

**CENTER FOR DRUG EVALUATION AND  
RESEARCH**

*APPLICATION NUMBER:*

**206500Orig1s000**

**PROPRIETARY NAME REVIEW(S)**

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**PROPRIETARY NAME REVIEW**

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

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

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<b>Date of This Review:</b>	March 30, 2015
<b>Application Type and Number:</b>	NDA 206500
<b>Product Name and Strength:</b>	Varubi (Rolapitant) Tablets, 90 mg
<b>Product Type:</b>	Single ingredient
<b>Rx or OTC:</b>	Rx
<b>Applicant/Sponsor Name:</b>	Tesaro, Inc.
<b>Panorama #:</b>	2015-47206
<b>DMEPA Primary Reviewer:</b>	Sherly Abraham, R.Ph
<b>DMEPA Team Leader:</b>	Kendra Worthy, Pharm.D.
<b>DMEPA Associate Director:</b>	Lubna Merchant, M.S., Pharm.D.

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## 1 INTRODUCTION

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

### 1.1 REGULATORY HISTORY

The applicant previously submitted the proposed proprietary name, (b) (4), on September 5, 2014. However, the Division of Medication Error Prevention and Analysis (DMEPA) found the name, (b) (4)

OSE Review #2014-26363, dated November 18, 2014.

Thus, the applicant submitted the name, Varubi, for review on January 14, 2015. On February 12, 2015, DGIEP communicated to the applicant that strength should be expressed in terms of the active moiety (rolapitant) due to the new USP salt policy. On March 27, 2015, the applicant submitted an amendment indicating the new strength for this product.

### 1.2 PRODUCT INFORMATION

The following product information is provided in the January 14, 2015, and March 27, 2015, proprietary name submission.

- Intended Pronunciation: va' roo bee
- Active Ingredient: Rolapitant
- Indication of Use: Prevention of chemotherapy induced nausea and vomiting
- Route of Administration: Oral
- Dosage Form: Tablets
- Strengths: 90 mg
- Dose and Frequency: 180 mg (2 x 90 mg) 1 to 2 hours prior to initiation of chemotherapy
- How Supplied:

(b) (4)

- A single dose package (2 tablets as one set of twinned blisters)
- Storage: Store at 20-25°C (68-77°F) [see USP Controlled Room Temperature]

- Container and Closure Systems: Rolapitant 90 mg tablets are packaged in an Aclar blister shell with aluminum foil backing.

## **2 RESULTS**

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

### **2.1 MISBRANDING ASSESSMENT**

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

### **2.2 SAFETY ASSESSMENT**

The following aspects were considered in the safety evaluation of the name.

#### ***2.2.1 United States Adopted Names (USAN) Search***

There is no USAN stem present in the proprietary name<sup>1</sup>.

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

The Applicant did not provide a derivation or intended meaning for the proposed name, Varubi in their submission. This proprietary name is comprised of single 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.

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

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

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

In response to the OSE, January 21, 2015, e-mail, the Division of Gastroenterology and Inborn Error Products (DGIEP) did not forward any comments or concerns relating to the proposed proprietary name at the initial phase of the review.

#### ***2.2.6 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<sup>2</sup> organized as highly similar, moderately similar

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<sup>1</sup>USAN stem search conducted on February 16, 2015.

<sup>2</sup> POCA search conducted on March 23, 2015.

or low similarity for further evaluation. Table 1 also includes names identified from the FDA Simulation Studies or by (b) (4)

<b>Table 1. POCA Search Results</b>	<b>Number of Names</b>
Highly similar name pair: combined match percentage score $\geq 70\%$	1
Moderately similar name pair: combined match percentage score $\geq 50\%$ to $\leq 69\%$	72
Low similarity name pair: combined match percentage score $\leq 49\%$	11

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

Our analysis of the 84 names contained in Table 1 determined 84 names will not pose a risk for confusion as described in Appendices C through H.

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

DMEPA communicated our findings to the Division of Division of Gastroenterology and Inborn Error Products (DGIEP) via e-mail on March 27, 2015. At that time we also requested additional information or concerns that could inform our review. Per e-mail correspondence from the DGIEP on March 30, 2015, they stated no additional concerns with the proposed proprietary name, Varubi.

## **3 CONCLUSIONS**

The proposed proprietary name is acceptable.

If you have further questions or need clarifications, please contact Alek Winiarski, OSE project manager, at 301-796-5295.

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

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

If any of the proposed product characteristics as stated in your January 14, 2015, submission are altered prior to approval of the marketing application, the name must be resubmitted for review.

## 4 REFERENCES

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

USAN Stems List contains all the recognized USAN stems.

### 2. **Phonetic and Orthographic Computer Analysis (POCA)**

POCA is a system that FDA designed. As part of the name similarity assessment, POCA is used to evaluate proposed names via a phonetic and orthographic algorithm. The proposed proprietary name is converted into its phonemic representation before it runs through the phonetic algorithm. Likewise, an orthographic algorithm exists that operates in a similar fashion. POCA is publicly accessible.

#### **Drugs@FDA**

Drugs@FDA is an FDA Web site that contains most of the drug products approved in the United States since 1939. The majority of labels, approval letters, reviews, and other information are available for drug products approved from 1998 to the present. Drugs@FDA contains official information about FDA-approved *brand name* and *generic drugs*; *therapeutic biological products*, *prescription* and *over-the-counter* human drugs; and *discontinued drugs* (see Drugs @ FDA Glossary of Terms, available at [http://www.fda.gov/Drugs/InformationOnDrugs/ucm079436.htm#ther\\_biological](http://www.fda.gov/Drugs/InformationOnDrugs/ucm079436.htm#ther_biological)).

#### **RxNorm**

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

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

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

#### **Division of Medication Errors Prevention and Analysis proprietary name consultation requests**

This is a list of proposed and pending names that is generated by the Division of Medication Error Prevention and Analysis from the Access database/tracking system

## 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.<sup>3</sup>

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

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

	Answer the questions in the checklist below. Affirmative answers to any of these questions indicate a potential area of concern that should be carefully evaluated as described in this guidance.
<b>Y/N</b>	<b>Is the proposed name obviously similar in spelling and pronunciation to other names?</b>
	Proprietary names should not be similar in spelling or pronunciation to proprietary names, established names, or ingredients of other products.
<b>Y/N</b>	<b>Are there medical and/or coined abbreviations in the proprietary name?</b>
	Proprietary names should not incorporate medical abbreviations (e.g., QD, BID, or others commonly used for prescription communication) or coined abbreviations that have no established meaning.
<b>Y/N</b>	<b>Are there inert or inactive ingredients referenced in the proprietary name?</b>
	Proprietary names should not incorporate any reference to an inert or inactive ingredient in a way that might create an impression that the ingredient's value is greater than its true functional role in the formulation (21 CFR 201.10(c)(4)).
<b>Y/N</b>	<b>Does the proprietary name include combinations of active ingredients?</b>
	Proprietary names of fixed combination drug products should not include or suggest the name of one or more, but not all, of its active ingredients (see 21 CFR 201.6(b)).
<b>Y/N</b>	<b>Is there a United States Adopted Name (USAN) stem in the proprietary name?</b>
	Proprietary names should not incorporate a USAN stem in the position that USAN designates for the stem.
<b>Y/N</b>	<b>Is this proprietary name used for another product that does not share at least one common active ingredient?</b>
	Drug products that do not contain at least one common active ingredient should not use the same (root) proprietary name.
<b>Y/N</b>	<b>Is this a proprietary name of a discontinued product?</b>
	Proprietary names should not use the proprietary name of a discontinued product if that discontinued drug product does not contain the same active ingredients.

b. Phonetic and Orthographic Computer Analysis (POCA): Following the preliminary screening of the proposed proprietary name, DMEPA staff evaluates the proposed name against potentially similar names. In order to identify names with potential similarity to the proposed proprietary name, DMEPA enters the proposed proprietary name in POCA and queries the name against the following drug reference databases, Drugs@fda, CernerRxNorm, and names in the review pipeline using a 50% threshold in POCA. DMEPA reviews the combined orthographic and phonetic matches and group the names into one of the following three categories:

- Highly similar pair: combined match percentage score  $\geq 70\%$ .
- Moderately similar pair: combined match percentage score  $\geq 50\%$  to  $\leq 69\%$ .
- Low similarity: combined match percentage score  $\leq 49\%$ .

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

- For highly similar names, differences in product characteristics often cannot mitigate the risk of a medication error, including product differences such as strength and dose. Thus, proposed proprietary names that have a combined score of  $\geq 70$  percent are at risk for a look-alike sound-alike confusion which is an area of concern (See Table 3).
- Moderately similar names with overlapping or similar strengths or doses represent an area for concern for FDA. The dosage and strength information is often located in close proximity to the drug name itself on prescriptions and medication orders, and it can be an important factor that either increases or decreases the potential for confusion

between similarly named drug pairs. The ability of other product characteristics to mitigate confusion (e.g., route, frequency, dosage form, etc.) may be limited when the strength or dose overlaps. We review such names further, to determine whether sufficient differences exist to prevent confusion. (See Table 4).

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

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

Three separate studies are conducted within the Centers of the FDA for the proposed proprietary name to determine the degree of confusion of the proposed proprietary name with marketed U.S. drug names (proprietary and established) due to similarity in visual appearance with handwritten prescriptions or verbal pronunciation of the drug name. The studies employ healthcare professionals (pharmacists, physicians, and nurses), and attempts to simulate the prescription ordering process. The primary Safety Evaluator uses the results to identify orthographic or phonetic vulnerability of the proposed name to be misinterpreted by healthcare practitioners.

In order to evaluate the potential for misinterpretation of the proposed proprietary name in handwriting and verbal communication of the name, inpatient medication orders and/or outpatient prescriptions are written, each consisting of a combination of marketed and unapproved drug products, including the proposed name. These orders are optically scanned and one prescription is delivered to a random sample of participating health professionals via e-mail. In addition, a verbal prescription is recorded on voice mail. The voice mail messages are then sent to a random sample of the participating health professionals for their interpretations and review. After receiving either the written or verbal prescription orders, the participants record their interpretations of the orders which are recorded electronically.

- d. Comments from Other Review Disciplines: DMEPA requests the Office of New Drugs (OND) and/or Office of Generic Drugs (OGD), ONDQA or OBP for their comments or concerns with the proposed proprietary name, ask for any clinical issues that may impact the DMEPA review during the initial phase of the name review. Additionally, when applicable, at the same time DMEPA requests concurrence/non-concurrence with OPDP’s decision on the name. The primary Safety Evaluator addresses any comments or concerns in the safety evaluator’s assessment.

The OND/OGD Regulatory Division is contacted a second time following our analysis of the proposed proprietary name. At this point, DMEPA conveys their decision to accept or reject the name. The OND or OGD Regulatory Division is requested to provide any further information that might inform DMEPA’s final decision on the proposed name.

Additionally, other review disciplines opinions such as ONDQA or OBP may be considered depending on the proposed proprietary name.

When provided, DMEPA considers external proprietary name studies conducted by or for the Applicant/Sponsor and incorporates the findings of these studies into the overall risk assessment.

The DMEPA primary reviewer assigned to evaluate the proposed proprietary name is responsible for considering the collective findings, and provides an overall risk assessment of the proposed proprietary name.

**Table 3. Highly Similar Name Pair Checklist (i.e., combined Orthographic and Phonetic score is ≥ 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.			
<u>Orthographic Checklist</u>		<u>Phonetic Checklist</u>	
<b>Y/N</b>	Do the names begin with different first letters? <i>Note that even when names begin with different first letters, certain letters may be confused with each other when scripted.</i>	<b>Y/N</b>	Do the names have different number of syllables?

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 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 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 ≥50% to ≤69%).**

Step 1	<p>Review the DOSAGE AND ADMINISTRATION and HOW SUPPLIED/STORAGE AND HANDLING sections of the prescribing information (or for OTC drugs refer to the Drug Facts label) to determine if strengths and doses of the name pair overlap or are very similar. Different strengths and doses for products whose names are moderately similar may decrease the risk of confusion between the moderately similar name pairs. Name pairs that have overlapping or similar strengths or doses have a higher potential for confusion and should be evaluated further (see Step 2). Because the strength or dose could be used to express an order or prescription for a particular drug product, overlap in one or both of these components would be reason for further evaluation.</p> <p>For single strength products, also consider circumstances where the strength may not be expressed.</p> <p>For any i.e. drug products comprised of more than one active ingredient, consider whether the strength or dose may be expressed using only one of the components.</p> <p>To determine whether the strengths or doses are similar to your proposed product, consider the following list of factors that may increase confusion:</p> <ul style="list-style-type: none"> <li>○ Alternative expressions of dose: 5 mL may be listed in the prescribing information, but the dose may be expressed in metric weight (e.g., 500 mg) or in non-metric units (e.g., 1 tsp, 1 tablet/capsule). Similarly, a strength or dose of 1000 mg may be expressed, in practice, as 1 g, or vice versa.</li> <li>○ Trailing or deleting zeros: 10 mg is similar in appearance to 100 mg which may potentiate confusion between a name pair with moderate similarity.</li> <li>○ Similar sounding doses: 15 mg is similar in sound to 50 mg</li> </ul>
Step 2	<p>Answer the questions in the checklist below. Affirmative answers to some of these questions suggest that the pattern of orthographic or phonetic differences in the names may reduce the likelihood of confusion for moderately similar names <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"> <li>• Do the names begin with different first letters?</li> </ul> <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"> <li>• Are the lengths of the names dissimilar* when scripted?</li> </ul> <p>*FDA considers the length of names different if the names differ by two or more letters.</p> <ul style="list-style-type: none"> <li>• Considering variations in scripting of some letters (such as <i>z</i> and <i>f</i>), is there a different number or placement of upstroke/downstroke letters present in the names?</li> <li>• Is there different number or placement of cross-stroke or dotted letters present in the names?</li> <li>• Do the infixes of the name appear dissimilar when scripted?</li> <li>• Do the suffixes of the names appear dissimilar when scripted?</li> </ul>	<p>Phonetic Checklist (Y/N to each question)</p> <ul style="list-style-type: none"> <li>• Do the names have different number of syllables?</li> <li>• Do the names have different syllabic stresses?</li> <li>• Do the syllables have different phonologic processes, such vowel reduction, assimilation, or deletion?</li> <li>• Across a range of dialects, are the names consistently pronounced differently?</li> </ul>
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**Table 5: Low Similarity Name Pair Checklist (i.e., combined score is ≤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. Varubi Study (Conducted on January 28, 2015)**

Handwritten Requisition Medication Order	Verbal Prescription
<p><u>Medication Order:</u></p> <p><i>Varubi 200mg po once</i></p>	<p>Varubi 100 mg</p> <p>2 tablets po at once 1 hour prior to Chemo</p> <p>#2</p>
<p><u>Outpatient Prescription:</u></p> <p><i>Varubi 100mg</i></p> <p><i>2 tablets po at once</i></p> <p><i>1hr prior to chemo</i></p> <p><i>#2</i></p>	

252 People Received Study  
83 People Responded

Study Name: Varubi

	Total	31	25	27
INTERPRETATION	OUTPATIENT	VOICE	INPATIENT	TOTAL
BAROOBI	0	1	0	1
BARUBI	0	2	0	2
BARUBY	0	1	0	1
CERUBI 100MG: TAKE 2 TABS	0	1	0	1
UARERBI	0	0	1	1
UARUBI	0	0	1	1
VARIBI	0	0	1	1
VARIBU	0	0	1	1
VARUBI	30	1	19	50
VARUBIA	0	0	1	1
VARUBIC	1	0	0	1

VARUBY	0	1	0	1
VARUFI	0	0	3	3
VERUBE	0	1	0	1
VERUBI	0	12	0	12
VERUBY	0	5	0	5

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

No.	Proposed name: Varubi Established name: Rolapitant Dosage form: Oral Tablets Strength(s): 90 mg Usual Dose: Take 2 tabs 1 hour prior to chemo	POCA Score (%)	Orthographic and/or phonetic differences in the names sufficient to prevent confusion  Other prevention of failure mode expected to minimize the risk of confusion between these two names.
1.	Varubi	100	Proposed proprietary name subject of this review.

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

No.	Name	POCA Score (%)
1.	Vaporub	65
2.	Virovir	62
3.	Vanobid	58
4.	Verluma	57
5.	Verrugon	56
6.	Valtrum	54
7.	Varivax	54

8.	Viberzi***	54
9.	Virazid	54
10.	(b) (4)	54
11.	Viridium	53
12.	Verdeso	51
13.	Viread	51
14.	Veletri	50
15.	Vi-sudo	50

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

No.	Proposed name: Varubi Established name: Rolapitant Dosage form: Oral Tablets Strength: 90 mg Usual Dose: Take 2 tablets at once 1 hour before chemo	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.	Varibar	64	Varibar is available as different flavors such as Varibar honey, Varibar nectar, Varibar pudding, Varibar thin honey and thin liquid, which would need to be identified on the prescription introducing additional orthographic differences between the two names.  The ending sound 'ar' vs. 'bi' sounds different when spoken.
2.	Varizig	64	The suffix of this name pair has sufficient orthographic differences.  The ending sound 'zig' vs. 'ubi' sounds different when spoken.
3.	Vazobid	64	The suffix of this name pair has sufficient orthographic differences.  The ending sound 'bid' vs. 'ubi' sounds different when spoken.
4.	Valrubicin	56	The prefix of this name pair has sufficient orthographic differences.  The ending sound 'cin' vs. 'ubi' sounds different when spoken.
5.	Vaprino	54	The infix of this name pair has sufficient orthographic differences.  The middle sound 'pri' vs. 'ru' sounds different when spoken.
6.	Viroptic	54	The infix of this name pair has sufficient orthographic differences.  The ending sound 'tic' vs. 'ubi' sounds different when spoken.

7.	Valoid	53	<p>The infix of this name pair has sufficient orthographic differences.</p> <p>The ending sound 'id' vs. 'bi' sounds different when spoken.</p>
8.	Valium	52	<p>The infix of this name pair has sufficient orthographic differences.</p> <p>The middle sound 'li' vs. 'ru' sounds different when spoken.</p>
9.	Valmid	52	<p>The infix of this name pair has sufficient orthographic differences.</p> <p>The ending sound 'mid' vs. 'ubi' sounds different when spoken.</p>
10.	Valpin 50	52	<p>The infix of this name pair has sufficient orthographic differences.</p> <p>The ending sound 'in' vs. 'bi' sounds different when spoken.</p>
11.	Vazotab	52	<p>The suffix of this name pair has sufficient orthographic differences.</p> <p>The ending sound 'tab' vs. 'ubi' sounds different when spoken.</p>
12.	Versed	52	<p>The suffix of this name pair has sufficient orthographic differences.</p> <p>The ending sound 'ed' vs. 'bi' sounds different when spoken.</p>
13.	Vertavis	52	<p>The infix of this name pair has sufficient orthographic differences.</p> <p>The ending sound 'vis' vs. 'ubi' sounds different when spoken.</p>
14.	Verv	52	<p>The suffix of this name pair has sufficient orthographic differences.</p> <p>The length of this name pair is dissimilar.</p> <p>The ending sound 'rv' vs. 'bi' sounds different when spoken.</p>
15.	Vayarin	51	<p>The infix of this name pair has sufficient orthographic differences.</p> <p>The ending sound 'rin' vs. 'ubi' sounds different when</p>

			spoken.
16.	Vitabee 12	51	The infix of this name pair has sufficient orthographic differences. The ending sound 'bee' vs. 'ubi' sounds different when spoken.
17.	Vivarin	51	The suffix of this name pair has sufficient orthographic differences. The ending sound 'in' vs. 'bi' sounds different when spoken.
18.	Berubigen	50	The infix of this name pair has sufficient orthographic differences. The ending sound 'gen' vs. 'ubi' sounds different when spoken.
19.	(b) (4)	50	(b) (4) Varubi is dosed as '2 tabs' or '180 mg'. There are significant dosing differences between these name pair. (b) (4)
20.	Vetribute	50	The infix of this name pair has sufficient orthographic differences. The length of this name pair is dissimilar. The middle sound 'tri' vs. 'ru' sounds different when spoken.
21.	Viramune	50	The suffix of this name pair has sufficient orthographic differences. The middle sound 'amu' vs. 'ru' sounds different when spoken.

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

No.	Name	POCA Score (%)
1.	Verapamil	43

2.	Verelan	42
3.	Vytorin	42
4.	Vasotec	40
5.	Vardenafil	40
6.	Varenicline	36
7.	Vicks Vaporub	36
8.	Valsartan	32
9.	Valtrex	32
10.	Vioxx	22
11.	Analgesic	20

**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.	Varidin	65	Discontinued product with no generic equivalent available.
2.	(b) (4)	62	This is an alternate proposed proprietary name and the product was approved under Enskyce (ANDA 201887).
3.	(b) (4)	59	This is a proposed proprietary name that was denied and another name was submitted for review but withdrawn.
4.	(b) (4)	52	This is an alternate proposed proprietary name and the product was approved under Auvi-Q (NDA 201739).
5.	(b) (4)	56	This is an alternate proposed proprietary name

			and the product was approved under Heather (ANDA 90454).
6.	(b) (4)	54	This is an alternate proposed proprietary name and the product was approved under Zutripro (NDA 22439).
7.	Vybrid	52	This is an alternate proposed proprietary name and the product was approved under Viibrid.
8.	(b) (4)	50	This proprietary name was withdrawn on April, 2010 and (b) (4) was issued a complete response on May 31, 2013.
9.	(b) (4)	50	This is an alternate proposed proprietary name and the product was approved under Latuda (NDA 20603).

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

No.	Name	POCA Score (%)
1.	Edarbi	62
2.	Darbid	58
3.	Froben	56
4.	(b) (4)	56
5.	Frusid	54
6.	Nardil	54
7.	(b) (4)	54
8.	Zarontin	54

9.	Naropin	53
10.	Aridil	52
11.	Farydak	52
12.	Ferro-bob	52
13.	Natroba	52
14.	Orudis	52
15.	Ferus Pic-150	51
16.	Larotid	51
17.	Zerit	51
18.	Aerobid	50
19.	Aredia	50
20.	Barium	50
21.	Ferrimin	50
22.	Ferrimin 150	50
23.	Foradil	50
24.	Iver-on	50
25.	Macrobid	50
26.	Parid	50
27.	Sarapin	50

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/s/  
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SHERLY ABRAHAM  
03/30/2015

KENDRA C WORTHY  
03/30/2015

LUBNA A MERCHANT  
03/30/2015

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**PROPRIETARY NAME REVIEW**

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

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

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**Date of This Review:** November 18, 2014  
**Application Type and Number:** NDA 206500  
**Product Name and Strength:** (b)(4) (Rolapitant) Tablets, 100 mg  
**Product Type:** Single ingredient  
**Rx or OTC:** Rx  
**Applicant/Sponsor Name:** Tesaro, Inc.  
**Submission Date:** September 5, 2014  
**Panorama #:** 2014-26363  
**DMEPA Primary Reviewer:** Sherly Abraham, R.Ph  
**DMEPA Team Leader:** Kendra Worthy, Pharm.D.  
**DMEPA Associate Director:** Lubna Merchant, M.S., Pharm.D.

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/s/  
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SHERLY ABRAHAM  
11/18/2014

KENDRA C WORTHY  
11/18/2014

LUBNA A MERCHANT  
11/18/2014