CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

205739Orig1s000

PROPRIETARY NAME REVIEW(S)

PROPRIETARY NAME REVIEW

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

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

Date of This Review:	November 18, 2014
Application Type and Number:	IND 075615 and NDA 205739
Product Name and Strength:	Veltassa (patiromer) Powder For Oral Suspension (b) (4) 8.4 g, (b) (4) 16.8 g, (b) (4) and 25.2 g
Product Type:	Single Ingredient Product
Rx or OTC:	Rx
Applicant/Sponsor Name:	Relypsa, Inc.
Submission Date:	June 19, 2014 and June 30, 2014 (IND) November 3, 2014 (NDA)
Panorama #:	2014-25713 and 2014-41935
DMEPA Primary Reviewer:	Janine Stewart, PharmD
DMEPA Team Leader:	Chi-Ming (Alice) Tu, PharmD

Contents

1 INTRODUCTION

This review evaluates the proposed proprietary name, Veltassa, 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 PRODUCT INFORMATION

The following product information is provided in the June 19, 2014 proprietary name submission, June 30, 2014 proprietary name amendment, and the November 3, 2014 proprietary name submission.

- Intended Pronunciation: vel tas' ah
- Active Ingredient: Patiromer
- Indication of Use: Treatment of hyperkalemia
- Route of Administration: Oral
- Dosage Form: Powder for oral suspension packaged in single-use packets
- Strength: (b) (4) 8.4 g, (b) (4) 16.8 g, (b) (4) and 25.2 g
- Dose and Frequency: One packet given (b) (4) Maximum daily dose is (b) (4) patiromer (b) (4)
- How Supplied: (b) (4) packets per carton; (b) (4) packets per carton
- Storage: VELTASSA is to be stored refrigerated up until the point that it is dispensed to the patient. Once dispensed to the patient, VELTASSA can be stored refrigerated or at room temperature.

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 does not misbrand the proposed product. 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 name[1].

2.2.2 Components of the Proposed Proprietary Name

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

One hundred one (101) 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. Common verbal misinterpretations identified in the prescription studies included mistaking the 'V' for 'X' or 'Z', the 't' for 'c' or 'k', and the first 'a' for 'o'. Common written misinterpretations included mistaking the first 'a' for 'o' or 'e'. 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 14, 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 ≥50% retrieved from our POCA search[2] organized as highly similar, moderately similar, or low similarity for further evaluation. Table 1 also includes names identified from the FDA Prescription Simulation or by (b) (4)

Table 1. POCA Search Results	**Number of Names**
Highly similar name pair: combined match percentage score ≥70%	2
Moderately similar name pair: combined match percentage score ≥50% to ≤ 69%	278
Low similarity name pair: combined match percentage score ≤49%	2

[1]USAN stem search conducted on July 17, 2014.

[2] POCA search conducted on September 26, 2014.

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

Our analysis of the 282 names contained in Table 1 determined 282 names will not pose a risk for confusion as described in Appendices C through H.

2.2.4 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 October 8, 2014. At that time, we also requested additional information or concerns that could inform our review. Per e-mail correspondence from the DCRP on October 14, 2014, they stated no additional concerns with the proposed proprietary name, Veltassa.

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, Veltassa, and have concluded that this name is acceptable.

If any of the proposed product characteristics as stated in your June 19, 2014, June 30, 2014, and November 3, 2014 submissions 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).

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 ≥70%.
- Moderately similar pair: combined match percentage score ≥50% to ≤ 69%.
- Low similarity: combined match percentage score ≤49%.

Using the criteria outlined in the checklist (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 ≥ 70%).

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

Table 4: Moderately Similar Name Pair Checklist (i.e., combined score is ≥50% to ≤69%).

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

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

Table 5: Low Similarity Name Pair Checklist (i.e., combined score is ≤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. Veltassa Study (Conducted on July 17, 2014)

Handwritten Requisition Medication Order	Verbal Prescription
Medication Order: (b) (4)	Veltassa (b) (4) One PO (b) (4) Dispense 1 month supply
Outpatient Prescription: (b) (4) (b) (4)	

FDA Prescription Simulation Responses (Aggregate 1 Rx Studies Report)

264 People Received Study 101 People Responded

Study Name: Veltassa

Total	37	30	34	

INTERPRETATION	OUTPATIENT	VOICE	INPATIENT	TOTAL
VALCAS	0	1	0	1
VALCASA	0	1	0	1
VALCOZZA	0	1	0	1
VALTAGA	0	1	0	1
VALTASA	0	1	0	1
VALTASSA	0	1	0	1
VALTAZA	0	1	0	1
VALTOSA	0	2	0	2
VALTOSSA	0	1	0	1
VELCASA	0	1	0	1
VELKASA	0	2	0	2
VELLTASSA	0	1	0	1
VELTASA	0	2	0	2
VELTASSA	31	0	31	62
VELTASSCE	0	0	1	1
VELTASSI	1	0	0	1
VELTAZA	0	1	0	1
VELTESSA	0	0	2	2
VELTOSSA	5	0	0	5
XELTAZA	0	1	0	1
ZALCASA	0	2	0	2
ZALTASSA	0	1	0	1
ZELKASSA	0	1	0	1
ZELTASA	0	2	0	2
ZELTASSA	0	1	0	1
ZELTAZA	0	1	0	1
ZELTOSA	0	2	0	2
ZELTOSSA	0	2	0	2

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

No.	**Proposed name:** Veltassa **Strength(s):** [redacted] 8.4 g, [redacted] 16.8 g, [redacted] or 25.2 g **Usual Dose:** [redacted] Maximum daily dose-patiromer [redacted]	**POCA Score (%)**	**Orthographic and/or phonetic differences in the names sufficient to prevent confusion**
1.	VELTASSA ***	100	The proprietary name that is the subject of this review
2.	Bel-Tabs (Phonetic: 75)	70	The suffixes of this name pair have sufficient orthographic and phonetic differences. The names do not contain the same number of syllables. Bel-Tabs contains 2 syllables while Veltassa contains 3 syllables. Bel-Tabs is a multi-ingredient drug with no strength designation while Veltassa is supplied in several strengths, thus a strength designation is required on a prescription or medication order. Bel-Tabs has non-overlapping strengths, dosing, and dosage form compared to Veltassa, thus providing differentiating product characteristics.

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

No.	Proposed Name	POCA Score (%)
1.	ALTAfed	50
2.	ALTAtapp	58
3.	ALTAVERA	50
4.	BeTASal	62
5.	BeTAStat	54
6.	CYCLESSA	56
7.	DELTA D3	59
8.	DELTALIN	51
9.	DELTASONE	58
10.	FoLTAbs	66
11.	Gildess (Phonetic: 70)	56
12.	GILDESS 1.5/30 (Phonetic: 70)	56
13.	GILDESS 1/20 (Phonetic: 70)	56
14.	[redacted] (Phonetic: 70)	56
15.	[redacted] (Phonetic: 70)	56

16.	[redacted] (Phonetic: 70)	56
17.	Giltuss (Phonetic: 71)	60
18.	GlASSia	50
19.	MARLISSA	52
20.	MeTASol	50
21.	MolASSes	52
22.	NuveSSA ***	51
23.	PENTASA	66
24.	[redacted]	54
25.	RESTASIS	52
26.	SiLTAne	50
27.	[redacted]	51
28.	Valenac	52
29.	Valertest	52
30.	VALNAC	56
31.	Valpax	64
32.	Valstar	62
33.	VALTREX	54
34.	Valtrum	50
35.	VALTURNA	60
36.	Vanatab	50
37.	VANTAS (Phonetic: 62; Ortho: 59)	60
38.	Vaqta	53
39.	VASCEPA	56
40.	VECTICAL	50
41.	VEETIDS	55
42.	VEETIDS '125'	55
43.	VEETIDS '250'	55
44.	VEETIDS '500'	55
45.	VELBAN	62
46.	VELCADE	58
47.	VELETRI	54
48.	VELIVET	55
49.	VELOSEF	64
50.	VELOSEF '125'	64
51.	VELOSEF '250'	64
52.	VELOSEF '500'	64
53.	VELPHORO	52
54.	VELTIN	62
55.	[redacted]	61
56.	Vental	52
57.	VENTAVIS	57
58.	Ventuss (Phonetic: 58; Ortho: 65)	62
59.	VEPESID	52
60.	VERDESO	60

61.	Verrustat	50
62.	VERSAPEN	54
63.	VERSED	52
64.	VERTAVIS	62
65.	Verucasep	52
66.	(b) (4)	59
67.	Vexa	57
68.	VICTOZA	57
69.	VIDAZA	60
70.	Vincasar	56
71.	Virasal	56
72.	Viscoat	50
73.	Visqid AA	52
74.	Vistacon	50
75.	Vistacot	50
76.	Vistra	54
77.	Vitabee 12	52
78.	Vitadil 2A	54
79.	Vitadil 5A	54
80.	Vitadye	50
81.	VITAMIN A	50
82.	Vitapap	58
83.	VITAPED	50
84.	Vita-Respa	56
85.	Vitazol	51
86.	Vitekta ***	58
87.	VITRASE	50
88.	VOLMAX	56
89.	(b) (4)	56
90.	VOLTAREN	58
91.	Vortex	50
92.	(b) (4)	52
93.	(b) (4)	56
94.	(b) (4) (Phonetic: 72)	55

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

No.	**Proposed name:** Veltassa **Strength(s):** (b) (4) 8.4 g, (b) (4) 16.8 g, (b) (4) or 25.2 g **Usual Dose:** (b) (4) Maximum daily dose- (b) (4) patiromer (b) (4)	**POCA Score (%)**	**Prevention of Failure Mode** **In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names**
1.	BenTASil	50	The prefix and suffix of this name pair have sufficient orthographic differences. The first and third syllables of this name pair sound different.
2.	Del-Beta (Phonetic Score 75)	63	The infix and suffix of this name pair have sufficient orthographic differences. The second and third syllables of this name pair sound different.
3.	VALCYTE	53	The infix and suffix of this name pair have sufficient orthographic differences. Veltassa and Valcyte have a different number of syllables. The last syllable of each name sounds different.
4.	VALSARTAN	57	The infix and suffix of this name pair have sufficient orthographic differences. The second and third syllables of this name pair sound different.
5.	VELTANE	64	The suffix of this name pair has sufficient orthographic differences. Veltassa and Veltane have a different number of syllables. The last syllable of each name sounds different.
6.	Vertab SR	60	The suffix of this name pair has sufficient orthographic differences. Veltassa and Vertab-SR have a different number of syllables. The last syllable of each name sounds different.

No.	**Proposed name:** Veltassa **Strength(s):** (b) (4) 8.4 g, (b) (4) 16.8 g, (b) (4) or 25.2 g **Usual Dose:** (b) (4) Maximum daily dose- (b) (4) patiromer (b) (4)	**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**
7.	Vi Q Tuss	54	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.
8.	Vicotuss	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.
9.	Vitussin	56	The prefix and suffix of this name pair have sufficient orthographic differences. The first and third syllables of this name pair sound different.

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

No.	Name	POCA Score (%)
1.	Vaseretic	36
2.	Vitasana	<30

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)	50	Name identified in Names Entered by SE database. This name was denied in OSE RCM# 2010-772.
2.	(b) (4)	52	Name identified in Names Entered by SE database. This name was denied in OSE RCM# 2010-2736. The product was approved under the name Omeclamox-Pak in OSE RCM# 2011-2256.
3.	(b) (4)	64	Name identified in Names Entered by SE database. This name was denied in OSE RCM# 2014-17099.
4.	(b) (4)	52	Name identified in Names Entered by SE database. This is an alternate name that was never reviewed. Applicant intends to market the product under the established name.
5.	(b) (4)	52	Name identified in Names Entered by SE database. This is an alternate name that was never reviewed. The product was approved under the name Vienva in OSE RCM# 2012-2120.
6.	(b) (4)	52	Name identified in Names Entered by SE database. This name was denied in OSE RCM# 2012-533. The product was approved under the name Orenitram in OSE RCM# 2013-2111.
7.	(b) (4)	58	Name identified in Names Entered by SE database. This is an alternate name that was never reviewed. Applicant intends to market the product under the established name.

No.	Name	POCA Score (%)	Failure preventions
8.	(b) (4)	52	Name identified in Names Entered by SE database. This is an alternate name that was never reviewed. The product was approved under the name Stribild in OSE RCM# 2012-758.
9.	(b) (4)	51	Name identified in Names Entered by SE database. This name was never reviewed. NDA (b) (4) was withdrawn by the applicant as of 11/22/2008.
10.	Valbazen	58	Name identified in RxNorm database. This is a veterinary antihelminthic drug product.
11.	Valicot	52	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
12.	Valu-Tapp SR	54	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
13.	(b) (4)	62	Name identified in Names Entered by SE database. This is an alternate name that was never reviewed. The name Asclera was granted in OSE RCM# 2009-1870.
14.	Vasad	50	Name identified in RxNorm database. International nifedipine product marketed in several countries.
15.	Vasaten	52	Name identified in RxNorm database. International atenolol or valsartan product marketed in several countries.
16.	Vascace	52	Name identified in RxNorm database. International cilazapril product marketed in several countries.

No.	Name	POCA Score (%)	Failure preventions
17.	(b) (4)	58	Name identified in Names Entered by SE database. This name was granted in OSE RCM# (b) (4); however, NDA (b) (4) received a Complete Response on (b) (4).
18.	(b) (4)	58	Name identified in Names Entered by SE database. This name was denied in OSE RCM# 2010-1751.
19.	Vazotab	50	Name identified in RxNorm database. International brompheniramine/phenylephrine product marketed in several countries.
20.	(b) (4)	52	Name identified in Names Entered by SE database. This is an alternate name that was never reviewed. IND (b) (4) is currently inactive.
21.	(b) (4)	54	Name identified in Names Entered by SE database. This is an alternate name that was never reviewed. The product was approved under the name Veltin in OSE RCM# 2009-2212.
22.	Venastat	56	Name identified in RxNorm database. Discontinued horse chestnut herbal product.
23.	(b) (4)	50	Name identified in Names Entered by SE database. This name was never reviewed. NDA 022007 approved under the name Perforomist.
24.	(b) (4)	52	Name identified in Names Entered by SE database. This name was denied in OSE RCM# 2009-1883. The product was approved under the name Orsythia in OSE RCM# 2011-1305.

No.	Name	POCA Score (%)	Failure preventions
25.	(b) (4)	50	Name identified in Names Entered by SE database. This is an alternate name that was never reviewed. The product was approved under the name Ilevro in OSE RCM# 2012-2490.
26.	(b) (4)	50	Name identified in Names Entered by SE database. This is an alternate name that was never reviewed. The product was approved under the name Heather in OSE RCM# 2009-1187.
27.	(b) (4)	55	Name identified in Names Entered by SE database. This name was withdrawn by the Applicant in OSE RCM# 2012-1477. The product was approved under the name Fulyzaq in OSE RCM# 2012-1779.
28.	(b) (4)	52	Name identified in Names Entered by SE database. This name was never reviewed. No names have been reviewed for inactive IND (b) (4)
29.	(b) (4)	58	Name identified in Names Entered by SE database. This is an alternate name that was never reviewed. The product was approved under the name Synribo in OSE RCM# 2012-1587.
30.	(b) (4)	52	Name identified in Names Entered by SE database. This name was denied in OSE RCM# 2010-1740/1741. The product was approved under the name Vienva in OSE RCM# 2012-2120.
31.	Veta-K1	54	Name identified in RxNorm database. This is a veterinary phytonadione drug product.
32.	Vetalar	60	Name identified in RxNorm database. This is a veterinary ketamine drug product.

No.	Name	POCA Score (%)	Failure preventions
33.	Veti-Foam	50	Name identified in RxNorm database. This is an antiseptic soap for veterinary use.
34.	(b) (4)	52	Name identified in Names Entered by SE database. This name was denied in OSE RCM# 2011-2498. The product was approved under the name Vitekta in OSE RCM# 2014-17202.
35.	(b) (4)	72	Name identified in Names Entered by SE database. This name was denied in OSE RCM# 2009-1810. The product was approved under the name Lastacaft in OSE RCM# 2010-1494.
36.	Visage	53	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
37.	(b) (4)	56	Name identified in Names Entered by SE database. This is an alternate name that was never reviewed. The product was approved under the name Atralin in OSE RCM# 2007-1163.
38.	Vistuss	59	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
39.	(b) (4)	58	Name identified in Names Entered by SE database. This is an alternate name that was never reviewed. The product was approved under the name Vitekta in OSE RCM# 2014-17202.
40.	(b) (4)	58	Name identified in Names Entered by SE database. This is an alternate name that was never reviewed. The product was approved under the name Vitekta in OSE RCM# 2014-17202.

No.	Name	POCA Score (%)	Failure preventions
41.	(b) (4)	56	Name identified in Names Entered by SE database. This name was denied in OSE RCM# 2007-799.
42.	(b) (4)	50	Name identified in Names Entered by SE database. This name was never reviewed. NDA 204516 approved under the name Brisdelle in OSE RCM# 2013-859.
43.	VoLTArene	50	Name identified in RxNorm database. International diclofenac product marketed in several countries.
44.	VoLTArol	57	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
45.	VoLTArol SR	51	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
46.	(b) (4)	52	Name identified in Names Entered by SE database. This is an alternate name that was never reviewed. The product was approved under the name Myorisan in OSE RCM# 2012-24.
47.	(b) (4)	70	Name identified in Names Entered by SE database. This is an alternate name that was never reviewed. The product was approved under the name Lastacaft in OSE RCM# 2010-1494.
48.	(b) (4)	57	Name identified in Names Entered by SE database. This is an alternate name that was never reviewed. The product was approved under the name Zenpep in OSE RCM# 2009-179.

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

No.	Name	POCA Score (%)
1.	(b) (4)	50
2.	Balanta	50
3.	Baltussin	55
4.	Balziva	50
5.	BALZIVA-21	50
6.	BALZIVA-28	50
7.	Belbuca ***	57
8.	(b) (4)	58
9.	(b) (4)	59
10.	(b) (4)	54
11.	Bellaspas	60
12.	Bellatal	57
13.	(b) (4)	60
14.	(b) (4)	50
15.	Belsomra ***	50
16.	BENLYSTA	50
17.	Betaloc-SA	52
18.	BETAPAR	51
19.	Betatan	56
20.	BETA-VAL	52
21.	Betvosa	56
22.	CELEXA	58
23.	(b) (4)	54
24.	Cepastat	50
25.	Certiva	58
26.	(b) (4)	55
27.	Certuss D	51
28.	Certuss-C	51
29.	(b) (4)	55
30.	DASETTA 1/35	50
31.	DASETTA 7/7/7	50
32.	Del-Aqua	51
33.	Delatest	50
34.	(b) (4)	54
35.	(b) (4)	51
36.	Diltia	56
37.	DILTZAC	52
38.	Dispas	50
39.	Duratuss A	50
40.	ELESTAT	50

No.	Name	POCA Score (%)
41.	FELBATOL	54
42.	(b) (4)	57
43.	FEMSTAT	50
44.	FEMSTAT 3	50
45.	FENTORA	52
46.	Feostat	50
47.	FEPRASAT	51
48.	FIV-ASA	56
49.	FLUDARA	53
50.	Flutabs	55
51.	Folcaps	56
52.	Folitab	50
53.	Fortabs	52
54.	FORTESTA	58
55.	Gelcosal	52
56.	(b) (4)	54
57.	Gel-Tin	50
58.	GENESA	51
59.	(b) (4)	50
60.	Jevtana ***	54
61.	Lortab ASA	50
62.	Maltose	55
63.	Melphalan	51
64.	(b) (4)	52
65.	Miltuss EX	50
66.	(b) (4)	58
67.	(b) (4)	50
68.	NEULASTA	56
69.	(b) (4)	51
70.	Palcaps	50
71.	(b) (4)	54
72.	Pelodis	53
73.	PHEN-TUSS AD	52
74.	RELPAX	54
75.	Repatha	54
76.	Respa-SA	62
77.	Restanza	52
78.	(b) (4)	52
79.	Savaysa ***	50
80.	(b) (4)	50
81.	Sil Tex	55
82.	Siladyl SA	54
83.	Silapap	52

No.	Name	POCA Score (%)
84.	SILDAFLO	50
85.	(b) (4)	54
86.	(b) (4)	52
87.	Siltuss DAS	57
88.	Siltussin	59
89.	Siltussin SA	56
90.	Solesta	54
91.	Solotuss	52
92.	(b) (4)	52
93.	(b) (4)	59
94.	(b) (4)	51
95.	(b) (4)	56
96.	Testa Span	51
97.	(b) (4)	51
98.	(b) (4)	57
99.	(b) (4)	66
100	ULTIVA	54
101	Ultrasal	52
102	ULTRESA	60
103	XALATAN	50
104	XELODA	52
105	(b) (4)	55
106	(b) (4)	52
107	Z Tuss AC	52
108	ZALTRAP	58
109	ZAVESCA	52
110	ZEBETA	56
111	(b) (4)	56
112	ZELAPAR	56
113	ZELBORAF	50
114	(b) (4)	53
115	Zerbaxa ***	56
116	Zetacet	53
117	ZETIA	51
118	ZETONNA	51
119	(b) (4)	52
120	(b) (4)	59
121	(b) (4)	54
122	ZOLYSE	50
123	ZOMETA	50
124	(b) (4)	52
125	(b) (4)	50
126	ZORTRESS	52

No.	Name	POCA Score (%)
127	(b) (4)	50

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/s/

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11/18/2014

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11/18/2014