CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

208159Orig1s000

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:	September 14, 2015
Application Type and Number:	NDA 208159
Product Name and Strength:	Vistogard (Uridine triacetate) packets, 10 g
Product Type:	Single Ingredient
Rx or OTC:	Rx
Applicant/Sponsor Name:	Wellstat Therapeutics Corporation
Panorama #:	2015-960684
DMEPA Primary Reviewer:	Davis Mathew, PharmD
DMEPA Primary Reviewer:	Tingting Gao, PharmD
DMEPA Team Leader:	Chi-Ming (Alice) Tu, PharmD
DMEPA Associate Director:	Lubna Merchant, MS, PharmD

Contents

1 INTRODUCTION

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

1.1 REGULATORY HISTORY

Wellstat previously submitted the proposed proprietary name, [redacted] on October 20, 2011 under IND 039571 for the following indications [redacted] The Division of Medication Error Prevention and Analysis (DMEPA) found the proprietary name, [redacted] acceptable in OSE Review # 2011-4185. On May 6, 2014, Wellstat submitted a proprietary name review request for Xuriden under IND 118931 for [redacted] indication, which is (3) "[redacted] hereditary orotic aciduria" in addition [redacted] DMEPA found the name acceptable in OSE Review # 2014-17316. Wellstat subsequently submitted a proprietary name review request for Xuriden under NDA 208169 [redacted] and DMEPA found the name acceptable in OSE Review # 2014-47663.

On July 10, 2015, Wellstat withdrew the proprietary name [redacted] for the indication for [redacted] and submitted the name, Vistogard, under NDA 208159 [redacted] Wellstat later submitted an amendment to its July 10, 2015 proprietary name review request [redacted] and added the proposed pediatric dosing regimen for the proposed indication [redacted] on September 3, 2015, which is the subject of this review.

1.2 PRODUCT INFORMATION

The following product information is provided in the July 10, 2015 proprietary name submission and September 3, 2015 proprietary name review request amendment.

- Intended Pronunciation: Vis′ toe gard
- Active Ingredient: Uridine triacetate
- Indication of Use:
  - [redacted].
- Route of Administration: Oral
- Dosage Form: Oral granules.

- Strength: [redacted] 10 gram packets [redacted]
- Dose and Frequency:
    - Adult: 10 gram taken by mouth every 6 hours for a total of 20 doses.
    - Pediatric: 6.2 grams/m^2 of body surface area (not to exceed 10 grams per dose) orally every 6 hours for 20 doses.
- How Supplied: 20 x 10 g packets provided in a carton; 4 x 10 g packets provided in a carton.
- Storage: Store at controlled room temperature, 25˚C (77˚F); Excursions permitted to 15˚C to 30˚C (59˚F to 86˚F).
- Container and Closure Systems: Sealed Sachet

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 Oncology Products 1 (DOP1) concurred with the findings of OPDP's assessment of the proposed name.

2.2 SAFETY ASSESSMENT

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

2.2.1 United States Adopted Names (USAN) Search

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

2.2.2 Components of the Proposed Proprietary Name

The Applicant did not provide a derivation or intended meaning for the proposed name, Vistogard, in their submission. This proprietary name is comprised of a single word that does not contain any components (i.e. a modifier, route of administration, dosage form, etc.) that are misleading or can contribute to medication error.

2.2.3 FDA Name Simulation Studies

Seventy nine practitioners participated in DMEPA's prescription studies. The responses did not overlap with any currently marketed products nor did the responses sound or look similar to any currently marketed products or any products in the pipeline. Twenty-eight practitioners interpreted the name correctly during the simulation study. Common misinterpretations during the outpatient written study included the letter "a" for "o" in the

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

infix (n=2). In the inpatient written study common misinterpretations included the letter "a" for "o" in the infix (n=26). In the voice study common misinterpretations included the letter "a" for "o" in the infix (n=6), the addition of the letter "u" in the suffix (n=14) and the misinterpretation of the letter "i" for "o" in the infix (n=3). Appendix B contains the results from the verbal and written prescription studies.

2.2.4 Comments from Other Review Disciplines at Initial Review

In response to the OSE, July 23, 2015 e-mail, the Division of Oncology Products 1 (DOP1) did not forward any comments or concerns relating to the proposed proprietary name at the initial phase of the review.

2.2.5 Phonetic and Orthographic Computer Analysis (POCA) Search Results

Table 1 lists the number of names with the combined orthographic and phonetic score of ≥50% retrieved from our POCA search[2] organized as highly similar, moderately similar or low similarity for further evaluation. Table 1 also includes names identified from the FDA Prescription Simulation Study.

Table 1. POCA Search Results	**Number of Names**
Highly similar name pair: combined match percentage score ≥70%	3
Moderately similar name pair: combined match percentage score ≥50% to ≤ 69%	131
Low similarity name pair: combined match percentage score ≤49%	0

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

Our analysis of the 134 names contained in Table 1 determined none of the names will pose a risk for confusion as described in Appendices C through H.

2.2.7 Discussion of Dual Proprietary Names

Wellstat originally intended to market the (b) (4) proprietary name (b) (4) for NDA 208159 (b) (4). However, Wellstat indicated that as the review process for NDAs proceeded, " (b) (4) (b) (4)

We note that the greatest risk of (b) (4)

[2] POCA search conducted on July 27, 2015.

(b) (4)

Xuriden is indicated for the treatment of patients with hereditary orotic aciduria. Vistogard is for patients with (b) (4) who overdosed on 5-fluorouracil treatment. Hereditary orotic aciduria is an extremely rare hereditary disease[3] (b) (4)

Additionally, the safety and effectiveness of Xuriden was evaluated in four patients with hereditary orotic aciduria ranging in age from three to 19 years of age.[4] The safety and effectiveness of 5-fluorouracil have not been established in patients younger than 18 years of age. Therefore, it's unlikely that pediatric patients who are undergoing Xuriden treatment for hereditary orotic aciduria will receive Vistogard (b) (4) to treat toxicity due to overdose of 5-fluorouracil.

(b) (4)

2.2.8 Communication of DMEPA's Analysis at Midpoint of Review

DMEPA communicated our findings to the Division of Oncology Products 1 (DOP1) via e-mail on August 18, 2015. At that time we also requested additional information or concerns that could inform our review. Per e-mail correspondence from DOP1 on August 24, 2015, they stated no additional concerns with the proposed proprietary name, Vistogard.

3 CONCLUSIONS

The proposed proprietary name is acceptable.

If you have any questions or need clarifications, please contact Frances Fahnbulleh, OSE project manager, at 301-796-0942.

3.1 COMMENTS TO THE APPLICANT

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

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[3] Grohmann K, et al. Hereditary orotic aciduria with epilepsy and without megaloblastic anemia. Neuropediatrics. 2015 Apr;46(2):123-5.

[4] FDA approveds new orphan drug to treat rare autosomal recessive disorder. Accessed 9/11/2015 online at http://www fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm457867.htm

If any of the proposed product characteristics as stated in your July 10, 2015 and September 3, 2015 submissions are altered prior to approval of the marketing application, the name must be resubmitted for review.

4 REFERENCES

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

   USAN Stems List contains all the recognized USAN stems.

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

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

Drugs@FDA

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

RxNorm

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

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

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

Division of Medication Errors Prevention and Analysis proprietary name consultation requests

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

APPENDICES

Appendix A

FDA's Proprietary Name Risk Assessment evaluates proposed proprietary names for misbranding and safety concerns.

1. **Misbranding Assessment**: For prescription drug products, OPDP assesses the name for misbranding concerns. . For over-the-counter (OTC) drug products, the misbranding assessment of the proposed name is conducted by DNDP. OPDP or DNDP evaluates proposed proprietary names to determine if the name is false or misleading, such as by making misrepresentations with respect to safety or efficacy. For example, a fanciful proprietary name may misbrand a product by suggesting that it has some unique effectiveness or composition when it does not (21 CFR 201.10(c)(3)). OPDP or DNDP provides their opinion to DMEPA for consideration in the overall acceptability of the proposed proprietary name.
2. **Safety Assessment**: The safety assessment is conducted by DMEPA, and includes the following:

a. Preliminary Assessment: We consider inclusion of USAN stems or other characteristics that when incorporated into a proprietary name may cause or contribute to medication errors (i.e., dosing interval, dosage form/route of administration, medical or product name abbreviations, names that include or suggest the composition of the drug product, etc.) See prescreening checklist below in Table 2*. DMEPA defines a medication error as any preventable event that may cause or lead to inappropriate medication use or patient harm while the medication is in the control of the health care professional, patient, or consumer. [5]

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

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

Step 1	Review the DOSAGE AND ADMINISTRATION and HOW SUPPLIED/STORAGE AND HANDLING sections of the prescribing information (or for OTC drugs refer to the Drug Facts label) to determine if strengths and doses of the name pair overlap or are very similar. Different strengths and doses for products whose names are moderately similar may decrease the risk of confusion between the moderately similar name pairs. Name pairs that have overlapping or similar strengths or doses have a higher potential for confusion and should be evaluated further (see Step 2). Because the strength or dose could be used to express an order or prescription for a particular drug product, overlap in one or both of these components would be reason for further evaluation. For single strength products, also consider circumstances where the strength may not be expressed. For any i.e. drug products comprised of more than one active ingredient, consider whether the strength or dose may be expressed using only one of the components. To determine whether the strengths or doses are similar to your proposed product, consider the following list of factors that may increase confusion: o Alternative expressions of dose: 5 mL may be listed in the prescribing information, but the dose may be expressed in metric weight (e.g., 500 mg) or in non-metric units (e.g., 1 tsp, 1 tablet/capsule). Similarly, a strength or dose of 1000 mg may be expressed, in practice, as 1 g, or vice versa. o Trailing or deleting zeros: 10 mg is similar in appearance to 100 mg which may potentiate confusion between a name pair with moderate similarity. o Similar sounding doses: 15 mg is similar in sound to 50 mg
Step 2	Answer the questions in the checklist below. Affirmative answers to some of these questions suggest that the pattern of orthographic or phonetic differences in the names may reduce the likelihood of confusion for moderately similar names **with** overlapping or similar strengths or doses.

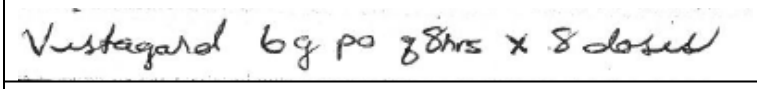
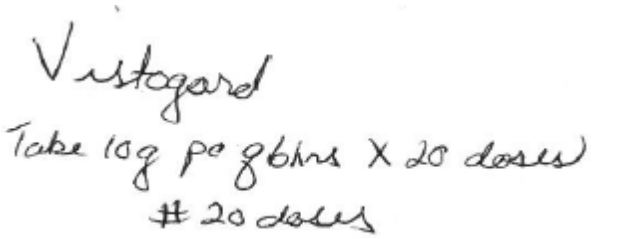
	Orthographic Checklist (Y/N to each question) • Do the names begin with different first letters? Note that even when names begin with different first letters, certain letters may be confused with each other when scripted. • Are the lengths of the names dissimilar* when scripted? *FDA considers the length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

Table 5: Low Similarity Name Pair Checklist (i.e., combined score is ≤49%).

In most circumstances, these names are viewed as sufficiently different to minimize confusion. Exceptions to this would occur in circumstances where, for example, there are data that suggest a name with low similarity is nonetheless misinterpreted as a marketed product name in a prescription simulation study. In such instances, FDA would reassign a low similarity name to the moderate similarity category and review according to the moderately similar name pair checklist.

Appendix B: Prescription Simulation Samples and Results

Figure 1. Vistogard Study (Conducted on July 24, 2015)

Handwritten Requisition Medication Order	Verbal Prescription
Medication Order:  	Vistogard Take 10 g by mouth every 6 hours for 20 doses.
Outpatient Prescription:  	Dispense #20 doses

FDA Prescription Simulation Responses (Aggregate 1 Rx Studies Report)

Study Name: Vistogard

As of Date 9/3/2015

245 People Received Study

79 People Responded

Total	**28**	**26**	**25**	
INTERPRETATION	**OUTPATIENT**	**VOICE**	**INPATIENT**	**TOTAL**
VISTA GUARD	0	1	0	1
VISTAGAR	0	1	0	1
VISTAGARD	2	6	23	31
VISTAGAURD	0	1	0	1
VISTAGUARD	0	9	0	9
VISTAGURAD	0	1	0	1
VISTIGARD	0	3	0	3
VISTIGUARD	0	2	0	2
VISTOGARD	26	1	1	28
VISTOGAURD	0	1	0	1
VITAGUARD	0	0	1	1

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

No.	**Proposed name:** Vistogard **Established name:** Uridine Triacetate **Dosage form:** Oral Granules **Strength(s):** 10 gram **Usual Dose:** Adult: 10 gm every 6 hours for 20 doses. Pediatric: 6.2 grams/m^2 of body surface area (not to exceed 10 grams per dose) orally every 6 hours for 20 doses	**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.	Vistogard	100	This name is the subject of this review.
2.	Nitrogard	70	The first syllable of this name pair has sufficient phonetic differences. Although the name pair have orthographic similarities and share numerically similar strengths (1 mg vs. 10 g), the brand product Nitrogard (nitroglycerin tablets, extended release) is discontinued with no generic equivalent available per RedBook. Additionally, the immediate release nitroglycerin tablets that are currently marketed do not overlap in strength with Vistogard (0.3 mg, 0.4 mg, and 0.6 mg vs. 10 g).
3.	Spectogard	70	The prefix of this name pair has sufficient orthographic differences. The first syllable of this name pair has sufficient phonetic differences. Spectogard is a veterinary Product.

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.	Name	POCA Score (%)
1.	3M Avagard	64
2.	Tonocard	57
3.	Vascor	52
4.	Vitamin D	56
5.	Vitamin D3	56
6.	Zinecard	60

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:** Vistogard **Established name:** Uridine Triacetate **Dosage form:** Oral Granules **Strength(s):** 10 gram **Usual Dose:** Adult: 10 gm every 6 hours for 20 doses. Pediatric: 6.2 grams/m^2 of body surface area (not to exceed 10 grams per dose) orally every 6 hours for 20 doses	**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.	Adenocard	52	The prefix and infix of this name pair have sufficient orthographic differences. The first, second and third syllables of this name pair have sufficient phonetic differences and Adenocard contains an extra syllable when compared to Vistogard.
2.	Aristocort	60	The prefix and suffix of this name pair have sufficient orthographic differences. The first and third syllables of this name pair have sufficient phonetic differences.
3.	Aristocort A	54	The prefix and suffix of this name pair have sufficient orthographic differences. The first and third syllables of this name pair have sufficient phonetic differences. Aristocort A contains an extra syllable from the modifier "A".
4.	Aristogel	55	The prefix of this name pair has sufficient orthographic differences. The first, second and third syllables of this name pair have sufficient phonetic differences and Aristogel contains an extra syllable when compared to Vistogard.

No.	**Proposed name:** Vistogard **Established name:** Uridine Triacetate **Dosage form:** Oral Granules **Strength(s):** 10 gram **Usual Dose:** Adult: 10 gm every 6 hours for 20 doses. Pediatric: 6.2 grams/m^2 of body surface area (not to exceed 10 grams per dose) orally every 6 hours for 20 doses	**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**
5.	Aristopak	51	The prefix of this name pair has sufficient orthographic differences. The first, second and third syllables of this name pair have sufficient phonetic differences and Aristopak contains an extra syllable when compared to Vistogard.
6.	Avagard	60	The prefix and infix of this name pair have sufficient orthographic differences. The first and second syllables of this name pair have sufficient phonetic differences.
7.	Bristagen	52	The prefix and suffix of this name pair have sufficient orthographic differences. The third syllable of this name pair has sufficient phonetic difference.
8.	Corgard	52	The prefix and infix of this name pair have sufficient orthographic differences. The first syllable of this name pair has sufficient phonetic difference and Vistogard contains an extra syllable when compared to Corgard.
9.	Cystografin	50	The prefix and suffix of this name pair have sufficient orthographic differences. The first and third syllables of this name pair have sufficient phonetic differences and Cystografin contains an extra syllable when compared to Vistogard.

No.	**Proposed name:** Vistogard **Established name:** Uridine Triacetate **Dosage form:** Oral Granules **Strength(s):** 10 gram **Usual Dose:** Adult: 10 gm every 6 hours for 20 doses. Pediatric: 6.2 grams/m^2 of body surface area (not to exceed 10 grams per dose) orally every 6 hours for 20 doses	**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**
10.	Cystospaz	52	The prefix and suffix of this name pair have sufficient orthographic differences. The first and third syllables of this name pair have sufficient phonetic differences.
11.	Cystospaz-M	51	The prefix and suffix of this name pair have sufficient orthographic differences. The first and third syllables of this name pair have sufficient phonetic differences.
12.	Cytogam	50	The prefix and suffix of this name pair have sufficient orthographic difference. The first and third syllables of this name pair have sufficient phonetic differences.
13.	Dristan Cold	53	The prefix and suffix of this name pair have sufficient orthographic differences. The first and third syllables of this name pair have sufficient phonetic differences.
14.	Eligard	52	The prefix of this name pair has sufficient orthographic differences. The first syllable of this name pair has sufficient phonetic difference, and Vistogard contains an extra syllable when compared to Eligard.

No.	**Proposed name:** Vistogard **Established name:** Uridine Triacetate **Dosage form:** Oral Granules **Strength(s):** 10 gram **Usual Dose:** Adult: 10 gm every 6 hours for 20 doses. Pediatric: 6.2 grams/m^2 of body surface area (not to exceed 10 grams per dose) orally every 6 hours for 20 doses	**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**
15.	Eligard 22.5	52	The prefix of this name pair has sufficient orthographic differences. The first syllable of this name pair has sufficient phonetic difference, and Eligard 22.5 contains extra syllables from the modifier “22.5”.
16.	Eligard 30	52	The prefix of this name pair has sufficient orthographic differences. The first syllable of this name pair has sufficient phonetic difference, and Eligard 30 contains extra syllables from the modifier “30”.
17.	Eligard 45	52	The prefix of this name pair has sufficient orthographic differences. The first syllable of this name pair has sufficient phonetic difference, and Eligard 45 contains extra syllables from the modifier “45”.
18.	Eligard 7.5	52	The prefix of this name pair has sufficient orthographic differences. The first syllable of this name pair has sufficient phonetic difference, and Eligard 7.5 contains extra syllables from the modifier “7.5”.

No.	**Proposed name:** Vistogard **Established name:** Uridine Triacetate **Dosage form:** Oral Granules **Strength(s):** 10 gram **Usual Dose:** Adult: 10 gm every 6 hours for 20 doses. Pediatric: 6.2 grams/m^2 of body surface area (not to exceed 10 grams per dose) orally every 6 hours for 20 doses	**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**
19.	Estraguard	63	The prefix of this name pair has sufficient orthographic difference. The first syllable of this name pair has sufficient phonetic difference. The brand product Estraguard (Dienestrol) is discontinued with no generic equivalent available per RedBook and Drugs@FDA.
20.	Fluorigard	52	The prefix and infix of this name pair have sufficient orthographic differences. The first and second syllables of this name pair have sufficient phonetic differences.
21.	Folgard	58	The prefix of this name pair has sufficient orthographic differences. The first syllable of this name pair has sufficient phonetic difference, and Vistogard contains an extra syllable when compared to Folgard.
22.	FUNGI-GUARD	54	The prefix and infix of this name pair have sufficient orthographic differences. The first and second syllables of this name pair have sufficient phonetic differences.
23.	Gammagard	52	The prefix and infix of this name pair have sufficient orthographic differences. The first and second syllables of this name pair have sufficient phonetic differences.

No.	**Proposed name:** Vistogard **Established name:** Uridine Triacetate **Dosage form:** Oral Granules **Strength(s):** 10 gram **Usual Dose:** Adult: 10 gm every 6 hours for 20 doses. Pediatric: 6.2 grams/m^2 of body surface area (not to exceed 10 grams per dose) orally every 6 hours for 20 doses	**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**
24.	Histafed	50	The prefix and suffix of this name pair have sufficient orthographic differences. The first and third syllables of this name pair have sufficient phonetic differences.
25.	Histatab D	58	The prefix and suffix of this name pair have sufficient orthographic differences. The first and third syllables of this name pair have sufficient phonetic differences.
26.	Infectiguard	56	The prefix and infix of this name pair have sufficient orthographic differences. The first, second and third syllables of this name pair have sufficient phonetic differences and Infectiguard contains an extra syllable when compared to Vistogard.
27.	Istodax	54	The prefix and suffix of this name pair have sufficient orthographic differences. The third syllable of this name pair has sufficient phonetic difference.
28.	Micro-Guard	58	The prefix and infix of this name pair have sufficient orthographic differences. The first and second syllables of this name pair have sufficient phonetic differences.
29.	Mitigare	50	The prefix, infix and suffix of this name pair have sufficient orthographic differences. The first, second and third syllables of this name pair have sufficient phonetic differences.

No.	**Proposed name:** Vistogard **Established name:** Uridine Triacetate **Dosage form:** Oral Granules **Strength(s):** 10 gram **Usual Dose:** Adult: 10 gm every 6 hours for 20 doses. Pediatric: 6.2 grams/m^2 of body surface area (not to exceed 10 grams per dose) orally every 6 hours for 20 doses	**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**
30.	Periguard	52	The prefix and infix of this name pair have sufficient orthographic differences. The first and second syllables of this name pair have sufficient phonetic differences.
31.	Periogard	59	The prefix and infix of this name pair have sufficient orthographic differences. The first, second and third syllables of this name pair have sufficient phonetic difference and Periogard contains an extra syllable when compared to Vistogard.
32.	Radiaguard	52	The prefix and infix of this name pair have sufficient orthographic differences. The first, second and third syllables of this name pair have sufficient phonetic differences.
33.	Relagard	52	The prefix of this name pair has sufficient orthographic difference. The first and second syllables of this name pair have sufficient phonetic differences.
34.	Sani Guard	56	The prefix and infix of this name pair have sufficient orthographic differences. The first and second syllables of this name pair have sufficient phonetic differences.

No.	**Proposed name:** Vistogard **Established name:** Uridine Triacetate **Dosage form:** Oral Granules **Strength(s):** 10 gram **Usual Dose:** Adult: 10 gm every 6 hours for 20 doses. Pediatric: 6.2 grams/m^2 of body surface area (not to exceed 10 grams per dose) orally every 6 hours for 20 doses	**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**
35.	Stangard	68	The prefix and infix of this name pair have sufficient orthographic differences. The first and second syllables of this name pair have sufficient phonetic differences and Vistogard contains an extra syllable when compared to Stangard.
36.	TESTODERM	61	The prefix and suffix of this name pair have sufficient orthographic differences. The first and third syllables of this name pair have sufficient phonetic differences.
37.	Testomar	58	The prefix and suffix of this name pair have sufficient orthographic differences. The first and third syllables of this name pair have sufficient phonetic differences.
38.	Valstar	54	The suffix of this name pair has sufficient orthographic difference. The second syllable of this name pair has sufficient phonetic difference and Vistogard contains an extra syllable when compared to Valstar.
39.	Vanspar	50	The infix and suffix of this name pair have sufficient orthographic differences. The second syllable of this name pair has sufficient phonetic difference and Vistogard contains an extra syllable when compared to Vanspar.

No.	**Proposed name:** Vistogard **Established name:** Uridine Triacetate **Dosage form:** Oral Granules **Strength(s):** 10 gram **Usual Dose:** Adult: 10 gm every 6 hours for 20 doses. Pediatric: 6.2 grams/m^2 of body surface area (not to exceed 10 grams per dose) orally every 6 hours for 20 doses	**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**
40.	Vascoray	50	The infix and suffix of this name pair have sufficient orthographic differences. The second and third syllables of this name pair have sufficient phonetic differences.
41.	Vasocidin	52	The infix and suffix of this name pair have sufficient orthographic differences. The third syllable of this name pair has sufficient phonetic difference and Vasocidin contains an extra syllable when compared to Vistogard.
42.	Vasoclear	52	The infix and suffix of this name pair have sufficient orthographic differences. The third syllable of this name pair has sufficient phonetic difference.
43.	Vasocon-A	50	The infix and suffix of this name pair have sufficient orthographic differences. The third syllable of this name pair has sufficient phonetic difference.
44.	Vasodilan	52	The infix and suffix of this name pair have sufficient orthographic differences. The third syllable of this name pair has sufficient phonetic difference.
45.	Vasotate	51	The infix and suffix of this name pair have sufficient orthographic differences. The third syllable of this name pair has sufficient phonetic difference.

No.	**Proposed name:** Vistogard **Established name:** Uridine Triacetate **Dosage form:** Oral Granules **Strength(s):** 10 gram **Usual Dose:** Adult: 10 gm every 6 hours for 20 doses. Pediatric: 6.2 grams/m^2 of body surface area (not to exceed 10 grams per dose) orally every 6 hours for 20 doses	**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**
46.	Verticalm	52	The suffix of this name pair has sufficient orthographic difference. The third syllable of this name pair has sufficient phonetic difference.
47.	Vesanoid	56	The infix and suffix of this name pair have sufficient orthographic differences. The second and third syllables of this name pair have sufficient phonetic differences.
48.	Vesicare	51	The infix and suffix of this name pair have sufficient orthographic differences. The second and third syllables of this name pair have sufficient phonetic differences.
49.	Vestura	54	The suffix of this name pair has sufficient orthographic difference. The third syllable of this name pair has sufficient phonetic difference.
50.	Vicoclear	52	The infix and suffix of this name pair have sufficient orthographic differences. The second and third syllables of this name pair have sufficient phonetic differences.
51.	Vicoclear DH	55	The infix and suffix of this name pair have sufficient orthographic differences. The second and third syllables of this name pair have sufficient phonetic differences.

No.	**Proposed name:** Vistogard **Established name:** Uridine Triacetate **Dosage form:** Oral Granules **Strength(s):** 10 gram **Usual Dose:** Adult: 10 gm every 6 hours for 20 doses. Pediatric: 6.2 grams/m^2 of body surface area (not to exceed 10 grams per dose) orally every 6 hours for 20 doses	**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**
52.	Victoza	56	The suffix of this name pair has sufficient orthographic differences. The third syllable of this name pair has sufficient phonetic difference.
53.	Visco Shield	58	The infix and suffix of this name pair have sufficient orthographic differences. The second and third syllables of this name pair have sufficient phonetic differences.
54.	Viscoat	58	The infix and suffix of this name pair have sufficient orthographic differences. The second syllable of this name pair has sufficient phonetic difference and Vistogard contains an extra syllable when compared to Viscoat.
55.	Visco-Gel	66	The infix of this name pair has sufficient orthographic differences. The second and third syllables of this name pair have sufficient phonetic differences.
56.	Viskazide	62	The infix and suffix of this name pair have sufficient orthographic differences. The second and third syllables of this name pair have sufficient phonetic differences.

No.	**Proposed name:** Vistogard **Established name:** Uridine Triacetate **Dosage form:** Oral Granules **Strength(s):** 10 gram **Usual Dose:** Adult: 10 gm every 6 hours for 20 doses. Pediatric: 6.2 grams/m^2 of body surface area (not to exceed 10 grams per dose) orally every 6 hours for 20 doses	**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**
57.	Vismodegib	52	The infix and suffix of this name pair have sufficient orthographic differences. The second and third syllables of this name pair have sufficient phonetic difference and Vismodegib contains an extra syllable when compared to Vistogard.
58.	Vistacot	61	The suffix of this name pair has sufficient orthographic differences. The third syllable of this name pair has sufficient phonetic differences.
59.	Vistaject-50	56	The suffix of this name pair has sufficient orthographic differences. The third syllable of this name pair has sufficient phonetic differences.
60.	VISTARIL	62	The suffix of this name pair has sufficient orthographic differences. The third syllable of this name pair has sufficient phonetic differences.
61.	Vistazine	60	The suffix of this name pair has sufficient orthographic differences. The third syllable of this name pair has sufficient phonetic differences.

No.	**Proposed name:** Vistogard **Established name:** Uridine Triacetate **Dosage form:** Oral Granules **Strength(s):** 10 gram **Usual Dose:** Adult: 10 gm every 6 hours for 20 doses. Pediatric: 6.2 grams/m^2 of body surface area (not to exceed 10 grams per dose) orally every 6 hours for 20 doses	**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**
62.	Vistide	62	The suffix of this name pair has sufficient orthographic differences. The second syllable of this name pair has sufficient phonetic differences and Vistogard contains an extra syllable when compared to Vistide.
63.	Vitaped	55	The suffix of this name pair has sufficient orthographic differences. The third syllable of this name pair has sufficient phonetic differences.
64.	Vitrasert	54	The suffix of this name pair has sufficient orthographic differences. The third syllable of this name pair has sufficient phonetic difference.

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

No.	Name	POCA Score (%)
1.	N/A	N/A

Appendix G: Names not likely to be confused or not used in usual practice settings for the reasons described**.**

No.	Name	POCA Score (%)	Failure preventions
1.	Aristocort R	54	International product marketed in Canada.
2.	Avagard D	59	International product marketed in Canada.
3.	Calcicard	52	International product marketed in South Africa.
4.	Caroguard	50	Name identified in RxNorm database. Unable to find product characterictics in commonly used drug databases.
5.	Cedocard	59	International product marketed in Austria, Thailand, Canada, UK, Indonesia and Belgium.
6.	Comboguard	51	Veterinary products.
7.	(b) (4) ***	53	Proposed Proprietary Name was withdrawn by the sponsor and product was approved under proprietary name Cystaran.
8.	Diclotard	59	International Product marketed in UK.
9.	Distigmine	50	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
10.	Eco-Gard	60	Veterinary product.
11.	Gestodene	50	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
12.	Heartgard	52	Veterinary product.
13.	Histamaxd	52	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
14.	ISMO Retard	56	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
15.	Isocard	64	International product marketed in France, UK, Belgium and Israel.
16.	Ketotard	59	International product marketed in the UK.
17.	Kiditard	54	International product marketed in the Netherlands.

No.	Name	POCA Score (%)	Failure preventions
18.	Neutragard	58	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
19.	Nexgard	59	Veterinary product.
20.	OXY Gard	58	Veterinary product.
21.	Safe-Guard	58	Veterinary product.
22.	Suscard	56	International product marketed in Norway, Sweden, UK and Italy.
23.	(b) (4) ***	54	Proposed Proprietary Name was found unacceptable by DDMAC due to the name overstating the efficacy of the drug product (OSE# (b) (4)). There has not been any new request for proposed proprietary name review since the completion of the previous review.
24.	Teat Guard	55	Veterinary product.
25.	Tristearin	52	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
26.	Ulcergard	50	Veterinary product.
27.	Vascardin	59	International product marketed in Indonesia.
28.	Vetalar	54	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
29.	Vetstarch	60	Veterinary product.
30.	Vincasar	50	International product marketed in Mexico.
31.	(b) (4) ***	53	Proposed Proprietary Name was found unacceptable by DMEPA (OSE# (b) (4)). Entire Application was withdrawn by the Applicant.
32.	Vis-Phos N	50	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
33.	Visqid	55	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.

No.	Name	POCA Score (%)	Failure preventions
34.	Vistacon	61	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
35.	Vistra	53	International product marketed in the Philippines.
36.	Vita-E Gels	51	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
37.	Xylocard	55	International product marketed in the Europe, Asia, New Zealand, Australia and Canada.

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

No.	Name	POCA Score (%)
1.	Astagraf	50
2.	Avitears	52
3.	Betnovate RD	50
4.	Citracal + D	50
5.	Codar D	50
6.	Cystadane	52
7.	Cystagon	54
8.	Cystaran	50
9.	Estraderm	50
10.	Fostex Bar	51
11.	Fostex Bar 10%	51
12.	Fototar	50
13.	Gastromark	52
14.	Instacort	52
15.	Instacort 10	52
16.	(b) (4) ***	53
17.	Masnoderm	52

No.	Name	POCA Score (%)
18.	Nystaform	50
19.	Oasis Tears	52
20.	Ostercal-D	52
21.	Oyst Cal D	52
22.	Oyster D	52
23.	Pseudo Carb	54
24.	Westcort	51

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/s/

TINGTING N GAO
09/14/2015

DAVIS MATHEW
09/14/2015

CHI-MING TU
09/14/2015

LUBNA A MERCHANT
09/14/2015