

**CENTER FOR DRUG EVALUATION AND  
RESEARCH**

*APPLICATION NUMBER:*

**209128Orig1s000**

**PROPRIETARY NAME REVIEW(S)**

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**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\*\*\***

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<b>Date of This Review:</b>	July 9, 2018
<b>Application Type and Number:</b>	NDA 209128
<b>Product Name and Strength:</b>	Dsuvia (Sufentanil) sublingual tablet 30 mcg
<b>Product Type:</b>	Single-Ingredient Combination Product
<b>Rx or OTC:</b>	Rx
<b>Applicant/Sponsor Name:</b>	AcelRx
<b>Panorama #:</b>	2018-22853202
<b>DMEPA Safety Evaluator:</b>	James Schlick, RPh, MBA
<b>DMEPA Team Leader:</b>	Otto L. Townsend, PharmD

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## 1 INTRODUCTION

This review evaluates the proposed proprietary name, Dsuvia, from a safety and misbranding perspective. The sources and methods used to evaluate the proposed name are outlined in the reference section and Appendix A respectively. The Applicant resubmitted an external name study conducted by [REDACTED] <sup>(b) (4)</sup>, previously reviewed by DMEPA, for this proposed proprietary name.

### 1.1 REGULATORY HISTORY

The Applicant previously submitted the proposed proprietary name, Dsuvia \*\*\* on January 9, 2017 under NDA 209128, and The Division of Medication Error Prevention and Analysis (DMEPA) found the name, Dsuvia\*\*\* acceptable.<sup>a</sup> However, the application was issued a Complete Response. As part of the resubmission of the NDA, the Sponsor submitted a request for re-review of the proprietary name on May 3, 2018.

### 1.2 PRODUCT INFORMATION

The following product information is provided in the proprietary name submission received on May 3, 2018.

- Intended Pronunciation: D sú via
- Indication of Use: Management of acute moderate-to-severe pain in adult patients in a medically supervised setting.
- Route of Administration: sublingual
- Dosage Form: sublingual tablet
- Strength: 30 mcg
- Dose and Frequency: 1 tablet every 1 hour as needed administered by a health care professional; maximum of 12 tablets in a 24-hour period.
- How Supplied: One tablet packaged in a single dose applicator placed in a laminate foil pouch.
- Storage: Room temperature

## 2 RESULTS

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

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<sup>a</sup> Schlick, J. Proprietary Name Review for Dsuvia IND 209128. Silver Spring (MD): FDA, CDER, OSE, DMEPA (US); 2017 Mar 7. RCM No.: 2017-12442783.

## **2.1 MISBRANDING ASSESSMENT**

The Office of Prescription Drug Promotion (OPDP) determined that the proposed name would not misbrand the proposed product. The Division of Medication Error Prevention and Analysis (DMEPA) and the Division of Anesthesia, Analgesia, and Addiction Products (DAAAP) concurred with the findings of OPDP's 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 proprietary name<sup>b</sup>.

### ***2.2.2 Components of the Proposed Proprietary Name***

The Applicant did not provide a derivation or intended meaning for the proposed name, Dsuvia, 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, May 23, 2018 e-mail, the Division of Anesthesia, Analgesia, and Addiction Products (DAAAP) did not forward any comments or concerns relating to the proposed proprietary name at the initial phase of the review.

### ***2.2.4 FDA Name Simulation Studies***

Fifty-five practitioners participated in DMEPA's prescription studies. The responses did not overlap with any currently marketed products nor did the responses sound or look similar to any currently marketed products or any products in the pipeline. Appendix B contains the results from the verbal and written prescription studies.

### ***2.2.5 Phonetic and Orthographic Computer Analysis (POCA) Search Results***

Our POCA search<sup>c</sup> identified 26 names with the combined score of  $\geq 55\%$  or individual orthographic or phonetic score of  $\geq 70\%$ . 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 9 names not previously analyzed. These names are included in Table 1 below.

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<sup>b</sup> USAN stem search conducted on May 17, 2018

<sup>c</sup> POCA search conducted on May 15, 2018 in version 4.2.

### 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 the (b) (4) external study. These name pairs are organized as highly similar, moderately similar or low similarity for further evaluation.

Table 1. Similarity Category	Number of Names
Highly similar name pair: combined match percentage score $\geq 70\%$	1
Moderately similar name pair: combined match percentage score $\geq 55\%$ to $\leq 69\%$	6
Low similarity name pair: combined match percentage score $\leq 54\%$	2

### 2.2.7 Communication of DMEPA's Analysis at Midpoint of Review

DMEPA communicated our findings to the Division of Anesthesia, Analgesia, and Addiction Products (DAAAP) via e-mail on July 2, 2018. At that time we also requested additional information or concerns that could inform our review. Per e-mail correspondence from DAAAP on July 9, 2018, they stated no additional concerns with the proposed proprietary name, Dsuvia.

## 3 CONCLUSION

The proposed proprietary name is acceptable.

If you have any questions or need clarifications, please contact Corwin Howard, OSE project manager, at 240-402-8654.

### 3.1 COMMENTS TO THE APPLICANT

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

If any of the proposed product characteristics as stated in your submission, received on May 3, 2018, are altered prior to approval of the marketing application, the name must be resubmitted for review.

## 4 REFERENCES

1. **USAN Stems** (<http://www.ama-assn.org/ama/pub/physician-resources/medical-science/united-states-adopted-names-council/naming-guidelines/approved-stems.page>)

USAN Stems List contains all the recognized USAN stems.

### **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](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.<sup>d</sup>

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<sup>d</sup> 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.
<b>Y/N</b>	<b>Is the proposed name obviously similar in spelling and pronunciation to other names?</b>
	Proprietary names should not be similar in spelling or pronunciation to proprietary names, established names, or ingredients of other products.
<b>Y/N</b>	<b>Are there inert or inactive ingredients referenced in the proprietary name?</b>
	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)).
<b>Y/N</b>	<b>Does the proprietary name include combinations of active ingredients?</b>
	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)).
<b>Y/N</b>	<b>Is there a United States Adopted Name (USAN) stem in the proprietary name?</b>
	Proprietary names should not incorporate a USAN stem in the position that USAN designates for the stem.
<b>Y/N</b>	<b>Is this proprietary name used for another product that does not share at least one common active ingredient?</b>
	Drug products that do not contain at least one common active ingredient should not use the same (root) proprietary name.
<b>Y/N</b>	<b>Is this a proprietary name of a discontinued product?</b>
	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  $\geq 70\%$ .
  - Moderately similar pair: combined match percentage score  $\geq 55\%$  to  $\leq 69\%$ .
  - Low similarity: combined match percentage score  $\leq 54\%$ .

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  $\geq 70$  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<sup>e</sup>. 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 a low similarity name to the moderate similarity category and review according to the moderately similar name pair checklist.

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<sup>e</sup> Shah, M, Merchant, L, Characteristics That May Help in the Identification of Potentially Confusing Proprietary Drug Names. Therapeutic Innovation & Regulatory Science, September 2016

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

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.

- 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  $\geq 70\%$ ).**

<p>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.</p>			
<u>Orthographic Checklist</u>		<u>Phonetic Checklist</u>	
<b>Y/N</b>	<p>Do the names begin with different first letters?</p> <p><i>Note that even when names begin with different first letters, certain letters may be confused with each other when scripted.</i></p>	<b>Y/N</b>	<p>Do the names have different number of syllables?</p>
<b>Y/N</b>	<p>Are the lengths of the names dissimilar* when scripted?</p> <p><i>*FDA considers the length of names different if the names differ by two or more letters.</i></p>	<b>Y/N</b>	<p>Do the names have different syllabic stresses?</p>
<b>Y/N</b>	<p>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?</p>	<b>Y/N</b>	<p>Do the syllables have different phonologic processes, such as vowel reduction, assimilation, or deletion?</p>
<b>Y/N</b>	<p>Is there different number or placement of cross-stroke or dotted letters present in the names?</p>	<b>Y/N</b>	<p>Across a range of dialects, are the names consistently pronounced differently?</p>
<b>Y/N</b>	<p>Do the infixes of the name appear dissimilar when scripted?</p>		
<b>Y/N</b>	<p>Do the suffixes of the names appear dissimilar when scripted?</p>		

**Table 4: Moderately Similar Name Pair Checklist (i.e., combined score is  $\geq 55\%$  to  $\leq 69\%$ ).**

<p>Step 1</p>	<p>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.</p> <p>For single strength products, also consider circumstances where the strength may not be expressed.</p> <p>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.</p> <p>To determine whether the strengths or doses are similar to your proposed product, consider the following list of factors that may increase confusion:</p> <ul style="list-style-type: none"> <li>• 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.</li> <li>• Trailing or deleting zeros: 10 mg is similar in appearance to 100 mg which may potentiate confusion between a name pair with moderate similarity.</li> <li>• Similar sounding doses: 15 mg is similar in sound to 50 mg</li> </ul>
<p>Step 2</p>	<p>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 <b>with</b> overlapping or similar strengths or doses.</p>

	<p>Orthographic Checklist (Y/N to each question)</p> <ul style="list-style-type: none"> <li>• 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.</li> <li>• 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.</li> <li>• Considering variations in scripting of some letters (such as <i>z</i> and <i>f</i>), is there a different number or placement of upstroke/downstroke letters present in the names?</li> <li>• Is there different number or placement of cross-stroke or dotted letters present in the names?</li> <li>• Do the infixes of the name appear dissimilar when scripted?</li> <li>• Do the suffixes of the names appear dissimilar when scripted?</li> </ul>	<p>Phonetic Checklist (Y/N to each question)</p> <ul style="list-style-type: none"> <li>• Do the names have different number of syllables?</li> <li>• Do the names have different syllabic stresses?</li> <li>• Do the syllables have different phonologic processes, such as vowel reduction, assimilation, or deletion?</li> <li>• Across a range of dialects, are the names consistently pronounced differently?</li> </ul>
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**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. Dsuvia Study (Conducted on May 18, 2018)**

Handwritten Medication Order/Prescription	Verbal Prescription
<p>Medication Order:</p> <p><i>Dsuvia one tab under the tongue every hr. <sup>pr</sup> pain</i></p>	<p>Dsuvia</p> <p>One tablet under the tongue every hour as needed for pain.</p>
<p>Outpatient Prescription:</p> <p><i>Dsuvia</i></p> <p><i>One tab under the tongue every hour as needed for pain Disp. #3</i></p>	<p>Disp# 3</p>

**FDA Prescription Simulation Responses (Aggregate 1 Rx Studies Report)**

309 People Received Study  
55 People Responded

Study Name: Dsuvia

<b>Total</b>	<b>17</b>	<b>18</b>	<b>20</b>	
<b>INTERPRETATION</b>	<b>OUTPATIENT</b>	<b>VOICE</b>	<b>INPATIENT</b>	<b>TOTAL</b>
DASUVEA	0	1	0	1
DASUVIA	0	2	0	2
DAUVIA	2	0	0	2
DESUVEA	0	1	0	1
DESUVIA	0	7	0	7
DESUVYIA	0	1	0	1
DISUVIA	0	1	0	1
DISZUVIA	0	1	0	1
DRUVIA	0	0	2	2
DSUIRA	0	0	12	12
DSURA	0	0	2	2
DSURIA	0	0	1	1
DSUVIA	14	0	2	16
DUSIVIA	0	1	0	1
DUSUVIA	0	2	0	2
DYSUVIA	0	1	0	1
ISUVIA	1	0	0	1
OSUIRA	0	0	1	1

**Appendix C:** Highly Similar Names (e.g., combined POCA score is  $\geq 70\%$ )

No.	Proposed name: Dsuvia Established name: sufentanil Dosage form: sublingual tablets Strength: 30 mcg Usual Dose: 1 sublingual tablet once every hour as needed for pain in a medically supervised setting	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.	Dsuvia ***	100	Proprietary name that is the subject of this review

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

No.	Name	POCA Score (%)
2.	(b) (4) ***	61
3.	Buvaya ***	55
4.	(b) (4) ***	54

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

No.	Proposed name: Dsuvia Established name: sufentanil Dosage form: sublingual tablets Strength: 30 mcg Usual Dose: 1 sublingual tablet once every hour as needed for pain in a medically supervised setting	POCA Score (%)	Prevention of Failure Mode
5.	(b) (4) ***	56	In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names  This name pair has sufficient orthographic and phonetic differences.

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\*\*\* This document contains proprietary information that cannot be released to the public\*\*\*

**Appendix F:** Low Similarity Names (e.g., combined POCA score is  $\leq 54\%$ )

No.	Name	POCA Score (%)
6.	N/A	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
7.	(b) (4)***	61	Name identified in Names Entered by Safety Evaluator database. Unable to find product characteristics in internal databases.
8.	Duvadilan	54	International product marketed in the United Kingdom, Australia, and India.

**Appendix H:** Names not likely to be confused due to absence of attributes that are known to cause name confusion<sup>f</sup>.

No.	Name	POCA Score (%)
9.	(b) (4)***	62
10.	Edsivo***	60

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<sup>f</sup> 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

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**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.**  
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/s/  
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JAMES H SCHLICK  
07/09/2018

OTTO L TOWNSEND  
07/09/2018

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**PROPRIETARY NAME REVIEW**

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<b>Rx or OTC:</b>	Rx
<b>Applicant/Sponsor Name:</b>	AcelRx
<b>Panorama #:</b>	2017-12442783
<b>DMEPA Primary Reviewer:</b>	James Schlick, RPh, MBA
<b>DMEPA Team Leader:</b>	Vicky Borders-Hemphill, PharmD
<b>DMEPA Deputy Director (Acting):</b>	Danielle Harris, PharmD, BCPS

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## 1 INTRODUCTION

This review evaluates the proposed proprietary name, Dsuvia, from a safety and misbranding perspective. The sources and methods used to evaluate the proposed name are outlined in the reference section and Appendix A respectively. The Applicant submitted an external name study, conducted by (b) (4) for this product.

### 1.1 REGULATORY HISTORY

The Applicant previously submitted the proposed proprietary name, Dsuvia\*\*\* on January 29, 2016 under IND 113059, and The Division of Medication Error Prevention and Analysis (DMEPA) found the name, Dsuvia\*\*\* acceptable.<sup>a</sup> The Sponsor is now submitting a request for re-review of the proprietary name on January 9, 2017, with the previously submitted external name study, under the NDA.

### 1.2 PRODUCT INFORMATION

The following product information is provided in the January 9, 2017 proprietary name submission.

- Intended Pronunciation: D sú via
- Indication of Use: Management of acute moderate-to-severe pain in adult patients in a medically supervised setting.
- Route of Administration: sublingual
- Dosage Form: sublingual tablet
- Strength: 30 mcg
- Dose and Frequency: 1 tablet every 1 hour as needed administered by a health care professional; maximum of 24 tablets (720 mcg) in a 24 hour period.
- How Supplied: One tablet packaged in a single dose applicator placed in a laminate foil pouch.
- Storage: Room temperature

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\*\*\* This document contains proprietary information that cannot be released to the public\*\*\*

<sup>a</sup> Schlick, J. Proprietary Name Review for Dsuvia IND 113059. Silver Spring (MD): FDA, CDER, OSE, DMEPA (US); 2016 May 11. RCM No.: 2016-2810306.

## 2 RESULTS

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

### 2.1 MISBRANDING ASSESSMENT

The Office of Prescription Drug Promotion (OPDP) determined that the proposed name would not misbrand the proposed product. DMEPA and the Division of Anesthesia, Analgesia, and Addiction Products (DAAAP) concurred with the findings of OPDP's 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 proprietary name<sup>b</sup>.

#### 2.2.2 *Components of the Proposed Proprietary Name*

The Applicant did not provide a derivation or intended meaning for the proposed name, Dsuvia 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 *FDA Name Simulation Studies*

Ninety-one practitioners participated in DMEPA's prescription studies. The responses did not overlap with any currently marketed products nor did the responses sound or look similar to any currently marketed products or any products in the pipeline. Eighteen participants provided the written response, 'Dsuvia', which was similar to the medical term, dysuria. However, the medical term was not found to be of concern for the proposed proprietary name, Dsuvia. Appendix B 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 26, 2017 e-mail, the Division of Anesthesia, Analgesia, and Addiction Products (DAAAP) did not forward any comments or concerns relating to the proposed proprietary name at the initial phase of the review.

#### 2.2.5 *Phonetic and Orthographic Computer Analysis (POCA) Search Results*

Our POCA search identified 21 names with the combined score of  $\geq 55\%$ .<sup>c</sup> We identified 14 of these names and all of the names in the (b) (4) external name study in our previous proprietary name review. We re-evaluated these names of concern considering any lessons learned from recent post-marketing experience, which may have altered our previous conclusion regarding the

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<sup>b</sup> USAN stem search conducted on January 25, 2017.

<sup>c</sup> POCA search conducted on January 12, 2017 in version 4.0.

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, Table 1 lists the 7 names not previously analyzed with the combined orthographic and phonetic score of  $\geq 55\%$  retrieved from our POCA search organized as highly similar, moderately similar or low similarity for further evaluation.

<b>Table 1. Similarity Category</b>	<b>Number of Names</b>
Highly similar name pair: combined match percentage score $\geq 70\%$	0
Moderately similar name pair: combined match percentage score $\geq 55\%$ to $\leq 69\%$	7
Low similarity name pair: combined match percentage score $\leq 54\%$	0

### ***2.2.6 Safety Analysis of Names with Potential Orthographic, Spelling, and Phonetic Similarities***

Our analysis of the seven names contained in Table 1 and determined seven names will not pose a risk for confusion as described in Appendices C through H.

### ***2.2.7 Discussion of Dual Proprietary Name***

AcelRx has proposed two different marketing applications using their sufentanil sublingual tablet. The first product is submitted under NDA (b) (4) (current application status as complete response) with the proposed proprietary name, Zalviso\*\*\*, and is a patient self-administered, non-invasive drug delivery system that delivers a 15 mcg sufentanil tablet as needed, based on a 20-minute lockout and other safety parameters designed into the system. The proposed product Dsuvia is a one-time use, disposable product that consists of one-30 mcg sufentanil tablet housed in a single- dose applicator (SDA). The SDA is used by the healthcare professional (HCP) as an aid to facilitate placement of the tablet in the patient’s sublingual space and is comprised of (b) (4) components and does not contain any hardware, software or electronics unlike Zalviso\*\*\*. Table 2 provides a side-by-side comparison of the two proposed products:

<b>Table 2 – Comparison of Dsuvia and Zalviso</b>		
<b>Attribute</b>	<b>Dsuvia</b>	<b>Zalviso***</b>
Regulatory History	IND 113059	NDA (b) (4) The name, Zalviso***, was found acceptable in OSE review# (b) (4) dated December 12, 2013. The application is pending.
Tablet color/strength	Blue tablet containing 30 mcg of sufentanil	(b) (4)
How supplied	Single-dose, disposable applicator	(b) (4)
Dosing and administration	HCP-administered prn dosing; No more frequently than 30 mcg every hour	Patient-controlled (b) (4) (b) (4) The full Zalviso*** System is required for patient to dose sufentanil.
Settings of Use	Intended for use in a medically supervised setting (eg. secure CII storage and supplemental oxygen available) for up to (b) (4). For example, ER's, ambulatory care centers, ambulance/paramedics	(b) (4)
Proposed Indication	Management of moderate-to-severe acute pain in a medically supervised setting. Proposed limitations of use include: (b) (4) and not for use in children	Management of moderate-to-severe acute pain in a hospital setting. Proposed limitations of use include: (b) (4) (b) (4)

We have evaluated the risks associated with this naming strategy and do not object to the use of a dual proprietary name in this case.

### ***2.2.8 Communication of DMEPA's Analysis at Midpoint of Review***

DMEPA communicated our findings to the Division of Anesthesia, Analgesia, and Addiction Products (DAAAP) via e-mail on February 28, 2017. At that time we also requested additional information or concerns that could inform our review. Per e-mail correspondence from the DAAAP on March 6, 2017, they stated no additional concerns with the proposed proprietary name, Dsuvia.

## **3 CONCLUSIONS**

The proposed proprietary name is acceptable.

If you have any questions or need clarifications, please contact Wendy Brown, OSE project manager, at 240-402-9140.

### **3.1 COMMENTS TO THE APPLICANT**

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

If any of the proposed product characteristics as stated in your January 9, 2017 submission are altered prior to approval of the marketing application, the name must be resubmitted for review.

## 4 REFERENCES

1. *USAN Stems* (<http://www.ama-assn.org/ama/pub/physician-resources/medical-science/united-states-adopted-names-council/naming-guidelines/approved-stems.page>)

USAN Stems List contains all the recognized USAN stems.

### 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](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.

### 3. *Electronic Drug Registration and Listing System (eDRLS) database*

The electronic Drug Registration and Listing System (eDRLS) was established to support the FDA's Center for Drug Evaluation and Research (CDER) goal to establish a common Structured Product Labeling (SPL) repository for all facilities that manufacture regulated drugs. The system is a reliable, up-to-date inventory of FDA-regulated, drugs and establishments that produce drugs and their associated information.

## 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.<sup>d</sup>

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<sup>d</sup> 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.
<b>Y/N</b>	<b>Is the proposed name obviously similar in spelling and pronunciation to other names?</b>
	Proprietary names should not be similar in spelling or pronunciation to proprietary names, established names, or ingredients of other products.
<b>Y/N</b>	<b>Are there inert or inactive ingredients referenced in the proprietary name?</b>
	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)).
<b>Y/N</b>	<b>Does the proprietary name include combinations of active ingredients?</b>
	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)).
<b>Y/N</b>	<b>Is there a United States Adopted Name (USAN) stem in the proprietary name?</b>
	Proprietary names should not incorporate a USAN stem in the position that USAN designates for the stem.
<b>Y/N</b>	<b>Is this proprietary name used for another product that does not share at least one common active ingredient?</b>
	Drug products that do not contain at least one common active ingredient should not use the same (root) proprietary name.
<b>Y/N</b>	<b>Is this a proprietary name of a discontinued product?</b>
	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  $\geq 70\%$ .
  - Moderately similar pair: combined match percentage score  $\geq 55\%$  to  $\leq 69\%$ .
  - Low similarity: combined match percentage score  $\leq 54\%$ .

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  $\geq 70$  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<sup>e</sup>. 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.,

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<sup>e</sup> Shah, M, Merchant, L, Characteristics That May Help in the Identification of Potentially Confusing Proprietary Drug Names. Therapeutic Innovation & Regulatory Science, September 2016

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 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.

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.

- 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  $\geq 70\%$ ).**

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.			
<u>Orthographic Checklist</u>		<u>Phonetic Checklist</u>	
<b>Y/N</b>	Do the names begin with different first letters?  <i>Note that even when names begin with different first letters, certain letters may be confused with each other when scripted.</i>	<b>Y/N</b>	Do the names have different number of syllables?
<b>Y/N</b>	Are the lengths of the names dissimilar* when scripted?  <i>*FDA considers the length of names different if the names differ by two or more letters.</i>	<b>Y/N</b>	Do the names have different syllabic stresses?
<b>Y/N</b>	Considering variations in scripting of some letters (such as z and f), is there a different number or placement of	<b>Y/N</b>	Do the syllables have different phonologic processes, such vowel reduction, assimilation,

	upstroke/downstroke letters present in the names?		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  $\geq 55\%$  to  $\leq 69\%$ ).**

Step 1	<p>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.</p> <p>For single strength products, also consider circumstances where the strength may not be expressed.</p> <p>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.</p> <p>To determine whether the strengths or doses are similar to your proposed product, consider the following list of factors that may increase confusion:</p> <ul style="list-style-type: none"> <li>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</li> </ul>
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	<p>versa.</p> <ul style="list-style-type: none"> <li>• Trailing or deleting zeros: 10 mg is similar in appearance to 100 mg which may potentiate confusion between a name pair with moderate similarity.</li> <li>• Similar sounding doses: 15 mg is similar in sound to 50 mg</li> </ul>	
Step 2	<p>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 <b>with</b> overlapping or similar strengths or doses.</p>	
	<p>Orthographic Checklist (Y/N to each question)</p> <ul style="list-style-type: none"> <li>• 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.</li> <li>• 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.</li> <li>• Considering variations in scripting of some letters (such as <i>z</i> and <i>f</i>), is there a different number or placement of upstroke/downstroke letters present in the names?</li> <li>• Is there different number or placement of cross-stroke or dotted letters present in the names?</li> <li>• Do the infixes of the name appear dissimilar when scripted?</li> <li>• Do the suffixes of the names appear dissimilar when</li> </ul>	<p>Phonetic Checklist (Y/N to each question)</p> <ul style="list-style-type: none"> <li>• Do the names have different number of syllables?</li> <li>• Do the names have different syllabic stresses?</li> <li>• Do the syllables have different phonologic processes, such as vowel reduction, assimilation, or deletion?</li> <li>• Across a range of dialects, are the names consistently pronounced differently?</li> </ul>

	scripted?	
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**Table 5: Low Similarity Name Pair Checklist (i.e., combined score is  $\leq 54\%$ ).**

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. Dsuvia Study (Conducted on February 3, 2017)**

Handwritten Medication Order/Prescription	Verbal Prescription
<p><u>Medication Order:</u></p> <p>Dsuvia one tablet under tongue every hour as needed</p>	<p>Dsuvia</p> <p>One tablet sublingually every hour as needed for pain. Bring to surgery center.</p> <p>Disp #3</p>
<p><u>Outpatient Prescription:</u></p> <p>Dsuvia</p> <p>one tablet SL every hour prn for pain. Bring to surgery center</p> <p>#3</p>	

**FDA Prescription Simulation Responses (Aggregate 1 Rx Studies Report)**

298 People Received Study 91 People Responded				
Study Name: Dsuvia				
<b>Total</b>	<b>32</b>	<b>22</b>	<b>37</b>	
INTERPRETATION	OUTPATIENT	VOICE	INPATIENT	TOTAL
D SUVIA	0	0	1	1
DANVIA	1	0	0	1
DASUVIA	0	1	0	1
DASUYVIA	0	1	0	1
DESUVIA	1	5	1	7
DISSUVIA	0	2	0	2
DISUVIA	0	7	0	7
DNSERIA	1	0	0	1
DONVIA	2	0	0	2
DSEIVIA	0	0	1	1
DSURIA	17	0	0	17
DSURIA (?)	1	0	0	1
DSUVIA	8	3	34	45
DYSUVIA	0	3	0	3
ISURIA	1	0	0	1

**Appendix C:** Highly Similar Names (e.g., combined POCA score is  $\geq 70\%$ )

No.	Proposed name: Dsuvia Established name: sufentanil Dosage form: sublingual tablets Strength: 30 mcg Usual Dose: 1 sublingual tablet once every hour as needed for pain in a medically supervised setting	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.	N/A	N/A	N/A

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

No.	Name	POCA Score (%)
1.	N/A	N/A

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

No.	Proposed name: Dsuvia Established name: sufentanil Dosage form: sublingual tablets Strength: 30 mcg Usual Dose: 1 sublingual tablet once every hour as needed for pain in a medically supervised setting	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.	Sinuva <sup>***</sup>	59	The beginning letter strings (Sin vs. Ds) look different when scripted.  Dsuvia <sup>***</sup> contains an additional syllable. The first syllables of this name pair (Si vs. D) sound different.

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\*\*\* This document contains proprietary information that cannot be released to the public\*\*\*

No.	<b>Proposed name: Dsuvia</b> <b>Established name:</b> <b>sufentanil Dosage form:</b> <b>sublingual</b> <b>tablets</b> <b>Strength: 30 mcg</b> <b>Usual Dose: 1 sublingual</b> <b>tablet once every hour as</b> <b>needed for pain in a</b> <b>medically supervised setting</b>	<b>POCA</b> <b>Score</b> <b>(%)</b>	<b>Prevention of Failure Mode</b>  <b>In the conditions outlined below, the following</b> <b>combination of factors, are expected to minimize the</b> <b>risk of confusion between these two names</b>
2.	Desal II	56	<p>The suffixes of this name pair have sufficient orthographic differences. The modifier ‘II’ adds additional orthographic differences when scripted.</p> <p>The second syllables (sal vs. suv) of this name pair sound different. Dsuvia contains an extra syllable. The modifier provides additional phonetic differences when spoken.</p>
3.	Korsuva***	56	<p>The prefixes of this name pair have sufficient orthographic differences.</p> <p>The first syllables of this name pair sound different. Dsuvia contains an extra syllable.</p>

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\*\*\* This document contains proprietary information that cannot be released to the public\*\*\*

**Appendix F:** Low Similarity Names (e.g., combined POCA score is  $\leq 54\%$ )

No.	Name	POCA Score (%)
1.	N/A	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
1.	(b) (4) ***	58	Name identified in Names Entered by Safety Evaluator database. Unable to find product characteristics in internal databases.
2.	Dasabuvir	58	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.  Dasabuvir is found only in the multi-ingredient product, Viekira Pak and Viekira XR (dasabuvir, ombitasvir, paritaprevir, ritonavir) which is packaged in unit dose daily dose packs.
3.	(b) (4) ***	58	Proposed proprietary name withdrawn by the Applicant. Product approved under new proprietary name, Pomalyst, under NDA 204026.

**Appendix H:** Names not likely to be confused due to absence of attributes that are known to cause name confusion<sup>f</sup>.

No.	Name	POCA Score (%)
1.	Vosevi***	56

**Appendix I:** Names identified in the eDRLS database not likely to be confused due to notable spelling, orthographic and phonetic differences.

No.	Name
1.	N/A

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

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**This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.**  
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/s/  
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BRENDA V BORDERS-HEMPHILL on behalf of JAMES H SCHLICK  
03/07/2017

BRENDA V BORDERS-HEMPHILL  
03/07/2017

DANIELLE M HARRIS  
03/07/2017