effects</i>
Look-alike	Similar spelling	Identical prefix Identical infix Identical suffix Length of the name Overlapping product characteristics	<ul style="list-style-type: none"> Names may appear similar in print or electronic media and lead to drug name confusion in printed or electronic communication Names may look similar when scripted and lead to drug name confusion in written communication
	Orthographic similarity	Similar spelling Length of the name/Similar shape Upstrokes Down strokes Cross-strokes Dotted letters Ambiguity introduced by scripting letters Overlapping product characteristics	<ul style="list-style-type: none"> Names may look similar when scripted, and lead to drug name confusion in written communication
Sound-alike	Phonetic similarity	Identical prefix Identical infix Identical suffix Number of syllables Stresses Placement of vowel sounds Placement of consonant sounds Overlapping product characteristics	<ul style="list-style-type: none"> Names may sound similar when pronounced and lead to drug name confusion in verbal communication

Lastly, DMEPA considers the potential for the proposed proprietary name to inadvertently function as a source of error for reasons other than name confusion. Post-marketing experience has demonstrated that proprietary names (or components of the proprietary name) can be a source of error in a variety of ways. Consequently, DMEPA considers and evaluates these broader safety implications of the name throughout this assessment and the medication error staff provides additional comments related to the

safety of the proposed proprietary name or product based on professional experience with medication errors.

1. Database and Information Sources

DMEPA searches the internet, several standard published drug product reference texts, and FDA databases to identify existing and proposed drug names that may sound-alike or look-alike to the proposed proprietary name. A standard description of the databases used in the searches is provided in the reference section of this review. To complement the process, the DMEPA uses a computerized method of identifying phonetic and orthographic similarity between medication names. The program, Phonetic and Orthographic Computer Analysis (POCA), uses complex algorithms to select a list of names from a database that have some similarity (phonetic, orthographic, or both) to the trademark being evaluated. Lastly, DMEPA reviews the USAN stem list to determine if any USAN stems are present within the proprietary name. The individual findings of multiple safety evaluators are pooled and presented to the CDER Expert Panel. DMEPA also evaluates if there are characteristics included in the composition that may render the name unacceptable from a safety perspective (abbreviation, dosing interval, etc.).

2. Expert Panel Discussion

DMEPA gathers CDER professional opinions on the safety of the proposed product and discussed the proposed proprietary name (Expert Panel Discussion). The Expert Panel is composed of Division of Medication Errors Prevention (DMEPA) staff and representatives from the Office of Prescription Drug Promotion (OPDP). We also consider input from other review disciplines (OND, ONDQA/OBP). The Expert Panel also discusses potential concerns regarding drug marketing and promotion related to the proposed names.

The primary Safety Evaluator presents the pooled results of the database and information searches to the Expert Panel for consideration. Based on the clinical and professional experiences of the Expert Panel members, the Panel may recommend additional names, additional searches by the primary Safety Evaluator to supplement the pooled results, or general advice to consider when reviewing the proposed proprietary name.

3. FDA Prescription Simulation Studies

Three separate studies are conducted within the Centers of the FDA for the proposed proprietary name to determine the degree of confusion of the proposed proprietary name with marketed U.S. drug names (proprietary and established) due to similarity in visual appearance with handwritten prescriptions or verbal pronunciation of the drug name. The studies employ healthcare professionals (pharmacists, physicians, and nurses), and attempts to simulate the prescription ordering process. The primary Safety Evaluator uses the results to identify orthographic or phonetic vulnerability of the proposed name to be misinterpreted by healthcare practitioners.

In order to evaluate the potential for misinterpretation of the proposed proprietary name in handwriting and verbal communication of the name, inpatient medication orders and/or outpatient prescriptions are written, each consisting of a combination of marketed and unapproved drug products, including the proposed name. These orders are optically

scanned and one prescription is delivered to a random sample of participating health professionals via e-mail. In addition, a verbal prescription is recorded on voice mail. The voice mail messages are then sent to a random sample of the participating health professionals for their interpretations and review. After receiving either the written or verbal prescription orders, the participants record their interpretations of the orders which are recorded electronically.

4. Comments from Other Review Disciplines

DMEPA requests the Office of New Drugs (OND) and/or Office of Generic Drugs (OGD), ONDQA or OBP for their comments or concerns with the proposed proprietary name, ask for any clinical issues that may impact the DMEPA review during the initial phase of the name review. Additionally, when applicable, at the same time DMEPA requests concurrence/non-concurrence with OPDP's decision on the name. The primary Safety Evaluator addresses any comments or concerns in the safety evaluator's assessment.

The OND/OGD Regulatory Division is contacted a second time following our analysis of the proposed proprietary name. At this point, DMEPA conveys their decision to accept or reject the name. The OND or OGD Regulatory Division is requested to provide any further information that might inform DMEPA's final decision on the proposed name.

Additionally, other review disciplines opinions such as ONDQA or OBP may be considered depending on the proposed proprietary name.

5. Safety Evaluator Risk Assessment of the Proposed Proprietary Name

The primary Safety Evaluator applies his/her individual expertise gained from evaluating medication errors reported to FDA, considers all aspects of the name that may be misleading or confusing, conducts a Failure Mode and Effects Analysis, and provides an overall decision on acceptability dependent on their risk assessment of name confusion. Failure Mode and Effects Analysis (FMEA) is a systematic tool for evaluating a process and identifying where and how it might fail.⁷ When applying FMEA to assess the risk of a proposed proprietary name, DMEPA seeks to evaluate the potential for a proposed proprietary name to be confused with another drug name because of name confusion and, thereby, cause errors to occur in the medication use system. FMEA capitalizes on the predictable and preventable nature of medication errors associated with drug name confusion. FMEA allows the Agency to identify the potential for medication errors due to orthographically or phonetically similar drug names prior to approval, where actions to overcome these issues are easier and more effective than remedies available in the post-approval phase.

In order to perform an FMEA of the proposed name, the primary Safety Evaluator must analyze the use of the product at all points in the medication use system. Because the proposed product is has not been marketed, the primary Safety Evaluator anticipates the use of the product in the usual practice settings by considering the clinical and product

⁷ Institute for Healthcare Improvement (IHI). Failure Mode and Effects Analysis. Boston. IHI:2004.

characteristics listed in Section 1.2 of this review. The Safety Evaluator then analyzes the proposed proprietary name in the context of the usual practice setting and works to identify potential failure modes and the effects associated with the failure modes.

In the initial stage of the Risk Assessment, the Safety Evaluator compares the proposed proprietary name to all of the names gathered from the above searches, Expert Panel Discussion, and prescription studies, external studies, and identifies potential failure modes by asking:

“Is the proposed proprietary name convincingly similar to another drug name, which may cause practitioners to become confused at any point in the usual practice setting? And are there any components of the name that may function as a source of error beyond sound/look-alike?”

An affirmative answer indicates a failure mode and represents a potential for the proposed proprietary name to be confused with another proprietary or established drug name because of look- or sound-alike similarity or because of some other component of the name. If the answer to the question is no, the Safety Evaluator is not convinced that the names possess similarity that would cause confusion at any point in the medication use system, thus the name is eliminated from further review.

In the second stage of the Risk Assessment, the primary Safety Evaluator evaluates all potential failure modes to determine the likely *effect* of the drug name confusion, by asking:

“Could the confusion of the drug names conceivably result in medication errors in the usual practice setting?”

The answer to this question is a central component of the Safety Evaluator’s overall risk assessment of the proprietary name. If the Safety Evaluator determines through FMEA that the name similarity would not ultimately be a source of medication errors in the usual practice setting, the primary Safety Evaluator eliminates the name from further analysis. However, if the Safety Evaluator determines through FMEA that the name similarity could ultimately cause medication errors in the usual practice setting, the Safety Evaluator will then recommend the use of an alternate proprietary name.

Moreover, DMEPA will object to the use of proposed proprietary name when the primary Safety Evaluator identifies one or more of the following conditions in the Overall Risk Assessment:

- a. OPDP finds the proposed proprietary name misleading from a promotional perspective, and the Review Division concurs with OPDP’s findings. The Federal Food, Drug, and Cosmetic Act provides that labeling or advertising can misbrand a product if misleading representations are made or suggested by statement, word, design, device, or any combination thereof, whether through a PROPRIETARY name or otherwise [21 U.S.C 321(n); See also 21 U.S.C. 352(a) & (n)].
- b. DMEPA identifies that the proposed proprietary name is misleading because of similarity in spelling or pronunciation to another proprietary or established name of a different drug or ingredient [CFR 201.10.(C)(5)].

- c. FMEA identifies the potential for confusion between the proposed proprietary name and other proprietary or established drug name(s), and demonstrates that medication errors are likely to result from the drug name confusion under the conditions of usual clinical practice.
- d. The proposed proprietary name contains an USAN (United States Adopted Names) stem.
- e. DMEPA identifies a potential source of medication error within the proposed proprietary name. For example, the proprietary name may be misleading or, inadvertently, introduce ambiguity and confusion that leads to errors. Such errors may not necessarily involve confusion between the proposed drug and another drug product but involve a naming characteristic that when incorporated into a proprietary name, may be confusing, misleading, cause or contribute to medication errors.

If DMEPA objects to a proposed proprietary name on the basis that drug name confusion could lead to medication errors, the primary Safety Evaluator uses the FMEA process to identify strategies to reduce the risk of medication errors. DMEPA generally recommends that the Sponsor select an alternative proprietary name and submit the alternate name to the Agency for review. However, in rare instances FMEA may identify plausible strategies that could reduce the risk of medication error of the currently proposed name. In that instance, DMEPA may be able to provide the Sponsor with recommendations that reduce or eliminate the potential for error and, thereby, would render the proposed name acceptable.

In the event that DMEPA objects to the use of the proposed proprietary name, based upon the potential for confusion with another proposed (but not yet approved) proprietary name, DMEPA will provide a contingency objection based on the date of approval. Whichever product, the Agency approves first has the right to use the proprietary name, while DMEPA will recommend that the second product to reach approval seek an alternative name.

The threshold set for objection to the proposed proprietary name may seem low to the Applicant/Sponsor. However, the safety concerns set forth in criteria a through e above are supported either by FDA regulation or by external healthcare authorities, including the Institute of Medicine (IOM), World Health Organization (WHO), the Joint Commission, and the Institute for Safe Medication Practices (ISMP). These organizations have examined medication errors resulting from look- or sound-alike drug names, confusing, or misleading names and called for regulatory authorities to address the issue prior to approval. Additionally, DMEPA contends that the threshold set for the Proprietary Name Risk Assessment is reasonable because proprietary drug name confusion is a predictable and preventable source of medication error that, in many instances, the Agency and/or Sponsor can identify and rectify prior to approval to avoid patient harm.

Furthermore, post-marketing experience has demonstrated that medication errors resulting from drug name confusion are notoriously difficult to rectify post-approval. Educational and other post-approval efforts are low-leverage strategies that have had limited effectiveness at alleviating medication errors involving drug name confusion. Sponsors have undertaken higher-leverage strategies, such as drug name changes, in the

past but at great financial cost to the Sponsor and at the expense of the public welfare, not to mention the Agency’s credibility as the authority responsible for approving the error-prone proprietary name. Moreover, even after Sponsors’ have changed a product’s proprietary name in the post-approval phase, it is difficult to eradicate the original proprietary name from practitioners’ vocabulary, and as a result, the Agency has continued to receive reports of drug name confusion long after a name change in some instances. Therefore, DMEPA believes that post-approval efforts at reducing name confusion errors should be reserved for those cases in which the potential for name confusion could not be predicted prior to approval.

Appendix B: Letters and Letter Strings with Possible Orthographic or Phonetic Misinterpretation

Letters in Name, Viekira Pak	Scripted May Appear as	Spoken May Be Interpreted as
Capital ‘V’	U, L,X,N	D, F, P, PH, T, VV,Z,L
Lower case ‘v’	s, r, u, w, n	d, f, p, ph, t, vv, z, l
Lower case ‘i’	e, l, j	y
Lower case ‘e’	a, i, l, o, u, p, c, s	Any vowel
Lower case ‘k’	h, la	c, g, q
Lower case ‘i’	e, l, j	y
Lower case ‘r’	s, n, e, v, x, c, i	
Lower case ‘a’	el, ci, cl, d, o, u, c, e, o, er, ce,n	Any vowel
Capital ‘P’	F, B, R	B
Lower case ‘p’	yn, ys, g, j, l, q	b
Lower case ‘a’	el, ci, cl, d, o, u, c, e, o, er, ce	Any vowel
Lower case ‘k’	x, h, la	c, g,q
Letter strings		
Letter string ‘ie’	ei, le, li, il, ii, ll, u	‘i’, ‘y’
Letter string ‘ir’	u	
Letter string ‘Viek’		‘Vic’
Letter string ‘ek’	d	

Appendix C: Prescription Simulation Samples and Results

Figure 1. Viekira Pak Study (Conducted on January 24, 2014)

Handwritten Requisition Medication Order	Verbal Prescription
<p data-bbox="186 493 414 535"><u>Medication Order:</u></p> <p data-bbox="186 546 917 619"><i>Viekira Pak Take supply from home as directed</i></p> <hr/> <p data-bbox="186 651 479 693"><u>Outpatient Prescription:</u></p> <p data-bbox="235 745 868 1092"><i>Viekira Pak UAD Disp: 4 cartons</i></p>	<p data-bbox="950 493 1096 535">Viekira Pak</p> <p data-bbox="950 546 1144 577">Use as directed</p> <p data-bbox="950 598 1144 640">Disp# 4 cartons</p>

FDA Prescription Simulation Responses (Aggregate 1 Rx Studies Report)

Study Name: Viekira Pak

193 People Received Study 85 People Responded				
Study Name: Viekira Pak				
Total	32	24	29	85
INTERPRETATION	OUTPATIENT	VOICE	INPATIENT	TOTAL
UIEKIRA PAK	0	0	1	1
VIAKIRA PACK	0	0	1	1
VICARA PAC	0	1	0	1
VICARA PACK	0	6	0	6
VICARA PAK	0	1	0	1
VICARAPAC	0	2	0	2
VICARAPAK	0	1	0	1
VICARFAC	0	1	0	1
VICIRA PAC	0	1	0	1
VICODIN	1	0	0	1
VICURA PAK	0	1	0	1
VIEKIRA	3	0	1	4
VIEKIRA PACK	0	0	1	1
VIEKIRA PAK	23	1	19	43
VIEKIRA PAK ?	0	0	1	1
VIEKIRA PAK- USE AS DIRECTED, DISP 4 CARTONS	1	0	0	1
VIEKIRN PACK	1	0	0	1
VIEKIRN PAK	2	0	3	5
VIERKIRA PAK	0	0	1	1
VIKERA PACK	0	2	0	2
VIKERA PAK	0	1	0	1

VIKERAPAK	0	1	0	1
VIKIRA PAC	0	2	0	2
VIKIRA PACK	0	1	0	1
VILKIRA PAK	1	0	0	1
VISKIRN PAK	0	0	1	1
VYKIRA PACK	0	2	0	2

Appendix D: Proprietary names not likely to be confused or not used in usual practice settings for the reasons described.

No.	Proprietary Name	Active Ingredient	Similarity to Viekira	Failure preventions
1.	(b) (4)	Rufinamide	Look alike	Name found unacceptable under 2008-485 dated September 2, 2008, NDA 021911. The name Banzel was approved November 14, 2008.
2.	Exubera	Insulin Recombinant Human	Look alike	The name pair has sufficient orthographic differences
3.	Viatro	(b) (4)	Look alike	Name identified in Red Book database. Unable to find product characteristics in commonly used databases.
4.	(b) (4)	(b) (4)	Look alike	Secondary name to (b) (4) The name (b) (4) was found acceptable by FDA General Counsel after DMEPA found the name unacceptable under OSE # 2008-57 dated August 18, 2008. The Application, NDA (b) (4), was withdrawn on October 13, 2009. The applicant for NDA (b) (4) is Abbvie, the same Applicant for the proposed name Viekira Pak. USPTO database lists the name (b) (4) as 'Dead' on February 13, 2012
5.	(b) (4)	Eltegravir	Look alike	Name denied under OSE# 2011-2498 dated December 22, 2011. The name Vitekta was approved under OSE # 2012-762 and 2012-2142 dated September 20, 2012. Application NDA 203093 is pending.
6.	(b) (4)	Lacosamide	Look alike	Secondary name to Vimpat reviewed under OSE# 2007-1610, NDA 22253. The name Vimpat was approved on October 28, 2008.
7.	Viactiv	Multivitamin with calcium	Look alike	The name pair has sufficient orthographic differences
8.	(b) (4)	Moxifloxacin	Look alike	Name found unacceptable under OSE# 2010-1323 dated September 2, 2010, NDA 022428. The name Moxeza was approved on November 19, 2010.

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No.	Proprietary Name	Active Ingredient	Similarity to Viekira	Failure preventions
9.		Anakinra	Look alike	The name pair has sufficient orthographic and phonetic differences
10.	Viramune	Nevirapine	Look and sound alike	The name pair has sufficient orthographic and phonetic differences
11.	Viokase	Pancrelipase	Look and sound alike	International name found in Canada for Pancrelipase. The name market in the United States, Viokace, is reviewed in Appendix E
12.	Voltaren	Diclofenac	Look alike	The name pair has sufficient orthographic and phonetic differences
13.	Lyrica	Pregabalin	Look alike	The name pair has sufficient orthographic and phonetic differences
14.	Viekira ^{***}	Dasabuvir and Veruprivir/ritonavir/ombitasvir	Look and sound alike	Name that is the subject of this review. This proposed name was originally submitted by the Applicant Abbvie under the same IND. The name was subsequently changed to Viekira Pak
15.	Viracept	Nelfinavir	Look and sound alike	The name pair has sufficient orthographic and phonetic differences
16.	(b) (4)	Loteprednol	Look and sound alike	Secondary name to Lotemax, NDA 202872. The name Lotemax was approved on September, 28, 2012
17.	(b) (4)	(b) (4)	Look and sound alike	The name was found unacceptable in OSE# 2010-1741, ANDA (b) (4). The name (b) (4) ^{***} was found acceptable in OSE# 2012-2120 dated October 1, 2013. The Application is pending.
18.	(b) (4)	Crofelemer	Look and sound alike	The name was found unacceptable in OSE# 2010-1741, NDA 202292. The name Fulyzaq was approved on December 31, 2012.
19.	Viadent		Look alike	The product characteristics for Viadent could not be found in standard pharmacy references such as Facts and Comparisons Online, Clinical Pharmacy Online, Lexicomp, cvs.com or walgreens.com.

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Appendix E: Risk of medication errors due to product confusion minimized by dissimilarity of the names and/ or use in clinical practice for the reasons described.

No.	<p>Proposed name: Viekira Pak (Dasabuvir and Veruprivir/Ritonavir/Ombitasvir)</p> <p>Dosage Form: Tablets</p> <p>Strengths: Dasabuvir: 250 mg Veruprivir/Ritonavir/Ombitasvir: 75 mg/50 mg/12.5 mg</p> <p>Usual Dose: Take 1 dasabuvir tablet orally twice daily; one tablet in the morning and one tablet in the evening. Take 2 Veruprivir/Ritonavir/Ombitasvir tablets orally once daily in the morning</p>	<p>Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion</p> <p>Causes (could be multiple)</p>	<p>Prevention of Failure Mode</p> <p>In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names</p>
1.	<p>Verdeso (Desonide)</p> <p>Topical Foam 0.5%</p> <p>Usual Dose: Apply to affected area twice daily</p>	<p>Orthographic Similarity to Viekira: Both names begin and end with similar looking letter strings 'Vi' vs. 'Ve' and 'ira' vs. 'eso', and both names have an upstroke letter in the middle of the name.</p> <p>Dose and Frequency: Both products can be taken twice daily</p>	<p>Orthographic Differences to Viekira: The letter 'k' in Viekira looks different than the letter 'd' when scripted. The letter 'a' at the end of Viekira has a trailing tail that points down where the letter 'o' in Verdeso has a tail that points upward; thus providing additional differentiation.</p>

No.	<p>Proposed name: Viekira Pak (Dasabuvir and Veruprivir/Ritonavir/Ombitasvir)</p> <p>Dosage Form: Tablets</p> <p>Strengths: Dasabuvir: 250 mg Veruprivir/Ritonavir/Ombitasvir: 75 mg/50 mg/12.5 mg</p> <p>Usual Dose: Take 1 dasabuvir tablet orally twice daily; one tablet in the morning and one tablet in the evening. Take 2 Veruprivir/Ritonavir/Ombitasvir tablets orally once daily in the morning</p>	<p>Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion</p> <p>Causes (could be multiple)</p>	<p>Prevention of Failure Mode</p> <p>In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names</p>
2.	<p>Xalkori (Crizotinib)</p> <p>Capsule 200 mg and 250 mg</p> <p>Usual Dose: 250 mg orally once daily or 200 mg to 250 mg orally twice daily</p>	<p>Orthographic Similarity to Viekira: Both names begin with similar looking letters when scripted. Both names have similar looking letter strings, 'ira' vs. 'ori' at the end of the name.</p> <p>Route of Administration: Both products are taken via the oral route</p> <p>Frequency of Administration: Both products can be taken twice daily</p>	<p>Orthographic Differences to Viekira: Valkori has an additional upstroke letter 'l' near the beginning of the name while Viekira does not.</p> <p>Strength: Xalkori contains multiple strengths that would need to be indicated on the prescription. There is no overlap or numerical similarity in strength</p>

No.	<p>Proposed name: Viekira Pak (Dasabuvir and Veruprivir/Ritonavir/Ombitasvir)</p> <p>Dosage Form: Tablets</p> <p>Strengths: Dasabuvir: 250 mg Veruprivir/Ritonavir/Ombitasvir: 75 mg/50 mg/12.5 mg</p> <p>Usual Dose: Take 1 dasabuvir tablet orally twice daily; one tablet in the morning and one tablet in the evening. Take 2 Veruprivir/Ritonavir/Ombitasvir tablets orally once daily in the morning</p>	<p>Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion</p> <p>Causes (could be multiple)</p>	<p>Prevention of Failure Mode</p> <p>In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names</p>
3.	(b) (4)		
4.	<p>Rezira (Hydrocodone and Pseudoephedrine)</p> <p>Oral Solution 5 mg/60 mg per 5 mL</p> <p>Usual Dose: 5 mL orally every 4 to 6 hours as needed</p>	<p>Orthographic Similarity to Viekira: Both names begin with similar letter strings 'vi' vs. 're' especially when the letter 'v' and 'r' are written in lower case. Both names end in the same letter string 'ira'.</p> <p>Route of Administration: Both products are taken via the oral route</p>	<p>Orthographic Differences to Viekira: The 'z' in Rezira does not look like 'ek' in Viekira.</p> <p>Dose: 5 mL or 1 teaspoon vs. 1 or 2 tablets</p> <p>Frequency: daily or twice daily vs. every 4 to 6 hours prn</p>

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No.	<p>Proposed name: Viekira Pak (Dasabuvir and Veruprivir/Ritonavir/Ombitasvir)</p> <p>Dosage Form: Tablets</p> <p>Strengths: Dasabuvir: 250 mg Veruprivir/Ritonavir/Ombitasvir: 75 mg/50 mg/12.5 mg</p> <p>Usual Dose: Take 1 dasabuvir tablet orally twice daily; one tablet in the morning and one tablet in the evening. Take 2 Veruprivir/Ritonavir/Ombitasvir tablets orally once daily in the morning</p>	<p>Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion</p> <p>Causes (could be multiple)</p>	<p>Prevention of Failure Mode</p> <p>In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names</p>
5.	<p>Viadur (Leuprolide)</p> <p>Subcutaneous Implant</p> <p>65 mg</p> <p>Usual Dose: Place one implant subcutaneously once every 12 months</p>	<p>Orthographic Similarity to Viekira: Both names begin with similar letter strings 'Vie' vs. 'Via' and both names have the letter 'r' at or near the end of the name. Both names contain an upstroke letter in the middle of the name.</p>	<p>Orthographic Differences to Viekira: Viadur does not contain the letter 'a' at the end of the name while Viekira does.</p> <p>Frequency: Once or once every 12 months vs. daily or twice daily</p>
6.	<p>Veletri (Epoprostenol)</p> <p>Injection</p> <p>0.5 mg and 1.5 mg per vial</p> <p>Usual Dose: 2 ng/kg/min to 20 ng/kg/min intravenously via continuous infusion</p>	<p>Orthographic Similarity to Viekira: Both names begin with letters 'V' and 'e' and have the letter 'r' near the end of the name. Both names have an upstroke letter in the middle of the name.</p>	<p>Orthographic Differences to Viekira: Veletri has an additional cross stroke letter 't' in the middle of the name while Viekira does not.</p> <p>Dose: Weight based in ng/kg/min vs. 1 or 2 tablets</p>

No.	<p>Proposed name: Viekira Pak (Dasabuvir and Veruprivir/Ritonavir/Ombitasvir)</p> <p>Dosage Form: Tablets</p> <p>Strengths: Dasabuvir: 250 mg Veruprivir/Ritonavir/Ombitasvir: 75 mg/50 mg/12.5 mg</p> <p>Usual Dose: Take 1 dasabuvir tablet orally twice daily; one tablet in the morning and one tablet in the evening. Take 2 Veruprivir/Ritonavir/Ombitasvir tablets orally once daily in the morning</p>	<p>Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion</p> <p>Causes (could be multiple)</p>	<p>Prevention of Failure Mode</p> <p>In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names</p>
7.	<p>Vestura (Drospirenone and Ethinyl Estradiol)</p> <p>Tablets 3 mg/0.02 mg</p> <p>Usual Dose: 1 tablet orally once daily</p>	<p>Orthographic Similarity to Viekira: Both names begin with the letter ‘V’ and end with the letter ‘a’. Both names have the same number of letters in the name.</p> <p>Dosage Form: Both products are tablets</p> <p>Route of Administration: Both products are taken via the oral route</p>	<p>Orthographic Differences to Viekira: The letter string ‘ek’ does not look similar to the letter string ‘st’. The modifier ‘Pak’ provides differentiation when scripted.</p>
8.	<p>Victoza (Liraglutide)</p> <p>Solution for Injection 0.6 mg, 1.2 mg, and 1.8 mg</p> <p>Usual Dose: Inject 0.6 mg to 1.8 mg once daily</p>	<p>Orthographic Similarity to Viekira: Both names have similar letter strings at the beginning and end of the names, ‘Vie’ vs. ‘Vic’ and ‘ra’ and ‘za’ especially when the letter ‘z’ is not scripted with a down stroke and a dash is not scripted through the letter. Both names have an upstroke letter in the middle of the name.</p>	<p>Dose: 0.6 mg, 1.2 mg, 1.8 mg vs. 1 or 2 tablets</p> <p>Strength: Victoza has multiple strengths that would need to be indicated on the prescription. There is no overlap or numerical similarity</p>

No.	<p>Proposed name: Viekira Pak (Dasabuvir and Veruprivir/Ritonavir/Ombitasvir)</p> <p>Dosage Form: Tablets</p> <p>Strengths: Dasabuvir: 250 mg Veruprivir/Ritonavir/Ombitasvir: 75 mg/50 mg/12.5 mg</p> <p>Usual Dose: Take 1 dasabuvir tablet orally twice daily; one tablet in the morning and one tablet in the evening. Take 2 Veruprivir/Ritonavir/Ombitasvir tablets orally once daily in the morning</p>	<p>Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion</p> <p>Causes (could be multiple)</p>	<p>Prevention of Failure Mode</p> <p>In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names</p>
9.	<p>Leukine (Sargramostim)</p> <p>Lyophilized Powder for Injection 250 mcg and 500 mcg</p> <p>Usual Dose: 250 mcg to 500 mcg subcutaneously or intravenously once daily for 5 to 15 days</p>	<p>Orthographic Similarity to Viekira: The letter string 'Viek' can look similar to the letter string 'Leuk'. The letter string 'ira' can look similar to the letter string 'ine'.</p>	<p>Strength: Leukine contains multiple strengths that would need to be indicated on the prescription. There is no overlap or numerical similarity in strength</p>
10.	<p>Verluma (Technetium Tc 99 Nofetumomab Merpentan)</p> <p>Injection 10 mg of Nofetumomab</p> <p>Usual Dose: 5 to 10 mg via intravenous administration over 3 to 5 minutes one time only</p>	<p>Orthographic Similarity to Viekira: Both names contain the similar letters 'V' and 'e' at the beginning of the name and have an upstroke letter in the same position. Both names end in the letter 'a'.</p>	<p>Orthographic Differences to Viekira: The letters 'u' and 'm' in Verluma make the name appear longer after the upstroke letter when compared to the name Viekira.</p> <p>Setting of Use: Verluma is a radiopharmaceutical that would only be sent to a radiopharmacy to be prepared and dispensed. This minimizes the risk for confusion between Viekira and Verluma since a Viekira order would not be sent to a radiopharmacy.</p>

No.	<p>Proposed name: Viekira Pak (Dasabuvir and Veruprivir/Ritonavir/Ombitasvir)</p> <p>Dosage Form: Tablets</p> <p>Strengths: Dasabuvir: 250 mg Veruprivir/Ritonavir/Ombitasvir: 75 mg/50 mg/12.5 mg</p> <p>Usual Dose: Take 1 dasabuvir tablet orally twice daily; one tablet in the morning and one tablet in the evening. Take 2 Veruprivir/Ritonavir/Ombitasvir tablets orally once daily in the morning</p>	<p>Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion</p> <p>Causes (could be multiple)</p>	<p>Prevention of Failure Mode</p> <p>In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names</p>
11.	<p>Vicodin (Hydrocodone/ Acetaminophen)</p> <p>Tablet 5 mg/300 mg</p> <p>Usual Dose: 1 to 2 tablets orally every 4 to 6 hours as needed</p>	<p>Phonetic Similarity to Viekira: The Beginning letter string ‘Vic’ and ‘Viek’ sound almost identical when spoken.</p> <p>Dosage Form: Both products are tablets</p> <p>Route of Administration: Both products are given via the oral route.</p>	<p>Phonetic Differences to Viekira: The letter string ‘ira’ does not sound similar to the letter string ‘odin’ when scripted.</p> <p>Frequency of Administration: Daily or twice daily vs. every four to six hours as needed.</p> <p>Strength: 5 mg/500 mg vs. Dasabuvir: 250 mg and Veruprivir/Ritonavir/Ombitasvir: 75 mg/50 mg/12.5 mg</p> <p>See section 2.2.5 for further discussion between the name pair</p>
12.	<p>Videx (Didanosine)</p> <p>Oral Solution 10 mg/mL</p> <p>Usual Dose: 50 mg to 200 mg orally twice daily or 250 mg to 400 mg orally once daily</p>	<p>Orthographic Similarity to Viekira: The letter string ‘Vid’ looks similar to the letter string ‘Viek’ when scripted.</p> <p>Route of Administration: Both products are taken via the oral route</p>	<p>Orthographic Differences to Viekira: The letter string ‘ira’ does not look similar to the letter string ‘ex’. Viekira contains 7 letters while Videx contains only 5 letters. Thus, Viekira appears longer when scripted.</p>

No.	<p>Proposed name: Viekira Pak (Dasabuvir and Veruprivir/Ritonavir/Ombitasvir)</p> <p>Dosage Form: Tablets</p> <p>Strengths: Dasabuvir: 250 mg Veruprivir/Ritonavir/Ombitasvir: 75 mg/50 mg/12.5 mg</p> <p>Usual Dose: Take 1 dasabuvir tablet orally twice daily; one tablet in the morning and one tablet in the evening. Take 2 Veruprivir/Ritonavir/Ombitasvir tablets orally once daily in the morning</p>	<p>Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion</p> <p>Causes (could be multiple)</p>	<p>Prevention of Failure Mode</p> <p>In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names</p>
13.	<p>Kira St. John's Wort</p> <p>Tablets 300 mg</p> <p>Usual Dose: 1 to 2 tablets orally once daily</p>	<p>Orthographic Similarity to Viekira: Both names contain the letter string 'kira'.</p> <p>Phonetic Similarity to Viekira: Both names contain the letter string 'kira'.</p> <p>Dosage Form: Both products are tablets</p> <p>Route of Administration: Both products are taken via the oral route</p>	<p>Orthographic Differences to Viekira: Viekira contains the letter string 'Vie' at the beginning of the name while Kira does not</p> <p>Phonetic Differences to Viekira: Viekira contains an additional syllable 'Vie' at the beginning of the name.</p> <p>Kira is a brand of herbal remedies. Therefore, if a prescription was written for Kira, a pharmacist would need to clarify what active ingredient the practitioner was prescribing.</p>

No.	<p>Proposed name: Viekira Pak (Dasabuvir and Veruprivir/Ritonavir/Ombitasvir)</p> <p>Dosage Form: Tablets</p> <p>Strengths: Dasabuvir: 250 mg Veruprivir/Ritonavir/Ombitasvir: 75 mg/50 mg/12.5 mg</p> <p>Usual Dose: Take 1 dasabuvir tablet orally twice daily; one tablet in the morning and one tablet in the evening. Take 2 Veruprivir/Ritonavir/Ombitasvir tablets orally once daily in the morning</p>	<p>Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion</p> <p>Causes (could be multiple)</p>	<p>Prevention of Failure Mode</p> <p>In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names</p>
14.	<p>Vistra 650 (Acetaminophen/Phenyltoloxamine)</p> <p>Tablets 650 mg and 50 mg</p> <p>Usual Dose: 0.5 to 1 tablets orally once every 4 hours</p>	<p>Orthographic Similarity to Viekira: Both names begin with the letter string 'Vi', have an upstroke letter in the middle of the name, and both names end with the letter string 'ra'.</p> <p>Phonetic Similarity to Viekira: Both names begin with the letter string 'Vi' and both names end with the letter string 'ra'.</p> <p>Dosage Form: Both products are tablets</p> <p>Route of Administration: Both products are taken via the oral route</p>	<p>Orthographic Differences to Viekira: The cross stroke in the letter 't' in Vistra provides differentiation when scripted. The letter 'i' between the upstroke letter 'k' and the letter 'r' provides additional orthographic differentiation.</p> <p>Phonetic Differences to Viekira: Viekira contains three syllables while Vistra contains only two syllables. The onset of the second syllable with the letter 'k' in Viekira does not sound like the onset of the second syllable with the letter 't' in Vistra when spoken.</p> <p>Frequency of Administration: Every 4 hours vs. daily or twice daily</p>

No.	<p>Proposed name: Viekira Pak (Dasabuvir and Veruprivir/Ritonavir/Ombitasvir)</p> <p>Dosage Form: Tablets</p> <p>Strengths: Dasabuvir: 250 mg Veruprivir/Ritonavir/Ombitasvir: 75 mg/50 mg/12.5 mg</p> <p>Usual Dose: Take 1 dasabuvir tablet orally twice daily; one tablet in the morning and one tablet in the evening. Take 2 Veruprivir/Ritonavir/Ombitasvir tablets orally once daily in the morning</p>	<p>Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion</p> <p>Causes (could be multiple)</p>	<p>Prevention of Failure Mode</p> <p>In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names</p>
15.	<p>Viokace (Pancrelipase)</p> <p>Tablets 39,150/10,440/39,150 Units 78,300/20,880/78,300 Units</p> <p>Usual Dose: 1 to 6 tablets orally with meals</p>	<p>Orthographic Similarity to Viekira: The letter string 'Viek' can look similar to the letter string 'Viok' and the letter strings 'ra' and 'ce' can look similar when scripted.</p> <p>Phonetic Similarity to Viekira: Both names begin with 'Vi' and contain the letter 'k' in the same position.</p> <p>Dosage Form: Both products are tablets</p> <p>Route of Administration: Both products are taken via the oral route</p>	<p>Orthographic Differences to Viekira: The second letter 'i' in Viekira does not look similar to the letter 'a' in Viokace when scripted.</p> <p>Phonetic Differences to Viekira: The letter 'o' in Viokace provides phonetic differentiation in the first syllable. The letter string 'ace' does not sound similar to the letter string 'ira'.</p> <p>Strength: Viokace has multiple strengths that would need to be indicated on the prescription. There is no overlap or numerical similarity</p>

No.	<p>Proposed name: Viekira Pak (Dasabuvir and Veruprivir/Ritonavir/Ombitasvir)</p> <p>Dosage Form: Tablets</p> <p>Strengths: Dasabuvir: 250 mg Veruprivir/Ritonavir/Ombitasvir: 75 mg/50 mg/12.5 mg</p> <p>Usual Dose: Take 1 dasabuvir tablet orally twice daily; one tablet in the morning and one tablet in the evening. Take 2 Veruprivir/Ritonavir/Ombitasvir tablets orally once daily in the morning</p>	<p>Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion</p> <p>Causes (could be multiple)</p>	<p>Prevention of Failure Mode</p> <p>In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names</p>
16.	<p>Lexiva (Fosamprenavir)</p> <p>Tablets and Suspension 700 mg – tablet 50 mg/mL – suspension</p> <p>Usual Dose: 2 tablets orally once daily or 1 tablet orally twice daily</p> <p>2 mL to 14 mL orally twice daily</p>	<p>Orthographic Similarity to Viekira: The letters ‘V’ and ‘e’ and letter string ‘ira’ in Viekira can look similar to the letter string ‘Le’ and ‘iva’ in Lexiva when scripted.</p> <p>Phonetic Similarity to Viekira: The letter ‘L’ and ‘V’ can sound similar when spoken. Both names have the letter ‘e’ in the first syllable. Both names have the letter ‘i’ and ‘a’ at the end of the name.</p> <p>Dosage Form: Both products are tablets</p> <p>Route of Administration: Both products are taken via the oral route</p> <p>Frequency of Administration: Both products can be given twice daily</p>	<p>Orthographic Differences to Viekira: The name Viekira has an upstroke letter ‘k’ in the middle of the name where Lexiva does not. The letter ‘i’ in Viekira at the beginning of the name provides additional differentiation by lengthening the prefix.</p> <p>Phonetic Differences to Viekira: The letter string ‘kir’ in Viekira does not sound similar to the letter string ‘xiv’ when spoken.</p>

No.	<p>Proposed name: Viekira Pak (Dasabuvir and Veruprivir/Ritonavir/Ombitasvir)</p> <p>Dosage Form: Tablets</p> <p>Strengths: Dasabuvir: 250 mg Veruprivir/Ritonavir/Ombitasvir: 75 mg/50 mg/12.5 mg</p> <p>Usual Dose: Take 1 dasabuvir tablet orally twice daily; one tablet in the morning and one tablet in the evening. Take 2 Veruprivir/Ritonavir/Ombitasvir tablets orally once daily in the morning</p>	<p>Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion</p> <p>Causes (could be multiple)</p>	<p>Prevention of Failure Mode</p> <p>In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names</p>
17.	<p>Visken (Pindolol)</p> <p>Tablets 5 mg and 10 mg</p> <p>Usual Dose: 1 to 3 tablets orally twice daily</p>	<p>Orthographic Similarity to Viekira: Both names begin with the letter string 'Vi', contain the letter 'k' in the same position and the letter 'r' in Viekira sounds looks similar to the letter 'n' in Visken when scripted.</p> <p>Phonetic Similarity to Viekira: Both names begin with the letter string 'Vi' and contain the letter 'k' in the same position.</p> <p>Dosage Form: Both products are tablets</p> <p>Route of Administration: Both products are taken via the oral route</p> <p>Frequency of Administration: Both products can be given twice daily</p>	<p>Orthographic Differences to Viekira: Viekira ends in the letter 'a' while Visken does not.</p> <p>Phonetic Differences to Viekira: Visken contains the letter 's' while Viekira does not. The letter 'n' in Visken does not sound similar to the letter string 'ra' when spoken.</p> <p>Strength: Visken has multiple strengths that would need to be indicated on the prescription. There is no overlap or numerical similarity</p>

No.	<p>Proposed name: Viekira Pak (Dasabuvir and Veruprivir/Ritonavir/Ombitasvir)</p> <p>Dosage Form: Tablets</p> <p>Strengths: Dasabuvir: 250 mg Veruprivir/Ritonavir/Ombitasvir: 75 mg/50 mg/12.5 mg</p> <p>Usual Dose: Take 1 dasabuvir tablet orally twice daily; one tablet in the morning and one tablet in the evening. Take 2 Veruprivir/Ritonavir/Ombitasvir tablets orally once daily in the morning</p>	<p>Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion</p> <p>Causes (could be multiple)</p>	<p>Prevention of Failure Mode</p> <p>In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names</p>
18.	<p>Viagra (Sildenafil)</p> <p>Tablets 25 mg, 50 mg, 100 mg</p> <p>Usual Dose: 1 tablet orally 1 hour before sexual activity, not more than once daily</p>	<p>Orthographic Similarity to Viekira: The letter string 'Via' can look similar to the letter string 'Vie' when scripted. Both names end in the letter string 'ra'.</p> <p>Phonetic Similarity to Viekira: The letter string 'Via' can sound similar to the letter string 'Vie' when spoken. Both names end in the letter string 'ra'.</p> <p>Dosage Form: Both products are tablets</p> <p>Route of Administration: Both products are taken via the oral route</p>	<p>Orthographic Differences to Viekira: The letter string 'ki' in Viekira does not look similar to the letter 'g' in Viagra when scripted.</p> <p>Phonetic Differences to Viekira: The letter 'k' in Viekira does not sound similar to the letter 'g' in Viagra.</p> <p>Strength: Viagra has multiple strengths that would need to be indicated on the prescription. There is no overlap or numerical similarity</p>

No.	<p>Proposed name: Viekira Pak (Dasabuvir and Veruprivir/Ritonavir/Ombitasvir)</p> <p>Dosage Form: Tablets</p> <p>Strengths: Dasabuvir: 250 mg Veruprivir/Ritonavir/Ombitasvir: 75 mg/50 mg/12.5 mg</p> <p>Usual Dose: Take 1 dasabuvir tablet orally twice daily; one tablet in the morning and one tablet in the evening. Take 2 Veruprivir/Ritonavir/Ombitasvir tablets orally once daily in the morning</p>	<p>Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion</p> <p>Causes (could be multiple)</p>	<p>Prevention of Failure Mode</p> <p>In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names</p>
19.	<p>Vidaza (Azacitidine)</p> <p>Powder for Injection 100 mg</p> <p>Usual Dose: 75 mg/m² to 100 mg/m² (100 mg to 200 mg) subcutaneously or intravenously daily for 7 days</p>	<p>Orthographic Similarity to Viekira: Both names begin with the letter string 'Vi' and the letter string 'ra' in Viekira can look similar to the letter string 'za', especially when the letter 'z' is not scripted with a down stroke and a dash is not scripted through the letter. Both names contain an upstroke letter in the middle of the name.</p> <p>Phonetic Similarity to Viekira: Both names begin with the letter string 'Vi' and both names end with the letter 'a'.</p>	<p>Orthographic Differences to Viekira: Viekira contains the letter 'e' in the third position while Vidaza does not. Vidaza contains the letter 'a' after the upstroke letter which does not look similar to the letter 'i' after the upstroke letter 'k' in Viekira.</p> <p>Phonetic Differences to Viekira: The letter string 'daz' does not sound similar to the letter string 'kir' when spoken.</p> <p>Dose: 100 mg to 200 mg based on BSA vs. 1 or 2 tabs.</p>

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

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04/29/2014

IRENE Z CHAN
04/29/2014

KELLIE A TAYLOR
05/05/2014