

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:

207620Orig1s000

PROPRIETARY NAME REVIEW(S)

PROPRIETARY NAME REVIEW MEMORANDUM

Division of Medication Error Prevention and Analysis (DMEPA)
Office of Medication Error Prevention and Risk Management (OMEPRM)
Office of Surveillance and Epidemiology (OSE)
Center for Drug Evaluation and Research (CDER)

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

Date of This Review:	June 11, 2015
Application Type and Number:	NDA 207620
Product Name and Strength:	Entresto (sacubitril/valsartan) Tablets, 24 mg/26 mg, 49 mg/51 mg, 97 mg/103 mg
Product Type:	Multi-Ingredient Product
Rx or OTC:	Rx
Applicant/Sponsor Name:	Novartis Pharmaceuticals Corporation
Submission Date:	April 24, 2015
Panorama #:	2015-47393-1
DMEPA Primary Reviewer:	Janine Stewart, PharmD
DMEPA Team Leader:	Chi-Ming (Alice) Tu, PharmD

1 INTRODUCTION

This memorandum is to re-assess the proposed proprietary name, Entresto, which was previously found acceptable in OSE Review #2014-25640, dated November 17, 2014 under IND 104628¹; and in OSE Review #2015-47393, dated January 28, 2015 under NDA 207620.² We note that there is [REDACTED] (b) (4) [REDACTED] 24 mg/26 mg, 49 mg/51 mg, and 97 mg/103 mg) since our last review. All other product characteristics remain the same.

2 METHODS AND DISCUSSION

For re-assessment of the proposed proprietary name, DMEPA conducted a gap analysis and searched the POCA database to identify names with orthographic and phonetic similarity to the proposed name that have been approved since the previous OSE proprietary name review #2014-25640. Additionally, we evaluated the previously identified names of concern considering any lessons learned from recent post-marketing experience, which may altered our previous conclusion regarding the acceptability of the proposed proprietary name. We also evaluated previously identified names taking into account the change in strength, dose, and frequency. Our evaluation has not altered our previous conclusion regarding the acceptability of the proposed proprietary name. Additionally, our POCA search did not identify any new names that represent a potential source of drug name confusion. As a result, we maintain that the name is acceptable.

Additionally, DMEPA searched the USAN stem list to determine if the name contains any USAN stems as of the last USAN updates. The May 22, 2015 search of USAN stems did not find any USAN stems in the proposed proprietary name.

3 CONCLUSIONS

DMEPA maintains the proposed proprietary name, Entresto, is acceptable from both a promotional and safety perspective under NDA 207620.

If you have further questions or need clarifications, please contact Darrell Lyons, OSE Project Manager, at 301-796-4092.

¹ Gao T. Proprietary Name Review for Entresto (IND 104628). 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); 20141117. 36 p. OSE RCM No.: 2014-25640.

² Stewart J. Proprietary Name Review Memo for Entresto (NDA 207620). 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); 20150128. 2 p. OSE RCM No.: 2015-47393.

4 COMMENTS TO THE APPLICANT

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

If any of the proposed product characteristics as stated in your April 24, 2015 submission are altered, the name must be resubmitted for review. If you have further questions or need clarifications, please contact Darrell Lyons, OSE project manager, at 301-796-4092.

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.

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/s/

JANINE A STEWART
06/11/2015

CHI-MING TU
06/11/2015

PROPRIETARY NAME REVIEW MEMORANDUM

Division of Medication Error Prevention and Analysis (DMEPA)
Office of Medication Error Prevention and Risk Management (OMEPRM)
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Date of This Review: January 28, 2015
Application Type and Number: NDA 207620
Product Name and Strength: Entresto (sacubitril/valsartan) Tablets,
[REDACTED] (b) (4)
Product Type: Multi-Ingredient Product
Rx or OTC: Rx
Applicant/Sponsor Name: Novartis Pharmaceuticals Corporation
Submission Date: January 15, 2015
Panorama #: 2015-47393
DMEPA Primary Reviewer: Janine Stewart, PharmD
DMEPA Team Leader: Chi-Ming (Alice) Tu, PharmD

1 INTRODUCTION

The proposed proprietary name, Entresto, was found acceptable in OSE Review # 2014-25640, dated November 17, 2014 under IND 104628.¹ We note that product characteristics are the same for NDA 207620 currently under review as they were under the IND. This memorandum is to communicate that DMEPA maintains the proposed proprietary name, Entresto, is acceptable from both a promotional and safety perspective under NDA 207620.

1.1 COMMENTS TO THE APPLICANT

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

If any of the proposed product characteristics as stated in your January 15, 2015 submission are altered, the name must be resubmitted for review. If you have further questions or need clarifications, please contact Darrell Lyons, OSE project manager, at 301-796-4092.

¹ Gao T. Proprietary Name Review for Entresto (IND 104628). 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); 20141117. 36 p. OSE RCM No.: 2014-25640.

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/s/

JANINE A STEWART
01/28/2015

CHI-MING TU
01/28/2015

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)

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Date of This Review:	November 17, 2014
Application Type and Number:	IND 104628
Product Name and Strength:	Entresto (sacubitril/valsartan) Tablets, 50 mg, 100 mg, 200 mg
Product Type:	Multi-Ingredient Product
Rx or OTC:	Rx
Applicant/Sponsor Name:	Novartis Pharmaceuticals Corporation
Submission Date:	June 19, 2014
Panorama #:	2014-25640
DMEPA Primary Reviewer:	Tingting Gao, PharmD
DMEPA Team Leader:	Chi-Ming (Alice) Tu, PharmD

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1 INTRODUCTION

This review evaluates the proposed proprietary name, Entresto, 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 did not submit an external name study for this proposed proprietary name.

1.1 PRODUCT INFORMATION

The following product information is provided in the June 19, 2014 proprietary name submission.

- Intended Pronunciation: Not provided
- Active Ingredient: sacubitril/valsartan [Established name not yet confirmed]
- Indication of Use: (b) (4)
- Route of Administration: Oral
- Dosage Form: Film-coated tablets
- Strength: 50 mg, 100 mg, 200 mg
 - 50 mg tablet contains 24 mg of sacubitril / 26 mg of valsartan
 - 100 mg tablet contains 49 mg of sacubitril / 51 mg of valsartan
 - 200 mg tablet contains 97 mg of sacubitril / 103 mg of valsartan
- Dose and Frequency: The therapeutic dose of Entresto is 200 mg twice a day. It is expected that lower doses will be introduced for up-titration and/or down-titration purposes. No dose adjustment is required for special subpopulations of patients.
- How Supplied:
 - Bottles of (b) (4) 60, and 180 tablets.
 - (b) (4)
- Storage: Store below 30°C

***We note in our internal July 18, 2014 email communication with Office of New Drug Quality Assessment (ONDQA), the proposed strengths 50 mg, 100 mg, and 200 mg may not be acceptable to ONDQA. Thus, we evaluated the proposed proprietary name by reviewing for dose and strength overlaps for:

- 50 mg, 100 mg, 200 mg
- 24 mg, 49 mg, 97 mg
- 26 mg, 51 mg, 103 mg
- 24 mg/26 mg, 49 mg/51 mg, and 97 mg/103 mg***

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) initially did not recommend the use of the proposed proprietary name Entresto because it overstates the efficacy and minimize the risks associated with the drug product on July 3, 2014. However, upon further discussion, OPDP withdrawn their objection and determined that the proposed name would not misbrand the proposed product on November 4, 2014.

DMEPA and the Division of Cardiovascular and Renal Products (DCRP) 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 name¹.

2.2.2 Components of the Proposed Proprietary Name

The Applicant did not provide a derivation or intended meaning for the proposed name, Entresto 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.

¹USAN stem search conducted on November 4, 2014.

In the outpatient written study, 24 of 32 participants correctly interpreted the prescription. In the inpatient written study, 23 of 30 participants correctly interpreted the prescription. Common misinterpretations in the written studies were substitution of ‘-trest-’ for ‘-trist-’ and ‘-tryt-’ and ‘-sto’ for ‘-sta’ or ‘-sti’. In the voice study, 14 of the 29 participants correctly interpreted the prescription. Common misinterpretations in the voice study include: ‘Ent-’ for ‘Ant-’ and ‘-trest-’ for ‘-trust-’.

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, July 3, 2014 e-mail, the Division of Cardiovascular and Renal Products (DCRP) 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

Table 1 lists the number of names with the combined orthographic and phonetic score of $\geq 50\%$ retrieved from our POCA search² organized as highly similar, moderately similar or low similarity for further evaluation.

Table 1. POCA Search Results	Number of Names
Highly similar name pair: combined match percentage score $\geq 70\%$	2
Moderately similar name pair: combined match percentage score $\geq 50\%$ to $\leq 69\%$	233
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 235 names contained in Table 1 determined 235 names will not 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 Cardiovascular and Renal Products (DCRP) via e-mail on November 10, 2014. At that time we also requested additional information or concerns that could inform our review. Per e-mail correspondence from the DCRP on November 17, 2014, they stated no additional concerns with the proposed proprietary name, Entresto.

² POCA search conducted on November 4, 2014.

3 CONCLUSIONS

The proposed proprietary name is acceptable.

If you have further questions or need clarifications, please contact Cherye Milburn, OSE project manager, at 301-796-2084.

3.1 COMMENTS TO THE APPLICANT

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

A request for proprietary name review for Entresto should be submitted once the NDA is submitted.

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).

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 DNCE. OPDP or DNCE 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 DNCE 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.³

³ National Coordinating Council for Medication Error Reporting and Prevention.
<http://www.nccmerp.org/aboutMedErrors.html>. Last accessed 10/11/2007.

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

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

- b. Phonetic and Orthographic Computer Analysis (POCA): Following the preliminary screening of the proposed proprietary name, DMEPA staff evaluates the proposed name against potentially similar names. In order to identify names with potential similarity to the proposed proprietary name, DMEPA enters the proposed proprietary name in POCA and queries the name against the following drug reference databases, Drugs@fda, CernerRxNorm, and names in the review pipeline using a 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 ≥ 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>	
Y/N	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>	Y/N	Do the names have different number of syllables?
Y/N	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>	Y/N	Do the names have different syllabic stresses?
Y/N	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?	Y/N	Do the syllables have different phonologic processes, such as vowel reduction, assimilation, or deletion?
Y/N	Is there different number or placement of cross-stroke or dotted letters present in the names?	Y/N	Across a range of dialects, are the names consistently pronounced differently?
Y/N	Do the infixes of the name appear dissimilar when scripted?		
Y/N	Do the suffixes of the names appear dissimilar when scripted?		

Table 4: Moderately Similar Name Pair Checklist (i.e., combined score is $\geq 50\%$ 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"> ○ Alternative expressions of dose: 5 mL may be listed in the prescribing information, but the dose may be expressed in metric weight (e.g., 500 mg) or in non-metric units (e.g., 1 tsp, 1 tablet/capsule). Similarly, a strength or dose of 1000 mg may be expressed, in practice, as 1 g, or vice versa. ○ Trailing or deleting zeros: 10 mg is similar in appearance to 100 mg which may potentiate confusion between a name pair with moderate similarity. ○ Similar sounding doses: 15 mg is similar in sound to 50 mg
<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 <u>with</u> overlapping or similar strengths or doses.</p>

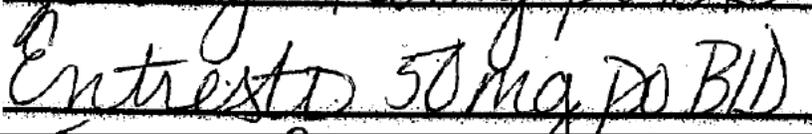
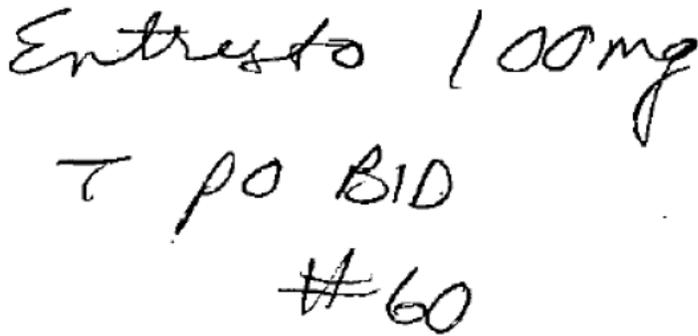
<p>Orthographic Checklist (Y/N to each question)</p> <ul style="list-style-type: none"> • Do the names begin with different first letters? <p>Note that even when names begin with different first letters, certain letters may be confused with each other when scripted.</p> <ul style="list-style-type: none"> • Are the lengths of the names dissimilar* when scripted? <p>*FDA considers the length of names different if the names differ by two or more letters.</p> <ul style="list-style-type: none"> • 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? • Is there different number or placement of cross-stroke or dotted letters present in the names? • Do the infixes of the name appear dissimilar when scripted? • Do the suffixes of the names appear dissimilar when scripted? 	<p>Phonetic Checklist (Y/N to each question)</p> <ul style="list-style-type: none"> • Do the names have different number of syllables? • Do the names have different syllabic stresses? • Do the syllables have different phonologic processes, such as vowel reduction, assimilation, or deletion? • Across a range of dialects, are the names consistently pronounced differently?
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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. Entresto Study (Conducted on July 2, 2014)

Handwritten Requisition Medication Order	Verbal Prescription
<p data-bbox="191 716 428 747"><u>Medication Order:</u></p> 	<p data-bbox="1052 716 1263 747">Entresto 100 mg</p> <p data-bbox="1052 768 1377 835">Take one by mouth twice daily</p> <p data-bbox="1052 856 1240 888">Dispense sixty</p>
<p data-bbox="191 919 500 951"><u>Outpatient Prescription:</u></p> 	

FDA Prescription Simulation Responses (Aggregate 1 Rx Studies Report)

265 People Received Study

91 People Responded

Total	32	29	30	
INTERPRETATION	OUTPATIENT	VOICE	INPATIENT	TOTAL
ANTRESTO	0	7	0	7
ANTRUSTO	0	2	0	2
EMTRESTO	0	1	0	1
ENTHRESTO	1	0	0	1
ENTRESO	0	0	1	1
ENTREST	0	0	1	1
ENTRESTA	0	0	2	2
ENTRESTI	0	0	2	2
ENTRESTO	24	14	23	61
ENTRESTS	0	0	1	1
ENTRISTO	3	0	0	3
ENTROSTO	0	1	0	1
ENTRUSTO	0	3	0	3
ENTRYTO	3	0	0	3
ENTRESTO	1	0	0	1
MATREXTO	0	1	0	1

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

No.	<p>Proposed name: Entresto</p> <p>Established name: sacubitril/valsartan</p> <p>Dosage form: Tablet</p> <p>Strength(s): 50 mg, 100 mg, 200 mg</p> <ul style="list-style-type: none"> • 50 mg tablet contains 24 mg of sacubitril / 26 mg of valsartan • 100 mg tablet contains 49 mg of sacubitril / 51 mg of valsartan • 200 mg tablet contains 97 mg of sacubitril / 103 mg of valsartan <p>Usual Dose: 200 mg twice a day (may titrate up or down)</p>	POCA Score (%)	Orthographic and/or phonetic differences in the names sufficient to prevent confusion
1.	Entresto	100	Name is subject of this review.
2.	Entre-S	74	<p>Entresto ends with the letter string 'to' which is absent in Entre-S, thus the suffix of this name pair has sufficient differences when scripted.</p> <p>The last syllables in the names sound different when spoken (En-tre-sto vs. En-tre-S).</p>

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

***We note in our internal July 18, 2014 email communication with Office of New Drug Quality Assessment (ONDQA), the proposed strengths 50 mg, 100 mg, and 200 mg may not be acceptable to ONDQA. Thus, we evaluated the proposed proprietary name by reviewing for dose and strength overlaps for:

- 50 mg, 100 mg, 200 mg
- 24 mg, 49 mg, 97 mg
- 26 mg, 51 mg, 103 mg
- 24 mg/26 mg, 49 mg/51 mg, and 97 mg/103 mg***

No.	Proposed Name	POCA Score (%)
1.	Amnest	54
2.	ATROVENT	50
3.	BETATREX	50
4.	BINOSTO	52
5.	Crest	52
6.	Dermarest	50
7.	DI-METREX	51
8.	Dutrebis***	50
9.	EGRIFTA	55
10.	ELESTAT	50
11.	eletriptan	50
12.	Emetrol	50
13.	(b) (4)***	56
14.	End-Zit	50
15.	ENPRESSE-21	60

No.	Proposed Name	POCA Score (%)
16.	ENPRESSE-28	60
17.	Entercote	54
18.	ENTEREG	57
19.	ENTEX	56
20.	ENTEX ER	56
21.	ENTEX LA	54
22.	ENTEX PSE	54
23.	entex T	65
24.	entocort	53
25.	entuss	50
26.	ENTYVIO	52
27.	ESTRASORB	56
28.	ESTRATAB	57
29.	estratest	64
30.	Estro-Cyp	56
31.	ESTROSTEP 21	66
32.	ESTROSTEP FE	53
33.	ESTROVIS	56
34.	FARESTON	54
35.	Gentran 40	51
36.	Gentran 70	51
37.	Ivarest	54
38.	LANTRISUL	54

No.	Proposed Name	POCA Score (%)
39.	MENEST	50
40.	METRETON	57
41.	MYTREX A	50
42.	NATESTO	66
43.	NUTRESTORE	62
44.	PENETREX	58
45.	Pentrax	59
46.	Phentride	52
47.	Sinarest	58
48.	Syntest	58
49.	TRELSTAR	54
50.	TREST	62
51.	UNOPROSTONE	50
52.	Zentrip	55
53.	(b) (4) ***	64

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.	<p>Proposed name: Entresto</p> <p>Established name: sacubitril/valsartan</p> <p>Dosage form: Tablet</p> <p>Strength(s): 50 mg, 100 mg, 200 mg</p> <ul style="list-style-type: none"> • 50 mg tablet contains 24 mg of sacubitril / 26 mg of valsartan • 100 mg tablet contains 49 mg of sacubitril / 51 mg of valsartan • 200 mg tablet contains 97 mg of sacubitril / 103 mg of valsartan <p>Usual Dose: 200 mg twice a day (may titrate up or down)</p>	POCA Score (%)	<p>Prevention of Failure Mode</p> <p>In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names</p>
1.	ABITREXATE	50	<p>The prefix, infix, and suffix of this name pair have sufficient orthographic differences.</p> <p>The first, second, and third syllables of this name pair sound different.</p> <p>Abitrexate contain extra syllables.</p>
2.	AMNESTEEM	51	<p>The prefix, infix, and suffix of this name pair have sufficient orthographic differences.</p> <p>The second and third syllables of this name pair sound different.</p> <p>Amnesteem contains an extra syllable.</p>
3.	Andro-Cyp	57	<p>The suffix of this name pair has sufficient orthographic differences.</p> <p>The second and third syllables of this name pair sound different.</p>
4.	Andro-Cyp 100	57	<p>The suffix of this name pair has sufficient orthographic differences.</p> <p>The second and third syllables of this name pair sound different. Andro-Cyp 100 contains extra syllables “100” from the modifier.</p>

No.	<p>Proposed name: Entresto</p> <p>Established name: sacubitril/valsartan</p> <p>Dosage form: Tablet</p> <p>Strength(s): 50 mg, 100 mg, 200 mg</p> <ul style="list-style-type: none"> • 50 mg tablet contains 24 mg of sacubitril / 26 mg of valsartan • 100 mg tablet contains 49 mg of sacubitril / 51 mg of valsartan • 200 mg tablet contains 97 mg of sacubitril / 103 mg of valsartan <p>Usual Dose: 200 mg twice a day (may titrate up or down)</p>	<p>POCA Score (%)</p>	<p>Prevention of Failure Mode</p> <p>In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names</p>
5.	Andro-Cyp 200	57	<p>The suffix of this name pair has sufficient orthographic differences.</p> <p>The second and third syllables of this name pair sound different. Andro-Cyp 200 contains extra syllables “200” from the modifier.</p>
6.	ANTRENYL	56	<p>The suffix of this name pair has sufficient orthographic differences.</p> <p>The third syllable of this name pair sound different.</p>
7.	Antrocol	61	<p>The suffix of this name pair has sufficient orthographic differences.</p> <p>The third syllable of this name pair sound different.</p>
8.	Arestin	52	<p>The prefix, infix, and suffix of this name pair have sufficient orthographic differences.</p> <p>The first, second, and third syllables of this name pair sound different.</p>
9.	(b) (4) ***	58	<p>The prefix of this name pair has sufficient orthographic differences.</p> <p>The first and third syllables of this name pair sound different.</p>
10.	Centrax	59	<p>The suffix of this name pair has sufficient orthographic differences.</p> <p>The first syllable of this name pair sound different. Entresto contains an extra syllable.</p>

No.	<p>Proposed name: Entresto</p> <p>Established name: sacubitril/valsartan</p> <p>Dosage form: Tablet</p> <p>Strength(s): 50 mg, 100 mg, 200 mg</p> <ul style="list-style-type: none"> • 50 mg tablet contains 24 mg of sacubitril / 26 mg of valsartan • 100 mg tablet contains 49 mg of sacubitril / 51 mg of valsartan • 200 mg tablet contains 97 mg of sacubitril / 103 mg of valsartan <p>Usual Dose: 200 mg twice a day (may titrate up or down)</p>	POCA Score (%)	<p>Prevention of Failure Mode</p> <p>In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names</p>
11.	Crestor	59	<p>The infix of this name pair has sufficient orthographic differences.</p> <p>The first syllable of this name pair sound different. Entresto contains an extra syllable.</p>
12.	Denti-Rinse	52	<p>The prefix, infix, and suffix of this name pair have sufficient orthographic differences.</p> <p>The first, second, and third syllables of this name pair sound different. Denti-Rinse contains an extra syllable.</p>
13.	Depotest	50	<p>The prefix, infix, and suffix of this name pair have sufficient orthographic differences.</p> <p>The first, second, and third syllables of this name pair sound different.</p>
14.	Dinoprostone	52	<p>The prefix, infix, and suffix of this name pair have sufficient orthographic differences.</p> <p>The first, second, and third syllables of this name pair sound different. Dinoprostone contains extra syllables.</p>
15.	EMTRIVA	56	<p>The suffix of this name pair has sufficient orthographic differences.</p> <p>The third syllable of this name pair sound different.</p>
16.	ENABLEX	50	<p>The infix and suffix of this name pair have sufficient orthographic differences.</p> <p>The second and third syllables of this name pair sound different.</p>

No.	<p>Proposed name: Entresto</p> <p>Established name: sacubitril/valsartan</p> <p>Dosage form: Tablet</p> <p>Strength(s): 50 mg, 100 mg, 200 mg</p> <ul style="list-style-type: none"> • 50 mg tablet contains 24 mg of sacubitril / 26 mg of valsartan • 100 mg tablet contains 49 mg of sacubitril / 51 mg of valsartan • 200 mg tablet contains 97 mg of sacubitril / 103 mg of valsartan <p>Usual Dose: 200 mg twice a day (may titrate up or down)</p>	POCA Score (%)	<p>Prevention of Failure Mode</p> <p>In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names</p>
17.	ENBREL	52	<p>The suffix of this name pair has sufficient orthographic differences.</p> <p>The second syllable of this name pair sound different and Entresto contains an extra syllable.</p>
18.	Endocet	52	<p>The infix and suffix of this name pair have sufficient orthographic differences.</p> <p>The second and third syllables of this name pair sound different.</p>
19.	Endrate	62	<p>The infix of this name pair has sufficient orthographic differences.</p> <p>The last syllable of this name pair sound different.</p> <p>Endrate is indicated in selected patients for the emergency treatment of hypercalcemia, and for control of ventricular arrhythmias associated with digitalis toxicity. Endrate is administered as intravenous infusion over 3 or more hours, and dose is repeated daily for 5 consecutive days followed by 2 days off. Dosing cycle can be repeated as necessary for up to 15 doses. Thus, the setting of use is likely inpatient/emergency vs. Entresto is likely used in outpatient setting.</p>
20.	Endur-Acin	50	<p>The infix and suffix of this name pair have sufficient orthographic differences.</p> <p>The second and third syllables of this name pair sound different. Endur-Acin contains an extra syllable.</p>

No.	<p>Proposed name: Entresto</p> <p>Established name: sacubitril/valsartan</p> <p>Dosage form: Tablet</p> <p>Strength(s): 50 mg, 100 mg, 200 mg</p> <ul style="list-style-type: none"> • 50 mg tablet contains 24 mg of sacubitril / 26 mg of valsartan • 100 mg tablet contains 49 mg of sacubitril / 51 mg of valsartan • 200 mg tablet contains 97 mg of sacubitril / 103 mg of valsartan <p>Usual Dose: 200 mg twice a day (may titrate up or down)</p>	POCA Score (%)	<p>Prevention of Failure Mode</p> <p>In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names</p>
21.	Enplus-HD	52	<p>The infix and suffix of this name pair have sufficient orthographic differences.</p> <p>The second syllable of this name pair sound different. Comparing the root names only, Entresto contains an extra syllable “to”. Enplus-HD contains extra syllables “H” and “D” from the modifier.</p>
22.	ENTEX LQ	52	<p>The suffix of this name pair has sufficient orthographic differences.</p> <p>Entresto contains an extra syllable when the modifier ‘LQ’ in Entex LQ is dropped. If modifier is included, then Entext LQ contains an extra syllable “Q” from the modifier.</p>
23.	Entrocel	62	<p>The suffix of this name pair has sufficient orthographic differences.</p> <p>The third syllable of this name pair sound different.</p>
24.	Envarsus***	52	<p>The infix and suffix of this name pair have sufficient orthographic differences.</p> <p>The second and third syllables of this name pair sound different.</p>
25.	EPREX	51	<p>The suffix of this name pair has sufficient orthographic differences.</p> <p>The second syllable of this name pair sounds different. Entresto contains an extra syllable.</p>

No.	<p>Proposed name: Entresto</p> <p>Established name: sacubitril/valsartan</p> <p>Dosage form: Tablet</p> <p>Strength(s): 50 mg, 100 mg, 200 mg</p> <ul style="list-style-type: none"> • 50 mg tablet contains 24 mg of sacubitril / 26 mg of valsartan • 100 mg tablet contains 49 mg of sacubitril / 51 mg of valsartan • 200 mg tablet contains 97 mg of sacubitril / 103 mg of valsartan <p>Usual Dose: 200 mg twice a day (may titrate up or down)</p>	POCA Score (%)	<p>Prevention of Failure Mode</p> <p>In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names</p>
26.	ESTRACE	52	<p>The suffix of this name pair has sufficient orthographic differences.</p> <p>The third syllable of this name pair sound different.</p>
27.	Estramustine	50	<p>The infix and suffix of this name pair have sufficient orthographic differences.</p> <p>The third syllables of this name pair sound different. Estramustine contains an extra syllable.</p>
28.	Estro-Span	58	<p>The suffix of this name pair has sufficient orthographic differences.</p> <p>The third syllable of this name pair sounds different.</p>
29.	Estro-Span 40	58	<p>The suffix of this name pair has sufficient orthographic differences.</p> <p>The third syllable of this name pair sounds different. Estro-Span 40 contains extra syllables “40” from the modifier.</p>
30.	Estro-Span C	51	<p>The suffix of this name pair has sufficient orthographic differences.</p> <p>The third syllable of this name pair sounds different. Estro-Span C contains an extra syllable “C” from the modifier.</p>
31.	Etrafon	52	<p>The suffix of this name pair has sufficient orthographic differences.</p> <p>The third syllable of this name pair sound different.</p>

No.	<p>Proposed name: Entresto</p> <p>Established name: sacubitril/valsartan</p> <p>Dosage form: Tablet</p> <p>Strength(s): 50 mg, 100 mg, 200 mg</p> <ul style="list-style-type: none"> • 50 mg tablet contains 24 mg of sacubitril / 26 mg of valsartan • 100 mg tablet contains 49 mg of sacubitril / 51 mg of valsartan • 200 mg tablet contains 97 mg of sacubitril / 103 mg of valsartan <p>Usual Dose: 200 mg twice a day (may titrate up or down)</p>	POCA Score (%)	<p>Prevention of Failure Mode</p> <p>In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names</p>
32.	ETRAFON 2-10	52	<p>The suffix of this name pair has sufficient orthographic differences.</p> <p>The third syllable of this name pair sound different.</p> <p>Etrafon 2-10 contains extra syllables from the modifier.</p>
33.	ETRAFON 2-25	52	<p>The suffix of this name pair has sufficient orthographic differences.</p> <p>The third syllable of this name pair sound different.</p> <p>Etrafon 2-25 contains extra syllables from the modifier.</p>
34.	ETRAFON-A	54	<p>The suffix of this name pair has sufficient orthographic differences.</p> <p>The third syllable of this name pair sound different.</p> <p>Etrafon-A contains an extra syllable from the modifier.</p>
35.	GANTRISIN	54	<p>The prefix and suffix of this name pair have sufficient orthographic differences.</p> <p>The first and third syllables of this name pair sound different.</p>
36.	GYNOREST	54	<p>The prefix, infix, and suffix of this name pair have sufficient orthographic differences.</p> <p>The first, second, and third syllables of this name pair sound different.</p>
37.	IMITREX	58	<p>The suffix of this name pair has sufficient orthographic differences.</p> <p>The first and third syllables of this name pair sound different.</p>

No.	<p>Proposed name: Entresto</p> <p>Established name: sacubitril/valsartan</p> <p>Dosage form: Tablet</p> <p>Strength(s): 50 mg, 100 mg, 200 mg</p> <ul style="list-style-type: none"> • 50 mg tablet contains 24 mg of sacubitril / 26 mg of valsartan • 100 mg tablet contains 49 mg of sacubitril / 51 mg of valsartan • 200 mg tablet contains 97 mg of sacubitril / 103 mg of valsartan <p>Usual Dose: 200 mg twice a day (may titrate up or down)</p>	POCA Score (%)	<p>Prevention of Failure Mode</p> <p>In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names</p>
38.	INTRON A	58	<p>The suffix of this name pair has sufficient orthographic differences.</p> <p>The third syllable of this name pair sound different, or Entresto contains an extra syllable when the modifier 'A' is dropped in Intron A.</p>
39.	INTROPIN	58	<p>The suffix of this name pair has sufficient orthographic differences.</p> <p>The third syllable of this name pair sounds different.</p>
40.	ISENTRESS	62	<p>The infix and suffix of this name pair have sufficient orthographic differences.</p> <p>The first, second, and third syllables of this name pair sound different.</p>
41.	JENTADUETO	50	<p>The prefix and infix of this name pair have sufficient orthographic differences.</p> <p>The first and third syllables of this name pair sound different. Jentadueto contains extra syllables.</p>
42.	KANTREX	60	<p>The prefix and suffix of this name pair have sufficient orthographic differences.</p> <p>The first syllable of this name pair sounds different. Entresto contains an extra syllable.</p>
43.	Meditest	54	<p>The prefix, infix, and suffix of this name pair have sufficient orthographic differences.</p> <p>The first, second, and third syllables of this name pair sound different.</p>

No.	Proposed name: Entresto Established name: sacubitril/valsartan Dosage form: Tablet Strength(s): 50 mg, 100 mg, 200 mg <ul style="list-style-type: none"> • 50 mg tablet contains 24 mg of sacubitril / 26 mg of valsartan • 100 mg tablet contains 49 mg of sacubitril / 51 mg of valsartan • 200 mg tablet contains 97 mg of sacubitril / 103 mg of valsartan Usual Dose: 200 mg twice a day (may titrate up or down)	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
44.	Mentadent	50	The prefix, infix, and suffix of this name pair have sufficient orthographic differences. The first, second, and third syllables of this name pair sound different.
45.	MINIPRESS	50	The prefix, infix, and suffix of this name pair have sufficient orthographic differences. The first, second, and third syllables of this name pair sound different.
46.	NATRECOR	54	The prefix and suffix of this name pair have sufficient orthographic differences. The first and third syllables of this name pair sound different.
47.	NEUTREXIN	50	The prefix and suffix of this name pair have sufficient orthographic differences. The first and third syllables of this name pair sound different.
48.	PENTIDS '200'	50	The prefix, infix and suffix of this name pair have sufficient orthographic differences. The first, second, and third syllables of this name pair sound different.
49.	PENTIDS '250'	50	The prefix, infix and suffix of this name pair have sufficient orthographic differences. The first, second, and third syllables of this name pair sound different.

No.	<p>Proposed name: Entresto</p> <p>Established name: sacubitril/valsartan</p> <p>Dosage form: Tablet</p> <p>Strength(s): 50 mg, 100 mg, 200 mg</p> <ul style="list-style-type: none"> • 50 mg tablet contains 24 mg of sacubitril / 26 mg of valsartan • 100 mg tablet contains 49 mg of sacubitril / 51 mg of valsartan • 200 mg tablet contains 97 mg of sacubitril / 103 mg of valsartan <p>Usual Dose: 200 mg twice a day (may titrate up or down)</p>	POCA Score (%)	<p>Prevention of Failure Mode</p> <p>In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names</p>
50.	PENTIDS '400'	50	<p>The prefix, infix and suffix of this name pair have sufficient orthographic differences.</p> <p>The first, second, and third syllables of this name pair sound different.</p>
51.	PENTIDS '800'	50	<p>The prefix, infix and suffix of this name pair have sufficient orthographic differences.</p> <p>The first, second, and third syllables of this name pair sound different.</p>
52.	Perestan	52	<p>The prefix, infix, and suffix of this name pair have sufficient orthographic differences.</p> <p>The first, second and third syllables of this name pair sound different.</p>
53.	Replesta	54	<p>The prefix and infix of this name pair have sufficient orthographic differences.</p> <p>The first and second syllables of this name pair sound different.</p>
54.	Testro	50	<p>The prefix of this name pair has sufficient orthographic differences.</p> <p>The first syllable of this name pair sound different, and Entresto contains an extra syllable.</p>
55.	TETREX	50	<p>The prefix and suffix of this name pair have sufficient orthographic differences.</p> <p>The first syllable of this name pair sound different, and Entresto contains an extra syllable.</p>

No.	Proposed name: Entresto Established name: sacubitril/valsartan Dosage form: Tablet Strength(s): 50 mg, 100 mg, 200 mg <ul style="list-style-type: none"> • 50 mg tablet contains 24 mg of sacubitril / 26 mg of valsartan • 100 mg tablet contains 49 mg of sacubitril / 51 mg of valsartan • 200 mg tablet contains 97 mg of sacubitril / 103 mg of valsartan Usual Dose: 200 mg twice a day (may titrate up or down)	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
56.	TRECATOR	53	The prefix, infix, and suffix of this name pair have sufficient orthographic differences. The first and second syllables of this name pair sound different.
57.	(b) (4) ***	50	The prefix, infix, and suffix of this name pair have sufficient orthographic differences. The first, second, and third syllables of this name pair sound different.
58.	UNIPRES	51	The prefix, infix, and suffix of this name pair have sufficient orthographic differences. The first, second and third syllables of this name pair sound different.

Appendix F: Low Similarity Names (e.g., combined POCA score is $\leq 49\%$)

No.	Name	POCA Score (%)	Failure preventions
1.	Invarest	$\leq 49\%$ Phonetic score 72%	The second and third syllables of this name pair sound different.

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.	Ancestim	60	International product marketed in Australia, Canada, and New Zealand
2.	Antipressan	53	International product marketed in United Kingdom and Hong Kong
3.	Anuprep-HC	58	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
4.	(b) (4) ***	51	Proposed Proprietary Name found unacceptable by DMEPA (OSE# 2012-1392). Product approved under new proprietary name Adempas (NDA 204819)
5.	Enaprilat	52	Product is not a drug. It appears to be a misspelling of Enalaprilat
6.	(b) (4) ***	64	This is a secondary proposed proprietary name and the product was approved under proprietary name Ofev
7.	Encron	52	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
8.	(b) (4) ***	58	This is a secondary proposed proprietary name and the product was approved under proprietary name Glydo
9.	Enfolast-N	52	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
10.	(b) (4) ***	56	This is a secondary proposed proprietary name and the primary proprietary name (b) (4) was withdrawn by the Applicant. The application (b) (4) is in "Inactive" status as of 09/18/2013.
11.	Enterocina	55	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.

No.	Name	POCA Score (%)	Failure preventions
12.	Entex S	57	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
13.	EntSUFON	54	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
14.	Entuss D	58	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
15.	(b) (4)***	50	Name identified in Names Entered by Safety Evaluator database. Unable to find product characteristics in internal databases. Name submitted in 2008, but was never fully evaluated. In 2011, OND notified Sponsor to submit the proposed name under the new regulatory pathway (with PDUFA clock).
16.	Estracyt	62	International product marketed in United Kingdom, Japan, Switzerland, Sweden, Spain, Poland, Hong Kong, and Israel
17.	Estrate	58	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
18.	Fanatrex	52	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
19.	Femtest	58	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
20.	Gene Press T	60	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
21.	Improvest	56	Veterinary product
22.	(b) (4)***	57	Proposed Proprietary Name found unacceptable by DMEPA (OSE# 2011-2599). Product approved under new proprietary name Oseni (NDA 022426)

No.	Name	POCA Score (%)	Failure preventions
23.	Infestat	60	International product marketed in United Kingdom
24.	(b) (4)***	58	This is a secondary proposed proprietary name and the product was approved under proprietary name Edurant
25.	Introl	54	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
26.	Isotrex	51	International product marketed in Canada, France, Hong King, Australia, Austria, New Zealand, Denmark, Italy, Mexico, Poland, and Thailand
27.	(b) (4)***	52	This is a secondary proposed proprietary name and the product was approved under proprietary name Binosto
28.	Menorest 37.5	63	International product marketed in Australia, United Kingdom, France, Germany, Greece, and Italy
29.	Menorest 50	63	International product marketed in Australia, United Kingdom, France, Germany, Greece, and Italy
30.	Menorest 75	63	International product marketed in Australia, United Kingdom, France, Germany, Greece, and Italy
31.	(b) (4)		
32.	Pentostam	56	International product marketed in United Kingdom and Israel
33.	Pentran	51	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.	ADCETRIS	50
2.	ANAPROX	52
3.	Anasept	50
4.	Ancrod	50
5.	Andec-TR	50
6.	Andehist	55
7.	ANDROID-F	52
8.	Androsterone	50
9.	Androxal	52
10.	Androxy	57
11.	Anorex	50
12.	Antepsin	50
13.	Anthraforte	51
14.	Antiflex	50
15.	Antihist	62
16.	Antihist-1	62
17.	Anti-Itch	53
18.	ANTIROBE	50
19.	Antisept	60
20.	Antispas	57
21.	ANTIVERT	58

No.	Name	POCA Score (%)
22.	ANTIZOL	52
23.	ANTURANE	51
24.	APRISO	53
25.	Aptryxol	50
26.	Atropisol	50
27.	Atrosept	52
28.	Benekraft	54
29.	BENEKRAFT-25	54
30.	BENLYSTA	52
31.	D & C Red No. 27	56
32.	D&C RED NO. 21	56
33.	D&C RED NO. 28	56
34.	D&C red no. 30	56
35.	D&C Red No. 34	56
36.	D&C RED NO. 6	56
37.	D&C RED NO. 7	56
38.	D.C. Red No. 33	56
39.	D.C. Red No. 36	56
40.	Dandrex	58
41.	Dandruff F-O	57
42.	DEAPRIL-ST	50
43.	Deproist	56
44.	DEXTROSTAT	52

No.	Name	POCA Score (%)
45.	Dinoprost	59
46.	DRISDOL	54
47.	Dristan	53
48.	FEMTRACE	50
49.	gemeprost	52
50.	GENCEPT 10/11-21	50
51.	GENCEPT 10/11-28	50
52.	Iloprost	50
53.	INCRELEX	50
54.	Incruse	52
55.	Indostat	55
56.	Inflectra	51
57.	INTELENCE	50
58.	INTERCEPTOR	57
59.	INTERMEZZO	56
60.	Intezor	51
61.	Lemtrada	50
62.	lenograstim	52
63.	Metrotop	55
64.	Neutracett	58
65.	Neutrahist	56
66.	NeutrapHor	50
67.	Neutra-Phos	52

No.	Name	POCA Score (%)
68.	Nitro Mist	54
69.	NITROMIST	54
70.	NITROSTAT	58
71.	Nutr-E-Sol	58
72.	Pedtrace-4	50
73.	Qinprezo	60
74.	rinesco	50
75.	SECREFLO	52
76.	SEMPREX-D	50
77.	SEPTRA DS	52
78.	Syntaris	51
79.	Tenkorex	51
80.	Trahist	50
81.	TRASICOR	51
82.	TRIOSTAT	52
83.	Tri-Pseudo	53
84.	Triscon	56
85.	Tri-Sudo	60
86.	Uni-Tris	52
87.	VINCREX	53
88.	vincristine	53
89.	XARELTO	52

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/s/

TINGTING N GAO
11/17/2014

CHI-MING TU
11/17/2014