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RESEARCH**

APPLICATION NUMBER:
202317Orig1s000

PROPRIETARY NAME REVIEW(S)

**Department of Health and Human Services
Public Health Service
Food and Drug Administration
Center for Drug Evaluation and Research
Office of Surveillance and Epidemiology
Office of Medication Error Prevention and Risk Management**

Proprietary Name Review

Date: June 25, 2013

Reviewer: Kevin Wright, PharmD
Division of Medication Error Prevention and Analysis

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Drug Name and Strength: Valchlor (Mechlorethamine HCl) Gel
0.02%

Application Type/Number: NDA 202317

Applicant/Sponsor: Ceptaris Therapeutics, Inc.

OSE RCM #: 2013-929

*** This document contains proprietary and confidential information that should not be released to the public.***

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1 INTRODUCTION

This review evaluates the proposed proprietary name, Valchlor, from a safety and promotional perspective. The sources and methods used to evaluate the proposed name are outlined in the reference section and Appendix A respectively.

1.1 REGULATORY HISTORY

The proposed proprietary name, Valchlor (Mechlorethamine HCl), was found conditionally acceptable in OSE Review #2011-3818 dated December 20, 2011.

1.2 PRODUCT INFORMATION

The following product information is provided in the April 1, 2013 proprietary name submission.

- Intended pronunciation: val'klor
- Active Ingredient: Mechlorethamine
- Indication of Use: treatment of mycosis fungoides
- Route of Administration: Topical
- Dosage Form: Gel
- Strength: 0.02%
- Dose and Frequency: Apply to affected lesions once daily
- How Supplied: 60 gram tube
- Storage: store at 2°C to 8°C
- Container and Closure Systems: 60 gram tube in carton

2 RESULTS

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

2.1 PROMOTIONAL ASSESSMENT

The Office of Prescription Drug Promotion OPDP determined the proposed name is acceptable from a promotional perspective. DMEPA and the Division of Hematology Products (DHP) concurred with the findings of OPDP's promotional 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

The May 31, 2013 search of the United States Adopted Name (USAN) stems did not identify that a USAN stem is present in the proposed proprietary name.

2.2.2 Components of the Proposed Proprietary Name

The Applicant indicated in their submission that the proposed name, Valchlor, was coined from Mechlorethamine. 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

Sixty-three practitioners participated in DMEPA's prescription studies. The interpretations did not overlap with any currently marketed products nor did they appear or sound similar to any currently marketed products or products pending approval. In the written studies, 34 of 44 participants correctly interpreted the prescription. Common misinterpretations in the written study were the substitution of 'i' for 'c' and 'dr' for 'ch'. In the voice study one participant correctly interpreted the prescription. Common misinterpretations in the voice study include 'lcl', for 'lchl'. These misinterpretations were considered in our evaluation of the proprietary name (See Appendix B). See Appendix C for the complete listing of interpretations from the verbal and written prescription studies.

2.2.4 Comments from Other Review Disciplines at Initial Review

In response to the OSE, April 23, 2013 e-mail, the Division of Hematology Products (DHP) did not forward any comments or concerns relating to the proposed name at the initial phase of the proprietary name review.

2.2.5 Failure Mode and Effects Analysis of Similar Names

Appendix B lists possible orthographic and phonetic misinterpretations of the letters and letter strings appearing in the proposed proprietary name, Valchlor. Additionally, for this review, DMEPA re-evaluated the names previously identified in OSE Review# 2011-3818 (see Table 1) and DMEPA identified additional names of concern since the last review (see Table 2).

Table 1: Collective List of Potentially Similar Names (DMEPA, EPD, Other Disciplines, and External Name Study) from OSE 2011-3818					
Look Similar					
Actonel	EPD	Caldolor	EPD	Ceclor	EPD
Kalbitor	EPD	Trichlor fresh pac	EPD	Valsartan	EPD
Valstar	EPD	Velcade	EPD	Veletri	EPD
Voltaren	EPD				
Look and Sound Similar					
Kaochlor	EPD	Valcyte	EPD	Welchol	EPD

Table 2: Collective List of Potentially Similar Names (DMEPA, EPD, Other Disciplines, and External Name Study)					
Look Similar					
Valclair	EPD	Valturna	EPD	Xalkori	EPD
Vot-Tab Rx	EPD				
Look and Sound Similar					
Balcor	EPD	Raniclor	EPD	Valchlor	EPD
Valrubicin	EPD	Xalatan	EPD		

Our analysis of the 13 names from the previous review (Table 1) and the 9 additional names located in Table 2 considered the information obtained in the previous sections along with their product characteristics. We determined all 22 names (13 from the previous review and 9 new names) will not pose a risk for confusion as described in Appendices D and E.

2.2.6 Communication of DMEPA's Analysis at Midpoint of Review

DMEPA communicated our findings to the Division of Hematology Products (DHP) via e-mail on June 10, 2013. At that time we also requested additional information or concerns that could inform our review. Per e-mail correspondence from the Division of Hematology Products (DHP) on June 24, 2013, they stated no additional concerns with the proposed proprietary name, Valchlor.

3 CONCLUSIONS

The proposed proprietary name is acceptable from both a promotional and safety perspective.

If you have further questions or need clarifications, please contact Sue Kang, OSE project manager, at 301-796-4216.

3.1 COMMENTS TO THE APPLICANT

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

The proposed proprietary name must be re-reviewed 90 days prior to approval of the NDA. The results are subject to change. If any of the proposed product characteristics as stated in your April 1, 2013 submission are altered, the name must be resubmitted for review.

4 REFERENCES

1. ***Micromedex Integrated Index*** (<http://csi.micromedex.com>)

Micromedex contains a variety of databases covering pharmacology, therapeutics, toxicology and diagnostics.

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

POCA is a database which was created for the Division of Medication Error Prevention and Analysis, FDA. As part of the name similarity assessment, proposed names are evaluated via a phonetic/orthographic algorithm. The proposed proprietary name is converted into its phonemic representation before it runs through the phonetic algorithm. Likewise, an orthographic algorithm exists which operates in a similar fashion.

3. ***Drug Facts and Comparisons, online version, St. Louis, MO***
(<http://factsandcomparisons.com>)

Drug Facts and Comparisons is a compendium organized by therapeutic course; it contains monographs on prescription and OTC drugs, with charts comparing similar products. This database also lists the orphan drugs.

4. ***FDA Document Archiving, Reporting & Regulatory Tracking System [DARRTS]***

DARRTS is a government database used to organize Applicant and Sponsor submissions as well as to store and organize assignments, reviews, and communications from the review divisions.

5. ***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.

6. ***Drugs@FDA*** (<http://www.accessdata.fda.gov/scripts/cder/drugsatfda/index.cfm>)

Drugs@FDA contains most of the drug products approved 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, generic drugs, therapeutic biological products, prescription and over-the-counter human drugs and discontinued drugs and “Chemical Type 6” approvals.

7. ***U.S. Patent and Trademark Office*** (<http://www.uspto.gov>)

USPTO provides information regarding patent and trademarks.

8. ***Clinical Pharmacology Online*** (www.clinicalpharmacology-ip.com)

Clinical Pharmacology contains full monographs for the most common drugs in clinical use, plus mini monographs covering investigational, less common,

combination, nutraceutical and nutritional products. It also provides a keyword search engine.

9. Data provided by Thomson & Thomson's SAEGIS™ Online Service, available at (www.thomson-thomson.com)

The Pharma In-Use Search database contains over 400,000 unique pharmaceutical trademarks and trade names that are used in about 50 countries worldwide. The data is provided under license by IMS HEALTH.

10. Natural Medicines Comprehensive Databases (www.naturaldatabase.com)

Natural Medicines contains up-to-date clinical data on the natural medicines, herbal medicines, and dietary supplements used in the western world.

11. Access Medicine (www.accessmedicine.com)

Access Medicine® from McGraw-Hill contains full-text information from approximately 60 titles; it includes tables and references. Among the titles are: Harrison's Principles of Internal Medicine, Basic & Clinical Pharmacology, and Goodman and Gilman's The Pharmacologic Basis of Therapeutics.

12. USAN Stems (<http://www.ama-assn.org/ama/pub/about-ama/our-people/coalitions-consortiums/united-states-adopted-names-council/naming-guidelines/approved-stems.shtml>)

USAN Stems List contains all the recognized USAN stems.

13. Red Book (www.thomsonhc.com/home/dispatch)

Red Book contains prices and product information for prescription, over-the-counter drugs, medical devices, and accessories.

14. Lexi-Comp (www.lexi.com)

Lexi-Comp is a web-based searchable version of the Drug Information Handbook.

15. Medical Abbreviations (www.medilexicon.com)

Medical Abbreviations dictionary contains commonly used medical abbreviations and their definitions.

16. CVS/Pharmacy (www.CVS.com)

This database contains commonly used over the counter products not usually identified in other databases.

17. Walgreens (www.walgreens.com)

This database contains commonly used over the counter products not usually identified in other databases.

18. Rx List (www.rxlist.com)

RxList is an online medical resource dedicated to offering detailed and current pharmaceutical information on brand and generic drugs.

19. Dogpile (www.dogpile.com)

Dogpile is a [Metasearch](#) engine that searches multiple search engines including Google, Yahoo! and Bing, and returns the most relevant results to the search.

20. Natural Standard (<http://www.naturalstandard.com>)

Natural Standard is a resource that aggregates and synthesizes data on complementary and alternative medicine.

APPENDICES

Appendix A

FDA's Proprietary Name Risk Assessment considers the promotional and safety aspects of a proposed proprietary name. The promotional review of the proposed name is conducted by OPDP. OPDP evaluates proposed proprietary names to determine if they are overly fanciful, so as to misleadingly imply unique effectiveness or composition, as well as to assess whether they contribute to overstatement of product efficacy, minimization of risk, broadening of product indications, or making of unsubstantiated superiority claims. OPDP provides their opinion to DMEPA for consideration in the overall acceptability of the proposed proprietary name.

The safety assessment is conducted by DMEPA. DMEPA staff search a standard set of databases and information sources to identify names that are similar in pronunciation, spelling, and orthographically similar when scripted to the proposed proprietary name. Additionally, 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.). 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.¹

Following the preliminary screening of the proposed proprietary name, DMEPA gathers to discuss their professional opinions on the safety of the proposed proprietary name. This meeting is commonly referred to the Center for Drug Evaluation and Research (CDER) Expert Panel discussion. DMEPA also considers other aspects of the name that may be misleading from a safety perspective. DMEPA staff conducts a prescription simulation studies using FDA health care professionals. 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. DMEPA bases the overall risk assessment on the findings of a Failure Mode and Effects Analysis (FMEA) of the proprietary name and misleading nature of the proposed proprietary name with a focus on the avoidance of medication errors.

DMEPA uses the clinical expertise of its staff to anticipate the conditions of the clinical setting where the product is likely to be used based on the characteristics of the proposed product. DMEPA considers the product characteristics associated with the proposed product throughout the risk assessment because the product characteristics of the

¹ National Coordinating Council for Medication Error Reporting and Prevention.
<http://www.nccmerp.org/aboutMedErrors.html>. Last accessed 10/11/2007.

proposed may provide a context for communication of the drug name and ultimately determine the use of the product in the *usual* clinical practice setting.

Typical product characteristics considered when identifying drug names that could potentially be confused with the proposed proprietary name include, but are not limited to; established name of the proposed product, proposed indication of use, dosage form, route of administration, strength, unit of measure, dosage units, recommended dose, typical quantity or volume, frequency of administration, product packaging, storage conditions, patient population, and prescriber population. DMEPA considers how these product characteristics may or may not be present in communicating a product name throughout the medication use system. Because drug name confusion can occur at any point in the medication use process, DMEPA considers the potential for confusion throughout the entire U.S. medication use process, including drug procurement, prescribing and ordering, dispensing, administration, and monitoring the impact of the medication.²

The DMEPA considers the spelling of the name, pronunciation of the name when spoken, and appearance of the name when scripted. DMEPA compares the proposed proprietary name with the proprietary and established name of existing and proposed drug products and names currently under review at the FDA. DMEPA compares the pronunciation of the proposed proprietary name with the pronunciation of other drug names because verbal communication of medication names is common in clinical settings. DMEPA examines the phonetic similarity using patterns of speech. If provided, DMEPA will consider the Sponsor's intended pronunciation of the proprietary name. However, DMEPA also considers a variety of pronunciations that could occur in the English language because the Sponsor has little control over how the name will be spoken in clinical practice. The orthographic appearance of the proposed name is evaluated using a number of different handwriting samples. DMEPA applies expertise gained from root-cause analysis of postmarketing medication errors to identify sources of ambiguity within the name that could be introduced when scripting (e.g., "T" may look like "F," lower case 'a' looks like a lower case 'u,' etc). Additionally, other orthographic attributes that determine the overall appearance of the drug name when scripted (see Table 1 below for details).

² Institute of Medicine. Preventing Medication Errors. The National Academies Press: Washington DC. 2006.

Table 1. Criteria Used to Identify Drug Names that Look- or Sound-Similar to a Proposed Proprietary Name.

Type of Similarity	Considerations when Searching the Databases		
	<i>Potential Causes of Drug Name Similarity</i>	<i>Attributes Examined to Identify Similar Drug Names</i>	<i>Potential Effects</i>
Look-alike	Similar spelling	Identical prefix Identical infix Identical suffix Length of the name Overlapping product characteristics	<ul style="list-style-type: none"> Names may appear similar in print or electronic media and lead to drug name confusion in printed or electronic communication Names may look similar when scripted and lead to drug name confusion in written communication
	Orthographic similarity	Similar spelling Length of the name/Similar shape Upstrokes Down strokes Cross-strokes Dotted letters Ambiguity introduced by scripting letters Overlapping product characteristics	<ul style="list-style-type: none"> Names may look similar when scripted, and lead to drug name confusion in written communication
Sound-alike	Phonetic similarity	Identical prefix Identical infix Identical suffix Number of syllables Stresses Placement of vowel sounds Placement of consonant sounds Overlapping product characteristics	<ul style="list-style-type: none"> Names may sound similar when pronounced and lead to drug name confusion in verbal communication

Lastly, DMEPA considers the potential for the proposed proprietary name to inadvertently function as a source of error for reasons other than name confusion. Post-marketing experience has demonstrated that proprietary names (or components of the proprietary name) can be a source of error in a variety of ways. Consequently, DMEPA considers and evaluates these broader safety implications of the name throughout this assessment and the medication error staff provides additional comments related to the

safety of the proposed proprietary name or product based on professional experience with medication errors.

1. Database and Information Sources

DMEPA searches the internet, several standard published drug product reference texts, and FDA databases to identify existing and proposed drug names that may sound-alike or look-alike to the proposed proprietary name. A standard description of the databases used in the searches is provided in the reference section of this review. To complement the process, the DMEPA uses a computerized method of identifying phonetic and orthographic similarity between medication names. The program, Phonetic and Orthographic Computer Analysis (POCA), uses complex algorithms to select a list of names from a database that have some similarity (phonetic, orthographic, or both) to the trademark being evaluated. Lastly, DMEPA reviews the USAN stem list to determine if any USAN stems are present within the proprietary name. The individual findings of multiple safety evaluators are pooled and presented to the CDER Expert Panel. DMEPA also evaluates if there are characteristics included in the composition that may render the name unacceptable from a safety perspective (abbreviation, dosing interval, etc.).

2. Expert Panel Discussion

DMEPA gathers CDER professional opinions on the safety of the proposed product and discussed the proposed proprietary name (Expert Panel Discussion). The Expert Panel is composed of Division of Medication Errors Prevention (DMEPA) staff and representatives from the Office of Prescription Drug Promotion (OPDP). We also consider input from other review disciplines (OND, ONDQA/OBP). The Expert Panel also discusses potential concerns regarding drug marketing and promotion related to the proposed names.

The primary Safety Evaluator presents the pooled results of the database and information searches to the Expert Panel for consideration. Based on the clinical and professional experiences of the Expert Panel members, the Panel may recommend additional names, additional searches by the primary Safety Evaluator to supplement the pooled results, or general advice to consider when reviewing the proposed proprietary name.

3. FDA Prescription Simulation Studies

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.

4. 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.

5. Safety Evaluator Risk Assessment of the Proposed Proprietary Name

The primary Safety Evaluator applies his/her individual expertise gained from evaluating medication errors reported to FDA, considers all aspects of the name that may be misleading or confusing, conducts a Failure Mode and Effects Analysis, and provides an overall decision on acceptability dependent on their risk assessment of name confusion. Failure Mode and Effects Analysis (FMEA) is a systematic tool for evaluating a process and identifying where and how it might fail.³ When applying FMEA to assess the risk of a proposed proprietary name, DMEPA seeks to evaluate the potential for a proposed proprietary name to be confused with another drug name because of name confusion and, thereby, cause errors to occur in the medication use system. FMEA capitalizes on the predictable and preventable nature of medication errors associated with drug name confusion. FMEA allows the Agency to identify the potential for medication errors due to orthographically or phonetically similar drug names prior to approval, where actions to overcome these issues are easier and more effective than remedies available in the post-approval phase.

In order to perform an FMEA of the proposed name, the primary Safety Evaluator must analyze the use of the product at all points in the medication use system. Because the proposed product is has not been marketed, the primary Safety Evaluator anticipates the use of the product in the usual practice settings by considering the clinical and product

³ Institute for Healthcare Improvement (IHI). Failure Mode and Effects Analysis. Boston. IHI:2004.

characteristics listed in Section 1.2 of this review. The Safety Evaluator then analyzes the proposed proprietary name in the context of the usual practice setting and works to identify potential failure modes and the effects associated with the failure modes.

In the initial stage of the Risk Assessment, the Safety Evaluator compares the proposed proprietary name to all of the names gathered from the above searches, Expert Panel Discussion, and prescription studies, external studies, and identifies potential failure modes by asking:

“Is the proposed proprietary name convincingly similar to another drug name, which may cause practitioners to become confused at any point in the usual practice setting? And are there any components of the name that may function as a source of error beyond sound/look-alike?”

An affirmative answer indicates a failure mode and represents a potential for the proposed proprietary name to be confused with another proprietary or established drug name because of look- or sound-alike similarity or because of some other component of the name. If the answer to the question is no, the Safety Evaluator is not convinced that the names possess similarity that would cause confusion at any point in the medication use system, thus the name is eliminated from further review.

In the second stage of the Risk Assessment, the primary Safety Evaluator evaluates all potential failure modes to determine the likely *effect* of the drug name confusion, by asking:

“Could the confusion of the drug names conceivably result in medication errors in the usual practice setting?”

The answer to this question is a central component of the Safety Evaluator’s overall risk assessment of the proprietary name. If the Safety Evaluator determines through FMEA that the name similarity would not ultimately be a source of medication errors in the usual practice setting, the primary Safety Evaluator eliminates the name from further analysis. However, if the Safety Evaluator determines through FMEA that the name similarity could ultimately cause medication errors in the usual practice setting, the Safety Evaluator will then recommend the use of an alternate proprietary name.

Moreover, DMEPA will object to the use of proposed proprietary name when the primary Safety Evaluator identifies one or more of the following conditions in the Overall Risk Assessment:

- a. OPDP finds the proposed proprietary name misleading from a promotional perspective, and the Review Division concurs with OPDP’s findings. The Federal Food, Drug, and Cosmetic Act provides that labeling or advertising can misbrand a product if misleading representations are made or suggested by statement, word, design, device, or any combination thereof, whether through a PROPRIETARY name or otherwise [21 U.S.C 321(n); See also 21 U.S.C. 352(a) & (n)].
- b. DMEPA identifies that the proposed proprietary name is misleading because of similarity in spelling or pronunciation to another proprietary or established name of a different drug or ingredient [CFR 201.10.(C)(5)].

- c. FMEA identifies the potential for confusion between the proposed proprietary name and other proprietary or established drug name(s), and demonstrates that medication errors are likely to result from the drug name confusion under the conditions of usual clinical practice.
- d. The proposed proprietary name contains an USAN (United States Adopted Names) stem.
- e. DMEPA identifies a potential source of medication error within the proposed proprietary name. For example, the proprietary name may be misleading or, inadvertently, introduce ambiguity and confusion that leads to errors. Such errors may not necessarily involve confusion between the proposed drug and another drug product but involve a naming characteristic that when incorporated into a proprietary name, may be confusing, misleading, cause or contribute to medication errors.

If DMEPA objects to a proposed proprietary name on the basis that drug name confusion could lead to medication errors, the primary Safety Evaluator uses the FMEA process to identify strategies to reduce the risk of medication errors. DMEPA generally recommends that the Sponsor select an alternative proprietary name and submit the alternate name to the Agency for review. However, in rare instances FMEA may identify plausible strategies that could reduce the risk of medication error of the currently proposed name. In that instance, DMEPA may be able to provide the Sponsor with recommendations that reduce or eliminate the potential for error and, thereby, would render the proposed name acceptable.

In the event that DMEPA objects to the use of the proposed proprietary name, based upon the potential for confusion with another proposed (but not yet approved) proprietary name, DMEPA will provide a contingency objection based on the date of approval. Whichever product, the Agency approves first has the right to use the proprietary name, while DMEPA will recommend that the second product to reach approval seek an alternative name.

The threshold set for objection to the proposed proprietary name may seem low to the Applicant/Sponsor. However, the safety concerns set forth in criteria a through e above are supported either by FDA regulation or by external healthcare authorities, including the Institute of Medicine (IOM), World Health Organization (WHO), the Joint Commission, and the Institute for Safe Medication Practices (ISMP). These organizations have examined medication errors resulting from look- or sound-alike drug names, confusing, or misleading names and called for regulatory authorities to address the issue prior to approval. Additionally, DMEPA contends that the threshold set for the Proprietary Name Risk Assessment is reasonable because proprietary drug name confusion is a predictable and preventable source of medication error that, in many instances, the Agency and/or Sponsor can identify and rectify prior to approval to avoid patient harm.

Furthermore, post-marketing experience has demonstrated that medication errors resulting from drug name confusion are notoriously difficult to rectify post-approval. Educational and other post-approval efforts are low-leverage strategies that have had limited effectiveness at alleviating medication errors involving drug name confusion. Sponsors have undertaken higher-leverage strategies, such as drug name changes, in the

past but at great financial cost to the Sponsor and at the expense of the public welfare, not to mention the Agency’s credibility as the authority responsible for approving the error-prone proprietary name. Moreover, even after Sponsors’ have changed a product’s proprietary name in the post-approval phase, it is difficult to eradicate the original proprietary name from practitioners’ vocabulary, and as a result, the Agency has continued to receive reports of drug name confusion long after a name change in some instances. Therefore, DMEPA believes that post-approval efforts at reducing name confusion errors should be reserved for those cases in which the potential for name confusion could not be predicted prior to approval.

Appendix B: Letters and Letter Strings with Possible Orthographic or Phonetic Misinterpretation

Letters in Valchlor,	Scripted May Appear as	Spoken May Be Interpreted as
Upper case ‘V’	U	D, F, P, PH, T, VV
Lower case ‘v’	r, u, w	d, f, p, ph, t, vv
Lower case ‘a’	el, ci, cl, d, o, u	Any Vowel
Lower case ‘l’	L	t
Lower case ‘c’	a, e, i, l	z, k, s if followed by an e or i
Lower case ‘h’	k, b, n, L	
Lower case ‘l’	L	t
Lower case ‘o’	a, c, e, u	Oh
Lower case ‘r’	E, n, s, v	
Letter strings		
al	d	
lo	b	
ch	di, dr	c, k, f
hl	w	

Appendix C: Prescription Simulation Samples and Results

Figure 1. Valchlor Study (Conducted on May 14, 2013)

Handwritten Requisition Medication Order	Verbal Prescription
<p><u>Medication Order:</u></p> <p><i>Valchlor 0.02% Apply to lesions once daily</i></p>	<p>Valchlor 0.02% Apply to lesions once daily</p>
<p><u>Outpatient Prescription:</u></p> <div data-bbox="203 741 894 1167" style="border: 1px solid black; padding: 5px;"><p>Patient _____ Date _____ Address _____</p><p>R</p><p><i>Valchlor 0.02%</i> <i>Apply to affected area qd</i> <i>#2</i></p><p>Refill(s): _____ Dr. <i>ose</i> _____ DEA No. _____ Address _____ Telephone _____</p></div>	

FDA Prescription Simulation Responses (Aggregate 1 Rx Studies Report)

190 People Received Study
63 People Responded

Study Name: Valchlor

Total	19	19	25	63
INTERPRETATION	OUTPATIENT	VOICE	INPATIENT	TOTAL
?	0	1	0	1
VAGLOR	0	1	0	1
VALCHLOR	15	1	17	33
VALCHLOR 0.02%	0	0	2	2
VALCKLOR	0	0	1	1
VALCLITOR	0	0	1	1
VALCLOR	0	8	0	8
VALCLOR 0.02%	0	1	0	1
VALDCHLOR	1	0	0	1
VALDELOR	1	0	0	1
VALDILON	1	0	0	1
VALDLOR	0	1	0	1
VALDRLOR	1	0	0	1
VALEHLOR	0	0	1	1
VALFLOR	0	1	0	1
VALFLORE	0	1	0	1
VALICHLOR	0	0	1	1
VALIHLOR	0	0	2	2
VALTLOR	0	1	0	1
VAZLOR	0	1	0	1
VOGLOR	0	1	0	1
VOLCHLOR	0	1	0	1

Appendix D: Proprietary names not likely to be confused or not used in usual practice settings for the reasons described.

No.	Proprietary Name	Active Ingredient	Similarity to Valchlor	Failure preventions
1.	Balcor	Diltiazem	Look and Sound	International product marketed in Brazil
2.	Valchlor	Methchlorothamine	Look and Sound	The subject of this review
3.	Valclair	Diazepam	Look	International product marketed in the United Kingdom
4.	Vot-Tab Rx		Look	The pair have sufficient orthographic and/or phonetic differences
5.	Xalatan	Latanoprost	Look and Sound	The pair have sufficient orthographic and/or phonetic differences

Appendix E: Risk of medication errors due to product confusion minimized by dissimilarity of the names and/ or use in clinical practice for the reasons described.

No.	<p>Proposed name: Valchlor (Mechlorethamine HCl)</p> <p>Dosage Form: Gel</p> <p>Strength(s): 0.02%</p> <p>Usual Dose: Apply to lesion(s) daily</p>	<p>Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion</p> <p>Causes (could be multiple)</p>	<p>Prevention of Failure Mode</p> <p>In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names</p>
1.	<p>Raniclор (Cefaclor) Chewable Tablet</p> <p>Dosage form: Chewable Tablet</p> <p>Strength: 125 mg, 187 mg, 250 mg, 375 mg</p> <p>Usual dose: 250 to 500 mg orally every 8 hours or 375 mg orally every 12 hours or 20 to 40 mg/kg/day</p>	<p><u>Orthographic Similarity to Valchlor</u></p> <ul style="list-style-type: none"> -The names Valchlor and Raniclор share the letter string, 'lor'. -When scripted the names, Valchlor and Raniclор, appear similar in length, 7 letters versus 8 letters. <p><u>Phonetic Similarity to Valchlor</u></p> <ul style="list-style-type: none"> -The names Valchlor and Raniclор share the sound 'klor'. 	<p><u>Orthographic Differences</u></p> <ul style="list-style-type: none"> -When scripted the letter 'V' looks different from 'R'. -Valchlor has two upstrokes in the 3rd and 5th positions ('l' and 'h') whereas Raniclор has one upstroke in the 6th position ('l'). <p><u>Phonetic Differences</u></p> <ul style="list-style-type: none"> -Valchlor is comprised of 2 syllables (val'klor) versus Raniclор is comprised of 3 syllables (ran î klor) <p><u>Differing Product Characteristics</u></p> <ul style="list-style-type: none"> -Dose (0.02% flat dose versus 250 to 500 mg orally every 8 hours or 375 mg orally every 12 hours or 20 to 40 mg/kg/day) -Single strength product (0.02%) versus multiple strength product (125 mg, 187 mg, 250 mg, 375 mg) with no overlap in strength.

Appendix E: Risk of medication errors due to product confusion minimized by dissimilarity of the names and/ or use in clinical practice for the reasons described.

No.	<p>Proposed name: Valchlor (Mechlorethamine HCl)</p> <p>Dosage Form: Gel</p> <p>Strength(s): 0.02%</p> <p>Usual Dose: Apply to lesion(s) daily</p>	<p>Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion</p> <p>Causes (could be multiple)</p>	<p>Prevention of Failure Mode</p> <p>In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names</p>
2.	<p>Valrubicin Generic for Valstar Dosage form: Solution for Injection Strength: 200 mg/5 mL Usual dose: 800 mg intravesically once a week for six weeks</p>	<p><u>Orthographic Similarity to Valchlor</u> -The names Valchlor and Valrubicin share the letter string, 'val'. -Both names have upstrokes in the 3rd ('l') and 6th ('l' v 'b') positions.</p> <p><u>Phonetic Similarity to Valchlor</u> -Valrubicin and Valchlor share the same first syllable 'val'.</p> <p><u>Frequency of Administration</u> -Both products are dosed once daily.</p> <p><u>Dosage form</u> -Both products are available as a single dosage form, the dosage form maybe omitted when prescribed.</p> <p><u>Strength</u> -Both products are available as a single strength products, the strength maybe omitted when prescribed.</p>	<p><u>Orthographic Differences</u> -When scripted the string '-ch' in the 4th and 5th position look different from '-ru' in Valrubicin. -Valrubicin appears longer in length than Valchlor, 10 letters versus 8 letters. - Additionally, Valchlor has an upstroke in the 5th position whereas Valrubicin does not, 'h' v 'u'.</p> <p><u>Phonetic Differences</u> -Valchlor is comprised of two syllables (val' klor) whereas Valrubicin is comprised of four syllables (val' ru bi cin).</p> <p><u>Differing Product Characteristics</u> -Dose (0.02% flat dose versus 800 mg or take as directed)</p>

Appendix E: Risk of medication errors due to product confusion minimized by dissimilarity of the names and/ or use in clinical practice for the reasons described.

No.	<p>Proposed name: Valchlor (Mechlorethamine HCl)</p> <p>Dosage Form: Gel</p> <p>Strength(s): 0.02%</p> <p>Usual Dose: Apply to lesion(s) daily</p>	<p>Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion</p> <p>Causes (could be multiple)</p>	<p>Prevention of Failure Mode</p> <p>In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names</p>
3.	<p>Valturna (Aliskiren and Valsartan)</p> <p>Dosage form: Tablet</p> <p>Strength: 150 mg/160 mg, 300 mg/320 mg</p> <p>Usual dose: Take 1 tablet by mouth daily</p>	<p><u>Orthographic Similarity to Valchlor</u> -The names Valchlor and Valturna share the letter string, 'val'. -Valchlor and Valturna have an upstroke, 'l', in the 3rd position.</p> <p><u>Frequency of Administration</u> -Both products are dosed once daily.</p> <p><u>Dosage form</u> -Both products are available as a single dosage form, the dosage form maybe omitted when prescribed.</p>	<p><u>Orthographic Differences</u> -Valchlor has upstrokes in the 5th and 6th positions whereas Valturna has an upstroke in the 4th position.</p> <p><u>Differing Product Characteristics</u> -Dose (0.02% flat dose gel versus 1 tablet or 150 mg/160 mg, or 300 mg/320 mg daily based on clinical response)</p> <p><u>Strength</u> -Single strength product (0.02%) versus multiple strength product (150 mg/160 mg and 300 mg/320 mg) with no overlap in strength.</p>

Appendix E: Risk of medication errors due to product confusion minimized by dissimilarity of the names and/ or use in clinical practice for the reasons described.

No.	<p>Proposed name: Valchlor (Mechlorethamine HCl)</p> <p>Dosage Form: Gel</p> <p>Strength(s): 0.02%</p> <p>Usual Dose: Apply to lesion(s) daily</p>	<p>Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion</p> <p>Causes (could be multiple)</p>	<p>Prevention of Failure Mode</p> <p>In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names</p>
4.	<p>Xalkori (Crizotinib)</p> <p>Dosage form: Capsule</p> <p>Strength: 200 mg, 250 mg</p> <p>Usual dose: Take 250 mg orally twice daily</p>	<p><u>Orthographic Similarity to Valchlor</u></p> <p>-When scripted the letter string ‘val’ may look similar to ‘xal’.</p> <p>-When scripted the Valchlor and Xalkori appear similar in length, 8 letters versus 7 letters.</p> <p>-Valchlor and Xalkori have an upstroke, ‘l’, in the 3rd position.</p> <p><u>Dosage form</u></p> <p>-Both products are available as a single dosage form, the dosage form maybe omitted when prescribed.</p>	<p><u>Orthographic Differences</u></p> <p>-When scripted the string ‘-ch’ in the 4th and 5th position look different from ‘-ru’ in Valrubicin.</p> <p>-Valrubicin appears longer in length than Valchlor, 10 letters versus 8 letters.</p> <p><u>Differing Product Characteristics</u></p> <p>-Dose (0.02% flat dose gel or Apply once daily versus 1 capsule or 200 mg or 250 mg twice daily)</p> <p><u>Strength</u></p> <p>-Single strength product (0.02%) versus multiple strength product (200 mg and 250 mg) with no overlap in strength.</p>

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/s/

KEVIN WRIGHT
06/25/2013

JAMES H SCHLICK
06/26/2013

CAROL A HOLQUIST
06/26/2013

Department of Health and Human Services
Public Health Service
Food and Drug Administration
Center for Drug Evaluation and Research
Office of Surveillance and Epidemiology
Office of Medication Error Prevention and Risk Management

Proprietary Name Review

Date: December 20, 2011

Reviewer: Kimberly DeFronzo, RPh, MS, MBA
Division of Medication Error Prevention and Analysis

Team Leader: Todd Bridges, RPh
Division of Medication Error Prevention and Analysis

Division Director: Carol Holquist, RPh
Division of Medication Error Prevention and Analysis

Drug Name(s) and Strength(s): Valchlor (Mechlorethamine HCl) Gel
0.02%

Application Type/Number: NDA 202317

Applicant/Sponsor: Yaupon Therapeutics, Inc.

OSE RCM #: 2011-3818

*** This document contains proprietary and confidential information that should not be released to the public.***

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1 INTRODUCTION

This review evaluates the proposed proprietary name, Valchlor, from a safety and promotional perspective. The sources and methods used to evaluate the proposed name are outlined in the reference section and Appendix A, respectively.

1.1 PRODUCT INFORMATION

The following product information is provided in the October 3, 2011, proprietary name submission.

- Established Name: Mechlorethamine HCl
- Indication of Use: For the topical treatment of (b) (4) Stage IA, IB (b) (4) mycosis fungoides type of cutaneous T-cell lymphoma (CTCL) who have received at least one prior skin-directed therapy (b) (4)
- Route of administration: Topical
- Dosage form: Gel
- Dose: Apply daily on completely dry skin (at least 4 hours before or 30 minutes after showering)
- How Supplied: 60 g tube in a carton
- Storage: Should be stored refrigerated (2°C to 8°C; 36°F to 46°F)
- Container and Closure systems: The drug product is filled into 60 g (b) (4) tubes (b) (4)

The commercial drug product tubes will be packaged in a unit-of-use carton. The dimensional specifications of the carton are: (b) (4). The materials of construction are high quality (b) (4)

2 RESULTS

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

2.1 PROMOTIONAL ASSESSMENT

OPDP determined the proposed name is acceptable from a promotional perspective. DMEPA and the Division of Hematology Products concurred with the findings of OPDP's promotional assessment of the proposed name.

2.2 SAFETY ASSESSMENT

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

2.2.1 United States Adopted Names (USAN) SEARCH

On October 13, 2011, the United States Adopted Name (USAN) stem search identified that a USAN stem is not present in the proposed proprietary name.

2.2.2 Components of the Proposed Proprietary Name

The Applicant states this proprietary name comprised of a single word derived from the established name “Mechlorethamine”. This word does not contain any components (i.e. a modifier, route of administration, dosage form, etc.) that is misleading or can contribute to medication error.

2.2.3 FDA Name Simulation Studies

Thirty eight practitioners participated in DMEPA’s prescription studies (n=16 in the “Inpatient” group, n=12 in the “Outpatient” group, and n=10 in the “Voice” or verbal group). The majority of the participants correctly identified the proposed name as Valchlor (n=29). The remainder of the group misinterpreted the proposed name Valchlor with variations in the spelling. None of the 38 participants indicated confusion with any currently marketed product.

See Appendix C for the complete listing of interpretations from the FDA verbal and written prescription studies.

2.2.4 Comments from Other Review Disciplines

In response to the OSE October 17, 2011, e-mail, the Division of Hematology Products (DHP) did not forward any comments or concerns relating to the proposed name at the initial phase of the proprietary name review.

2.2.5 Failure Mode and Effects Analysis of Similar Names

Appendix B lists possible orthographic and phonetic misinterpretations of the letters appearing in the proposed proprietary name, Valchlor. Table 1 lists the names with orthographic, phonetic, or spelling similarity to the proposed proprietary name, Valchlor identified by the primary reviewer, the Expert Panel Discussion (EPD), and other review disciplines. Table 1 also includes the names identified from the FDA Prescription Simulation or by Drug Safety Institute, Inc. (DSI) not previously identified by DMEPA. These names will be included in the analysis.

Table 1: Collective List of Potentially Similar Names (DMEPA, EPD, Other Disciplines, FDA Name Simulation Studies, and External Name Study if applicable)

Look Similar		Sound Similar		Look & Sound Similar	
<i>Name</i>	<i>Source</i>	<i>Name</i>	<i>Source</i>	<i>Name</i>	<i>Source</i>
Valobar	FDA	Vascor	FDA& External	Valcor	FDA
Actonel	FDA	Altacor	FDA		
Vol-Care Rx	FDA	Kalbitor	FDA		
Ceclor	FDA	Xalkori	FDA		
Velcote	FDA				
Velcade	FDA				
Veletri	FDA				
(b) (4)	FDA				
Valsartan	FDA				
Wellbutrin	FDA				
Advicor	FDA				
Velban	FDA				
Velvachol	FDA				
Valcyte	FDA & External				
Valstar	FDA& External				
Valium	FDA & External				
Valtrex	FDA& External				
Welchol	FDA & External				
Caldalor (misspelling of Caldolor)	FDA & External				
(b) (4)	FDA				
(b) (4)	FDA				
Valturna	FDA				
Voltaren	FDA				
Naldex	FDA				

Table 1: Collective List of Potentially Similar Names (DMEPA, EPD, Other Disciplines, FDA Name Simulation Studies, and External Name Study if applicable)

Look Similar		Sound Similar		Look & Sound Similar	
<i>Name</i>	<i>Source</i>	<i>Name</i>	<i>Source</i>	<i>Name</i>	<i>Source</i>
Natachew	FDA				
Altaflor	External				
Chlor-3	External				
Dexchlor	External				
K-Chlor	External				
Kaochlor	External				
Sochlor	External				
Tri-Chlor	External				
Valacyclovir	External				
Valnac	External				
Vancor	External				
VariClear	External				
Velosulin	External				
Vincrex	External				
Vontrol	External				

Our analysis of the 44 names contained in Table 1 considered the information obtained in the previous sections along with their product characteristics. We determined all 44 names will not pose a risk for confusion as described in Appendix D through E.

2.2.6 Communication of DMEPA's Final Decision to Other Disciplines

DMEPA communicated our findings to the Division of Hematology Products (DHP) via e-mail on December 16, 2011. At that time we also requested additional information or concerns that could inform our review. Per e-mail correspondence from the Division of Hematology Products on December 20, 2011, they stated no concern with the proposed proprietary name, Valchlor.

3 CONCLUSIONS

The proposed proprietary name is acceptable from both a promotional and safety perspective.

If you have further questions or need clarifications, please contact Sue Kang, OSE Project Manager, at 301-796-4216.

3.1 COMMENTS TO THE APPLICANT

We have completed our review of the proposed proprietary name, Valchlor, and have concluded that this name is acceptable. However, if any of the proposed product characteristics as stated in your October 3, 2011, submission are altered, DMEPA rescinds this finding and the name must be resubmitted for review. Additionally, this proprietary name must be re-evaluated 90 days prior to the approval of the application. The conclusions upon re-review are subject to change.

4 REFERENCES

1. ***Micromedex Integrated Index*** (<http://csi.micromedex.com>)

Micromedex contains a variety of databases covering pharmacology, therapeutics, toxicology and diagnostics.

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

POCA is a database which was created for the Division of Medication Error Prevention and Analysis, FDA. As part of the name similarity assessment, proposed names are evaluated via a phonetic/orthographic algorithm. The proposed proprietary name is converted into its phonemic representation before it runs through the phonetic algorithm. Likewise, an orthographic algorithm exists which operates in a similar fashion.

3. ***Drug Facts and Comparisons, online version, St. Louis, MO***
(<http://factsandcomparisons.com>)

Drug Facts and Comparisons is a compendium organized by therapeutic course; it contains monographs on prescription and OTC drugs, with charts comparing similar products. This database also lists the orphan drugs.

4. ***FDA Document Archiving, Reporting & Regulatory Tracking System [DARRTS]***

DARRTS is a government database used to organize Applicant and Sponsor submissions as well as to store and organize assignments, reviews, and communications from the review divisions.

5. ***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.

6. ***Drugs@FDA*** (<http://www.accessdata.fda.gov/scripts/cder/drugsatfda/index.cfm>)

Drugs@FDA contains most of the drug products approved 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, generic drugs, therapeutic biological products, prescription and over-the-counter human drugs and discontinued drugs and "Chemical Type 6" approvals.

7. ***U.S. Patent and Trademark Office*** (<http://www.uspto.gov>)

USPTO provides information regarding patent and trademarks.

8. ***Clinical Pharmacology Online*** (www.clinicalpharmacology-ip.com)

Clinical Pharmacology contains full monographs for the most common drugs in clinical use, plus mini monographs covering investigational, less common, combination, nutraceutical and nutritional products. It also provides a keyword search engine.

9. ***Data provided by Thomson & Thomson's SAEGIS™ Online Service, available at*** (www.thomson-thomson.com)

The Pharma In-Use Search database contains over 400,000 unique pharmaceutical trademarks and trade names that are used in about 50 countries worldwide. The data is provided under license by IMS HEALTH.

10. ***Natural Medicines Comprehensive Databases*** (www.naturaldatabase.com)

Natural Medicines contains up-to-date clinical data on the natural medicines, herbal medicines, and dietary supplements used in the western world.

11. ***Access Medicine*** (www.accessmedicine.com)

Access Medicine® from McGraw-Hill contains full-text information from approximately 60 titles; it includes tables and references. Among the titles are: Harrison's Principles of Internal Medicine, Basic & Clinical Pharmacology, and Goodman and Gilman's The Pharmacologic Basis of Therapeutics.

12. ***USAN Stems*** (<http://www.ama-assn.org/ama/pub/about-ama/our-people/coalitions-consortiums/united-states-adopted-names-council/naming-guidelines/approved-stems.shtml>)

USAN Stems List contains all the recognized USAN stems.

13. ***Red Book Pharmacy's Fundamental Reference***

Red Book contains prices and product information for prescription, over-the-counter drugs, medical devices, and accessories.

14. ***Lexi-Comp*** (www.lexi.com)

Lexi-Comp is a web-based searchable version of the Drug Information Handbook.

15. ***Medical Abbreviations Book***

Medical Abbreviations Book contains commonly used medical abbreviations and their definitions.

16. ***CVS/Pharmacy*** (www.CVS.com)

This database contains commonly used over the counter products not usually identified in other databases.

17. Walgreens (www.walgreens.com)

This database contains commonly used over the counter products not usually identified in other databases.

18. Rx List (www.rxlist.com)

RxList is an online medical resource dedicated to offering detailed and current pharmaceutical information on brand and generic drugs.

19. Dogpile (www.dogpile.com)

Dogpile is a Metasearch engine that searches multiple search engines including Google, Yahoo! and Bing, and returns the most relevant results to the search.

APPENDICES

Appendix A

FDA's Proprietary Name Risk Assessment considers the promotional and safety aspects of a proposed proprietary name. The promotional review of the proposed name is conducted by OPDP. OPDP evaluates proposed proprietary names to determine if they are overly fanciful, so as to misleadingly imply unique effectiveness or composition, as well as to assess whether they contribute to overstatement of product efficacy, minimization of risk, broadening of product indications, or making of unsubstantiated superiority claims. OPDP provides their opinion to DMEPA for consideration in the overall acceptability of the proposed proprietary name.

The safety assessment is conducted by DMEPA. DMEPA staff search a standard set of databases and information sources to identify names that are similar in pronunciation, spelling, and orthographically similar when scripted to the proposed proprietary name. Additionally, 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.). 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.¹

Following the preliminary screening of the proposed proprietary name, DMEPA gathers to discuss their professional opinions on the safety of the proposed proprietary name. This meeting is commonly referred to the Center for Drug Evaluation and Research (CDER) Expert Panel discussion. DMEPA also considers other aspects of the name that may be misleading from a safety perspective. DMEPA staff conducts a prescription simulation studies using FDA health care professionals. 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. DMEPA bases the overall risk assessment on the findings of a Failure Mode and Effects Analysis (FMEA) of the proprietary name and misleading nature of the proposed proprietary name with a focus on the avoidance of medication errors.

DMEPA uses the clinical expertise of its staff to anticipate the conditions of the clinical setting where the product is likely to be used based on the characteristics of the proposed product. DMEPA considers the product characteristics associated with the proposed product throughout the risk assessment because the product characteristics of the

¹ National Coordinating Council for Medication Error Reporting and Prevention.
<http://www.nccmerp.org/aboutMedErrors.html>. Last accessed 10/11/2007.

proposed may provide a context for communication of the drug name and ultimately determine the use of the product in the *usual* clinical practice setting.

Typical product characteristics considered when identifying drug names that could potentially be confused with the proposed proprietary name include, but are not limited to; established name of the proposed product, proposed indication of use, dosage form, route of administration, strength, unit of measure, dosage units, recommended dose, typical quantity or volume, frequency of administration, product packaging, storage conditions, patient population, and prescriber population. DMEPA considers how these product characteristics may or may not be present in communicating a product name throughout the medication use system. Because drug name confusion can occur at any point in the medication use process, DMEPA considers the potential for confusion throughout the entire U.S. medication use process, including drug procurement, prescribing and ordering, dispensing, administration, and monitoring the impact of the medication.² The product characteristics considered for this review appears in Appendix B1 of this review.

The DMEPA considers the spelling of the name, pronunciation of the name when spoken, and appearance of the name when scripted. DMEPA compares the proposed proprietary name with the proprietary and established name of existing and proposed drug products and names currently under review at the FDA. DMEPA compares the pronunciation of the proposed proprietary name with the pronunciation of other drug names because verbal communication of medication names is common in clinical settings. DMEPA examines the phonetic similarity using patterns of speech. If provided, DMEPA will consider the Sponsor's intended pronunciation of the proprietary name. However, DMEPA also considers a variety of pronunciations that could occur in the English language because the Sponsor has little control over how the name will be spoken in clinical practice. The orthographic appearance of the proposed name is evaluated using a number of different handwriting samples. DMEPA applies expertise gained from root-cause analysis of postmarketing medication errors to identify sources of ambiguity within the name that could be introduced when scripting (e.g., "T" may look like "F," lower case "a" looks like a lower case "u," etc). Additionally, other orthographic attributes that determine the overall appearance of the drug name when scripted (see Table 1 below for details).

² Institute of Medicine. Preventing Medication Errors. The National Academies Press: Washington DC. 2006.

Table 1. Criteria Used to Identify Drug Names that Look- or Sound-Similar to a Proposed Proprietary Name.

Type of Similarity	Considerations when Searching the Databases		
	<i>Potential Causes of Drug Name Similarity</i>	<i>Attributes Examined to Identify Similar Drug Names</i>	<i>Potential Effects</i>
Look-alike	Similar spelling	Identical prefix Identical infix Identical suffix Length of the name Overlapping product characteristics	<ul style="list-style-type: none"> Names may appear similar in print or electronic media and lead to drug name confusion in printed or electronic communication Names may look similar when scripted and lead to drug name confusion in written communication
	Orthographic similarity	Similar spelling Length of the name/Similar shape Upstrokes Down strokes Cross-strokes Dotted letters Ambiguity introduced by scripting letters Overlapping product characteristics	<ul style="list-style-type: none"> Names may look similar when scripted, and lead to drug name confusion in written communication
Sound-alike	Phonetic similarity	Identical prefix Identical infix Identical suffix Number of syllables Stresses Placement of vowel sounds Placement of consonant sounds Overlapping product characteristics	<ul style="list-style-type: none"> Names may sound similar when pronounced and lead to drug name confusion in verbal communication

Lastly, DMEPA considers the potential for the proposed proprietary name to inadvertently function as a source of error for reasons other than name confusion. Post-marketing experience has demonstrated that proprietary names (or components of the proprietary name) can be a source of error in a variety of ways. Consequently, DMEPA

considers and evaluates these broader safety implications of the name throughout this assessment and the medication error staff provides additional comments related to the safety of the proposed proprietary name or product based on professional experience with medication errors.

1. Database and Information Sources

DMEPA searches the internet, several standard published drug product reference texts, and FDA databases to identify existing and proposed drug names that may sound-alike or look-alike to the proposed proprietary name. A standard description of the databases used in the searches is provided in the reference section of this review. To complement the process, the DMEPA uses a computerized method of identifying phonetic and orthographic similarity between medication names. The program, Phonetic and Orthographic Computer Analysis (POCA), uses complex algorithms to select a list of names from a database that have some similarity (phonetic, orthographic, or both) to the trademark being evaluated. Lastly, DMEPA reviews the USAN stem list to determine if any USAN stems are present within the proprietary name. The individual findings of multiple safety evaluators are pooled and presented to the CDER Expert Panel. DMEPA also evaluates if there are characteristics included in the composition that may render the name unacceptable from a safety perspective (abbreviation, dosing interval, etc.).

2. Expert Panel Discussion

DMEPA gathers CDER professional opinions on the safety of the proposed product and discussed the proposed proprietary name (Expert Panel Discussion). The Expert Panel is composed of Division of Medication Errors Prevention (DMEPA) staff and representatives from the Division of Drug Marketing, Advertising, and Communications (OPDP). We also consider input from other review disciplines (OND, ONDQA/OBP). The Expert Panel also discusses potential concerns regarding drug marketing and promotion related to the proposed names.

The primary Safety Evaluator presents the pooled results of the database and information searches to the Expert Panel for consideration. Based on the clinical and professional experiences of the Expert Panel members, the Panel may recommend additional names, additional searches by the primary Safety Evaluator to supplement the pooled results, or general advice to consider when reviewing the proposed proprietary name.

3. FDA Prescription Simulation Studies

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.

4. 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.

5. Safety Evaluator Risk Assessment of the Proposed Proprietary Name

The primary Safety Evaluator applies his/her individual expertise gained from evaluating medication errors reported to FDA, considers all aspects of the name that may be misleading or confusing, conducts a Failure Mode and Effects Analysis, and provides an overall decision on acceptability dependent on their risk assessment of name confusion. Failure Mode and Effects Analysis (FMEA) is a systematic tool for evaluating a process and identifying where and how it might fail.³ When applying FMEA to assess the risk of a proposed proprietary name, DMEPA seeks to evaluate the potential for a proposed proprietary name to be confused with another drug name because of name confusion and, thereby, cause errors to occur in the medication use system. FMEA capitalizes on the predictable and preventable nature of medication errors associated with drug name confusion. FMEA allows the Agency to identify the potential for medication errors due to orthographically or phonetically similar drug names prior to approval, where actions to overcome these issues are easier and more effective than remedies available in the post-approval phase.

³ Institute for Healthcare Improvement (IHI). Failure Mode and Effects Analysis. Boston. IHI:2004.

In order to perform an FMEA of the proposed name, the primary Safety Evaluator must analyze the use of the product at all points in the medication use system. Because the proposed product is has not been marketed, the primary Safety Evaluator anticipates the use of the product in the usual practice settings by considering the clinical and product characteristics listed in Appendix B1 of this review. The Safety Evaluator then analyzes the proposed proprietary name in the context of the usual practice setting and works to identify potential failure modes and the effects associated with the failure modes.

In the initial stage of the Risk Assessment, the Safety Evaluator compares the proposed proprietary name to all of the names gathered from the above searches, Expert Panel Discussion, and prescription studies, external studies, and identifies potential failure modes by asking:

“Is the proposed proprietary name convincingly similar to another drug name, which may cause practitioners to become confused at any point in the usual practice setting? And Are there any components of the name that may function as a source of error beyond sound/look-alike”

An affirmative answer indicates a failure mode and represents a potential for the proposed proprietary name to be confused with another proprietary or established drug name because of look- or sound-alike similarity or because of some other component of the name. If the answer to the question is no, the Safety Evaluator is not convinced that the names posses similarity that would cause confusion at any point in the medication use system, thus the name is eliminated from further review.

In the second stage of the Risk Assessment, the primary Safety Evaluator evaluates all potential failure modes to determine the likely *effect* of the drug name confusion, by asking:

“Could the confusion of the drug names conceivably result in medication errors in the usual practice setting?”

The answer to this question is a central component of the Safety Evaluator’s overall risk assessment of the proprietary name. If the Safety Evaluator determines through FMEA that the name similarity would not ultimately be a source of medication errors in the usual practice setting, the primary Safety Evaluator eliminates the name from further analysis. However, if the Safety Evaluator determines through FMEA that the name similarity could ultimately cause medication errors in the usual practice setting, the Safety Evaluator will then recommend the use of an alternate proprietary name.

Moreover, DMEPA will object to the use of proposed proprietary name when the primary Safety Evaluator identifies one or more of the following conditions in the Overall Risk Assessment:

- a. OPDP finds the proposed proprietary name misleading from a promotional perspective, and the Review Division concurs with OPDP’s findings. The Federal Food, Drug, and Cosmetic Act provides that labeling or advertising can misbrand a product if misleading representations are made or suggested by statement, word, design, device, or any combination thereof, whether through a PROPRIETARY name or otherwise [21 U.S.C 321(n); See also 21 U.S.C. 352(a) & (n)].

- b. DMEPA identifies that the proposed proprietary name is misleading because of similarity in spelling or pronunciation to another proprietary or established name of a different drug or ingredient [CFR 201.10.(C)(5)].
- c. FMEA identifies the potential for confusion between the proposed proprietary name and other proprietary or established drug name(s), and demonstrates that medication errors are likely to result from the drug name confusion under the conditions of usual clinical practice.
- d. The proposed proprietary name contains an USAN (United States Adopted Names) stem.
- e. DMEPA identifies a potential source of medication error within the proposed proprietary name. For example, the proprietary name may be misleading or, inadvertently, introduce ambiguity and confusion that leads to errors. Such errors may not necessarily involve confusion between the proposed drug and another drug product but involve a naming characteristic that when incorporated into a proprietary name, may be confusing, misleading, cause or contribute to medication errors.

If DMEPA objects to a proposed proprietary name on the basis that drug name confusion could lead to medication errors, the primary Safety Evaluator uses the FMEA process to identify strategies to reduce the risk of medication errors. DMEPA generally recommends that the Sponsor select an alternative proprietary name and submit the alternate name to the Agency for review. However, in rare instances FMEA may identify plausible strategies that could reduce the risk of medication error of the currently proposed name. In that instance, DMEPA may be able to provide the Sponsor with recommendations that reduce or eliminate the potential for error and, thereby, would render the proposed name acceptable.

In the event that DMEPA objects to the use of the proposed proprietary name, based upon the potential for confusion with another proposed (but not yet approved) proprietary name, DMEPA will provide a contingency objection based on the date of approval. Whichever product, the Agency approves first has the right to use the proprietary name, while DMEPA will recommend that the second product to reach approval seek an alternative name.

The threshold set for objection to the proposed proprietary name may seem low to the Applicant/Sponsor. However, the safety concerns set forth in criteria a through e above are supported either by FDA regulation or by external healthcare authorities, including the Institute of Medicine (IOM), World Health Organization (WHO), the Joint Commission, and the Institute for Safe Medication Practices (ISMP). These organizations have examined medication errors resulting from look- or sound-alike drug names, confusing, or misleading names and called for regulatory authorities to address the issue prior to approval. Additionally, DMEPA contends that the threshold set for the Proprietary Name Risk Assessment is reasonable because proprietary drug name confusion is a predictable and preventable source of medication error that, in many instances, the Agency and/or Sponsor can identify and rectify prior to approval to avoid patient harm.

Furthermore, post-marketing experience has demonstrated that medication errors resulting from drug name confusion are notoriously difficult to rectify post-approval. Educational and other post-approval efforts are low-leverage strategies that have had limited effectiveness at alleviating medication errors involving drug name confusion. Sponsors have undertaken higher-leverage strategies, such as drug name changes, in the past but at great financial cost to the Sponsor and at the expense of the public welfare, not to mention the Agency’s credibility as the authority responsible for approving the error-prone proprietary name. Moreover, even after Sponsors” have changed a product’s proprietary name in the post-approval phase, it is difficult to eradicate the original proprietary name from practitioners” vocabulary, and as a result, the Agency has continued to receive reports of drug name confusion long after a name change in some instances. Therefore, DMEPA believes that post-approval efforts at reducing name confusion errors should be reserved for those cases in which the potential for name confusion could not be predicted prior to approval.

Appendix B: Letters with Possible Orthographic or Phonetic Misinterpretation

Letters in Name, Valchlor	Scripted May Appear as	Spoken May Be Interpreted as
V	L, U, X, W	F
a	e, o, er, c, ce, ci, cl, u, el, d	Any vowel
l	e, b, d, t, s, I, A, P	-----
c	a, e, l, o, r, u, i	z, k, s if followed by an e or i
h	b, k, n, L	-----
l	e, b, d, t, s, I, A, P	-----
o	a, c, e, u	oh
r	a, v, n, s, e, l, u	-----

Appendix C: Prescription Simulation Samples and Results

Figure 1. Valchlor Study (Conducted on October 14, 2011)

Handwritten Requisition Medication Order	Verbal Prescription
<p><u>Medication Order:</u> <i>Valchlor Apply to affected areas qd</i></p> <p><u>Outpatient Prescription:</u></p> <div style="border: 1px solid black; padding: 5px;"> <p>Patient _____ Date <u>10/13</u> Address _____</p> <p>R</p> <p><i>Valchlor #1 tube apply to affected areas QD</i></p> <p>Refill(s): _____ Dr. <u>GSE</u> DEA No. _____ Address _____ Telephone _____</p> </div>	<p>“Valchlor Apply to affected areas daily. Dispense 1 tube”</p>

FDA Prescription Simulation Responses

Study Name: Valchlor

Study Conducted on 10/14/2011 Results As of Date 12/2/2011

85 People Received Study

38 People Responded

Study Name: Valchlor

INPATIENT	STRENGTH	VOICE	STRENGTH	OUTPATIENT	STRENGTH
VALCHLOR		VALCHLOR		VACHLOR	
VALCHLOR		VALCHLOR		VALCHLOR	
VALCHLOR	None	VALCHLOR		VALCHLOR	
VALCHLOR		VALCHLOR		VALCHLOR	
VALCHLOR		VALCHLOR APPLY TO AFFECTED AREAS DAILY	1 tube	VALCHLOR	
VALCHLOR	none	VALCLOR	na	VALCHLOR	
VALCHLOR	none	VALCLOR	none	VALCHLOR	
VALCHLOR		VALCLOR	one tube	VALCHLOR	
VALCHLOR		VALCLOR	1 tube	VALCHLOR	
VALCHLOR		VALKLOR		VALCHLOR	
VALCHLOR				VALCHLOR	
VALCHLOR	none given			VALCHLOR	
VALCHLOR					
VALCHLOR					
VALEHLOR					
VALEXLOR	None given				

Appendix D: Proprietary names not likely to be confused or not used in usual practice settings for the reasons described.

Proprietary Name	Active Ingredient	Similarity to Valchlor	Failure Preventions
Actonel	Risedronate Sodium	Orthographic	Lack of convincing orthographic similarity
Advicor	Niacin/Lovastatin	Orthographic	Lack of convincing orthographic similarity
Altaflor	Sodium Fluoride	Orthographic	Lack of convincing orthographic similarity
Ceclor	Cefaclor	Orthographic	Lack of convincing orthographic similarity
Chlor-3	Sodium Fluoride/ Potassium Chloride/ Magnesium Chloride	Orthographic	Lack of convincing orthographic similarity
Dexchlor	Dexchlorpheniramine Maleate	Orthographic	Lack of convincing orthographic similarity
Kaochlor	Potassium Chloride	Orthographic	Lack of convincing orthographic similarity
K-Chlor	Potassium Chloride	Orthographic	Lack of convincing orthographic similarity
Naldex	Dexchlorpheniramine/ Phenylephrine	Orthographic	Lack of convincing orthographic similarity
Natachew	Prenatal Vitamins with Minerals	Orthographic	Lack of convincing orthographic similarity
Sochlor	Sodium Chloride	Orthographic	Lack of convincing orthographic similarity
Tri-Chlor	Trichloroacetic Acid	Orthographic	Lack of convincing orthographic similarity
Valacyclovir	Valacyclovir	Orthographic	Lack of convincing orthographic similarity
Valium	Diazepam	Orthographic	Lack of convincing orthographic similarity
Valnac	Betamethasone Valerate	Orthographic	Lack of convincing orthographic similarity
Valobar	-----	Orthographic	No product characteristics can be found for this name in the databases cited under the References section in this review. Preliminary drug usage data indicates Valobar has not been prescribed for the past 5 years.
Vancor	Vancomycin HCl	Orthographic	Lack of convincing orthographic similarity
Velban	Vinblastine	Orthographic	Lack of convincing orthographic similarity
Vincrex	Vincristine Sulfate	Orthographic	Lack of convincing orthographic similarity

Appendix D: Proprietary names not likely to be confused or not used in usual practice settings for the reasons described.

Proprietary Name	Active Ingredient	Similarity to Valchlor	Failure Preventions
(b) (4)			
Velcote	Alpha-linolenic acid, Linoleic acid, Palmitic, Stearic, Oleic and Arachidic acids with Vitamin A 1000 iu., Vitamin D ₃ 100 iu., Vitamin E 5 iu., Wheat Germ Oil and Lecithin	Orthographic	Velcote is a veterinary preparation used only in dogs, cats and horses.
Vol-Care Rx	Vitamin B Complex/ Vitamin C/ Biotin/ Folic Acid	Orthographic	Lack of convincing orthographic similarity

*** This document contains proprietary and confidential information that should not be released to the public.

Appendix D: Proprietary names not likely to be confused or not used in usual practice settings for the reasons described.

Proprietary Name	Active Ingredient	Similarity to Valchlor	Failure Preventions
Welchol	Colesevelam	Orthographic	Lack of convincing orthographic similarity
Wellbutrin	Bupropion HCl	Orthographic	Lack of convincing orthographic similarity
Valcor	-----	Orthographic & Phonetic	Valcor is a registered trademark name owned by Merrell Dow Pharmaceuticals, Inc. but there is no approved or pending drug product associated with this name.
Altacor	Lovastatin	Phonetic	Lack of convincing phonetic similarity Altacor name was changed to Altoprev by the manufacturer, Andrx Pharmaceuticals, Inc. in 2004.
Kalbitor	Ecallantide	Phonetic	Lack of convincing phonetic similarity
Xalkori	Crizotinib	Phonetic	Lack of convincing phonetic similarity

Appendix E: Risk of medication errors due to product confusion minimized by dissimilarity of the names and/or use in clinical practice for the reasons described.

<p>Proposed name: Valchlor (Mechlorethamine HCl) Gel</p>	<p>Strength(s): 0.02%</p>	<p>Usual dose: Apply thin film to affected areas once daily</p>
<p>Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion</p>	<p>Causes (could be multiple)</p>	<p>Prevention of Failure Mode</p>
<p>Caldolor (Ibuprofen) Injection 400 mg/4 mL and 800 mg/ 8 mL <i>Usual dose:</i> 400 mg to 800 mg intravenously every 6 hours as needed</p>	<p>Orthographic similarity stems from the fact that both names share a similar middle letter string “ald” and “alch” where “d” and “ch” looks similar when scripted, and the same ending letters “lor”.</p>	<p>Caldolor has different beginning letter and the middle upstroke is in a different position compared to the proposed name, Valchlor. Both products have different strength, dose, frequency and direction for use.</p>
<p>Vontrol (Diphenidol HCl) Tablet 25 mg <i>Usual dose:</i> 25 mg to 50 mg orally every 4 hours as needed</p>	<p>Orthographic similarity stems from the fact that both names share the same beginning letter “V” followed by the vowel “a” and “o” that look similar when scripted, and the ending letters “rol” and “lor” since “r” and “l” looks similar when scripted. Both are single strength products that can be prescribed without the strength designation.</p>	<p>Vontrol has only 3 upstrokes vs. 4 upstrokes in Valchlor and Vontrol has a different middle letter string “nt” than “lch” in Valchlor. Both products have different dose, frequency and direction for use.</p>

Appendix E: Risk of medication errors due to product confusion minimized by dissimilarity of the names and/or use in clinical practice for the reasons described.

<p>Proposed name: Valchlor (Mechlorethamine HCl) Gel</p>	<p>Strength(s): 0.02%</p>	<p>Usual dose: Apply thin film to affected areas once daily</p>
<p>Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion</p>	<p>Causes (could be multiple)</p>	<p>Prevention of Failure Mode</p>
<p>VariClear (Aescin) Cream 20% <i>Usual dose:</i> Apply each morning and evening to any areas which may be prone to varicose veins, or where varicose veins may already be present. Massage in lightly. For best results, use regularly.</p>	<p>Orthographic similarity stems from the fact that both names share the same beginning letters “Va” followed by the letters “r” and “l” that can look similar when scripted, and same ending letter of “r” preceded by the letters “ea” and “lo” that can look similar when scripted. There is a numerical overlap in strengths (20% and 0.02%). Both products are topical preparations.</p>	<p>VariClear has only 3 upstrokes vs. 4 upstrokes in Valchlor and VariClear has a dotted letter “i” not present in Valchlor. Both products have different handling and storage conditions (refrigerate vs. room temperature). VariClear is an OTC product that is readily available for purchase online as compared to the Valchlor product with a REMS program.</p>
<p>Velosulin (Insulin Purified Pork) Suspension for Injection 100 units/mL <i>Usual dose:</i> 0.5 and 1 unit/kg/day subcutaneously within 15 minutes of meal initiation</p>	<p>Orthographic similarity stems from the fact that both names share the same or overlapping beginning letters “Velo” that can look similar to “Valc” since the letters “e” and “a” and letters “o” and “c” can look similar when scripted. Both names also share similar ending letters since the letters “n” and “r” can look similar when scripted.</p>	<p>Velosulin has only 3 upstrokes vs. 4 upstrokes in Valchlor and Velosulin has a dotted letter “i” not present in Valchlor. Both products have different strength, dose, frequency and direction for use.</p>

Appendix E: Risk of medication errors due to product confusion minimized by dissimilarity of the names and/or use in clinical practice for the reasons described.

<p>Proposed name: Valchlor (Mechlorethamine HCl) Gel</p>	<p>Strength(s): 0.02%</p>	<p>Usual dose: Apply thin film to affected areas once daily</p>
<p>Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion</p>	<p>Causes (could be multiple)</p>	<p>Prevention of Failure Mode</p>
<p>Velcade (Bortezomib) for Injection 3.5 mg single use vial <i>Usual dose:</i> 1.3 mg/m² administered as a 3 to 5 second bolus intravenous injection in varying frequency depending on treatment cycle</p>	<p>Orthographic similarity stems from the fact that both names share the same or overlapping beginning letters “Velc” and “Valc” since the letters “e” and “a” can look similar when scripted. Both names also have similar ending letters “e” that can look similar to “r” when scripted. Both products have oncology indications.</p>	<p>Velcade has only 3 upstrokes vs. 4 upstrokes in Valchlor and the missing middle upstroke “h” helps differentiate these two names orthographically. Both products have different strength, dose, frequency and direction for use.</p>
<p>Veletri (Epoprostenol Sodium) Powder for Injection 1.5 mg (1,500,000 ng) per 10 ml vial <i>Usual dose:</i> Infusion of Veletri should be initiated at 2 ng/kg/min and increased in increments of 2 ng/kg/min every 15 minutes or longer by continuous intravenous infusion via a central venous catheter using an ambulatory infusion pump</p>	<p>Orthographic similarity stems from the fact that both names share the same or overlapping beginning letters “Vele” and “Valc” since the letters “e”, “a”, and “c” can look similar when scripted. Both are single strength products that can be prescribed without the strength designation.</p>	<p>Veletri has only 3 upstrokes vs. 4 upstrokes in Valchlor and Veletri has an ending dotted letter “i” not present in Valchlor. Both products have different dose, frequency and direction for use.</p>

Appendix E: Risk of medication errors due to product confusion minimized by dissimilarity of the names and/or use in clinical practice for the reasons described.

<p>Proposed name: Valchlor (Mechlorethamine HCl) Gel</p>	<p>Strength(s): 0.02%</p>	<p>Usual dose: Apply thin film to affected areas once daily</p>
<p>Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion</p>	<p>Causes (could be multiple)</p>	<p>Prevention of Failure Mode</p>
<p>Valsartan (brand name is Diovan®) Capsule 40 mg, 80 mg, 160 mg, and 320 mg <i>Usual dose:</i> 40 mg orally twice daily for heart failure indication and 80 mg to 320 mg once daily orally for hypertension indication</p>	<p>Orthographic similarity stems from the fact that both names share the same beginning letters “Val” and “Val”. Both names also have similar ending letter string “tan” that can look similar to “lor” when scripted. Both products have same frequency of administration (once daily).</p>	<p>Valsartan has only 3 upstrokes vs. 4 upstrokes in Valchlor and Valsartan has a different middle letter string “sar” compared to “ch” in Valchlor. Both products have different strength, dose, and direction for use. Valsartan is available in multiple strengths, thus the strength would need to be indicated on a prescription.</p>
<p>Velvachol (Water, Petrolatum, Mineral Oil, Cetyl Alcohol, Stearyl Alcohol, Sodium Lauryl Sulfate, Cholesterol, Methylparaben, Butylparaben, Propylparaben) Cream No strength <i>Usual dose:</i> Apply to skin as needed</p>	<p>Orthographic similarity stems from the fact that both names share the same or overlapping beginning letters “Vel” and “Val” since the letters “e” and “a” can look similar when scripted. Both products are intended for external topical use only.</p>	<p>Velvachol has the two upstroke letters “h” and “l” in different positions within the name compared to the proposed name, Valchlor. Both products have different handling and storage conditions (refrigerate vs. room temperature). Velvachol is an OTC moisturizing cream non-drug product that is readily available for purchase online as compared to the Valchlor product with a REMS program.</p>

Appendix E: Risk of medication errors due to product confusion minimized by dissimilarity of the names and/or use in clinical practice for the reasons described.

<p>Proposed name: Valchlor (Mecloretamine HCl) Gel</p>	<p>Strength(s): 0.02%</p>	<p>Usual dose: Apply thin film to affected areas once daily</p>
<p>Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion</p>	<p>Causes (could be multiple)</p>	<p>Prevention of Failure Mode</p>
<p>Valcyte (Valganciclovir HCl) Tablet and Powder for Oral Solution 450 mg tablets and 50 mg/mL oral solution <i>Usual dose:</i> 900-1800 mg/day orally 1-2 times daily</p>	<p>Orthographic similarity stems from the fact that both names share the same beginning letters “Valc” and “Valc” and similar ending letters “e” that can look similar to “r” when scripted. Both products have same frequency of administration (once daily).</p>	<p>Valcyte has only 3 upstrokes vs. 4 upstrokes in Valchlor and Valcyte has a downstroke “y” as well as a cross stroke “t” not present in Valchlor. Both products have different strength, dose, and direction for use.</p>
<p>Valstar (Valrubicin) Sterile Solution for Intravesical Instillation 200 mg/5 mL <i>Usual dose:</i> 800 mg/day intravesically once weekly for 6 weeks</p>	<p>Orthographic similarity stems from the fact that both names share the same beginning letters “Val” and “Val”. Both names also have the same ending letter “r” and similar preceding letters “a” that can look similar to “o” when scripted. There is a numerical overlap in strengths (200 mg and 0.02%). Both products have oncology indications.</p>	<p>Valstar has only 3 upstrokes vs. 4 upstrokes in Valchlor and Valstar has a cross stroke “t” not present in Valchlor. Both products have different dose, frequency and direction for use.</p>
<p>Valtrex (Valacyclovir HCl) Tablet 500 mg and 1 gm <i>Usual dose:</i> 500mg to 2 grams once to three times daily depending on indication</p>	<p>Orthographic similarity stems from the fact that both names share the same beginning letters “Val”. Both products have same frequency of administration (once daily).</p>	<p>Valtrex has only 3 upstrokes vs. 4 upstrokes in Valchlor and Valtrex has a cross stroke “t” not present in Valchlor. Both products have different strength, dose, and direction for use.</p>

Appendix E: Risk of medication errors due to product confusion minimized by dissimilarity of the names and/or use in clinical practice for the reasons described.

<p>Proposed name: Valchlor (Mechlorethamine HCl) Gel</p>	<p>Strength(s): 0.02%</p>	<p>Usual dose: Apply thin film to affected areas once daily</p>
<p>Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion</p>	<p>Causes (could be multiple)</p>	<p>Prevention of Failure Mode</p>
<p>Valturna (Aliskiren and Valsartan) Tablet 150 mg/160 mg and 300 mg/320 mg <i>Usual dose:</i> 150/160 mg then titrate up to 300 mg/320 mg orally once daily</p>	<p>Orthographic similarity stems from the fact that both names share the same beginning letters “Val”. Both products have same frequency of administration (once daily).</p>	<p>Valturna has only 3 upstrokes vs. 4 upstrokes in Valchlor and Valturna has a cross stroke “t” not present in Valchlor. Both products have different strength, dose, and direction for use.</p>
<p>Voltaren (Diclofenac sodium) Gel, Solution, Extended Release Tablet 1% (or 10 mg per gram) Gel 0.1% Ophthalmic Solution 100 mg Extended Release Tablet <i>Usual dose:</i> Topical Gel: Apply 2 gm to 4 gm (as measured onto the accompanying dosing card) to the affected foot or knee or ankle 4 times daily Ophthalmic Solution: 1-2 drops to affected eye 4 times daily post-op Oral extended release tablet: 100 mg qd to bid</p>	<p>Orthographic similarity stems from the fact that both names share the same or overlapping beginning letters “Vol” and “Val” where the letter “o” and “a” can look similar when scripted. Both names also have the similar ending letters with “en” and “or” that can look similar when scripted. The oral extended release tablet formulation of Voltaren has the same frequency of administration (once daily) with Valchlor. Both Voltaren Gel and Valchlor Gel are gel formulations intended for external topical use only.</p>	<p>Voltaren has only 3 upstrokes vs. 4 upstrokes in Valchlor and Voltaren has a cross stroke “t” not present in Valchlor. Both products have different dose and direction for use. Valchlor Gel and Voltaren Gel have different frequency of administration (once daily vs. 4 times daily, respectively), and handling and storage conditions (refrigerate vs. room temperature, respectively).</p>

Appendix E: Risk of medication errors due to product confusion minimized by dissimilarity of the names and/or use in clinical practice for the reasons described.

Proposed name: Valchlor (Mechlorethamine HCl) Gel	Strength(s): 0.02%	Usual dose: Apply thin film to affected areas once daily
Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion	Causes (could be multiple)	Prevention of Failure Mode
Vascor (Bepiridil HCl) Tablet 200 mg, 300 mg, 400 mg <u>Usual dose:</u> 200 mg to 400 mg orally once daily	Orthographic similarity stems from the fact that both names share the same beginning letter string “Va-c” and “Va-c” and same ending letters “or”. Phonetic similarity stems from the fact that both names have two syllables. Both products have same frequency of administration (once daily).	Vascor is shorter in length and only has one upstroke compared to the proposed name, Valchlor, with four upstrokes. Vascor has a different sound with the letter “s” in “Vas” compared to the sound from letter “l” in “Val”, and lacks the ending sound from the letter “l” in “lor”. Both products have different strength, dose, and direction for use.

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/s/

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12/20/2011

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