# CENTER FOR DRUG EVALUATION AND RESEARCH

***APPLICATION NUMBER:***

# 207975Orig1s000

# 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:** | February 24, 2015 |
| **Application Type and Number:** | NDA 207975 |
| **Product Name and Strength:** | Vantrela ER (hydrocodone bitartrate extended-release tablets), 15 mg, 30 mg, 45 mg, 60 mg, and 90 mg |
| **Product Type:** | Single ingredient |
| **Rx or OTC:** | Rx |
| **Applicant/Sponsor Name:** | Teva Branded Pharmaceutical Products R&D, Inc. |
| **Submission Date:** | 12/23/14 |
| **Panorama #:** | 2014-46940 |
| **DMEPA Primary Reviewer:** | Millie Brahmbhatt, PharmD, BCPS |
| **DMEPA Acting Team Leader:** | Vicky Borders-Hemphill, PharmD |

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# 1 INTRODUCTION

This review evaluates the proposed proprietary name, Vantrela ER, 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 sponsor previously submitted the proposed proprietary name, Vantrela ER, on June 13, 2013 for IND 105587. The Division of Medication Error Prevention and Analysis (DMEPA) found the name, Vantrela ER, acceptable from a promotional and safety perspective in OSE Review #2013-1419, dated October 3, 2013.

## 1.2 PRODUCT INFORMATION

The Sponsor provided the following product information in the December 23, 2014 proprietary name submission.

- Intended Pronunciation: \van-tre'-lah\
- Active Ingredient: hydrocodone bitartrate
- Indication of Use: for the management of pain severe enough to require daily, around-the-clock, long-term opioid treatment and for which alternative treatment options are inadequate.
- Route of Administration: Oral
- Dosage Form: Oral tablet, extended-release
- Strength: 15 mg, 30 mg, 45 mg, 60 mg, and 90 mg
- Dose and Frequency: Dosing interval is every 12 hours with a maximum daily dose of 180 mg per day (90 mg every 12 hours). (b) (4)
- How Supplied and Container/Closure System: Bottles containing 100 tablets
- Storage: 20°C to 25°C (68°F to 77°F) [See USP Controlled 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 would not misbrand the proposed product. DMEPA and the Division of Anesthesia,

Analgesia, and Addiction Products (DAAAP) concurred with the findings of OPDP's assessment of the proposed name.

## 2.1 SAFETY ASSESSMENT

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

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

There is no USAN stem present in the proprietary name[1].

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

The Applicant did not provide a derivation or intended meaning for the proposed name, Vantrela ER, in their submission. This proprietary name is comprised of a single word that contains the modifier ER, which refers to the extended-release formulation. We find the use of this modifier to be appropriate.

### *2.1.3 FDA Name Simulation Studies*

Seventy-eight 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.

In the outpatient study, 26 out of 28 participants correctly interpreted the name. One participant misinterpreted the 'a' for 'e' in the prefix. Another participant misinterpreted the 'l' for 't' in the suffix.

In the voice study, 2 out of 22 participants correctly interpreted the name. A common misinterpretation occurred in the suffix of the name where the single 'l' was misinterpreted as double 'll' by 14 out of 22 participants. Another common misinterpretation occurred in the prefix of the name where 'a' was misinterpreted as 'e' by 9 out of 22 participants.

In the inpatient study, 25 out of 28 participants correctly interpreted the name. A common misinterpretation occurred in the suffix of the name where the 'a' was misinterpreted as 'o' by 3 out of 28 participants.

Appendix B contains the results from the verbal and written prescription studies.

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

In response to the OSE January 22, 2015 e-mail, the Division of Anesthesia, Analgesia, and Addiction Products (DAAAP) did not forward any comments or concerns relating to the proposed proprietary name at the initial phase of the review.

[1]USAN stem search conducted on January 20, 2015.

### *2.1.5 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 by (b) (4)

| **Table 1. POCA Search Results** | **Number of Names** |
|---|---|
| Highly similar name pair:<br>combined match percentage score ≥70% | 7 |
| Moderately similar name pair:<br>combined match percentage score ≥50% to ≤ 69% | 297 |
| Low similarity name pair:<br>combined match percentage score ≤49% | 21 |

### *2.1.6 Names with Potential Orthographic, Spelling, and Phonetic Similarities that overlap in strength*

The proposed product, Vantrela ER, will be available in strengths of 30 mg, 45 mg, 60 mg, and 90 mg. Since these are not commonly marketed strengths, we searched the Pragmatic® Regulated Product Labeling Listing and Registration System (PR°PLLR™) database to identify any names with potential orthographic, spelling, and phonetic similarities with Vantrela ER that were not identified in POCA, and found to have an overlap in strength with Vantrela ER.

| **Table 1A.** (PR°PLLR™) **Search Results** | **POCA score** |
|---|---|
| None | N/A |

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

Our analysis of the 325 names contained in Table 1 determined 325 names will not pose a risk for confusion as described in Appendices C through H.

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

DMEPA communicated our findings to the Division of Anesthesia, Analgesia, and Addiction Products (DAAAP) via e-mail on February 11, 2015. At that time we also requested additional information or concerns that could inform our review. Per e-mail correspondence from DAAAP on February 24, 2015, they stated no additional concerns with the proposed proprietary name, Vantrela ER.

[2] POCA search conducted on January 20, 2015.

## 3 CONCLUSIONS

The proposed proprietary name is acceptable.

If you have further questions or need clarifications, please contact Vaishali Jarral, OSE project manager, at 301-796-4248.

### 3.1 COMMENTS TO THE APPLICANT

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

If any of the proposed product characteristics as stated in your December 23, 2014 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).

***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 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 ≥ 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?<br>*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?<br><br>**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.<br><br>For single strength products, also consider circumstances where the strength may not be expressed.<br><br>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.<br><br>To determine whether the strengths or doses are similar to your proposed product, consider the following list of factors that may increase confusion:<br><br>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.<br><br>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.<br><br>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)<br>• Do the names begin with different first letters?<br><br>Note that even when names begin with different first letters, certain letters may be confused with each other when scripted.<br><br>• Are the lengths of the names dissimilar* when scripted?<br><br>*FDA considers the length of names different if the names differ by two or more letters.<br><br>• 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?<br><br>• Is there different number or placement of cross-stroke or dotted letters present in the names?<br><br>• Do the infixes of the name appear dissimilar when scripted?<br><br>• Do the suffixes of the names appear dissimilar when scripted? | Phonetic Checklist (Y/N to each question)<br>• Do the names have different number of syllables?<br><br>• Do the names have different syllabic stresses?<br><br>• Do the syllables have different phonologic processes, such vowel reduction, assimilation, or deletion?<br><br>• 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. Vantrela ER Study (Conducted on January 23, 2015)**

| Handwritten Requisition Medication Order | Verbal Prescription |
|---|---|
| Medication Order:<br>Vantrela ER 15mg PO q 12 hours | Vantrela ER<br>15 mg<br>1 tablet PO Q 12 hours<br>Dispense 100 |
| Outpatient Prescription:<br>Vantrela ER 15mg<br>1 po q12hrs<br>#100 | |

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

252 People Received Study
78 People Responded

**Study Name: Vantrela ER**

| Total | 28 | 22 | 28 | |
|---|---|---|---|---|
| **INTERPRETATION** | **OUTPATIENT** | **VOICE** | **INPATIENT** | **TOTAL** |
| BENTRELA ER | 0 | 1 | 0 | 1 |
| VANTRELA ER | 25 | 2 | 24 | 51 |
| VANTRELA ER 115MG | 1 | 0 | 0 | 1 |
| VANTRELA ER 15 MG | 0 | 0 | 1 | 1 |
| VANTRELER ER | 0 | 1 | 0 | 1 |
| VANTRELLA ER | 0 | 8 | 0 | 8 |
| VANTRELLS ER | 0 | 1 | 0 | 1 |
| VANTRELO ER | 0 | 0 | 3 | 3 |
| VANTRETA ER | 1 | 0 | 0 | 1 |
| VENTRALLA ER | 0 | 1 | 0 | 1 |
| VENTRELA ER | 1 | 2 | 0 | 3 |
| VENTRELLA | 0 | 1 | 0 | 1 |
| VENTRELLA ER | 0 | 3 | 0 | 3 |
| VENTRILA ER | 0 | 1 | 0 | 1 |
| ZANTRELA ER | 0 | 1 | 0 | 1 |

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

| No. | **Proposed name: Vantrela ER**<br>**Established name: hydrocodone bitartrate**<br>**Dosage form: extended-release tablets**<br>**Strength(s): 15 mg, 30 mg, 45 mg, 60 mg, 90 mg**<br>**Usual Dose: Dosing interval is every 12 hours with a maximum daily dose of 180 mg per day** | **POCA Score (%)** | **Orthographic and/or phonetic differences in the names sufficient to prevent confusion**<br>**Other prevention of failure mode expected to minimize the risk of confusion between these two names.** |
|---|---|---|---|
| 1. | Vantrela ER*** | 79 | Name is the subject of this review. |
| 2. | Vontrol | 78 | The suffixes 'la' and 'trol' have sufficient orthographic differences. The last syllables of this name pair sound different. Vantrela has an extra syllable. Vontrol is no longer marketed and there are no therapeutic equivalents available. |
| 3. | Zantryl | 77 | The suffixes 'la' and 'tryl' have sufficient orthographic differences. The last syllables of this name pair sound different. Vantrela has an extra syllable. |
| 4. | Andro LA | 72 | The prefixes 'Van' and 'And' and suffixes 'la' and 'dro' have sufficient orthographic differences. The root name Andro has 5 letters, whereas Vantrela has 8 letters, giving it a longer length when scripted. The last syllables of this name pair sound different. Vantrela has an extra syllable. |
| 5. | Andro LA 200 | 72 | The prefixes 'Van' and 'And' and suffixes 'la' and 'dro' have sufficient orthographic differences. The root name Andro has 5 letters, whereas Vantrela has 8 letters, giving it a longer length when scripted. The last syllables of this name pair sound different. Vantrela has an extra syllable. |
| 6. | Vanceril | 72 | The infixes 'tre' and 'cer' and suffixes 'la' and 'il' have sufficient orthographic differences. The second and last syllables of this name pair sound different. This product is withdrawn (FR Effective 6/16/2006). |

| No. | Proposed name: Vantrela ER<br>Established name: hydrocodone bitartrate<br>Dosage form: extended-release tablets<br>Strength(s): 15 mg, 30 mg, 45 mg, 60 mg, 90 mg<br>Usual Dose: Dosing interval is every 12 hours with a maximum daily dose of 180 mg per day | POCA Score (%) | Orthographic and/or phonetic differences in the names sufficient to prevent confusion<br><br>Other prevention of failure mode expected to minimize the risk of confusion between these two names. |
|---|---|---|---|
| 7. | (b) (4) *** | 70 | (b) (4) |

**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. | Victrelis | 65 |
| 2. | Nostrilla | 64 |
| 3. | Vivitrol | 62 |
| 4. | Mandelay | 59 |
| 5. | Fanatrex | 58 |
| 6. | Anthralin | 56 |
| 7. | Entrocel | 56 |
| 8. | Gentlelax | 56 |
| 9. | Santyl | 56 |
| 10. | Vaprisol | 56 |
| 11. | Gentran 40 | 54 |
| 12. | Gentran 70 | 54 |
| 13. | Jetrea | 54 |

| No. | Proposed Name | POCA Score (%) |
|---|---|---|
| 14. | Kcentra | 54 |
| 15. | Soolantra | 54 |
| 16. | Vaniply | 54 |
| 17. | Vazculep | 53 |
| 18. | Ventavis | 53 |
| 19. | Hizentra | 52 |
| 20. | Increlex | 52 |
| 21. | Mantadil | 52 |
| 22. | Ovidrel | 52 |
| 23. | Pentrax | 52 |
| 24. | Vectical | 52 |
| 25. | Vincasar | 52 |
| 26. | Acthrel | 51 |
| 27. | Antizol | 51 |
| 28. | Pyrantel | 51 |
| 29. | Victoza | 51 |
| 30. | Vaniqa | 50 |
| 31. | Vaseline | 50 |
| 32. | Vasoclear A | 50 |
| 33. | Vitrase | 50 |

**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: Vantrela ER**<br>**Established name: hydrocodone bitartrate**<br>**Dosage form: extended-release tablets**<br>**Strength(s): 15 mg, 30 mg, 45 mg, 60 mg, 90 mg**<br>**Usual Dose: Dosing interval is every 12 hours with a maximum daily dose of 180 mg per day** | **POCA Score (%)** | **Prevention of Failure Mode**<br>**In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names** |
|---|---|---|---|
| 1. | Vanex-LA | 68 | The suffixes of this name pair have sufficient orthographic differences. The root name Vanex has 5 letters, whereas Vantrela has 8 letters, giving it a longer length when scripted.<br>The last syllables of this name pair sound different. Vantrela contains an extra syllable. |
| 2. | Bontril | 66 | The suffixes of this name pair have sufficient orthographic differences.<br>The last syllables of this name pair sound different. Vantrela contains an extra syllable. |
| 3. | Vental | 65 | The suffixes of this name pair have sufficient orthographic differences.<br>The last syllables of this name pair sound different. Vantrela contains an extra syllable. |
| 4. | (b) (4) *** | 64 | The prefixes and suffixes of this name pair have sufficient orthographic differences.<br>The first and last syllables of this name pair sound different. |
| 5. | Vancoled | 64 | The infixes and suffixes of this name pair have sufficient orthographic differences.<br>The second and last syllables of this name pair sound different. |

| No. | Proposed name: Vantrela ER<br>Established name: hydrocodone bitartrate<br>Dosage form: extended-release tablets<br>Strength(s): 15 mg, 30 mg, 45 mg, 60 mg, 90 mg<br>Usual Dose: Dosing interval is every 12 hours with a maximum daily dose of 180 mg per day | POCA Score (%) | Prevention of Failure Mode<br>In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names |
|---|---|---|---|
| 6. | Ventolin | 64 | The suffixes of this name pair have sufficient orthographic differences.<br>The last syllables of this name pair sound different. |
| 7. | Fematrol | 63 | The prefixes and suffixes of this name pair have sufficient orthographic differences.<br>The first and last syllables of this name pair sound different. |
| 8. | Avandaryl | 62 | The suffixes of this name pair have sufficient orthographic differences.<br>The last syllables of this name pair sound different. |
| 9. | Vanatrip | 62 | The suffixes of this name pair have sufficient orthographic differences.<br>The last syllables of this name pair sound different. |
| 10. | Femintrol | 60 | The prefixes and suffixes of this name pair have sufficient orthographic differences.<br>The first and last syllables of this name pair sound different. |
| 11. | Genpril | 60 | The prefixes and suffixes of this name pair have sufficient orthographic differences.<br>The last syllables of this name pair sound different. Vantrela contains an extra syllable. |
| 12. | Naprelan | 60 | The prefixes and suffixes of this name pair have sufficient orthographic differences.<br>The first and last syllables of this name pair sound different. |

| No. | **Proposed name: Vantrela ER**<br>**Established name: hydrocodone bitartrate**<br>**Dosage form: extended-release tablets**<br>**Strength(s): 15 mg, 30 mg, 45 mg, 60 mg, 90 mg**<br>**Usual Dose: Dosing interval is every 12 hours with a maximum daily dose of 180 mg per day** | **POCA Score (%)** | **Prevention of Failure Mode**<br>**In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names** |
|---|---|---|---|
| 13. | Vansil | 60 | The suffixes of this name pair have sufficient orthographic differences. Vansil contains 6 letters, whereas Vantrela contains 8 letters, giving it a longer length when scripted.<br>The last syllables of this name pair sound different. Vantrela contains an extra syllable. |
| 14. | Verelan | 60 | The suffixes of this name pair have sufficient orthographic differences.<br>The last syllables of this name pair sound different. |
| 15. | Vistaril | 60 | The suffixes of this name pair have sufficient orthographic differences.<br>The first and last syllables of this name pair sound different. |
| 16. | Zestril | 60 | The prefixes and suffixes of this name pair have sufficient orthographic differences.<br>The first and last syllables of this name pair sound different. Vantrela contains an extra syllable. |
| 17. | Dantrolene | 59 | The suffixes of this name pair have sufficient orthographic differences. Dantrolene contains 10 letters, whereas Vantrela contains 8 letters, giving it a shorter length when scripted.<br>The last syllables of this name pair sound different. |

| No. | Proposed name: Vantrela ER<br>Established name: hydrocodone bitartrate<br>Dosage form: extended-release tablets<br>Strength(s): 15 mg, 30 mg, 45 mg, 60 mg, 90 mg<br>Usual Dose: Dosing interval is every 12 hours with a maximum daily dose of 180 mg per day | POCA Score (%) | Prevention of Failure Mode<br>In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names |
|---|---|---|---|
| 18. | Vilanterol | 59 | The suffixes of this name pair have sufficient orthographic differences. Vilanterol contains 10 letters, whereas Vantrela contains 8 letters, giving it a shorter length when scripted.<br>The last syllables of this name pair sound different. Vilanterol contains an extra syllable. |
| 19. | Antrocol | 58 | The suffixes of this name pair have sufficient orthographic differences.<br>The last syllables of this name pair sound different. |
| 20. | Atreza | 58 | The prefixes and suffixes of this name pair have sufficient orthographic differences. Atreza contains 6 letters, whereas Vantrela contains 8 letters, giving it a longer length when scripted.<br>The first and last syllables of this name pair sound different. Vantrela contains an extra syllable. |
| 21. | Caprelsa | 58 | The prefixes of this name pair have sufficient orthographic differences.<br>The first syllables of this name pair sound different. |
| 22. | Valtrex | 58 | The suffixes of this name pair have sufficient orthographic differences.<br>The last syllables of this name pair sound different. Vantrela contains an extra syllable. |
| 23. | Vanachol | 58 | The infixes and suffixes of this name pair have sufficient orthographic differences.<br>The second and last syllables of this name pair sound different. |

| No. | Proposed name: Vantrela ER<br>Established name: hydrocodone bitartrate<br>Dosage form: extended-release tablets<br>Strength(s): 15 mg, 30 mg, 45 mg, 60 mg, 90 mg<br>Usual Dose: Dosing interval is every 12 hours with a maximum daily dose of 180 mg per day | POCA Score (%) | Prevention of Failure Mode<br>In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names |
|---|---|---|---|
| 24. | (b) (4) *** | 58 | The suffixes of this name pair have sufficient orthographic differences.<br>The last syllables of this name pair sound different. |
| 25. | Lantex-LA | 57 | The suffixes of this name pair have sufficient orthographic differences. Lantex contains 6 letters, whereas Vantrela contains 8 letters, giving it a longer length when scripted.<br>The last syllables of this name pair sound different. Vantrela contains an extra syllable. |
| 26. | Vantas | 57 | The suffixes of this name pair have sufficient orthographic differences. Vantas contains 6 letters, whereas Vantrela contains 8 letters, giving it a longer length when scripted.<br>The last syllables of this name pair sound different. Vantrela contains an extra syllable. |
| 27. | Enbrel | 56 | The suffixes of this name pair have sufficient orthographic differences. Enbrel contains 6 letters, whereas Vantrela contains 8 letters, giving it a longer length when scripted.<br>The last syllables of this name pair sound different. Vantrela contains an extra syllable. |
| 28. | Guanadrel | 56 | The prefixes of this name pair have sufficient orthographic differences.<br>The second and last syllables of this name pair sound different. |

| No. | Proposed name: Vantrela ER<br>Established name: hydrocodone bitartrate<br>Dosage form: extended-release tablets<br>Strength(s): 15 mg, 30 mg, 45 mg, 60 mg, 90 mg<br>Usual Dose: Dosing interval is every 12 hours with a maximum daily dose of 180 mg per day | POCA Score (%) | Prevention of Failure Mode<br>In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names |
|---|---|---|---|
| 29. | Intron A | 56 | The prefixes and suffixes of this name pair have sufficient orthographic differences. Intron contains 6 letters, whereas Vantrela contains 8 letters, giving it a longer length when scripted.<br>The first and last syllables of this name pair sound different. Vantrela contains an extra syllable. |
| 30. | Pimtrea | 56 | The prefixes of this name pair have sufficient orthographic differences.<br>The first syllables of this name pair sound different. |
| 31. | Renvela | 56 | The prefixes of this name pair have sufficient orthographic differences.<br>The first syllables of this name pair sound different. |
| 32. | Valu-Dryl | 56 | The infixes and suffixes of this name pair have sufficient orthographic differences.<br>The second and last syllables of this name pair sound different. |
| 33. | Vandazole | 56 | The infixes and suffixes of this name pair have sufficient orthographic differences.<br>The second and last syllables of this name pair sound different. |
| 34. | Vistra | 56 | The suffixes of this name pair have sufficient orthographic differences. Vistra contains 6 letters, whereas Vantrela contains 8 letters, giving it a longer length when scripted.<br>The last syllables of this name pair sound different. Vantrela contains an extra syllable. |

| No. | Proposed name: Vantrela ER<br>Established name: hydrocodone bitartrate<br>Dosage form: extended-release tablets<br>Strength(s): 15 mg, 30 mg, 45 mg, 60 mg, 90 mg<br>Usual Dose: Dosing interval is every 12 hours with a maximum daily dose of 180 mg per day | POCA Score (%) | Prevention of Failure Mode<br>In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names |
|---|---|---|---|
| 35. | Zentrip | 56 | The suffixes of this name pair have sufficient orthographic differences.<br>The last syllables of this name pair sound different. |
| 36. | Cantil | 55 | The suffixes of this name pair have sufficient orthographic differences. Cantil contains 6 letters, whereas Vantrela contains 8 letters, giving it a longer length when scripted.<br>The last syllables of this name pair sound different. Vantrela contains an extra syllable. |
| 37. | Nortrel | 55 | The prefixes of this name pair have sufficient orthographic differences.<br>The first syllables of this name pair sound different. Vantrela contains an extra syllable. |
| 38. | Nortrel 0.5/35-21 | 55 | The prefixes of this name pair have sufficient orthographic differences.<br>The first syllables of this name pair sound different. Vantrela contains an extra syllable. |
| 39. | Nortrel 0.5/35-28 | 55 | The prefixes of this name pair have sufficient orthographic differences.<br>The first syllables of this name pair sound different. Vantrela contains an extra syllable. |
| 40. | Nortrel 1/35-21 | 55 | The prefixes of this name pair have sufficient orthographic differences.<br>The first syllables of this name pair sound different. Vantrela contains an extra syllable. |

| No. | Proposed name: Vantrela ER<br>Established name: hydrocodone bitartrate<br>Dosage form: extended-release tablets<br>Strength(s): 15 mg, 30 mg, 45 mg, 60 mg, 90 mg<br>Usual Dose: Dosing interval is every 12 hours with a maximum daily dose of 180 mg per day | POCA Score (%) | Prevention of Failure Mode<br>In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names |
|---|---|---|---|
| 41. | Nortrel 1/35-28 | 55 | The prefixes of this name pair have sufficient orthographic differences.<br>The first syllables of this name pair sound different. Vantrela contains an extra syllable. |
| 42. | Nortrel 7/7/7 | 55 | The prefixes of this name pair have sufficient orthographic differences.<br>The first syllables of this name pair sound different. Vantrela contains an extra syllable. |
| 43. | Avandia | 54 | The suffixes of this name pair have sufficient orthographic differences.<br>The last syllables of this name pair sound different. |
| 44. | Dantrium | 54 | The suffixes of this name pair have sufficient orthographic differences.<br>The last syllables of this name pair sound different. |
| 45. | Isentress | 54 | The prefixes and suffixes of this name pair have sufficient orthographic differences.<br>The first and last syllables of this name pair sound different. |
| 46. | Norel LA | 54 | The prefixes of this name pair have sufficient orthographic differences. Norel contains 5 letters, whereas Vantrela contains 8 letters, giving it a longer length when scripted.<br>The first syllables of this name pair sound different. Vantrela contains an extra syllable. |

| No. | **Proposed name: Vantrela ER**<br>**Established name: hydrocodone bitartrate**<br>**Dosage form: extended-release tablets**<br>**Strength(s): 15 mg, 30 mg, 45 mg, 60 mg, 90 mg**<br>**Usual Dose: Dosing interval is every 12 hours with a maximum daily dose of 180 mg per day** | **POCA Score (%)** | **Prevention of Failure Mode**<br>**In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names** |
|---|---|---|---|
| 47. | Vantin | 54 | The suffixes of this name pair have sufficient orthographic differences. Vantin contains 6 letters, whereas Vantrela contains 8 letters, giving it a longer length when scripted.<br>The last syllables of this name pair sound different. Vantrela contains an extra syllable. |
| 48. | Vita-Respa | 54 | The prefixes and suffixes of this name pair have sufficient orthographic differences.<br>The first and second syllables of this name pair sound different. |
| 49. | Antara | 53 | The suffixes of this name pair have sufficient orthographic differences. Antara contains 6 letters, whereas Vantrela contains 8 letters, giving it a longer length when scripted.<br>The last syllables of this name pair sound different. |
| 50. | Ventolin HFA | 53 | The suffixes of this name pair have sufficient orthographic differences.<br>The last syllables of this name pair sound different. |
| 51. | Crantex LA | 52 | The prefixes and suffixes of this name pair have sufficient orthographic differences.<br>The first and last syllables of this name pair sound different. Vantrela contains an extra syllable. |

| No. | Proposed name: Vantrela ER<br>Established name: hydrocodone bitartrate<br>Dosage form: extended-release tablets<br>Strength(s): 15 mg, 30 mg, 45 mg, 60 mg, 90 mg<br>Usual Dose: Dosing interval is every 12 hours with a maximum daily dose of 180 mg per day | POCA Score (%) | Prevention of Failure Mode<br>In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names |
|---|---|---|---|
| 52. | Entre-B | 52 | The prefixes and suffixes of this name pair have sufficient orthographic differences. Entre-B contains 6 letters, whereas Vantrela contains 8 letters, giving it a longer length when scripted.<br>The first and last syllables of this name pair sound different. Vantrela contains an extra syllable. |
| 53. | Entre-S | 52 | The prefixes and suffixes of this name pair have sufficient orthographic differences. Entre-B contains 6 letters, whereas Vantrela contains 8 letters, giving it a longer length when scripted.<br>The first and last syllables of this name pair sound different. Vantrela contains an extra syllable. |
| 54. | Evomela*** | 52 | The prefixes and infixes of this name pair have sufficient orthographic differences.<br>The first syllables of this name pair sound different. |
| 55. | (b) (4) *** | 52 | The prefixes and infixes of this name pair have sufficient orthographic differences.<br>The first and second syllables of this name pair sound different. |
| 56. | Lotrel | 52 | The prefixes of this name pair have sufficient orthographic differences. Lotrel contains 6 letters, whereas Vantrela contains 8 letters, giving it a longer length when scripted.<br>The first syllables of this name pair sound different. Vantrela contains an extra syllable. |

| No. | Proposed name: Vantrela ER<br>Established name: hydrocodone bitartrate<br>Dosage form: extended-release tablets<br>Strength(s): 15 mg, 30 mg, 45 mg, 60 mg, 90 mg<br>Usual Dose: Dosing interval is every 12 hours with a maximum daily dose of 180 mg per day | POCA Score (%) | Prevention of Failure Mode<br>In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names |
|---|---|---|---|
| 57. | Metaprel | 52 | The prefixes of this name pair have sufficient orthographic differences.<br>The first syllables of this name pair sound different. |
| 58. | Vancocin | 52 | The infixes and suffixes of this name pair have sufficient orthographic differences.<br>The second and last syllables of this name pair sound different. |
| 59. | Vanspar | 52 | The suffixes of this name pair have sufficient orthographic differences.<br>The last syllables of this name pair sound different. Vantrela contains an extra syllable. |
| 60. | Vestura*** | 52 | The infixes of this name pair have sufficient orthographic differences.<br>The second syllables of this name pair sound different. |
| 61. | Entresto*** | 51 | The suffixes of this name pair have sufficient orthographic differences.<br>The last syllables of this name pair sound different. |
| 62. | Photrexa*** | 51 | The prefixes of this name pair have sufficient orthographic differences.<br>The first syllables of this name pair sound different. |
| 63. | Avanafil | 50 | The infixes and suffixes of this name pair have sufficient orthographic differences.<br>The second and last syllables of this name pair sound different. Avanafil contains an extra syllable. |

| No. | **Proposed name: Vantrela ER**<br>**Established name: hydrocodone bitartrate**<br>**Dosage form: extended-release tablets**<br>**Strength(s): 15 mg, 30 mg, 45 mg, 60 mg, 90 mg**<br>**Usual Dose: Dosing interval is every 12 hours with a maximum daily dose of 180 mg per day** | **POCA Score (%)** | **Prevention of Failure Mode**<br>**In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names** |
|---|---|---|---|
| 64. | Bontril PDM | 50 | The suffixes of this name pair have sufficient orthographic differences.<br>The last syllables of this name pair sound different. Vantrela contains an extra syllable. |
| 65. | Limbrel | 50 | The prefixes of this name pair have sufficient orthographic differences.<br>The first syllables of this name pair sound different. Vantrela contains an extra syllable. |
| 66. | Nasarel | 50 | The prefixes and infixes of this name pair have sufficient orthographic differences.<br>The first and second syllables of this name pair sound different. |
| 67. | Ogestrel | 50 | The prefixes of this name pair have sufficient orthographic differences.<br>The first and second syllables of this name pair sound different. |
| 68. | Ogestrel 0.5/50-21 | 50 | The prefixes of this name pair have sufficient orthographic differences.<br>The first and second syllables of this name pair sound different. |
| 69. | Ogestrel 0.5/50-28 | 50 | The prefixes of this name pair have sufficient orthographic differences.<br>The first and second syllables of this name pair sound different. |

| No. | Proposed name: Vantrela ER<br>Established name: hydrocodone bitartrate<br>Dosage form: extended-release tablets<br>Strength(s): 15 mg, 30 mg, 45 mg, 60 mg, 90 mg<br>Usual Dose: Dosing interval is every 12 hours with a maximum daily dose of 180 mg per day | POCA Score (%) | Prevention of Failure Mode<br>In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names |
|---|---|---|---|
| 70. | Phentride | 50 | The prefixes and suffixes of this name pair have sufficient orthographic differences.<br>The first and last syllables of this name pair sound different. Vantrela contains an extra syllable. |
| 71. | Vanatab | 50 | The prefixes and infixes of this name pair have sufficient orthographic differences.<br>The second and last syllables of this name pair sound different. |
| 72. | Vectrin | 50 | The suffixes of this name pair have sufficient orthographic differences.<br>The last syllables of this name pair sound different. Vantrela contains an extra syllable. |
| 73. | Venelex | 50 | The infixes and suffixes of this name pair have sufficient orthographic differences.<br>The second and last syllables of this name pair sound different. |
| 74. | Verelan PM | 50 | The infixes and suffixes of this name pair have sufficient orthographic differences.<br>The second and last syllables of this name pair sound different. |
| 75. | (b) (4) *** | 50 | The suffixes of this name pair have sufficient orthographic differences.<br>The last syllables of this name pair sound different. Vantrela contains an extra syllable. |

| No. | **Proposed name: Vantrela ER**<br>**Established name: hydrocodone bitartrate**<br>**Dosage form: extended-release tablets**<br>**Strength(s): 15 mg, 30 mg, 45 mg, 60 mg, 90 mg**<br>**Usual Dose: Dosing interval is every 12 hours with a maximum daily dose of 180 mg per day** | **POCA Score (%)** | **Prevention of Failure Mode**<br>**In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names** |
|---|---|---|---|
| 76. | Virilon | 50 | The infixes and suffixes of this name pair have sufficient orthographic differences.<br>The second and last syllables of this name pair sound different. |
| 77. | Vitrax | 50 | The suffixes of this name pair have sufficient orthographic differences.<br>The last syllables of this name pair sound different. Vantrela contains an extra syllable. |
| 78. | Vivactil | 50 | The infixes and suffixes of this name pair have sufficient orthographic differences.<br>The second and last syllables of this name pair sound different. |

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

| No. | Name | POCA Score (%) |
|---|---|---|
| 1. | Trelstar | 48 |
| 2. | valacyclovir | 46 |
| 3. | Vantas | 46 |
| 4. | Varithena | 46 |
| 5. | Karbinal ER | 44 |
| 6. | Vagisil | 38 |
| 7. | Zantac | 38 |
| 8. | Zohydro ER | 38 |
| 9. | Targiniq ER | 36 |
| 10. | Vyfemla | 35 |
| 11. | vancomycin | 34 |
| 12. | Xartemis XR | 33 |
| 13. | Zenatane | 33 |
| 14. | ondansetron | 32 |
| 15. | Pirmella 1/35 | 30 |
| 16. | Zydelig | 28 |
| 17. | Gilotrif | 26 |
| 18. | Otezla | 26 |
| 19. | Xanax | 25 |
| 20. | Tivorbex | 22 |
| 21. | Osphena | 14 |

**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. | Factrel | 69 | Veterinary product |

| No. | Name | POCA Score (%) | Failure preventions |
|---|---|---|---|
| 2. | Sandrena | 68 | Name identified in Rx Norm database. Unable to find product characteristics in commonly used drug databases. |
| 3. | Sandril | 66 | Withdrawn FR effective 1992. No generics available. |
| 4. | (b) (4) *** | 65 | (b) (4) |
| 5. | (b) (4) *** | 63 | NDA 21897 is approved with the proprietary name Vivitrol. |
| 6. | Antrenyl | 62 | Withdrawn FR effective 1993. No generics available. |
| 7. | Slentrol | 62 | Veterinary product |
| 8. | Anturol | 60 | Name identified in Rx Norm database. Unable to find product characteristics in commonly used drug databases. |
| 9. | Gastrese-LA | 60 | Name identified in Rx Norm database. Unable to find product characteristics in commonly used drug databases. |
| 10. | Introl | 60 | Name identified in Rx Norm database. Unable to find product characteristics in commonly used drug databases. |

| No. | Name | POCA Score (%) | Failure preventions |
|---|---|---|---|
| 11. | (b) (4) *** | 60 | (b) (4) |
| 12. | (b) (4) *** | 60 | |
| 13. | Vincrex | 60 | Withdrawn FR effective 2006. No generics available. |
| 14. | (b) (4) *** | 59 | (b) (4) |
| 15. | Lantrisul | 59 | Name identified in Drugs at FDA database. Unable to find dose information in commonly used drug databases. |
| 16. | Santex LA | 59 | Name identified in Rx Norm database. Unable to find product characteristics in commonly used drug databases. |
| 17. | Vetadryl | 59 | Veterinary product |
| 18. | Vitadil 2A | 59 | Name identified in Rx Norm database. Unable to find product characteristics in commonly used drug databases. |

| No. | Name | POCA Score (%) | Failure preventions |
|---|---|---|---|
| 19. | Vitadil 5A | 59 | Name identified in Rx Norm database. Unable to find product characteristics in commonly used drug databases. |
| 20. | Bonjela | 58 | Name identified in Rx Norm database. Unable to find product characteristics in commonly used drug databases. |
| 21. | Santura | 58 | Name identified in Rx Norm database. Unable to find product characteristics in commonly used drug databases. |
| 22. | Vanceril DS | 58 | Name identified in Rx Norm database. Unable to find product characteristics in commonly used drug databases. |
| 23. | Vasyrol | 58 | Name identified in Rx Norm database. Unable to find product characteristics in commonly used drug databases. |
| 24. | Vetoryl | 58 | Veterinary product |
| 25. | Vivapryl | 58 | Name identified in Rx Norm database. Unable to find product characteristics in commonly used drug databases. |
| 26. | Kantrex | 57 | Withdrawn FR effective 2004. No generics available. |
| 27. | Symmetrel | 57 | Withdrawn FR effective 2010. |

| No. | Name | POCA Score (%) | Failure preventions |
|---|---|---|---|
| 28. | (b) (4) *** | 57 | (b) (4) |
| 29. | Febantel | 56 | Veterinary product |
| 30. | (b) (4) *** | 56 | Proprietary name request withdrawn. (b) (4) |
| 31. | Valturna | 56 | Withdrawn FR effective 2015. No generics available. |
| 32. | (b) (4) *** | 56 | Proprietary name request withdrawn. Product approved under new proprietary name Vasostrict. |
| 33. | Vetalar | 56 | Name identified in Rx Norm database. Unable to find product characteristics in commonly used drug databases. |
| 34. | Viril Lam | 56 | Name identified in Rx Norm database. Unable to find product characteristics in commonly used drug databases. |
| 35. | (b) (4) *** | 55 | (b) (4) |
| 36. | Contraflam | 55 | Name identified in Rx Norm database. Unable to find product characteristics in commonly used drug databases. |

| No. | Name | POCA Score (%) | Failure preventions |
|---|---|---|---|
| 37. | Voltarol | 55 | Name identified in Rx Norm database. Unable to find product characteristics in commonly used drug databases. |
| 38. | Betnelan | 54 | Name identified in Rx Norm database. Unable to find product characteristics in commonly used drug databases. |
| 39. | Centrax | 54 | Withdrawn FR effective 1996. No generics available. |
| 40. | Elantan LA | 54 | Name identified in Rx Norm database. Unable to find product characteristics in commonly used drug databases. |
| 41. | Vanillin | 53 | Product is not a drug but is used as a flavor and in perfumery. |
| 42. | Ventaire | 53 | Withdrawn FR effective 1983. No generics available. |
| 43. | Vi-twel | 53 | Withdrawn FR effective 2002. No generics available. |
| 44. | Anti Cle | 52 | Name identified in Rx Norm database. Unable to find product characteristics in commonly used drug databases. |
| 45. | Gantrisin | 52 | Withdrawn FR effective 2011. No generics available. |

| No. | Name | POCA Score (%) | Failure preventions |
|---|---|---|---|
| 46. | Lutrelin | 52 | Name identified in Rx Norm database. Unable to find product characteristics in commonly used drug databases. |
| 47. | Novantrone | 52 | Withdrawn FR effective 2012. No generics available. |
| 48. | Paxarel | 52 | Name identified in Rx Norm database. Unable to find product characteristics in commonly used drug databases. |
| 49. | Pentran | 52 | Name identified in Rx Norm database. Unable to find product characteristics in commonly used drug databases. |
| 50. | Point relief | 52 | Name identified in Rx Norm database. Unable to find product characteristics in commonly used drug databases. |
| 51. | Prantal | 52 | Withdrawn FR effective 1990. No generics available. |
| 52. | (b) (4) *** | 52 | (b) (4) |
| 53. | Tantalum | 52 | Name identified in Rx Norm database. Unable to find product characteristics in commonly used drug databases. |

| No. | Name | POCA Score (%) | Failure preventions |
|---|---|---|---|
| 54. | Vagilia | 52 | Name identified in Drugs at FDA database. Unable to find dose information in commonly used drug databases. Marketing status is discontinued. No therapeutic equivalents. |
| 55. | Vancor | 52 | Withdrawn FR effective 1992. No therapeutic equivalents. |
| 56. | (b) (4) *** | 52 | This is a secondary proposed proprietary name for NDA 022484 and product was approved under the proprietary name Onmel. |
| 57. | (b) (4) *** | 52 | (b) (4) |
| 58. | Morantel | 51 | Veterinary product |
| 59. | (b) (4) *** | 51 | (b) (4) |
| 60. | Vascoray | 51 | Withdrawn FR effective 2009. No therapeutic equivalents. |
| 61. | Antisedan | 50 | Veterinary product |
| 62. | Centrapryl | 50 | Name identified in Rx Norm database. Unable to find product characteristics in commonly used drug databases. |

| No. | Name | POCA Score (%) | Failure preventions |
|---|---|---|---|
| 63. | Centrine | 50 | Veterinary product |
| 64. | (b) (4) *** | 50 | NDA 22204 approved under the proprietary name Gelnique. |
| 65. | (b) (4) *** | 50 | (b) (4) |
| 66. | Vetrimec | 50 | Veterinary product |

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

| No. | Name | POCA Score (%) |
|---|---|---|
| 1. | Detrol LA | 62 |
| 2. | Inderal LA | 62 |
| 3. | Inderal-LA | 62 |
| 4. | Petrola | 62 |
| 5. | Testro-L.A. | 62 |
| 6. | Flamatrol | 60 |
| 7. | Sano-Drol | 60 |
| 8. | Tanderil | 60 |
| 9. | Atripla | 59 |
| 10. | Amitril | 58 |
| 11. | Andryl 200 | 58 |
| 12. | Aventyl | 58 |
| 13. | Benadryl | 58 |
| 14. | Fentora | 58 |
| 15. | Fostril | 58 |
| 16. | Gabitril | 58 |
| 17. | Zinbryta | 58 |
| 18. | Jinteli | 57 |
| 19. | Yenrila | 57 |
| 20. | Activella | 56 |
| 21. | Banex-LA | 56 |
| 22. | Campral | 56 |
| 23. | Cartrol | 56 |
| 24. | Cebatrol | 56 |
| 25. | Fenex-LA | 56 |
| 26. | Fortral | 56 |
| 27. | Lemtrada | 56 |
| 28. | Parpreza | 56 |

| No. | Name | POCA Score (%) |
|---|---|---|
| 29. | Banaril | 55 |
| 30. | Baytril | 55 |
| 31. | Bentyl | 55 |
| 32. | Dandrex | 55 |
| 33. | Rivotril | 55 |
| 34. | Abstral | 54 |
| 35. | Aknetrol | 54 |
| 36. | Ampriva | 54 |
| 37. | Anadrol-50 | 54 |
| 38. | Anipryl | 54 |
| 39. | Benoral | 54 |
| 40. | Bentasil | 54 |
| 41. | Benzepril | 54 |
| 42. | Enaprilat | 54 |
| 43. | Fenoterol | 54 |
| 44. | Mitrolan | 54 |
| 45. | Monopril | 54 |
| 46. | Nandrolone | 54 |
| 47. | Pandel | 54 |
| 48. | Penidural-LA | 54 |
| 49. | Phentex LA | 54 |
| 50. | Ramipril | 54 |
| 51. | Ramiprilat | 54 |
| 52. | Sanfed A | 54 |
| 53. | Titralac | 54 |
| 54. | Wartrol | 54 |
| 55. | Westrim LA | 54 |
| 56. | Winstrol | 54 |
| 57. | Xamoterol | 54 |
| 58. | Xtra-Lax | 54 |

| No. | Name | POCA Score (%) |
|---|---|---|
| 59. | AK-Trol | 53 |
| 60. | Emtriva | 53 |
| 61. | Papreeza | 53 |
| 62. | Phenydryl | 53 |
| 63. | Tandearil | 53 |
| 64. | Zactran | 53 |
| 65. | Zamdray | 53 |
| 66. | Acerola | 52 |
| 67. | Afemtra | 52 |
| 68. | Amprol | 52 |
| 69. | Amprol 128 | 52 |
| 70. | Anatuss LA | 52 |
| 71. | Androgel | 52 |
| 72. | Banzel | 52 |
| 73. | Capitrol | 52 |
| 74. | Dentagel | 52 |
| 75. | Entex LA | 52 |
| 76. | Estrate LA | 52 |
| 77. | Gentex LA | 52 |
| 78. | Inderide LA | 52 |
| 79. | Inderide LA 120/50 | 52 |
| 80. | Inderide LA 160/50 | 52 |
| 81. | Inderide LA 80/50 | 52 |
| 82. | Natroba | 52 |
| 83. | Pentacel | 52 |
| 84. | Preventoral | 52 |
| 85. | Sanctura | 52 |
| 86. | Sectral | 52 |
| 87. | Statrol | 52 |
| 88. | Tanoral | 52 |

| No. | Name | POCA Score (%) |
|---|---|---|
| 89. | Yosprala | 52 |
| 90. | Zavryl | 52 |
| 91. | Zodryl AC | 52 |
| 92. | Atralin | 51 |
| 93. | Detrol | 51 |
| 94. | Estarylla | 51 |
| 95. | Fentanyl | 51 |
| 96. | Fentanyl-100 | 51 |
| 97. | Fentanyl-12 | 51 |
| 98. | Fentanyl-25 | 51 |
| 99. | Fentanyl-50 | 51 |
| 100. | Fentanyl-75 | 51 |
| 101. | Gentle | 51 |
| 102. | Habitrol | 51 |
| 103. | Natrilix | 51 |
| 104. | Solvent red 27 | 51 |
| 105. | Solvent red 4 | 51 |
| 106. | Xatral SR | 51 |
| 107. | Benorilate | 50 |
| 108. | Bismatrol | 50 |
| 109. | Carbatrol | 50 |
| 110. | Centyl | 50 |
| 111. | Citral | 50 |
| 112. | Daytrana | 50 |
| 113. | Febuprol | 50 |
| 114. | Femtrace | 50 |
| 115. | Inderal | 50 |
| 116. | Macrilen | 50 |
| 117. | Pancreplus | 50 |
| 118. | Qinprezo | 50 |

| No. | Name | POCA Score (%) |
|---|---|---|
| 119. | Semprana | 50 |
| 120. | Zyprexa | 50 |

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/s/

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MILLIE C BRAHMBHATT
02/24/2015

BRENDA V BORDERS-HEMPHILL
02/25/2015