

**CENTER FOR DRUG EVALUATION AND  
RESEARCH**

*APPLICATION NUMBER:*

**208325Orig1s000**

**PROPRIETARY NAME REVIEW(S)**

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**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\*\*\***

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<b>Date of This Review:</b>	December 23, 2016
<b>Application Type and Number:</b>	NDA 208325
<b>Product Name and Strength:</b>	Parsabiv (Etelcalcetide) injection, 5 mg/mL
<b>Total Product Strength:</b>	2.5 mg/0.5 mL, 5 mg/mL, 10 mg/2 mL
<b>Product Type:</b>	Single
<b>Rx or OTC:</b>	Rx
<b>Applicant/Sponsor Name:</b>	Amgen
<b>Panorama #:</b>	2016-11918972
<b>DMEPA Primary Reviewer:</b>	Sarah K. Vee, PharmD
<b>DMEPA Associate Director (Acting):</b>	Mishale Mistry, PharmD, MPH

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## **1 INTRODUCTION**

This memorandum is to reassess the proposed proprietary name, Parsabiv, which was found conditionally acceptable under NDA 208325 on November 13, 2015.<sup>a</sup> We note that all product characteristics remain the same.

## **2 METHODS AND DISCUSSION**

### **2.1 MISBRANDING ASSESSMENT**

The Office of Prescription Drug Promotion (OPDP) determined that the proposed name would not misbrand the proposed product. DMEPA and the Division of Metabolism and Endocrinology Products (DMEP) concurred with the findings of OPDP's assessment of the proposed name.

### **2.2 SAFETY ASSESSMENT**

For re-assessment of the proposed proprietary name, DMEPA evaluated the previously identified names of concern considering any lessons learned from recent post-marketing experience, which may have altered our previous conclusion regarding the acceptability of the proposed proprietary name. Additionally, DMEPA searched the USAN stem list to determine if the name contains any USAN stems as of the last USAN updates. The December 16, 2016 search of USAN stems did not find any USAN stems in the proposed proprietary name.

## **3 CONCLUSIONS**

Our re-assessment did not identify any names that represent a potential source of drug name confusion. Therefore, we maintain that the proposed proprietary name is acceptable.

If you have any questions or need clarifications, please contact Deveonne Hamilton-Stokes, OSE project manager, at 301-796-2253.

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

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

If any of the proposed product characteristics as stated in your December 9, 2016 submission are altered prior to approval of the marketing application, the name must be resubmitted for review.

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<sup>a</sup> Mistry, M. Proprietary Name Review for Parsabiv NDA 208325. Silver Spring (MD): Food and Drug Administration, Center for Drug Evaluation and Research, Office of Surveillance and Epidemiology, Division of Medication Error Prevention and Analysis (US); 2015 NOV 13. Panorama No. 2015-1332918.

#### 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.

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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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SARAH K VEE  
01/03/2017

MISHALE P MISTRY  
01/03/2017

## PROPRIETARY NAME REVIEW

Division of Medication Error Prevention and Analysis (DMEPA)  
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<b>Date of This Review:</b>	November 13, 2015
<b>Application Type and Number:</b>	NDA 208325
<b>Product Name and Strength:</b>	Parsabiv (Etelcalcetide) injection, 5 mg/mL
<b>Total Product Strength:</b>	2.5 mg/0.5 mL, 5 mg/mL, 10 mg/2 mL
<b>Product Type:</b>	Single ingredient
<b>Rx or OTC:</b>	Rx
<b>Applicant/Sponsor Name:</b>	Amgen
<b>Panorama #:</b>	2015-1332918
<b>DMEPA Primary Reviewer:</b>	Mishale Mistry, PharmD, MPH
<b>DMEPA Team Leader:</b>	Yelena Maslov, PharmD

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## 1 INTRODUCTION

This review evaluates the proposed proprietary name, Parsabiv, 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, (b) (4) on February 4, 2015. However, the Division of Medication Error Prevention and Analysis (DMEPA) found the name, (b) (4) unacceptable due to (b) (4)

Thus, the Applicant submitted the name, Parsabiv, for review on August 25, 2015.

### 1.2 PRODUCT INFORMATION

The following product information is provided in the August 25, 2015 proprietary name submission.

- Intended Pronunciation:
- Active Ingredient: etelcalcetide
- Indication of Use: Treatment of secondary hyperparathyroidism (SHPT) in patients with chronic kidney disease (CKD) on maintenance hemodialysis therapy.
- Route of Administration: intravenous
- Dosage Form: injection
- Strength: 2.5 mg/0.5 mL, 5 mg/mL, 10 mg/2 mL (5 mg/mL)
- Dose and Frequency: Formulated for IV administration as a bolus dose thrice-weekly at the end of hemodialysis. Dose is titrated monthly until parathyroid hormone (PTH) is within desired range or maximum tolerated dose is reached. Dose ranges from 2.5 to 15 mg. Dose may be reduced in the event of hypocalcemia or low PTH.
- How Supplied: Single-use glass vials are packaged in a carton. Each carton will contain 10 vials per dose strength. The carton is constructed of paperboard that serves to shield the drug product from light.
- Storage: The finished drug product is required to be stored in a refrigerator at 2 - 8°C (36 - 46°F) in the original carton in order to protect from light. Once removed from the refrigerator, the product must not be exposed to temperatures above 25°C (77°F), must be used within 7 days if stored in the original carton, must be used within 4 hours, and must not be exposed to direct sunlight if removed from the original carton.

- Container Closure: 3-cc Type I glass single-use vial with 13 mm stopper.

## 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 Metabolism and Endocrinology Products (DMEP) 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>1</sup>.

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

The Applicant did not provide a derivation or intended meaning for the proposed name, Parsabiv in their submission.

Review of the proposed name noted that the name contained the letters 'iv', which may be interpreted as representing the medical abbreviation "IV" or intravenous, a route of administration. Because the route of administration for the product is intravenous, the inclusion of the two letters "iv" is not misleading.

Additionally, the proposed name Parsabiv could be interpreted as "Parsab IV", with "IV" as a modifier. A POCA search of the name "Parsab" did not identify any names that would pose a risk for confusion.<sup>2</sup> Furthermore, the letters 'iv' are not separated from the name, capitalized, or bolded, to make the letters 'iv' more prominent in the name.

#### 2.2.3 *FDA Name Simulation Studies*

Seventy (70) 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. Twenty-eight (28) participants identified the name correctly (outpatient n=3, voice n=4, inpatient n=21). Four (4) participants misinterpreted the infix 'sa' as 'ce' (voice n=4), 'ci' (voice n=6), and 'si' (voice n=6). Seventeen (17) participants misinterpreted the suffix 'biv' as 'bin' (outpatient n=17). Appendix B contains the results from the verbal and written prescription studies.

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<sup>1</sup>USAN stem search conducted on September 14, 2015.

<sup>2</sup> POCA search for 'Parsab' conducted on September 28, 2015.

#### **2.2.4 Comments from Other Review Disciplines at Initial Review**

In response to the OSE, September 10, 2015 e-mail, the Division of Metabolism and Endocrinology Products (DMEP) forwarded a concern relating to the proposed proprietary name at the initial phase of the review. The concern involved the proposed name ending in the letters ‘biv’, which may be confused with ‘bid’, which represents twice daily dosing frequency.

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

Table 1 lists the number of names with the combined orthographic and phonetic score of  $\geq 50\%$  retrieved from our POCA search<sup>3</sup> organized as highly similar, moderately similar or low similarity for further evaluation. Table 1 also includes names identified from the by (b) (4)

<b>Table 1. POCA Search Results</b>	<b>Number of Names</b>
Highly similar name pair: combined match percentage score $\geq 70\%$	1
Moderately similar name pair: combined match percentage score $\geq 50\%$ to $\leq 69\%$	126
Low similarity name pair: combined match percentage score $\leq 49\%$	0

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

Our analysis of the 127 names contained in Table 1 determined that none of the names will pose a risk for confusion as described in Appendices C through H.

#### **2.2.7 Communication of DMEPA’s Analysis at Midpoint of Review**

DMEPA communicated our findings to the Division of Metabolism and Endocrinology (DMEP) via e-mail on November 2, 2015. At that time we also requested additional information or concerns that could inform our review. Per e-mail correspondence from the DMEP on November 12, 2015, they stated no additional concerns with the proposed proprietary name, Parsabiv.

### **3 CONCLUSIONS**

The proposed proprietary name is acceptable.

If you have any questions or need clarifications, please contact Deveonne Hamilton-Stokes, OSE project manager, at 301-796-2253.

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<sup>3</sup> POCA search conducted on September 28, 2015.

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

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

If any of the proposed product characteristics as stated in your August 25, 2015 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>4</sup>

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<sup>4</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 medical and/or coined abbreviations in the proprietary name?</b>
	Proprietary names should not incorporate medical abbreviations (e.g., QD, BID, or others commonly used for prescription communication) or coined abbreviations that have no established meaning.
<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 50% 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  $\geq 50\%$  to  $\leq 69\%$ .
  - Low similarity: combined match percentage score  $\leq 49\%$ .

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 with overlapping or similar strengths or doses represent an area for concern for FDA. The dosage and strength information is often located in close proximity to the drug name itself on prescriptions and medication orders, and it 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, etc.) may be limited when the strength or dose overlaps. We review 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  $\geq 70\%$ ).**

<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 upstroke/downstroke letters present in the names?	<b>Y/N</b>	Do the syllables have different phonologic processes, such vowel reduction, assimilation, or deletion?
<b>Y/N</b>	Is there different number or placement of cross-stroke or dotted letters present in the names?	<b>Y/N</b>	Across a range of dialects, are the names consistently pronounced differently?
<b>Y/N</b>	Do the infixes of the name appear dissimilar when scripted?		
<b>Y/N</b>	Do the suffixes of the names appear dissimilar when scripted?		

**Table 4: Moderately Similar Name Pair Checklist (i.e., combined score is  $\geq 50\%$  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 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>
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>

	Orthographic Checklist (Y/N to each question)	Phonetic Checklist (Y/N to each question)
	<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>	<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>

**Table 5: Low Similarity Name Pair Checklist (i.e., combined score is  $\leq 49\%$ ).**

In most circumstances, these names are viewed as sufficiently different to minimize confusion. Exceptions to this would occur in circumstances where, for example, there are data that suggest a name with low similarity is nonetheless misinterpreted as a marketed product name in a prescription simulation study. In such instances, FDA 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. Parsabiv Study (Conducted on September 18, 2015)**

Handwritten Requisition Medication Order	Verbal Prescription
<p>Medication Order:</p> <p><i>Parsabiv 10mg IV bolus at end of HD</i></p>	<p>Parsabiv 2.5 mg Bring to Clinic Dispense #3 vials</p>
<p>Outpatient Prescription:</p> <p><i>Parsabiv 2.5mg Bring to Clinic #3 vials</i></p>	

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

243 People Received Study 70 People Responded				
Study Name: Parsabiv				
<b>Total</b>	<b>22</b>	<b>23</b>	<b>25</b>	
<b>INTERPRETATION</b>	<b>OUTPATIENT</b>	<b>VOICE</b>	<b>INPATIENT</b>	<b>TOTAL</b>
PARCEBIB	0	1	0	1
PARCEBIV	0	2	0	2
PARCEPID	0	1	0	1
PARCIBIV	0	3	0	3
PARCIBIVE	0	1	0	1
PARCIPIV	0	2	0	2
PARCIPIZ	0	1	0	1
PARSABIN	8	0	0	8
PARSABIO	0	0	1	1
PARCEBIB	0	1	0	1
PARSABIV	3	4	21	28
PARSABRIV	0	0	1	1

<b>INTERPRETATION</b>	<b>OUTPATIENT</b>	<b>VOICE</b>	<b>INPATIENT</b>	<b>TOTAL</b>
PARSALIV	0	0	1	1
PARSEBIV	0	2	0	2
PARSIBIV	0	6	0	6
PARSOBIN	8	0	0	8
PARSOBIV	1	0	0	1
PARSUBIN	1	0	0	1
PARSUBIV	1	0	0	1
PASSABIV	0	0	1	1

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

No.	Proposed name: Parsabiv Established name: etelcalcetide Dosage form: injection Strength(s): 2.5 mg/0.5 mL (5 mg/mL), 5 mg/mL, 10 mg/2 mL (5 mg/mL) Usual Dose: 2.5 to 15 mg IV administered three times weekly after hemodialysis	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.	Parsabiv	100	N/A – Subject of review

**Appendix D:** Moderately Similar Names (e.g., combined POCA score is  $\geq 50\%$  to  $\leq 69\%$ )  
with no overlap or numerical similarity in Strength and/or Dose

No.	Name	POCA Score (%)
1.	Nasabid	57
2.	Percodan	56
3.	Panretin	54
4.	Paremyd	54
5.	Permapen	54
6.	Tears Again	54
7.	Pataday	53
8.	Palladium	52
9.	Paritaprevir	52
10.	(b) (4)	52
11.	Perestan	52
12.	Cortane-B	52
13.	Xartemis	52
14.	Perjeta	51
15.	Phenabid	51
16.	Dasabuvir	50

No.	Name	POCA Score (%)
17.	Panafil	50
18.	Patanase	50
19.	Peridex	50
20.	Pertuzumab	50
21.	(b) (4)	50

**Appendix E:** Moderately Similar Names (e.g., combined POCA score is  $\geq 50\%$  to  $\leq 69\%$ ) with overlap or numerical similarity in Strength and/or Dose

No.	<b>Proposed name:</b> Parsabiv <b>Established name:</b> etelcalcetide <b>Dosage form:</b> injection <b>Strength(s):</b> 2.5 mg/0.5 mL (5 mg/mL), 5 mg/mL, 10 mg/2 mL (5 mg/mL) <b>Usual Dose:</b> 2.5 to 15 mg IV administered three times weekly after hemodialysis	POCA Score (%)	<b>Prevention of Failure Mode</b>  <b>In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names</b>
1.	Parsidol	66	The suffixes of this name pair have sufficient orthographic differences.  The third syllables of this name pair sound different.  Dose must be specified for both products and no overlap in dose.
2.	Persa-Gel	62	The suffixes of this name pair have sufficient orthographic differences.  The third syllables of this name pair sound different.
3.	Barstatin 100	60	The infixes of this name pair have sufficient orthographic differences.  The second/third syllables of this name pair sound different.
4.	Proactiv	58	The prefixes/infixes of this name pair have sufficient orthographic differences.  The first/second syllables of this name pair sound different.
5.	Paraplatin	57	Paraplatin contains two extra letters. The infixes of this name pair have sufficient orthographic differences.  Paraplatin contains an extra syllable. The second/third/fourth syllables of this name pair sound different.
6.	Parlodel	57	The infixes/suffixes of this name pair have sufficient orthographic differences.  The second/third syllables of this name pair sound different.

No.	<b>Proposed name:</b> Parsabiv <b>Established name:</b> etelcalcetide <b>Dosage form:</b> injection <b>Strength(s):</b> 2.5 mg/0.5 mL (5 mg/mL), 5 mg/mL, 10 mg/2 mL (5 mg/mL) <b>Usual Dose:</b> 2.5 to 15 mg IV administered three times weekly after hemodialysis	<b>POCA Score (%)</b>	<b>Prevention of Failure Mode</b>  <b>In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names</b>
7.	Persantine	57	Persantine contains two extra letters. The suffixes of this name pair have sufficient orthographic differences.  The third syllables of this name pair sound different.
8.	Parasal	56	The suffixes of this name pair have sufficient orthographic differences.  The third syllables of this name pair sound different.
9.	Parcopa	56	The suffixes of this name pair have sufficient orthographic differences.  The second/third syllables of this name pair sound different.
10.	Peramivir	56	The infixes of this name pair have sufficient orthographic differences.  Peramivir contains an extra syllable. The second/third/fourth syllables of this name pair sound different.
11.	Pertussin	56	The infixes of this name pair have sufficient orthographic differences.  The second/third syllables of this name pair sound different.
12.	Prevacid IV	56	The suffixes of this name pair have sufficient orthographic differences.  The first/third syllables of this name pair sound different.
13.	Marsilid	54	The prefixes of this name pair have sufficient orthographic differences.  The third syllables of this name pair sound different.

No.	<b>Proposed name:</b> Parsabiv <b>Established name:</b> etelcalcetide <b>Dosage form:</b> injection <b>Strength(s):</b> 2.5 mg/0.5 mL (5 mg/mL), 5 mg/mL, 10 mg/2 mL (5 mg/mL) <b>Usual Dose:</b> 2.5 to 15 mg IV administered three times weekly after hemodialysis	<b>POCA Score (%)</b>	<b>Prevention of Failure Mode</b>  <b>In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names</b>
14.	P.A.S. Sodium	54	The suffixes of this name pair have sufficient orthographic differences.  P.A.S. Sodium contains 3 extra syllables. The third syllables of this name pair sound different.
15.	Para-Time S. R.	54	Para-Time S.R. contains two extra letters. The infixes/suffixes of this name pair have sufficient orthographic differences.  Para-Time S.R. contains 2 extra syllables. The third syllables of this name pair sound different.
16.	Parcaine	54	The suffixes of this name pair have sufficient orthographic differences.  Parsabiv contains an extra syllable. The second/third syllables of this name pair sound different.
17.	Pazopanib	54	The infixes/suffixes of this name pair have sufficient orthographic differences.  Pazopanib contains an extra syllable. The third/fourth syllables of this name pair sound different.
18.	Persa-Gel W	54	The suffixes of this name pair have sufficient orthographic differences.  Persa-Gel W contains an extra syllable. The third/fourth syllables of this name pair sound different.
19.	Sulfabid	54	The prefixes/infixes of this name pair have sufficient orthographic differences.  The first/second syllables of this name pair sound different.

No.	<b>Proposed name:</b> Parsabiv <b>Established name:</b> etelcalcetide <b>Dosage form:</b> injection <b>Strength(s):</b> 2.5 mg/0.5 mL (5 mg/mL), 5 mg/mL, 10 mg/2 mL (5 mg/mL) <b>Usual Dose:</b> 2.5 to 15 mg IV administered three times weekly after hemodialysis	<b>POCA Score (%)</b>	<b>Prevention of Failure Mode</b>  <b>In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names</b>
20.	Tanabid	54	The prefixes/infixes of this name pair have sufficient orthographic differences.  The first/second syllables of this name pair sound different.
21.	Paradione	53	The infixes/suffixes of this name pair have sufficient orthographic differences.  Paradione contains an extra syllable. The third/fourth syllables of this name pair sound different.
22.	Arsenic	52	The suffixes of this name pair have sufficient orthographic differences.  The third syllables of this name pair sound different.
23.	Panshape M	52	The infixes/suffixes of this name pair have sufficient orthographic differences.  The second/third syllables of this name pair sound different.
24.	Paramol	52	The suffixes of this name pair have sufficient orthographic differences.  The third syllables of this name pair sound different.
25.	Parathar	52	The suffixes of this name pair have sufficient orthographic differences.  The third syllables of this name pair sound different.
26.	Parnate	52	The suffixes of this name pair have sufficient orthographic differences.  Parsabiv contains an extra syllable. The second/third syllables of this name pair sound different.

No.	<b>Proposed name:</b> Parsabiv <b>Established name:</b> etelcalcetide <b>Dosage form:</b> injection <b>Strength(s):</b> 2.5 mg/0.5 mL (5 mg/mL), 5 mg/mL, 10 mg/2 mL (5 mg/mL) <b>Usual Dose:</b> 2.5 to 15 mg IV administered three times weekly after hemodialysis	<b>POCA Score (%)</b>	<b>Prevention of Failure Mode</b>  <b>In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names</b>
27.	Permitil	52	The infixes/suffixes of this name pair have sufficient orthographic differences.  The second/third syllables of this name pair sound different.
28.	Pharmadine	52	Pharmadine contains two extra letters. The infixes/suffixes of this name pair have sufficient orthographic differences.  The second/third syllables of this name pair sound different.
29.	Prevacid	52	The suffixes of this name pair have sufficient orthographic differences.  The first/third syllables of this name pair sound different.
30.	Primalev	52	The prefixes/infixes of this name pair have sufficient orthographic differences.  The first/third syllables of this name pair sound different.
31.	Primalev 300/10	52	The prefixes/infixes of this name pair have sufficient orthographic differences.  The first/third syllables of this name pair sound different.
32.	Primalev 300/5	52	The prefixes/infixes of this name pair have sufficient orthographic differences.  The first/third syllables of this name pair sound different.

No.	<b>Proposed name:</b> Parsabiv <b>Established name:</b> etelcalcetide <b>Dosage form:</b> injection <b>Strength(s):</b> 2.5 mg/0.5 mL (5 mg/mL), 5 mg/mL, 10 mg/2 mL (5 mg/mL) <b>Usual Dose:</b> 2.5 to 15 mg IV administered three times weekly after hemodialysis	<b>POCA Score (%)</b>	<b>Prevention of Failure Mode</b>  <b>In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names</b>
33.	Primalev 300/7.5	52	The prefixes/infixes of this name pair have sufficient orthographic differences.  The first/third syllables of this name pair sound different.
34.	Procanbid	52	The prefixes/infixes of this name pair have sufficient orthographic differences.  The first/second syllables of this name pair sound different.
35.	Piribedil	51	The infixes/suffixes of this name pair have sufficient orthographic differences.  Piribedil contains an extra syllable. The second/third/fourth syllables of this name pair sound different.
36.	Posimir***	51	The suffixes of this name pair have sufficient orthographic differences.  The third syllables of this name pair sound different.
37.	Presamine	51	The infixes/suffixes of this name pair have sufficient orthographic differences.  The first/third syllables of this name pair sound different.
38.	Primlev	51	The prefixes/infixes of this name pair have sufficient orthographic differences.  Parsabiv contains an extra syllable. The second/third syllables of this name pair sound different.
39.	Palcaps	50	The infixes/suffixes of this name pair have sufficient orthographic differences.  Parsabiv contains an extra syllable. The second/third syllables of this name pair sound different.

No.	<b>Proposed name:</b> Parsabiv <b>Established name:</b> etelcalcetide <b>Dosage form:</b> injection <b>Strength(s):</b> 2.5 mg/0.5 mL (5 mg/mL), 5 mg/mL, 10 mg/2 mL (5 mg/mL) <b>Usual Dose:</b> 2.5 to 15 mg IV administered three times weekly after hemodialysis	<b>POCA Score (%)</b>	<b>Prevention of Failure Mode</b>  <b>In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names</b>
40.	Pennsaid	50	The infixes/suffixes of this name pair have sufficient orthographic differences.  Parsabiv contains an extra syllable. The second/third syllables of this name pair sound different.
41.	Perdiem	50	The infixes/suffixes of this name pair have sufficient orthographic differences.  The second/third syllables of this name pair sound different.
42.	Pergonal	50	The infixes/suffixes of this name pair have sufficient orthographic differences.  The second/third syllables of this name pair sound different.
43.	Periactin	50	The infixes of this name pair have sufficient orthographic differences.  Periactin contains an extra syllable. The second/third/fourth syllables of this name pair sound different.
44.	Peri-D.O.S.	50	The infixes/suffixes of this name pair have sufficient orthographic differences.  Peri-D.O.S. contains two extra syllables. The third/fourth/fifth fourth syllables of this name pair sound different.
45.	Permax	50	Parsabiv contains two extra letters. The infixes/suffixes of this name pair have sufficient orthographic differences.  The second/third syllables of this name pair sound different.

No.	<b>Proposed name:</b> Parsabiv <b>Established name:</b> etelcalcetide <b>Dosage form:</b> injection <b>Strength(s):</b> 2.5 mg/0.5 mL (5 mg/mL), 5 mg/mL, 10 mg/2 mL (5 mg/mL) <b>Usual Dose:</b> 2.5 to 15 mg IV administered three times weekly after hemodialysis	<b>POCA Score (%)</b>	<b>Prevention of Failure Mode</b>  <b>In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names</b>
46.	Peroderm	50	The infixes/suffixes of this name pair have sufficient orthographic differences.  The second/third syllables of this name pair sound different.
47.	Pherazine VC	50	The infixes/suffixes of this name pair have sufficient orthographic differences.  Pherazine VC contains two extra syllables. The third/fourth/fifth syllables of this name pair sound different.
48.	Piracetam	50	The infixes/suffixes of this name pair have sufficient orthographic differences.  Piracetam contains an extra syllable. The third/fourth syllables of this name pair sound different.
49.	Piretanide	50	The infixes/suffixes of this name pair have sufficient orthographic differences.  Piretanide contains an extra syllable. The third/fourth syllables of this name pair sound different.
50.	Portalac	50	The infixes/suffixes of this name pair have sufficient orthographic differences.  The first/third syllables of this name pair sound different.
51.	Procysbi	50	The prefixes/infixes of this name pair have sufficient orthographic differences.  The first/second syllables of this name pair sound different.

No.	<b>Proposed name:</b> Parsabiv <b>Established name:</b> etelcalcetide <b>Dosage form:</b> injection <b>Strength(s):</b> 2.5 mg/0.5 mL (5 mg/mL), 5 mg/mL, 10 mg/2 mL (5 mg/mL) <b>Usual Dose:</b> 2.5 to 15 mg IV administered three times weekly after hemodialysis	<b>POCA Score (%)</b>	<b>Prevention of Failure Mode</b>  <b>In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names</b>
52.	Progabide	50	The prefixes/infixes of this name pair have sufficient orthographic differences.  The first/second syllables of this name pair sound different.
53.	Prohibit	50	The prefixes/infixes of this name pair have sufficient orthographic differences.  The first/second syllables of this name pair sound different.

**Appendix F:** Low Similarity Names (e.g., combined POCA score is  $\leq 49\%$ ) – 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)	63	Proposed proprietary name found unacceptable due to (b) (4)  Applicant subsequently submitted proposed proprietary name, Parsabiv (subject of this review).
2.	(b) (4)	59	Secondary proposed proprietary name. Primary proposed name found unacceptable (OSE RCM #2012-901). Applicant subsequently submitted proposed proprietary name, Yosprala, which was found acceptable - application received Complete Response.
3.	Paraffin	58	Wax/emollient
4.	Paracets	56	International product marketed in United Kingdom.
5.	Parmid	56	International product marketed in United Kingdom.
6.	Paroven	56	International product marketed in several countries.
7.	Vertavis	56	Name identified through RxNorm database. Unable to find product characteristics in commonly used databases.
8.	Pharmaseb	55	Veterinary product
9.	(b) (4)	54	Proposed proprietary name found unacceptable (OSE RCM# (b) (4)) due to potential for name confusion with established name, (b) (4). Applicant submitted proposed proprietary name, (b) (4) which was found acceptable (OSE RCM# (b) (4)) – (b) (4)
10.	Parnaparin	54	International product (established name) marketed in several countries.

No.	Name	POCA Score (%)	Failure preventions
11.	Partobulin	54	International product marketed in several countries.
12.	Prosaid	54	International product marketed in United Kingdom
13.	Protium I.V	54	International product marketed in United Kingdom and Ireland
14.	Versapen	54	Name identified through RxNorm database. Unable to find product characteristics in commonly used databases.
15.	Palm Acid	52	Name identified through RxNorm database. Unable to find product characteristics in commonly used databases.
16.	Paradyne	52	Veterinary product
17.	(b) (4)	52	Proposed proprietary name found unacceptable (OSE RCM (b) (4)) due to potential for confusion with proposed name, (b) (4). Sponsor submitted another name for consideration. (b) (4)
18.	Perifix	51	B.Braun epidural catheters
19.	Perox-Aid	51	Veterinary product
20.	Panaleve	50	International product marketed in Ireland.
21.	Partuss-LA	50	In December 2005, the FDA issued a proposed rule that reclassifies all over-the-counter decongestant and weight loss phenylpropanolamine products as nonmonograph (Category II) - not generally recognized as safe and effective.
22.	Pennsaid 2% (b) (4) ***	50	Name withdrawn by Sponsor (b) (4). Application approved under proprietary name Pennsaid (OSE RCM #2013-1822).
23.	Pertussin ES	50	Name identified through RxNorm database. Unable to find product characteristics in commonly used databases.
24.	Pharmasal	50	Veterinary product

No.	Name	POCA Score (%)	Failure preventions
25.	Phor Pain	50	International product marketed in United Kingdom.

**Appendix H:** Names not likely to be confused due to notable spelling, orthographic and phonetic differences.

No.	Name	POCA Score (%)
1.	Trovan IV	59
2.	Carbatab 12	56
3.	Carbilev	56
4.	Cardene IV	56
5.	Marfarin	56
6.	Klaricid IV	55
7.	Fortabs	54
8.	Narfarin	54
9.	Orbactiv	54
10.	Brabantiv	52
11.	Carnexiv	52
12.	Cresatin	52
13.	Dermasav	52
14.	Gardasil	52
15.	Gardasil 9	52
16.	Orfadin	52
17.	Salsitab	52
18.	Tarceva	52
19.	Terlivaz	52
20.	Atnativ	51
21.	Calcitab	50
22.	Darbid	50

No.	Name	POCA Score (%)
23.	Dermabet	50
24.	Ipreziv	50
25.	Marten-Tab	50
26.	Sarapin	50
27.	Vertab SR	50

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

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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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MISHALE P MISTRY  
11/13/2015

YELENA L MASLOV  
11/16/2015