CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

212887Orig1s000
212888Orig1s000

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:	June 20, 2019
Application Type and Number:	NDA 212887
Product Name and Strength:	Vocabria (cabotegravir) Tablets, 30 mg
Product Type:	Single Ingredient Product
Rx or OTC:	Prescription (Rx)
Applicant/Sponsor Name:	ViiV Healthcare Company (ViiV)
Panorama #:	2019-31379681
DMEPA Safety Evaluator:	Valerie Wilson, PharmD
DMEPA Team Leader:	Sevan Kolejian, PharmD, MBA

1 INTRODUCTION

This memorandum is to reassess the proposed proprietary name, Vocabria, which was found conditionally acceptable under IND 101429 on January 9, 2019.[a] We note that all product characteristics remain the same.

ViiV submitted an external name study conducted by (b) (4) dated June 25, 2018. We previously reviewed and considered the findings of this report in our previous review of the proposed proprietary name, Vocabria, under IND 101429. Therefore, this review does not include reassessment of (b) (4) external name study.

2 METHODS AND DISCUSSION

2.1 MISBRANDING ASSESSMENT

The Office of Prescription Drug Promotion (OPDP) determined that Vocabria would not misbrand the proposed product. The Division of Medication Error Prevention and Analysis (DMEPA) and the Division of Antiviral Products (DAVP) concurred with the findings of OPDP's assessment for Vocabria.

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. Our evaluation determined that our previous conclusion regarding previously identified names of concern remains unchanged.

Furthermore, DMEPA searched the USAN stem list to determine if the proposed proprietary name contains any USAN stems as of the last USAN updates. The May 13, 2019 search of USAN stems did not find any USAN stems in the proposed proprietary name, Vocabria.

2.3 COMMUNICATION OF DMEPA'S ANALYSIS AT MIDPOINT OF REVIEW

DMEPA communicated our findings to the Division of Antiviral Products (DAVP) via e-mail on June 3, 2019. 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 (DAVP) on June 3, 2019, they stated no additional concerns with the proposed proprietary name, Vocabria.

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, Vocabria, is acceptable.

If you have any questions or need clarifications, please contact Mammah Borbor, OSE project manager, at 301-796-7731.

---

[a] Wilson, V. Proprietary Name Review for Vocabria (IND 101429). Silver Spring (MD): FDA, CDER, OSE, DMEPA (US); 2019 JAN 09. Panorama No.: 2018-25117183.

3.1 COMMENTS TO VIIV HEALTHCARE COMPANY

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

If any of the proposed product characteristics as stated in your submission, received on May 3, 2019, 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/

VALERIE S WILSON
06/20/2019 09:44:37 AM

SEVAN H KOLEJIAN
06/20/2019 10:43:59 AM

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:	June 20, 2019
Application Type and Number:	NDA 212888
Product Name and Strength:	Cabenuva (cabotegravir and rilpivirine) Extended-Release Injectable Suspensions, cabotegravir 600 mg/3 mL and rilpivirine 900 mg/3 mL cabotegravir 400 mg/2 mL and rilpivirine 600 mg/2 mL
Product Type:	Multiple Ingredients, Co-Packaged Product
Rx or OTC:	Prescription (Rx)
Applicant/Sponsor Name:	ViiV Healthcare Company (ViiV)
Panorama #:	2019-31379724
DMEPA Safety Evaluator:	Valerie S. Wilson, PharmD
DMEPA Team Leader:	Sevan Kolejian, PharmD, MBA

1 INTRODUCTION

This memorandum is to reassess the proposed proprietary name, Cabenuva, which was found conditionally acceptable under IND 109678 on January 29, 2019.[a] We note that all product characteristics remain the same.

ViiV submitted an external name study conducted by (b) (4) dated May 30, 2018. We previously reviewed and considered the findings of this report in our previous review of the proposed proprietary name, Cabenuva, under IND 109678. Therefore, this review does not include reassessment of (b) (4) external name study.

2 METHODS AND DISCUSSION

2.1 MISBRANDING ASSESSMENT

The Office of Prescription Drug Promotion (OPDP) determined that Cabenuva would not misbrand the proposed product. The Division of Medication Error Prevention and Analysis (DMEPA) and the Division of Antiviral Products (DAVP) concurred with the findings of OPDP's assessment for Cabenuva.

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. Our evaluation determined that our previous conclusion regarding previously identified names of concern remains unchanged.

Additionally, DMEPA searched the USAN stem list to determine if the proposed proprietary name contains any USAN stems as of the last USAN updates. The May 15, 2019 search of USAN stems did not find any USAN stems in the proposed proprietary name, Cabenuva.

2.3 COMMUNICATION OF DMEPA'S ANALYSIS AT MIDPOINT OF REVIEW

DMEPA communicated our findings to the Division of Antiviral Products (DAVP) via e-mail on June 4, 2019. 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 (DAVP) on June 4, 2019, they stated no additional concerns with the proposed proprietary name, Cabenuva.

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, Cabenuva, is acceptable.

If you have any questions or need clarifications, please contact Mammah Borbor, OSE project manager, at 301-796-7731.

---

[a] Wilson, V. Proprietary Name Review for Cabenuva (NDA 212888). Silver Spring (MD): FDA, CDER, OSE, DMEPA (US); 2019 JAN 29. Panorama No.: 2018-25117225.

3.1 COMMENTS TO VIIV HEALTHCARE COMPANY

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

If any of the proposed product characteristics as stated in your submission, received on May 3, 2019, 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.

APPEARS THIS WAY ON ORIGINAL

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/

VALERIE S WILSON
06/20/2019 01:08:33 PM

SEVAN H KOLEJIAN
06/20/2019 02:31:01 PM

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:	October 20, 2020
Application Type and Number:	NDA 212887
Product Name and Strength:	Vocabria (cabotegravir) Tablets, 30 mg
Product Type:	Single Ingredient Product
Rx or OTC:	Prescription (Rx)
Applicant/Sponsor Name:	ViiV Healthcare Company (ViiV)
Panorama #:	2020-41714359
DMEPA Safety Evaluator:	Valerie S. Vaughan, PharmD
DMEPA Team Leader:	Sevan Kolejian, PharmD, MBA, BCPPS

Contents

1 INTRODUCTION

This review is to reassess the proposed proprietary name, Vocabria, from a safety and misbranding perspective. The sources and methods used to evaluate the proposed proprietary name are outlined in the reference section and Appendix A respectively.

ViiV submitted an external name study dated June 25, 2018, conducted by (b) (4) ((b) (4) which was previously reviewed for this proposed proprietary name.

1.1 REGULATORY HISTORY

The proposed proprietary name, Vocabria, was found conditionally acceptable under IND 101429 on January 9, 2019[a] and under NDA 212887 on June 20, 2019[b]. However, the application received a Complete Response from the Agency on December 19, 2019. Thus

Thus, ViiV resubmitted the name, Vocabria, for review under NDA 212887 on July 28, 2020.

1.2 PRODUCT INFORMATION

The following product information is provided in the proprietary name submission received on July 28, 2020.

- Intended Pronunciation: voe kab' ree ah
- Active Ingredient: cabotegravir
- Indication of Use: Indicated in combination with EDURANT for short term use for patients with HIV-1 infection who are virologically suppressed (HIV-1 RNA <50 copies/mL) and have no known or suspected resistance to either cabotegravir or rilpivirine:
    - of one month (oral lead-in) to assess tolerability of cabotegravir and rilpivirine prior to administration of long acting CABENUVA***.
- Route of Administration: Oral
- Dosage Form: Tablets
- Strength: 30 mg
- Dose and Frequency: One tablet (30 mg) once daily
- How Supplied: supplied in HDPE (high density polyethylene) bottles with child-resistant closures
- Storage: Store up to 30°C

---

[a] Wilson, V. Proprietary Name Review for Vocabria (IND 101429). Silver Spring (MD): FDA, CDER, OSE, DMEPA (US); 2019 JAN 09. Panorama No. 2018-25117183.

[b] Wilson, V. Proprietary Name Review for Vocabria (NDA 212887). Silver Spring (MD): FDA, CDER, OSE, DMEPA (US); 2019 JUN 20. Panorama No. 2019-31379681.

2 RESULTS

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

2.1 MISBRANDING ASSESSMENT

The Office of Prescription Drug Promotion (OPDP) determined that Vocabria would not misbrand the proposed product. The Division of Medication Error Prevention and Analysis (DMEPA) and the Division of Antivirals (DAV) concurred with the findings of OPDP's assessment for Vocabria.

2.2 SAFETY ASSESSMENT

The following aspects were considered in the safety evaluation of the proposed proprietary name, Vocabria.

2.2.1 United States Adopted Names (USAN) Search

There is no USAN stem present in the proposed proprietary name[c].

2.2.2 Components of the Proposed Proprietary Name

ViiV did not provide a derivation or intended meaning for the proposed proprietary name, Vocabria, in their submission. This proprietary name is comprised of a single word that does not contain any components (i.e. a modifier, route of administration, dosage form, etc.) that are misleading or can contribute to medication error.

2.2.3 Comments from Other Review Disciplines at Initial Review

In response to the OSE, August 11, 2020 e-mail, the Division of Antivirals (DAV) did not forward any comments or concerns relating to Vocabria at the initial phase of the review.

2.2.4 FDA Name Simulation Studies

Seventy-seven practitioners participated in DMEPA's prescription studies for Vocabria. One inpatient response overlapped with the currently marketed product, rilpivirine; however, after further investigation, we note that the participant who provided the response of rilpivirine inadvertently entered three of his or her responses under the wrong prescription study name. We note that the participant provided the response "Vocabrea" under another prescription study name. Despite the error, we assessed the name pair and determined the names, rilpivirine and Vocabria, can safely coexist on the market due to low similarity between the names (Appendix F).

Appendix B contains the results from the prescription simulation studies.

[c] USAN stem search conducted on September 27, 2020.

2.2.5 Phonetic and Orthographic Computer Analysis (POCA) Search Results

Our POCA search[d] identified 62 names with the combined score of ≥55% or individual orthographic or phonetic score of ≥70%. We had identified and evaluated some of the names in our previous proprietary name review. 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 name. We note that none of the product characteristics have changed and we agree with the findings from our previous review for the names evaluated previously. Therefore, we identified 10 names not previously analyzed. These names are included in Table 1 below.

2.2.6 Names Retrieved for Review Organized by Name Pair Similarity

Table 1 lists the number of names retrieved from our POCA search and FDA Prescription Simulation Study. These name pairs are organized as highly similar, moderately similar or low similarity for further evaluation.

Table 1. Names Retrieved for Review Organized by Name Pair Similarity

Similarity Category	Number of Names
Highly similar name pair: combined match percentage score ≥70%	1
Moderately similar name pair: combined match percentage score ≥55% to ≤ 69%	9
Low similarity name pair: combined match percentage score ≤54%	1

2.2.7 Safety Analysis of Names with Potential Orthographic, Spelling, and Phonetic Similarities

Our analysis of the 11 names contained in Table 1 determined none of the names will pose a risk for confusion with Vocabria as described in Appendices C through H.

2.2.8 Communication of DMEPA's Analysis at Midpoint of Review

DMEPA communicated our findings to the Division of Antivirals (DAV) via e-mail on October 20, 2020. At that time we also requested additional information or concerns that could inform our review. Per e-mail correspondence from the Division of Antivirals (DAV) on October 20, 2020, they stated no additional concerns with the proposed proprietary name, Vocabria.

3 CONCLUSION

The proposed proprietary name, Vocabria, is acceptable.

[d] POCA search conducted on September 27, 2020 in version 4.4.

If you have any questions or need clarifications, please contact Mammah Borbor, OSE project manager, at 301-796-7731.

3.1 COMMENTS TO VIIV HEALTHCARE COMPANY

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

If any of the proposed product characteristics as stated in your submission, received on July 28, 2020, are altered prior to approval of the marketing application, the name must be resubmitted for review.

4 REFERENCES

1. USAN Stems (https://www.ama-assn.org/about/united-states-adopted-names-approved-stems)

USAN Stems List contains all the recognized USAN stems.

2. 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.

Drugs@FDA

Drugs@FDA is an FDA Web site that contains most of the drug products approved in the United States 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* and *generic drugs*; *therapeutic biological products*, *prescription* and *over-the-counter* human drugs; and *discontinued drugs* (see Drugs @ FDA Glossary of Terms, available at http://www.fda.gov/Drugs/InformationOnDrugs/ucm079436.htm#ther_biological).

RxNorm

RxNorm contains the names of prescription and many OTC drugs available in the United States. RxNorm includes generic and branded:

- Clinical drugs – pharmaceutical products given to (or taken by) a patient with therapeutic or diagnostic intent
- Drug packs – packs that contain multiple drugs, or drugs designed to be administered in a specified sequence

Radiopharmaceuticals, contrast media, food, dietary supplements, and medical devices, such as bandages and crutches, are all out of scope for RxNorm (http://www.nlm.nih.gov/research/umls/rxnorm/overview.html).

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.

APPENDICES

Appendix A

FDA's Proprietary Name Risk Assessment evaluates proposed proprietary names for misbranding and safety concerns.

1. **Misbranding Assessment**: For prescription drug products, OPDP assesses the name for misbranding concerns. For over-the-counter (OTC) drug products, the misbranding assessment of the proposed name is conducted by DNDP. OPDP or DNDP evaluates proposed proprietary names to determine if the name is false or misleading, such as by making misrepresentations with respect to safety or efficacy. For example, a fanciful proprietary name may misbrand a product by suggesting that it has some unique effectiveness or composition when it does not (21 CFR 201.10(c)(3)). OPDP or DNDP provides their opinion to DMEPA for consideration in the overall acceptability of the proposed proprietary name.
2. **Safety Assessment**: The safety assessment is conducted by DMEPA, and includes the following:

a. Preliminary Assessment: 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.) See prescreening checklist below in Table 2*. 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. [e]

[e] National Coordinating Council for Medication Error Reporting and Prevention. http://www nccmerp.org/aboutMedErrors html. Last accessed 10/11/2007.

***Table 2- Prescreening Checklist for Proposed Proprietary Name**

	Answer the questions in the checklist below. Affirmative answers to any of these questions indicate a potential area of concern that should be carefully evaluated as described in this guidance.
Y/N	**Is the proposed name obviously similar in spelling and pronunciation to other names?**
	Proprietary names should not be similar in spelling or pronunciation to proprietary names, established names, or ingredients of other products.
Y/N	**Are there inert or inactive ingredients referenced in the proprietary name?**
	Proprietary names should not incorporate any reference to an inert or inactive ingredient in a way that might create an impression that the ingredient's value is greater than its true functional role in the formulation (21 CFR 201.10(c)(4)).
Y/N	**Does the proprietary name include combinations of active ingredients?**
	Proprietary names of fixed combination drug products should not include or suggest the name of one or more, but not all, of its active ingredients (see 21 CFR 201.6(b)).
Y/N	**Is there a United States Adopted Name (USAN) stem in the proprietary name?**
	Proprietary names should not incorporate a USAN stem in the position that USAN designates for the stem.
Y/N	**Is this proprietary name used for another product that does not share at least one common active ingredient?**
	Drug products that do not contain at least one common active ingredient should not use the same (root) proprietary name.
Y/N	**Is this a proprietary name of a discontinued product?**
	Proprietary names should not use the proprietary name of a discontinued product if that discontinued drug product does not contain the same active ingredients.

b. Phonetic and Orthographic Computer Analysis (POCA): Following the preliminary screening of the proposed proprietary name, DMEPA staff evaluates the proposed name against potentially similar names. In order to identify names with potential similarity to the proposed proprietary name, DMEPA enters the proposed proprietary name in POCA and queries the name against the following drug reference databases, Drugs@fda, CernerRxNorm, and names in the review pipeline using a 55% threshold in POCA. DMEPA reviews the combined orthographic and phonetic matches and group the names into one of the following three categories:

- Highly similar pair: combined match percentage score ≥70%.
- Moderately similar pair: combined match percentage score ≥55% to ≤ 69%.

- Low similarity: combined match percentage score ≤54%.

Using the criteria outlined in the check list (Table 3-5) that corresponds to each of the three categories (highly similar pair, moderately similar pair, and low similarity), DMEPA evaluates the name pairs to determine the acceptability or non-acceptability of a proposed proprietary name. The intent of these checklists is to increase the transparency and predictability of the safety determination of whether a proposed name is vulnerable to confusion from a look-alike or sound-alike perspective. Each bullet below corresponds to the name similarity category cross-references the respective table that addresses criteria that DMEPA uses to determine whether a name presents a safety concern from a look-alike or sound-alike perspective.

- For highly similar names, differences in product characteristics often cannot mitigate the risk of a medication error, including product differences such as strength and dose. Thus, proposed proprietary names that have a combined score of ≥ 70 percent are at risk for a look-alike sound-alike confusion which is an area of concern (See Table 3).
- Moderately similar names are further evaluated to identify the presence of attributes that are known to cause name confusion.
    - Name attributes: We note that the beginning of the drug name plays a significant role in contributing to confusion. Additionally, drug name pairs that start with the same first letter and contain a shared letter string of at least 3 letters in both names are major contributing factor in the confusion of drug names[f]. We evaluate all moderately similar names retrieved from POCA to identify the above attributes. These names are further evaluated to identify overlapping or similar strengths or doses.
    - Product attributes: Moderately similar names of products that have overlapping or similar strengths or doses represent an area for concern for FDA. The dose and strength information is often located in close proximity to the drug name itself on prescriptions and medication orders, and the information can be an important factor that either increases or decreases the potential for confusion between similarly named drug pairs. The ability of other product characteristics to mitigate confusion (e.g., route, frequency, dosage form) may be limited when the strength or dose overlaps. DMEPA reviews such names further, to determine whether sufficient differences exist to prevent confusion. (See Table 4).

- Names with low similarity that have no overlap or similarity in strength and dose are generally acceptable (See Table 5) unless there are data to suggest that the name might be vulnerable to confusion (e.g., prescription simulation study suggests that the name is likely to be misinterpreted as a marketed product). In these instances, we would reassign

[f] Shah, M, Merchant, L, Characteristics That May Help in the Identification of Potentially Confusing Proprietary Drug Names. Therapeutic Innovation & Regulatory Science, September 2016

a low similarity name to the moderate similarity category and review according to the moderately similar name pair checklist.

c. FDA Prescription Simulation Studies: DMEPA staff also conducts a prescription simulation studies using FDA health care professionals.

   Four 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, verbal pronunciation of the drug name or during computerized provider order entry. 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 vulnerability of the proposed name to be misinterpreted by healthcare practitioners during written, verbal, or electronic prescribing.

   In order to evaluate the potential for misinterpretation of the proposed proprietary name during written, verbal, or electronic prescribing of the name, written inpatient medication orders, written outpatient prescriptions, verbal orders, and electronic orders are simulated, each consisting of a combination of marketed and unapproved drug products, including the proposed name.

d. 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.

   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.

Table 3. Highly Similar Name Pair Checklist (i.e., combined Orthographic and Phonetic score is ≥ 70%).

Answer the questions in the checklist below. Affirmative answers to some of these questions suggest that the pattern of orthographic or phonetic differences in the names may render the names less likely to confusion, provided that the pair does not share a common strength or dose.			
Orthographic Checklist		Phonetic Checklist	
Y/N	Do the names begin with different first letters? *Note that even when names begin with different first letters, certain letters may be confused with each other when scripted.*	**Y/N**	Do the names have different number of syllables?
Y/N	Are the lengths of the names dissimilar* when scripted? **FDA considers the length of names different if the names differ by two or more letters.*	**Y/N**	Do the names have different syllabic stresses?
Y/N	Considering variations in scripting of some letters (such as *z* and *f*), is there a different number or placement of upstroke/downstroke letters present in the names?	**Y/N**	Do the syllables have different phonologic processes, such vowel reduction, assimilation, or deletion?
Y/N	Is there different number or placement of cross-stroke or dotted letters present in the names?	**Y/N**	Across a range of dialects, are the names consistently pronounced differently?
Y/N	Do the infixes of the name appear dissimilar when scripted?		
Y/N	Do the suffixes of the names appear dissimilar when scripted?		

Table 4: Moderately Similar Name Pair Checklist (i.e., combined score is ≥55% to ≤69%).

Step 1	Review the DOSAGE AND ADMINISTRATION and HOW SUPPLIED/STORAGE AND HANDLING sections of the prescribing information (or for OTC drugs refer to the Drug Facts label) to determine if strengths and doses of the name pair overlap or are very similar. Different strengths and doses for products whose names are moderately similar may decrease the risk of confusion between the moderately similar name pairs. Name pairs that have overlapping or similar strengths or doses have a higher potential for confusion and should be evaluated further (see Step 2). Because the strength or dose could be used to express an order or prescription for a particular drug product, overlap in one or both of these components would be reason for further evaluation. For single strength products, also consider circumstances where the strength may not be expressed. For any i.e. drug products comprised of more than one active ingredient, consider whether the strength or dose may be expressed using only one of the components. To determine whether the strengths or doses are similar to your proposed product, consider the following list of factors that may increase confusion: • Alternative expressions of dose: 5 mL may be listed in the prescribing information, but the dose may be expressed in metric weight (e.g., 500 mg) or in non-metric units (e.g., 1 tsp, 1 tablet/capsule). Similarly, a strength or dose of 1000 mg may be expressed, in practice, as 1 g, or vice versa. • Trailing or deleting zeros: 10 mg is similar in appearance to 100 mg which may potentiate confusion between a name pair with moderate similarity. • Similar sounding doses: 15 mg is similar in sound to 50 mg
Step 2	Answer the questions in the checklist below. Affirmative answers to some of these questions suggest that the pattern of orthographic or phonetic differences in the names may reduce the likelihood of confusion for moderately similar names **with** overlapping or similar strengths or doses.

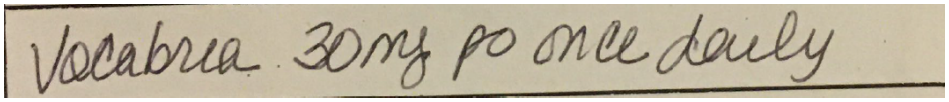
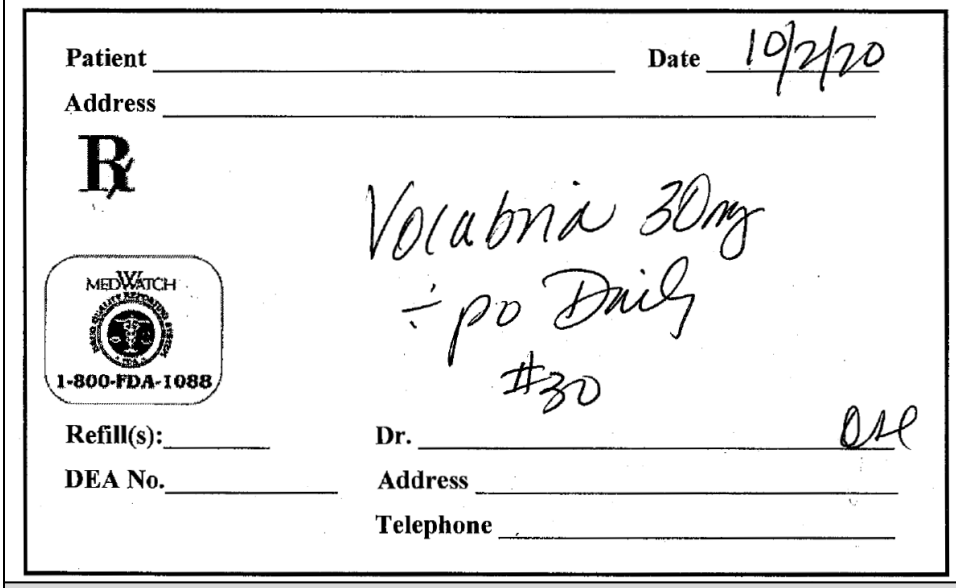
	Orthographic Checklist (Y/N to each question) • Do the names begin with different first letters? Note that even when names begin with different first letters, certain letters may be confused with each other when scripted. • Are the lengths of the names dissimilar* when scripted? *FDA considers the length of names different if the names differ by two or more letters. • Considering variations in scripting of some letters (such as *z* and *f*), is there a different number or placement of upstroke/downstroke letters present in the names? • Is there different number or placement of cross-stroke or dotted letters present in the names? • Do the infixes of the name appear dissimilar when scripted? • Do the suffixes of the names appear dissimilar when scripted?	Phonetic Checklist (Y/N to each question) • Do the names have different number of syllables? • Do the names have different syllabic stresses? • Do the syllables have different phonologic processes, such vowel reduction, assimilation, or deletion? • Across a range of dialects, are the names consistently pronounced differently?

Table 5: Low Similarity Name Pair Checklist (i.e., combined score is ≤54%).

Names with low similarity are generally acceptable unless there are data to suggest that the name might be vulnerable to confusion (e.g., prescription simulation study suggests that the name is likely to be misinterpreted as a marketed product). In these instances, we would reassign a low similarity name to the moderate similarity category and review according to the moderately similar name pair checklist.

Appendix B: Prescription Simulation Samples and Results

Figure 1. Vocabria Study (Conducted on October 2, 2020)

Handwritten Medication Order/Prescription	**Verbal Prescription**
Medication Order:  Outpatient Prescription:  	Vocabria 30 mg Take 1 tablet by mouth once daily Dispense # 30
CPOE Study Sample (displayed as sans-serif, 12-point, bold font)	
Vocabria	

FDA Prescription Simulation Responses (Aggregate Report)

209 People Received Study
77 People Responded

Study Name: Vocabria

Total	**15**	**30**	**17**	**15**	
INTERPRETATION	**OUTPATIENT**	**CPOE**	**VOICE**	**INPATIENT**	**TOTAL**
BOCAPREA	0	0	1	0	1
BOCAVRIA	0	0	1	0	1

COVABREA	0	0	0	1	1
FOCABRIA	0	0	1	0	1
OKABRIA	0	0	1	0	1
PROKABRIA	0	0	1	0	1
RILPIVIRINE[g]	0	0	0	1	1
VACABREA	0	0	0	1	1
VOCABNA	1	0	0	0	1
VOCABREA	0	0	0	11	11
VOCABRIA	7	30	9	1	47
VOCAVRIA	0	0	1	0	1
VOKABRIA	0	0	1	0	1
VOKAVRIA	0	0	1	0	1
VOLABINA	1	0	0	0	1
VOLABRIA	6	0	0	0	6

[g] Participant inadvertently entered three interpretations under the incorrect study name. Participant's actual interpretation was "Vocabrea."

Appendix C: Highly Similar Names (e.g., combined POCA score is ≥70%)

No.	**Proposed name:** Vocabria **Established name:** cabotegravir **Dosage form:** Tablets **Strength(s):** 30 mg **Usual Dose:** One tablet (30 mg) once daily	**POCA Score (%)**	**Orthographic and/or phonetic differences in the names sufficient to prevent confusion** **Other prevention of failure mode expected to minimize the risk of confusion between these two names.**
1.	Vocabria	100	Subject of review.

Appendix D: Moderately Similar Names (e.g., combined POCA score is ≥55% to ≤69%) with no overlap or numerical similarity in Strength and/or Dose

No.	Name	POCA Score (%)
1.	(b) (4)***	58

Appendix E: Moderately Similar Names (e.g., combined POCA score is ≥55% to ≤69%) with overlap or numerical similarity in Strength and/or Dose

No.	**Proposed name:** Vocabria **Established name:** cabotegravir **Dosage form:** Tablets **Strength(s):** 30 mg **Usual Dose:** One tablet (30 mg) once daily	**POCA Score (%)**	**Prevention of Failure Mode** **In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names**
1.	(b) (4)***	60	This name pair has sufficient orthographic and phonetic differences.
2.	(b) (4)***	60	This name pair has sufficient orthographic and phonetic differences.
3.	(b) (4)***	58	Orthographically, the infixes of this name pair ((b) (4) vs. 'cabr') look different. Additionally, (b) (4)*** contains the letter (b) (4) which could be written with a downstroke and afford additionally orthographic difference when scripted. Phonetically, the sounds of the rimes of the first syllables ((b) (4) vs. /o/), the sounds of the rimes of the second syllables ((b) (4)vs. /ab/), and the onsets of the third syllables ((b) (4)vs. /r/) sound different.

No.	**Proposed name:** Vocabria **Established name:** cabotegravir **Dosage form:** Tablets **Strength(s):** 30 mg **Usual Dose:** One tablet (30 mg) once daily	**POCA Score (%)**	**Prevention of Failure Mode** **In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names**
			In addition, there are differences in product characteristics that, when considered in totality may mitigate the risk of confusion between the two products, when included on a prescription. The products differ in dosage form ([(b) (4)] vs. tablet), and route of administration ([(b) (4)] vs. oral). Furthermore, Vocabria is indicated for use in specific population of patients with HIV-1, who are followed closely by their physician and require frequent blood draws and monitoring. [(b) (4)] does not require frequent monitoring or follow-up. Thus, considering the totality of factors listed above, we find the risk for name confusion is adequately minimized.
4.	[(b) (4)]***	62	Orthographically, the infixes of this name pair (cabr vs [(b) (4)]) look different. Phonetically, the second syllables of this name pair ([(b) (4)] vs. kab') sound different. The [(b) (4)] vs "r" in the third syllables sound different. [(b) (4)]*** is indicated in [(b) (4)] While both products are [(b) (4)] Vocabria has a single set dose (30 mg) while [(b) (4)] which decreases the likelihood of an overlapping dose for adult patients. The products also differ in terms of dosage form ([(b) (4)] vs. tablet), route

No.	**Proposed name:** Vocabria **Established name:** cabotegravir **Dosage form:** Tablets **Strength(s):** 30 mg **Usual Dose:** One tablet (30 mg) once daily	**POCA Score (%)**	**Prevention of Failure Mode** **In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names**
			of administration (b) (4) vs. oral) and frequency of administration (b) (4) vs. once daily), which further minimizes the potential for an error to occur when indicated on a prescription.
5.	(b) (4) ***	57	Orthographically, the first letters of this name pair (V vs (b) (4) look different. Additionally, (b) (4) *** contains the (b) (4) which affords additional orthographic difference. This name pair has sufficient phonetic differences.

Appendix F: Low Similarity Names (e.g., combined POCA score is ≤54%)

No.	Name	POCA Score (%)
1.	Rilpivirine	33

Appendix G: Names not likely to be confused or not used in usual practice settings for the reasons described.

No.	Name	POCA Score (%)	Failure preventions
1.	(b) (4) ***	56	Proposed proprietary name submitted under (b) (4) that was found unacceptable on (b) (4) Subsequently, the applicant submitted the name (b) (4)

Appendix H: Names not likely to be confused due to absence of attributes that are known to cause name confusion[h].

No.	Name	POCA Score (%)
1.	Rukobia	60
2.	Xcopri	56

[h] Shah, M, Merchant, L, Chan, I, and Taylor, K. Characteristics That May Help in the Identification of Potentially Confusing Proprietary Drug Names. Therapeutic Innovation & Regulatory Science, September 2016

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/

VALERIE S VAUGHAN
10/20/2020 04:25:24 PM

SEVAN H KOLEJIAN
10/20/2020 05:25:26 PM

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:	October 16, 2020
Application Type and Number:	NDA 212888
Product Name and Strength:	Cabenuva (cabotegravir and rilpivirine) Extended-Release Injectable Suspension
Total Product Strength:	cabotegravir 600 mg/3 mL and rilpivirine 900 mg/3 mL cabotegravir 400 mg/2 mL and rilpivirine 600 mg/2 mL
Product Type:	Multiple Ingredients, Co-packaged Product
Rx or OTC:	Prescription (Rx)
Applicant/Sponsor Name:	ViiV Healthcare Company (ViiV)
Panorama #:	2020-41714489
DMEPA Safety Evaluator:	Valerie S. Vaughan, PharmD
DMEPA Team Leader:	Sevan Kolejian, PharmD, MBA, BCPPS

Contents

1 INTRODUCTION

This review is to reassess the proposed proprietary name, Cabenuva, from a safety and misbranding perspective. The sources and methods used to evaluate the proposed proprietary name are outlined in the reference section and Appendix A, respectively.

ViiV submitted an external name study dated May 30, 2018, conducted by (b) (4) ((b) (4) which was previously reviewed for this proposed proprietary name.

1.1 REGULATORY HISTORY

The proposed proprietary name, Cabenuva, was found conditionally acceptable under IND 109678 on January 29, 2019[a] and under NDA 212888 on June 20, 2019[b]. However, the application received a Complete Response from the Agency on December 19, 2019. Thus, ViiV responded to the Complete Response and re-submitted the name, Cabenuva, under NDA 212888 for review on July 28, 2020.

1.2 PRODUCT INFORMATION

The following product information is provided in the proprietary name submission received on July 28, 2020.

- Intended Pronunciation: kah ben' ue vah
- Active Ingredient: cabotegravir and rilpivirine
- Indication of Use: Indicated as a complete regimen for the treatment of HIV-1 infection in adults to replace the current antiretroviral regimen in those patients who meet all of the following conditions:
    - are virologically-suppressed (HIV-1 RNA less than 50 copies per mL);
    - have no known substitutions associated with resistance to either cabotegravir or rilpivirine.
- Route of Administration: Intramuscular
- Dosage Form: Extended-Release Injectable Suspension
- Strength:
    - cabotegravir 600 mg/3 mL and rilpivirine 900 mg/3 mL
    - cabotegravir 400 mg/2 mL and rilpivirine 600 mg/2 mL

---

[a] Wilson, V. Proprietary Name Review for Cabenuva (IND 109678). Silver Spring (MD): FDA, CDER, OSE, DMEPA (US); 2019 JAN 29. Panorama No.: 2018-25117225.

[b] Wilson, V. Proprietary Name Review for Cabenuva (NDA 212888). Silver Spring (MD): FDA, CDER, OSE, DMEPA (US); 2019 JUN 20. Panorama No.: 2019-31379724.

- Dose and Frequency: once monthly injections following oral cabotegravir and rilpivirine lead-in dosing

cabotegravir 600 mg/3 mL and rilpivirine 900 mg/3 mL	Administer a single 600 mg (3 mL from 1 vial) IM injection of cabotegravir and a single 900 mg (3 mL from 1 vial) IM injection of rilpivirine on the last day of oral lead-in dosing (Day1).
cabotegravir 400 mg/2 mL and rilpivirine 600 mg/2 mL	Administer a single 400 mg (2 mL from 1 vial) IM injection of cabotegravir and a single 600 mg (2 mL from 1 vial) IM injection of rilpivirine starting one month after 3 mL injection and monthly thereafter.

- How Supplied: Cabenuva is supplied as two kits containing:
    - One single-dose vial of cabotegravir 600 mg/3 mL, one single-dose vial of rilpivirine 900 mg/3 mL, two single-use 5 mL Luer-lock syringes, two vial adapters, and two single-use 23-guage, 1.5 inch safety needles for injection
    - One single-dose vial of cabotegravir 400 mg/2 mL, one single-dose vial of rilpivirine 600 mg/2 mL, two single-use 5 mL Luer-lock syringes, two vial adapters, and two single-use 23-guage, 1.5 inch safety needles for injection
- Storage: Store at 2°C to 8°C. Do not freeze.

2 RESULTS

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

2.1 MISBRANDING ASSESSMENT

The Office of Prescription Drug Promotion (OPDP) determined that Cabenuva would not misbrand the proposed product. The Division of Medication Error Prevention and Analysis (DMEPA) and the Division of Antivirals (DAV) concurred with the findings of OPDP's assessment for Cabenuva.

2.2 SAFETY ASSESSMENT

The following aspects were considered in the safety evaluation of the proposed proprietary name, Cabenuva.

2.2.1 United States Adopted Names (USAN) Search

There is no USAN stem present in the proposed proprietary name[c].

2.2.2 Components of the Proposed Proprietary Name

ViiV did not provide a derivation or intended meaning for the proposed proprietary name, Cabenuva, in their submission. This proprietary name is comprised of a single word that does not contain any components (i.e. a modifier, route of administration, dosage form, etc.) that are misleading or can contribute to medication error.

2.2.3 Comments from Other Review Disciplines at Initial Review

In response to the OSE, August 11, 2020 e-mail, the Division of Antivirals (DAV) did not forward any comments or concerns relating to Cabenuva at the initial phase of the review.

2.2.4 FDA Name Simulation Studies

Eighty practitioners participated in DMEPA's prescription studies for Cabenuva. One computerized physician order entry (CPOE) study participant identified "Cavirinse" for Cabenuva. Cavirinse is a sodium fluoride oral rinse. It appears that this participant incorrectly typed the letters 'c-a-v' instead of 'c-a-b' when searching for the study name. As a result, the CPOE generated a pick list that did not contain Cabenuva as a choice. The participant proceeded to select the name Cavirinse from a list of names that contained the letters c-a-v. Thus, in this case, it appears the participant attempted to select an answer that was closest to the response needed given the goal of the simulated study. We assessed the name pair, Cabenuva and Cavirinse, and determined that this name pair can safely coexist on the market because there are sufficient orthographic and phonetic differences between the names (see Appendix E).

Appendix B contains the results from the prescription simulation studies.

2.2.5 Phonetic and Orthographic Computer Analysis (POCA) Search Results

Our POCA search[d] identified 62 names with the combined score of ≥55% or individual orthographic or phonetic score of ≥70%. We had identified and evaluated some of the names in our previous proprietary name review. 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 name. We note that none of the product characteristics have changed and we agree with the findings from our previous review for the names evaluated previously. Therefore, we identified two names not previously analyzed. These names are included in Table 1 below.

[c] USAN stem search conducted on September 18, 2020.

[d] POCA search conducted on September 18, 2020 in version 4.4.

2.2.6 Names Retrieved for Review Organized by Name Pair Similarity

Table 1 lists the number of names retrieved from our POCA search and FDA Prescription Simulation Study. These name pairs are organized as highly similar, moderately similar or low similarity for further evaluation.

Table 1. Names Retrieved for Review Organized by Name Pair Similarity

Similarity Category	Number of Names
Highly similar name pair: combined match percentage score ≥70%	0
Moderately similar name pair: combined match percentage score ≥55% to ≤ 69%	3
Low similarity name pair: combined match percentage score ≤54%	0

2.2.7 Safety Analysis of Names with Potential Orthographic, Spelling, and Phonetic Similarities

Our analysis of the three names contained in Table 1 determined neither of the names will pose a risk for confusion with Cabenuva as described in Appendices C through H.

2.2.8 Communication of DMEPA's Analysis at Midpoint of Review

DMEPA communicated our findings to the Division of Antivirals (DAV) via e-mail on October 16, 2020. At that time we also requested additional information or concerns that could inform our review. Per e-mail correspondence from the Division of Antivirals (DAV) on October 16, 2020, they stated no additional concerns with the proposed proprietary name, Cabenuva.

3 CONCLUSION

The proposed proprietary name, Cabenuva, is acceptable.

If you have any questions or need clarifications, please contact Mammah Borbor, OSE project manager, at 301-796-7731.

3.1 COMMENTS TO VIIV HEALTHCARE COMPANY

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

If any of the proposed product characteristics as stated in your submission, received on July 28, 2020, are altered prior to approval of the marketing application, the name must be resubmitted for review.

4 REFERENCES

1. USAN Stems (https://www.ama-assn.org/about/united-states-adopted-names-approved-stems)

USAN Stems List contains all the recognized USAN stems.

2. 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.

Drugs@FDA

Drugs@FDA is an FDA Web site that contains most of the drug products approved in the United States 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* and *generic drugs*; *therapeutic biological products*, *prescription* and *over-the-counter* human drugs; and *discontinued drugs* (see Drugs @ FDA Glossary of Terms, available at http://www.fda.gov/Drugs/InformationOnDrugs/ucm079436.htm#ther_biological).

RxNorm

RxNorm contains the names of prescription and many OTC drugs available in the United States. RxNorm includes generic and branded:

- Clinical drugs – pharmaceutical products given to (or taken by) a patient with therapeutic or diagnostic intent
- Drug packs – packs that contain multiple drugs, or drugs designed to be administered in a specified sequence

Radiopharmaceuticals, contrast media, food, dietary supplements, and medical devices, such as bandages and crutches, are all out of scope for RxNorm (http://www.nlm.nih.gov/research/umls/rxnorm/overview.html).

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.

APPENDICES

Appendix A

FDA's Proprietary Name Risk Assessment evaluates proposed proprietary names for misbranding and safety concerns.

1. **Misbranding Assessment**: For prescription drug products, OPDP assesses the name for misbranding concerns. For over-the-counter (OTC) drug products, the misbranding assessment of the proposed name is conducted by DNDP. OPDP or DNDP evaluates proposed proprietary names to determine if the name is false or misleading, such as by making misrepresentations with respect to safety or efficacy. For example, a fanciful proprietary name may misbrand a product by suggesting that it has some unique effectiveness or composition when it does not (21 CFR 201.10(c)(3)). OPDP or DNDP provides their opinion to DMEPA for consideration in the overall acceptability of the proposed proprietary name.
2. **Safety Assessment**: The safety assessment is conducted by DMEPA, and includes the following:

a. Preliminary Assessment: 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.) See prescreening checklist below in Table 2*. 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. [e]

[e] National Coordinating Council for Medication Error Reporting and Prevention. http://www nccmerp.org/aboutMedErrors html. Last accessed 10/11/2007.

***Table 2- Prescreening Checklist for Proposed Proprietary Name**

	Answer the questions in the checklist below. Affirmative answers to any of these questions indicate a potential area of concern that should be carefully evaluated as described in this guidance.
Y/N	**Is the proposed name obviously similar in spelling and pronunciation to other names?**
	Proprietary names should not be similar in spelling or pronunciation to proprietary names, established names, or ingredients of other products.
Y/N	**Are there inert or inactive ingredients referenced in the proprietary name?**
	Proprietary names should not incorporate any reference to an inert or inactive ingredient in a way that might create an impression that the ingredient's value is greater than its true functional role in the formulation (21 CFR 201.10(c)(4)).
Y/N	**Does the proprietary name include combinations of active ingredients?**
	Proprietary names of fixed combination drug products should not include or suggest the name of one or more, but not all, of its active ingredients (see 21 CFR 201.6(b)).
Y/N	**Is there a United States Adopted Name (USAN) stem in the proprietary name?**
	Proprietary names should not incorporate a USAN stem in the position that USAN designates for the stem.
Y/N	**Is this proprietary name used for another product that does not share at least one common active ingredient?**
	Drug products that do not contain at least one common active ingredient should not use the same (root) proprietary name.
Y/N	**Is this a proprietary name of a discontinued product?**
	Proprietary names should not use the proprietary name of a discontinued product if that discontinued drug product does not contain the same active ingredients.

b. Phonetic and Orthographic Computer Analysis (POCA): Following the preliminary screening of the proposed proprietary name, DMEPA staff evaluates the proposed name against potentially similar names. In order to identify names with potential similarity to the proposed proprietary name, DMEPA enters the proposed proprietary name in POCA and queries the name against the following drug reference databases, Drugs@fda, CernerRxNorm, and names in the review pipeline using a 55% threshold in POCA. DMEPA reviews the combined orthographic and phonetic matches and group the names into one of the following three categories:

- Highly similar pair: combined match percentage score ≥70%.
- Moderately similar pair: combined match percentage score ≥55% to ≤ 69%.

- Low similarity: combined match percentage score ≤54%.

Using the criteria outlined in the check list (Table 3-5) that corresponds to each of the three categories (highly similar pair, moderately similar pair, and low similarity), DMEPA evaluates the name pairs to determine the acceptability or non-acceptability of a proposed proprietary name. The intent of these checklists is to increase the transparency and predictability of the safety determination of whether a proposed name is vulnerable to confusion from a look-alike or sound-alike perspective. Each bullet below corresponds to the name similarity category cross-references the respective table that addresses criteria that DMEPA uses to determine whether a name presents a safety concern from a look-alike or sound-alike perspective.

- For highly similar names, differences in product characteristics often cannot mitigate the risk of a medication error, including product differences such as strength and dose. Thus, proposed proprietary names that have a combined score of ≥ 70 percent are at risk for a look-alike sound-alike confusion which is an area of concern (See Table 3).
- Moderately similar names are further evaluated to identify the presence of attributes that are known to cause name confusion.
    - Name attributes: We note that the beginning of the drug name plays a significant role in contributing to confusion. Additionally, drug name pairs that start with the same first letter and contain a shared letter string of at least 3 letters in both names are major contributing factor in the confusion of drug names[f]. We evaluate all moderately similar names retrieved from POCA to identify the above attributes. These names are further evaluated to identify overlapping or similar strengths or doses.
    - Product attributes: Moderately similar names of products that have overlapping or similar strengths or doses represent an area for concern for FDA. The dose and strength information is often located in close proximity to the drug name itself on prescriptions and medication orders, and the information can be an important factor that either increases or decreases the potential for confusion between similarly named drug pairs. The ability of other product characteristics to mitigate confusion (e.g., route, frequency, dosage form) may be limited when the strength or dose overlaps. DMEPA reviews such names further, to determine whether sufficient differences exist to prevent confusion. (See Table 4).

- Names with low similarity that have no overlap or similarity in strength and dose are generally acceptable (See Table 5) unless there are data to suggest that the name might be vulnerable to confusion (e.g., prescription simulation study suggests that the name is likely to be misinterpreted as a marketed product). In these instances, we would reassign

[f] Shah, M, Merchant, L, Characteristics That May Help in the Identification of Potentially Confusing Proprietary Drug Names. Therapeutic Innovation & Regulatory Science, September 2016

a low similarity name to the moderate similarity category and review according to the moderately similar name pair checklist.

c. FDA Prescription Simulation Studies: DMEPA staff also conducts a prescription simulation studies using FDA health care professionals.

   Four 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, verbal pronunciation of the drug name or during computerized provider order entry. 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 vulnerability of the proposed name to be misinterpreted by healthcare practitioners during written, verbal, or electronic prescribing.

   In order to evaluate the potential for misinterpretation of the proposed proprietary name during written, verbal, or electronic prescribing of the name, written inpatient medication orders, written outpatient prescriptions, verbal orders, and electronic orders are simulated, each consisting of a combination of marketed and unapproved drug products, including the proposed name.

d. 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.

   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.

Table 3. Highly Similar Name Pair Checklist (i.e., combined Orthographic and Phonetic score is ≥ 70%).

Answer the questions in the checklist below. Affirmative answers to some of these questions suggest that the pattern of orthographic or phonetic differences in the names may render the names less likely to confusion, provided that the pair does not share a common strength or dose.			
Orthographic Checklist		Phonetic Checklist	
Y/N	Do the names begin with different first letters? *Note that even when names begin with different first letters, certain letters may be confused with each other when scripted.*	**Y/N**	Do the names have different number of syllables?
Y/N	Are the lengths of the names dissimilar* when scripted? **FDA considers the length of names different if the names differ by two or more letters.*	**Y/N**	Do the names have different syllabic stresses?
Y/N	Considering variations in scripting of some letters (such as *z* and *f*), is there a different number or placement of upstroke/downstroke letters present in the names?	**Y/N**	Do the syllables have different phonologic processes, such vowel reduction, assimilation, or deletion?
Y/N	Is there different number or placement of cross-stroke or dotted letters present in the names?	**Y/N**	Across a range of dialects, are the names consistently pronounced differently?
Y/N	Do the infixes of the name appear dissimilar when scripted?		
Y/N	Do the suffixes of the names appear dissimilar when scripted?		

Table 4: Moderately Similar Name Pair Checklist (i.e., combined score is ≥55% to ≤69%).

Step 1	Review the DOSAGE AND ADMINISTRATION and HOW SUPPLIED/STORAGE AND HANDLING sections of the prescribing information (or for OTC drugs refer to the Drug Facts label) to determine if strengths and doses of the name pair overlap or are very similar. Different strengths and doses for products whose names are moderately similar may decrease the risk of confusion between the moderately similar name pairs. Name pairs that have overlapping or similar strengths or doses have a higher potential for confusion and should be evaluated further (see Step 2). Because the strength or dose could be used to express an order or prescription for a particular drug product, overlap in one or both of these components would be reason for further evaluation. For single strength products, also consider circumstances where the strength may not be expressed. For any i.e. drug products comprised of more than one active ingredient, consider whether the strength or dose may be expressed using only one of the components. To determine whether the strengths or doses are similar to your proposed product, consider the following list of factors that may increase confusion: • Alternative expressions of dose: 5 mL may be listed in the prescribing information, but the dose may be expressed in metric weight (e.g., 500 mg) or in non-metric units (e.g., 1 tsp, 1 tablet/capsule). Similarly, a strength or dose of 1000 mg may be expressed, in practice, as 1 g, or vice versa. • Trailing or deleting zeros: 10 mg is similar in appearance to 100 mg which may potentiate confusion between a name pair with moderate similarity. • Similar sounding doses: 15 mg is similar in sound to 50 mg
Step 2	Answer the questions in the checklist below. Affirmative answers to some of these questions suggest that the pattern of orthographic or phonetic differences in the names may reduce the likelihood of confusion for moderately similar names **with** overlapping or similar strengths or doses.

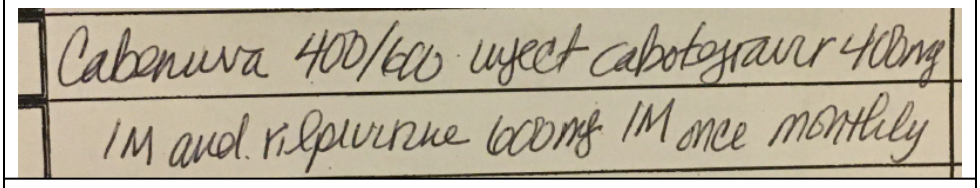
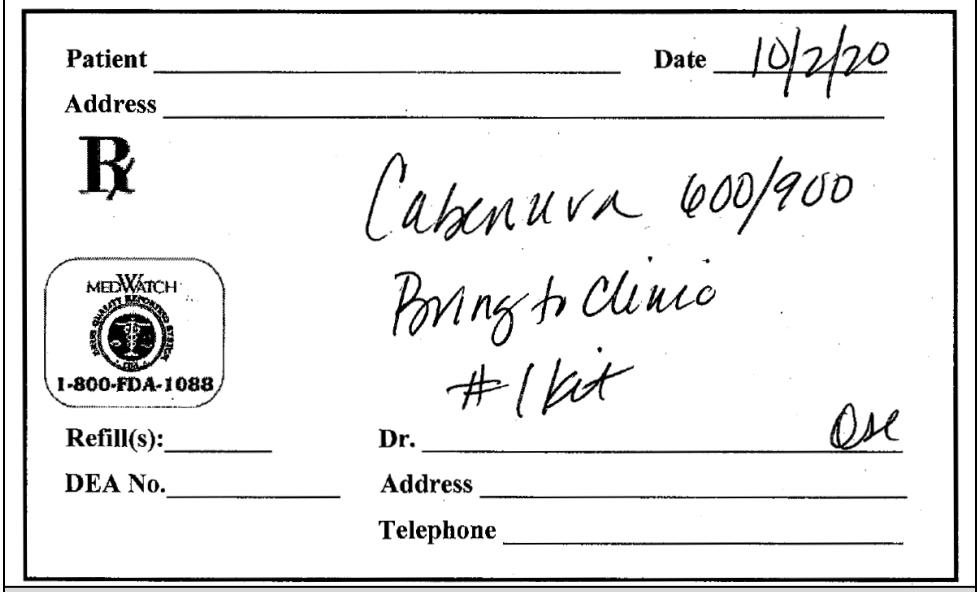
	Orthographic Checklist (Y/N to each question) • Do the names begin with different first letters? Note that even when names begin with different first letters, certain letters may be confused with each other when scripted. • Are the lengths of the names dissimilar* when scripted? *FDA considers the length of names different if the names differ by two or more letters. • Considering variations in scripting of some letters (such as *z* and *f*), is there a different number or placement of upstroke/downstroke letters present in the names? • Is there different number or placement of cross-stroke or dotted letters present in the names? • Do the infixes of the name appear dissimilar when scripted? • Do the suffixes of the names appear dissimilar when scripted?	Phonetic Checklist (Y/N to each question) • Do the names have different number of syllables? • Do the names have different syllabic stresses? • Do the syllables have different phonologic processes, such vowel reduction, assimilation, or deletion? • Across a range of dialects, are the names consistently pronounced differently?

Table 5: Low Similarity Name Pair Checklist (i.e., combined score is ≤54%).

Names with low similarity are generally acceptable unless there are data to suggest that the name might be vulnerable to confusion (e.g., prescription simulation study suggests that the name is likely to be misinterpreted as a marketed product). In these instances, we would reassign a low similarity name to the moderate similarity category and review according to the moderately similar name pair checklist.

Appendix B: Prescription Simulation Samples and Results

Figure 1. Cabenuva Study (Conducted on October 2, 2020)

Handwritten Medication Order/Prescription	**Verbal Prescription**
Medication Order:  Outpatient Prescription:  	Cabenuva 600/900 Bring to clinic Dispense #1 kit
CPOE Study Sample (displayed as sans-serif, 12-point, bold font)	
Cabenuva	

FDA Prescription Simulation Responses (Aggregate Report)

209 People Received Study
80 People Responded

Study Name: Cabenuva

Total	16	30	19	15	
INTERPRETATION	**OUTPATIENT**	**CPOE**	**VOICE**	**INPATIENT**	**TOTAL**
CABENDIVA 600/900	0	0	1	0	1
CABENIVA	0	0	1	0	1
CABENJA	0	0	1	0	1
CABENNUVA	0	0	1	0	1
CABENUCA	0	0	1	0	1
CABENURA	4	0	0	0	4
CABENUVA	11	29	7	15	62
CABENUVA 600/900	1	0	0	0	1
CAPENUBA	0	0	1	0	1
CAPENUVA	0	0	2	0	2
CAVIRINSE	0	1	0	0	1
KABENIVA	0	0	1	0	1
KABENUBA	0	0	1	0	1
KABENUVA	0	0	2	0	2

Appendix C: Highly Similar Names (e.g., combined POCA score is ≥70%)

No.	**Proposed name:** Cabenuva **Established name:** cabotegravir and rilpivirine **Dosage form:** Extended-Release Injectable Suspension **Strength(s):** cabotegravir 600 mg/3 mL and rilpivirine 900 mg/3 mL cabotegravir 400 mg/2 mL and rilpivirine 600 mg/2 mL **Usual Dose:** Administer a single 600 mg IM injection of cabotegravir and a single 900 mg IM injection of rilpivirine on the last day of oral lead-in dosing; followed by a single 400mg IM injection of cabotegravir and a single 600mg IM injection of rilpivirine starting one month after initial injection and once monthly thereafter.	**POCA Score (%)**	**Orthographic and/or phonetic differences in the names sufficient to prevent confusion** **Other prevention of failure mode expected to minimize the risk of confusion between these two names.**
	N/A		

Appendix D: Moderately Similar Names (e.g., combined POCA score is ≥55% to ≤69%) with no overlap or numerical similarity in Strength and/or Dose

No.	Name	POCA Score (%)
1.	(b) (4) ***	56

Appendix E: Moderately Similar Names (e.g., combined POCA score is ≥55% to ≤69%) with overlap or numerical similarity in Strength and/or Dose

No.	**Proposed name:** Cabenuva **Established name:** cabotegravir and rilpivirine **Dosage form:** Extended-Release Injectable Suspension **Strength(s):** cabotegravir 600 mg/3 mL and rilpivirine 900 mg/3 mL cabotegravir 400 mg/2 mL and rilpivirine 600 mg/2 mL **Usual Dose:** Administer a single 600 mg IM injection of cabotegravir and a single 900 mg IM injection of rilpivirine on the last day of oral lead-in dosing; followed by a single 400mg IM injection of cabotegravir and a single 600mg IM injection of rilpivirine starting one month after initial injection and once monthly thereafter.	**POCA Score (%)**	**Prevention of Failure Mode** **In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names**
2.	(b) (4) ***	55	This name pair has sufficient orthographic and phonetic differences.
3.	Cavirinse	52	This name pair has sufficient orthographic and phonetic differences.

Appendix F: Low Similarity Names (e.g., combined POCA score is ≤54%)

No.	Name	POCA Score (%)
	N/A	

Appendix G: Names not likely to be confused or not used in usual practice settings for the reasons described**.**

No.	Name	POCA Score (%)	Failure preventions
	N/A		

Appendix H: Names not likely to be confused due to absence of attributes that are known to cause name confusion[g].

No.	Name	POCA Score (%)
	N/A	

[g] Shah, M, Merchant, L, Chan, I, and Taylor, K. Characteristics That May Help in the Identification of Potentially Confusing Proprietary Drug Names. Therapeutic Innovation & Regulatory Science, September 2016

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/

VALERIE S VAUGHAN
10/16/2020 01:32:00 PM

SEVAN H KOLEJIAN
10/16/2020 10:23:21 PM