

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:

203479Orig1s000

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--Final

Date: February 4, 2013
Reviewer: Loretta Holmes, BSN, PharmD
Division of Medication Error Prevention and Analysis
Team Leader Irene Z. Chan, PharmD, BCPS
Division of Medication Error Prevention and Analysis
Drug Name and Strength: Versacloz (Clozapine) Oral Suspension
50 mg per mL
Application Type/Number: NDA 203479
Applicant: Douglas Pharmaceuticals America Limited
OSE RCM #: 2013-236

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

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1 INTRODUCTION

This re-assessment of the proposed proprietary name, Versacloz, is written in response to the anticipated approval of this NDA within 90 days from the date of this review. DMEPA found the proposed name, Versacloz, acceptable in OSE Review 2012-738, dated June 22, 2012 and OSE Review 2012-1840 dated September 17, 2012.

2 METHODS AND DISCUSSION

For re-assessments of proposed proprietary names, DMEPA searches a standard set of databases and information sources (see Section 4) to identify names with orthographic and phonetic similarity to the proposed name that have been approved since the previous OSE proprietary name review. For this review we used the same search criteria described in OSE Review 2012-1840. We note that none of the proposed product characteristics were altered. However, we evaluated the previously identified names of concern considering any lessons learned from recent post-marketing experience, which may have altered our previous conclusion regarding the acceptability of the proposed proprietary name. Our evaluation has not altered our previous conclusion regarding the acceptability of the proposed proprietary name. The searches of the databases yielded no new names thought to look or sound similar to Versacloz and represent a potential source of drug name confusion.

Additionally, DMEPA searched the United States Adopted Names (USAN) stem list to determine if the name contains any USAN stems as of the last USAN update. The Safety Evaluator did not identify any United States Adopted Names (USAN) stems in the proposed proprietary name, as of January 28, 2013. The Office of Prescription Drug Promotion (OPDP) re-reviewed the proposed name on January 30, 2013 and had no concerns regarding the proposed name from a promotional perspective.

3 CONCLUSIONS

The re-evaluation of the proposed proprietary name, Versacloz, did not identify any vulnerability that would result in medication errors with any additional names. Thus, DMEPA has no objection to the proprietary name, Versacloz, for this product at this time.

DMEPA considers this a final review; however, if approval of the NDA is delayed beyond 90 days from the date of this review, the Division of Psychiatry Products should notify DMEPA because the proprietary name must be re-reviewed prior to the new approval date.

If you have further questions or need clarifications, please contact Sandra Rimmel, OSE Project Manager, at 301-796-2445.

4 REFERENCES

1. OSE Reviews

Holmes, Loretta. Versacloz Proprietary Name Review, OSE Review 2012-738, dated May 22, 2012.

Holmes, Loretta. Versacloz Proprietary Name Review-Final, OSE Review 2012-1840, dated September 17, 2012.

2. *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.

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

USAN Stems List contains all the recognized USAN stems.

4. *Division of Medication Error Prevention and Analysis Proprietary Name Consultation Request*

Compiled list of proposed proprietary names submitted to the Division of Medication Error Prevention and Analysis for review. The list is generated on a weekly basis from the Access database/tracking system.

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/s/

LORETTA HOLMES
02/04/2013

IRENE Z CHAN
02/04/2013

**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--Final

Date: September 14, 2012
Reviewer: Loretta Holmes, BSN, PharmD
Division of Medication Error Prevention and Analysis
Team Leader Irene Z. Chan, PharmD, BCPS
Division of Medication Error Prevention and Analysis
Drug Name and Strength: Versacloz (Clozapine) Oral Suspension
50 mg per mL
Application Type/Number: NDA 203479
Applicant: Douglas Pharmaceuticals America Limited
OSE RCM #: 2012-1840

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1 INTRODUCTION

This re-assessment of the proposed proprietary name, Versacloz is written in response to the anticipated approval of this NDA within 90 days from the date of this review. DMEPA found the proposed name, Versacloz, unacceptable in OSE Review 2012-738 dated May 22, 2012 due to look-alike similarities to a pending name within the Agency. However, the conflicting name was withdrawn and thus, Douglas Pharmaceuticals, decided to continue to pursue the name Versacloz for this application.

2 METHODS AND DISCUSSION

For re-assessments of proposed proprietary names, DMEPA searches a standard set of databases and information sources (see Section 4) to identify names with orthographic and phonetic similarity to the proposed name that have been approved since the previous OSE proprietary name review. For this review we used the same search criteria described in OSE Review 2012-738. We note that none of the proposed product characteristics were altered. However, we evaluated the previously identified names of concern considering any lessons learned from recent post-marketing experience, which may have altered our previous conclusion regarding the acceptability of the proposed proprietary name. Our evaluation has not altered our previous conclusion regarding the acceptability of the proposed proprietary name. The searches of the databases yielded one new name, (b) (4) *** thought to look or sound similar to Versacloz and represent a potential source of drug name confusion. Failure mode and effects analysis was applied to determine if (b) (4) *** could potentially be confused with Versacloz and lead to medication errors. This analysis determined that the name similarity between Versacloz and the (b) (4) *** was unlikely to result in medication errors for the reasons presented in Appendix A.

Additionally, DMEPA searched the United States Adopted Names (USAN) stem list to determine if the name contains any USAN stems as of the last USAN update. The Safety Evaluator did not identify any United States Adopted Names (USAN) stems in the proposed proprietary name as of September 13, 2012. The Office of Prescription Drug Promotion (OPDP) re-reviewed the proposed name on August 23, 2012 and had no concerns regarding the proposed name from a promotional perspective.

3 CONCLUSIONS

The re-evaluation of the proposed proprietary name, Versacloz, did not identify any vulnerability that would result in medication errors with the additional name noted in this review. Thus, DMEPA has no objection to the proprietary name, Versacloz, for this product at this time.

DMEPA considers this a final review; however, if approval of the NDA is delayed beyond 90 days from the date of this review, the Office of Psychiatry Products (DPP) should notify DMEPA because the proprietary name must be re-reviewed prior to the new approval date.

If you have further questions or need clarifications, please contact Sandra Rimmel, OSE Project Manager, at 301-796-2445.

4 REFERENCES

1. OSE Reviews

Holmes, Loretta. Versacloz Proprietary Name Review, OSE Review 2012-738, dated May 22, 2012.

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

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

USAN Stems List contains all the recognized USAN stems.

4. *Division of Medication Error Prevention and Analysis Proprietary Name Consultation Request*

Compiled list of proposed proprietary names submitted to the Division of Medication Error Prevention and Analysis for review. The list is generated on a weekly basis from the Access database/tracking system.

Appendix A: FMEA Table

	<p><u>Proposed name:</u> Versacloz (Clozapine) Oral Suspension</p>	<p><u>Strength:</u> 50 mg per mL</p>	<p><u>Usual dose:</u> Begin with a 12.5 mg dose once or twice daily. Increase the dose with daily dosage increments of 25 mg to 50 mg per day, if well tolerated, to achieve a target dose of 300 mg to 450 mg per day by the end of 2 weeks. Subsequent dosage increases should be made no more than once or twice weekly in increments not to exceed 100 mg. Dosing should not exceed 900 mg per day. Cautious titration and a divided dosage schedule are necessary to minimize the risks of hypotension, seizure and sedation.</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>1</p>	<p>(b) (4) *** (b) (4)</p>	<p><u>Orthographic:</u> The beginning letters “Ve” vs. (b) (4)” may look similar when written. The suffixes “loz” vs. “(b) (4)” may look similar when written.</p> <p><u>Dose:</u> There is numerical similarity between the doses of the products (i.e., 1 inhalation vs. 1 (b) (4)</p>	<p><u>Orthographic:</u> Versacloz appears longer in length when written as compared to (b) (4) (9 letters vs. (b) (4) letters, respectively). The infixes “rsac” vs. (b) (4) look different.</p>

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/s/

LORETTA HOLMES
09/17/2012

IRENE Z CHAN
09/17/2012

**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 22, 2012

Reviewer: Loretta Holmes, BSN, PharmD
Division of Medication Error Prevention and Analysis

Team Leader Irene Z. Chan, PharmD, BCPS
Division of Medication Error Prevention and Analysis

Deputy Director: Kellie Taylor, PharmD, MPH
Division of Medication Error Prevention and Analysis

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

Drug Name and Strength: VersaCloz (Clozapine) Oral Suspension
50 mg per mL

Application Type/Number: NDA 203479

Applicant: Douglas Pharmaceuticals America Limited

OSE RCM #: 2012-738

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1 INTRODUCTION

This review evaluates the proposed proprietary name, VersaCloz, 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 name, (b) (4) was initially submitted for this product during the IND phase of the application process. The Division of Medication Error Prevention and Analysis (DMEPA) found the name, (b) (4) unacceptable due to look-alike and product characteristic similarities to the products (b) (4) (see OSE Review 2011-3262). Thus, the Applicant submitted the name, VersaCloz, for our review and comment.

1.2 PRODUCT INFORMATION

The following product information was provided in the March 27, 2012 proprietary name submission.

- **Active Ingredient:** Clozapine
- **Indication of Use:** Management of severely ill schizophrenic patients who fail to respond adequately to standard drug treatment for schizophrenia; reducing the risk of recurrent suicidal behavior in patients with schizophrenia or schizoaffective disorder who are judged to be at chronic risk for re-experiencing suicidal behavior, based on history and recent clinical state.
- **Route of administration:** Oral
- **Dosage form:** Oral Suspension
- **Strength:** 50 mg per mL
- **Dose and Frequency of Administration:** Begin with a 12.5 mg dose once or twice daily. The dosing should be continued with daily dosage increments of 25 mg to 50 mg per day, if well tolerated, to achieve a target dose of 300 mg to 450 mg per day by the end of 2 weeks. Subsequent dosage increments should be made no more than once or twice weekly, in increments not to exceed 100 mg. Cautious titration and a divided dosage schedule are necessary to minimize the risks of hypotension, seizure and sedation.
- **How Supplied:** Cartons containing one amber bottle containing 100 mL or oral suspension, one 1 mL oral syringe, one 9 mL oral syringe, and one bottle adaptor
- **Storage:** Store at or below 25°C (77°F). Protect from light. Shake well before use.
- **Container and Closure Systems:** The bottles have (b) (4) caps.
- **Intended Pronunciation:** vur-suh-kloze
- **Derivation of Proprietary Name:** None provided

2 RESULTS

The following sections provide the information obtained and considered in the 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 Psychiatry Products (DPP) 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 safety evaluation.

2.2.1 United States Adopted Names (USAN) SEARCH

The May 2, 2012 search of the United States Adopted Name (USAN) stems did not identify a USAN stem present in the proposed proprietary name.

2.2.2 Components of the Proposed Proprietary Name

According to the Applicant, the name has no derivation. However, we note the proposed proprietary name, VersaCloz, is comprised of a single word that contains the first five letters of the name of the company who serves as the US Regulatory Agent for Douglas Pharmaceuticals (“**Versa**Pharm”) and the first four letters of the established name (**clozapine**). Additionally, we note the letter “C” is capitalized in the name. See section 2.2.6 below.

2.2.3 FDA Name Simulation Studies

Thirty-eight practitioners participated in DMEPA's prescription studies. The interpretations did not overlap with, appear or sound similar to any currently marketed product. Fourteen participants in the Inpatient Study and eleven participants in the Outpatient Study interpreted the name correctly. None of the participants in the Voice Study interpreted the name correctly. See Appendix C for the complete listing of interpretations from the verbal and written prescription studies.

2.2.4 Comments from Other Review Disciplines

In response to the OSE, April 5, 2012 e-mail, the Division of Psychiatry Products (DPP) responded “VersaCloz could sound like Versed.” This name was also identified by the EPD Panel and the external name study and was therefore added to our list of names to be evaluated in this review.

2.2.5 Failure Mode and Effects Analysis (FMEA) of Similar Names

Appendix B lists possible orthographic and phonetic misinterpretations of the letters appearing in the proposed proprietary name, VersaCloz. Table 1 lists the names with orthographic, phonetic, or spelling similarity to the proposed proprietary name, VersaCloz, identified by the primary reviewer, the Expert Panel Discussion (EPD), and

other review disciplines. Table 1 also includes the names identified by (b) (4) in their external name study, but not identified by DMEPA, that require further evaluation.

Table 1: Collective List of Potentially Similar Names [EPD Panel, Other Disciplines, and the (b) (4) External Name Study]

Look Similar					
<i>Name</i>	<i>Source</i>	<i>Name</i>	<i>Source</i>	<i>Name</i>	<i>Source</i>
Cefactor	EPD Panel	VersaPlus	EPD Panel	Versapen	EPD Panel
Voraxaze	EPD Panel	Vesicare	EPD Panel	Verelan	EPD Panel
Vaseretic	EPD Panel	Viracept	EPD Panel	Vasocidin	EPD Panel
Veracolate	EPD Panel	Welchol	EPD Panel	Verapamil	(b) (4)
Versa-Cells	EPD Panel	Vencedor	EPD Panel	Benza Clear	Primary Safety Evaluator
BenzaClin	Primary Safety Evaluator	Variclear	Primary Safety Evaluator	VersaBase	Primary Safety Evaluator
(b) (4)	Primary Safety Evaluator	(b) (4)	Primary Safety Evaluator		
Sound Similar					
<i>Name</i>	<i>Source</i>	<i>Name</i>	<i>Source</i>	<i>Name</i>	<i>Source</i>
Visicol	Primary Safety Evaluator				
Look and Sound Similar					
<i>Name</i>	<i>Source</i>	<i>Name</i>	<i>Source</i>	<i>Name</i>	<i>Source</i>
Varisolve***	EPD Panel	(b) (4)	EPD Panel	Versal	(b) (4)
Versed	EPD Panel Other Discipline (b) (4)	Versacaps	EPD	Varizole	(b) (4)
Versiclear	EPD Panel (b) (4)	Clozaril	(b) (4)		

Our analysis of the 29 names contained in Table 1 considered the information obtained in the previous sections along with the product characteristics. We determined 28 names will not pose a risk for confusion as described in Appendices D and E. However, the proposed name could be confused with (b) (4)***, a pending name within the Agency. The rationale for the risk of confusion is described below since this proprietary name is associated with a pending application and cannot be released to the Applicant.

The proposed proprietary name, VersaCloz, is orthographically similar to and shares overlapping product characteristics with the proposed name (b) (4)*** (b) (4), a pending name and application within the Agency. The orthographic similarity stems from identical prefixes (b) (4) a similar number of letters (nine vs (b) (4)), which give the names a similar length, and both names ending with a (b) (4). Although (b) (4) contains a (b) (4) this may not be sufficient to prevent confusion that can lead to a medication error.

(b) (4)

In addition to the orthographic similarities, VersaCloz and (b) (4) share similar product characteristics that increase the likelihood of a medication error to occur in the usual practice setting. These overlapping product characteristics include the following: dose (25 mg to (b) (4) route of administration (oral), and frequency of administration (once or twice daily vs. (b) (4) daily). Although the dosage forms differ (oral suspension vs. (b) (4)), this difference may not be denoted on a prescription and, therefore, does not help to prevent medication errors from occurring. Thus, “VersaCloz 25 mg once daily” could be misinterpreted as “(b) (4) (b) (4)mg (b) (4) daily”.

2.2.6 FMEA of Name Composition and Capitalization of the Letter “C”

As previously stated, the proposed proprietary name, VersaCloz, can be divided into two components; the prefix “Versa” and the suffix “Cloz”. The prefix “Versa” is the same prefix contained in the name of the company that serves as the US Regulatory Agent for Douglas Pharmaceuticals, which is VersaPharm, Inc. Although not a concern with this name, continued use of the prefix “Versa” may affect the acceptability of future proposed proprietary names. Therefore, this naming strategy needs to be limited to a single product in order to avoid confusion within or between the Applicant’s product lines.

The proposed name also consists of the four letter suffix “Cloz”. “Cloz” is also a prefix in “Clozapine”, the established name of the product. However, due to its different location in the two names, there are no look-alike safety concerns between “VersaCloz” and “Clozapine”. Additionally, we note that Clozapine, the active ingredient in the product, is being represented in the proprietary name. According to 21 CFR 201.6(b), the proprietary name of a drug containing two or more ingredients should not include or suggest the name of one or some, but not all, of the ingredients. VersaCloz only contains one ingredient, thus, it is acceptable according to this regulation.

Moreover, the Applicant proposes spelling “VersaCloz”, with the use of a capital letter “C”. Thus, in our evaluation of the name, we considered the fact that in the marketplace, the name may be spelled with the letter “C” capitalized or in lower case.

Our evaluation of the use of capitalization inside the name also noted this is an example of tall-man (mixed-case or enlarged) lettering. Tall-man letters are used to emphasize the differing portions of two names in order to help differentiate them by drawing attention to their dissimilarities. It is typically used to differentiate known look-alike names that have been confused and resulted in wrong drug medication errors (e.g., ZyrTEC and ZyPREXA).¹ Thus, the use of tall-man lettering in the proposed proprietary name is inappropriate and should not be used. Therefore, “VersaCloz” should appear as “Versacloz”.

2.2.7 Communication of DMEPA’s Final Decision to Other Disciplines

DMEPA communicated our findings to the Division of Psychiatry Products via e-mail on May 15, 2012. At that time we also requested additional information or concerns that could inform our review. Per e-mail correspondence from the Division of Psychiatry Products on May 22, 2012, they stated no additional concerns with the proposed proprietary name, VersaCloz.

3 CONCLUSIONS

The proposed proprietary name is acceptable from a promotional perspective but is not acceptable from a safety perspective. The proposed name is vulnerable to name confusion with another proposed name, (b) (4)***, should both make it to the marketplace. Therefore, the following comments in Section 3.1 will be communicated to the Applicant via letter.

If you have further questions or need clarifications, please contact Sandra Griffith, OSE Project Manager, at 301-796-2445.

3.1 COMMENTS TO THE APPLICANT

We have completed our review of the proposed proprietary name, Versacloz, and have concluded that it is vulnerable to name confusion that could lead to medication errors with a pending proposed name due to orthographic similarity and shared product characteristics. Therefore, at this time, the acceptability of the proposed proprietary name, Versacloz, is dependent upon which application is approved first. If Versacloz is approved first, we will advise the second product to seek an alternate name. If the second name application is approved prior to your application, then you will be requested to submit another name. Additionally, we have the following comments.

Our display of your proposed proprietary name is in title case lettering as “Versacloz” rather than “VersaCloz”. Presenting Versacloz with the capital letter “C” within the name is typically reserved for differentiating known look-alike and sound-alike

¹ Michael R. Cohen, *Medication Errors*, 2nd ed., American Pharmacists Association, Washington, D.C., 2007, pp. 89-90.

established name pairs or in rare circumstances for proprietary names to help reduce the risk of wrong drug name errors.² Since Versacloz is not a name that has been involved in drug name confusion or wrong drug errors, the capitalization of the letter “C” is inappropriately applied.

We also note the prefix “Versa” is the same prefix contained in the name of the company who serves as your US Regulatory Agent, VersaPharm, Inc. Although not a concern with this name, continued use of the prefix “Versa” may affect the acceptability of future proposed proprietary names. Therefore, this naming strategy needs to be limited to a single product in order to avoid confusion within or between your product lines.

We note that you have not proposed an alternate proprietary name in your submission dated March 26, 2012. If you wish to withdraw Versacloz and have an alternate name reviewed to avoid potential conflict with the pending name, please submit a request for withdrawal and submit a new complete request for proprietary name review for your alternate name. The review of this alternative name will not be initiated until the new submission is received (See the Guidance for Industry, *Contents of a Complete Submission for the Evaluation of Proprietary Names*, <http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM075068.pdf> and “PDUFA Reauthorization Performance Goals and Procedures Fiscal Years 2008 through 2012”).

² Michael R. Cohen, *Medication Errors*, 2nd ed., American Pharmacists Association, Washington, D.C., 2007, pp. 89-90.

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.³

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 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.

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

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.⁴

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).

⁴ 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.⁵ 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

⁵ 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

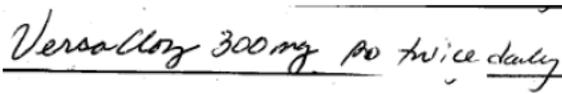
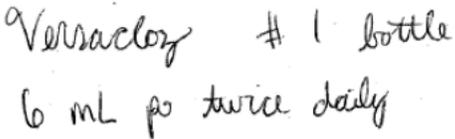
past but at great financial cost to the Sponsor and at the expense of the public welfare, not to mention the Agency's credibility as the authority responsible for approving the error-prone proprietary name. Moreover, even after Sponsors' have changed a product's proprietary name in the post-approval 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 with Possible Orthographic or Phonetic Misinterpretation

Letters in Name NAME	Scripted May Appear as	Spoken May Be Interpreted as
V	C, b, L, M, R, U, X	B
v	c, b, L, r, u, x	B
e	a, i, l, p	Any vowel
r	s, n, e, ,v	
s	G, g, n, r	x, z
a	eI, ci, cl, d, o, u	Any vowel
c	a, e, i, l	k
l	b,e, s, A, P, i	
o	a, c, e, u	Any vowel
z	c, e, g, n, m, q, r, s, v	
sa		sah, se, si, zah
cloz		claus, clos, close, cross, klaus

Appendix C: Prescription Simulation Samples and Results

Figure 1. VersaCloz Study (Conducted on April 13, 2012)

Handwritten Requisition Medication Order	Verbal Prescription
<p><u>Inpatient Medication Order:</u></p> 	<p>“VersaCloz 300 mg orally twice a day”</p>
<p><u>Outpatient Prescription:</u></p> 	

FDA Prescription Simulation Responses (Aggregate 1 Rx Studies Report)

				84 People Received Study
				38 People Responded
Study Name: VersaCloz				
Total	16	10	12	
INTERPRETATION	INPATIENT	VOICE	OUTPATIENT	TOTAL
BIRTHACLOS	0	1	0	1
VERACLOS	0	1	0	1
VERACLOZ	1	0	0	1
VERDACLAUS	0	1	0	1
VERRACLOZ	0	0	1	1
VERSACLAS	0	1	0	1
VERSACLAUS	0	1	0	1
VERSACLAUSE	0	1	0	1
VERSACLOSS	0	2	0	2
VERSACLOZ	14	0	11	25
VERSAFLOX	0	1	0	1
VERSALLOZ	1	0	0	1
VERSIKLAUS	0	1	0	1

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

	Proprietary Name	Similarity to VersaCloz	Failure preventions
1	Verapamil	Look	The pair have sufficient orthographic differences.
2	Viracept (Nelfinavir Mesylate)	Look	The pair have sufficient orthographic and/or phonetic differences.
3	Welchol (Colesevelam HCl)	Look	The pair have sufficient orthographic differences.
4	Verelan (Verapamil HCl)	Look	The pair have sufficient orthographic differences.
5	Versal (Peru Balsam, Benzyl Benzoate, Zinc Oxide, and Bismuth Subgallate)	Look and Sound	The pair have sufficient orthographic and/or phonetic differences.
6	Versed (Midazolam HCl)	Look and Sound	The pair have sufficient orthographic and/or phonetic differences.
7	Virazole (Ribavirin)	Look and Sound	The pair have sufficient orthographic and/or phonetic differences.
8	Clozaril (Clozapine)	Look and Sound	The pair have sufficient orthographic and/or phonetic differences.
9	(b) (4)	Look and Sound	(b) (4) was the name initially proposed for this NDA. However, DMEPA found the name unacceptable due to orthographic similarity to the names (b) (4).
10	Versa-Cells	Look	This name was found in Red Book, however, no information was provided in the link for further information. The name was also found in an internet search on Google at the following website, http://haystack.ihs.com/partnumber/12556807 where Versa-Cells was described as a “Test Kit, Antibody Detection, Red Blood Cells”.
11	VersaPlus	Look	VersaPlus is a compounding vehicle that would not be dispensed to a patient.
12	VersaBase (Family Tradename): VersaBase Gel VersaBase Cream VersaBase Lotion VersaBase Foam VersaBase Shampoo	Look	VersaBase is a family tradename for multiple products available in different dosage forms which are used as bases in pharmaceutical compounding. These products would not be dispensed to a patient.

	Proprietary Name	Similarity to VersaCloz	Failure preventions
13	Vencedor	Look	Vencedor is not a drug. It is copper sulfate hydrate 98%.
14	Versapen (Hetacillin) Powder for Oral Suspension	Look	This product has been discontinued. The Application was withdrawn FR effective 12/07/92. There are no generics of this product available.
15	Variclear	Look and Sound	Two products were identified with this name. One is a capsule and the other is a cream. We were unable to find dosage and administration information for these products in our usual databases.
16	(b) (4) *** (b) (4)	Look	This name was reviewed by DMEPA and found unacceptable. A new name was submitted by the Applicant for our review.

Appendix E: Summary Findings of the FMEA

	<p>Proposed name: VersaCloz (Clozapine) Oral Suspension</p>	<p>Strength: 50 mg per mL</p>	<p>Usual dose: Begin with a 12.5 mg dose once or twice daily. Increase the dose with daily dosage increments of 25 mg to 50 mg per day, if well tolerated, to achieve a target dose of 300 mg to 450 mg per day by the end of 2 weeks. Subsequent dosage increases should be made no more than once or twice weekly in increments not to exceed 100 mg. Dosing should not exceed 900 mg per day. Cautious titration and a divided dosage schedule are necessary to minimize the risks of hypotension, seizure and sedation.</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>17</p>	<p>Varisolve*** (Polidocanol) Endovenous Microfoam</p> <p><u>Strengths:</u> 0.5% and 1%</p> <p><u>Dosage:</u> 5 mL to 15 mL injected into the varicose vein during a treatment session</p>	<p><u>Orthographic:</u> The beginning letters “Ver” vs. “Var” may look similar when written. Both names contain the letters “s” and “l” in similar positions.</p> <p><u>Dose:</u> The products have overlapping doses (e.g., 5 mL)</p>	<p><u>Orthographic:</u> The suffixes look different when written (“cloz” vs. “solve”).</p> <p><u>Strength:</u> 50 mg/mL (single strength) vs. 0.5% and 1%</p> <p><u>Context of use:</u> Varisolve*** use is limited to areas such as a physician’s office and will be administered using ultrasound guidance whereas VersaCloz would not.</p>

	<p>Proposed name:</p> <p>VersaCloz (Clozapine) Oral Suspension</p>	<p>Strength:</p> <p>50 mg per mL</p>	<p>Usual dose:</p> <p>Begin with a 12.5 mg dose once or twice daily. Increase the dose with daily dosage increments of 25 mg to 50 mg per day, if well tolerated, to achieve a target dose of 300 mg to 450 mg per day by the end of 2 weeks. Subsequent dosage increases should be made no more than once or twice weekly in increments not to exceed 100 mg. Dosing should not exceed 900 mg per day. Cautious titration and a divided dosage schedule are necessary to minimize the risks of hypotension, seizure and sedation.</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>18</p>	<p>Cefaclor Capsules Extended-release Tablets Oral Suspension</p> <p><u>Strengths:</u> <i>Capsules</i> 250 mg and 500 mg</p> <p><i>Extended-release Tablets</i> 500 mg</p> <p><i>Powder for Oral Suspension</i> 125 mg/5 mL, 187 mg/5 mL, 250 mg/5 ml and 375 mg/5 mL</p> <p><u>Dosage:</u> <i>Adults</i> 250 mg to 50 mg orally three times per day; Extended-release Tablets: 500 mg orally every 12 hours</p> <p><i>Children</i> 20 mg/kg to 40 mg/kg orally twice daily or three times per day</p>	<p><u>Orthographic:</u> The beginning letters “Ve” vs. “Ce” may look similar when written. Both names contain the sequential infix letters “clo”. The names end with letters that may look similar when written [“z” (when written without a downstroke) vs. “r”].</p> <p><u>Dose:</u> The products have overlapping doses (e.g., 2.5 mL, 5 mL, 125 mg, 250 mg)</p>	<p><u>Orthographic:</u> The infix letters “rs” vs. “f” look different due to the upstroke and cross-stroke characteristics of the letter “f” in Cefaclor which help to differentiate the names.</p>

	Proposed name: VersaCloz (Clozapine) Oral Suspension	Strength: 50 mg per mL	Usual dose: Begin with a 12.5 mg dose once or twice daily. Increase the dose with daily dosage increments of 25 mg to 50 mg per day, if well tolerated, to achieve a target dose of 300 mg to 450 mg per day by the end of 2 weeks. Subsequent dosage increases should be made no more than once or twice weekly in increments not to exceed 100 mg. Dosing should not exceed 900 mg per day. Cautious titration and a divided dosage schedule are necessary to minimize the risks of hypotension, seizure and sedation.
	Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion	Causes (could be multiple)	Prevention of Failure Mode
19	Voraxaze (Glucarpidase) for Injection <u>Strength:</u> 1,000 units per vial <u>Dosage:</u> A single intravenous injection of 50 units/kg given via bolus injection over 5 minutes	<u>Orthographic:</u> The beginning letters of the names may look similar when written (“Versa” vs. “Vora”). Both names contain the letter “z” at the ending portion of the name. <u>Dose:</u> The doses of the products may have numerical overlap or numerical similarity (e.g., 750 mg vs. 750 units and 250 mg vs. 2500 units)	<u>Orthographic:</u> The suffixes look different (“cloz” vs. “xaze”) when written. <u>Unit of measure:</u> mg or mL vs. units
20	Veracolate (Bisacodyl) Enteric Coated Tablets <u>Strength:</u> 5 mg <u>Dosage:</u> 5 mg to 15 mg orally in a single daily dose as needed.	<u>Orthographic:</u> The beginning letters “Versac” vs. “Verac” may look similar when written. <u>Dose:</u> The doses of the products may have numerical similarity (e.g., 50 mg vs. 5 mg; 100 mg vs. 10 mg; and 150 mg vs. 15 mg)	<u>Orthographic:</u> Versacloz contains one upstroke letter whereas Veracolate contains two which helps to differentiate the names.

	Proposed name: VersaCloz (Clozapine) Oral Suspension	Strength: 50 mg per mL	Usual dose: Begin with a 12.5 mg dose once or twice daily. Increase the dose with daily dosage increments of 25 mg to 50 mg per day, if well tolerated, to achieve a target dose of 300 mg to 450 mg per day by the end of 2 weeks. Subsequent dosage increases should be made no more than once or twice weekly in increments not to exceed 100 mg. Dosing should not exceed 900 mg per day. Cautious titration and a divided dosage schedule are necessary to minimize the risks of hypotension, seizure and sedation.
	Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion	Causes (could be multiple)	Prevention of Failure Mode
21	Vesicare (Solifenacin Succinate) Tablets <u>Strengths:</u> 5 mg and 10 mg <u>Dosage:</u> 5 mg to 10 mg orally once daily	<u>Orthographic:</u> Both names begin with the letters “Ve” and contain the letters “s” and “c” in similar positions. <u>Dose:</u> The doses of the products may have numerical similarity (e.g., 50 mg vs. 5 mg and 100 mg vs. 10 mg)	<u>Orthographic:</u> The suffixes look different (“loz” vs. “are”) when written.
22	Versiclear (Sodium Thiosulfate and Salicylic Acid) Lotion <u>Strength:</u> 25%/1% <u>Dosage:</u> Apply a thin film to the affected area(s) twice daily	<u>Orthographic:</u> Both names contain 10 letters and begin with the letters “Vers”. Both names contain the sequential infix letters “cl”. <u>Phonetic:</u> The first two syllables in the names have phonetic similarity (“Ver-sa-” vs. “Ver-si-”)	<u>Orthographic:</u> The ending letters “oz” vs. “ear” look different when written. <u>Phonetic:</u> The ending syllables sound different (“-cloz” vs. “-clear”). <u>Dose:</u> 12.5 mg to 450 mg vs. apply a thin layer (or “use as directed”)

	Proposed name: VersaCloz (Clozapine) Oral Suspension	Strength: 50 mg per mL	Usual dose: Begin with a 12.5 mg dose once or twice daily. Increase the dose with daily dosage increments of 25 mg to 50 mg per day, if well tolerated, to achieve a target dose of 300 mg to 450 mg per day by the end of 2 weeks. Subsequent dosage increases should be made no more than once or twice weekly in increments not to exceed 100 mg. Dosing should not exceed 900 mg per day. Cautious titration and a divided dosage schedule are necessary to minimize the risks of hypotension, seizure and sedation.
	Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion	Causes (could be multiple)	Prevention of Failure Mode
23	Versacaps (Guaifenesin and Pseudoephedrine HCl) Extended-release Capsules <u>Strength:</u> 300 mg/60 mg <u>Dosage:</u> 1 or 2 capsules orally every 12 hours as needed	<u>Orthographic:</u> Both names begin with the letters “Versac”. <u>Phonetic:</u> The first two syllables in the names are identical (“Ver-sa-”). <u>Dose:</u> The doses of the products may have numerical overlap (e.g., 1 mL vs. 1 capsule and 2 mL vs. 2 capsules)	<u>Orthographic:</u> The ending letters “loz” vs. “aps” look different when written. <u>Phonetic:</u> The last syllable in the names sound different (“-cloz” vs. “-caps”). <u>Unit of measure:</u> mL vs. capsules
24	Baza Clear (Vitamin A & D) Ointment <u>Strength:</u> Not applicable <u>Dosage:</u> Unable to find dosage information specific to this product. However, Vitamin A & D ointments is usually administered as follows: apply liberally to the affected area(s) and rub it in thoroughly. Apply as often as necessary.	<u>Orthographic:</u> The beginning letters “V” vs. “B” (when in lower case) may look similar when scripted. The letter “s” may look similar to the letter “z” (when scripted without a downstroke). Both names contain the sequential letters “acl”.	<u>Orthographic:</u> The suffixes “oz” vs. “ear” look different when written. <u>Dosage:</u> 12.5 mg to 450 mg vs. apply liberally to the affected area (or “use as directed”)

	Proposed name: VersaCloz (Clozapine) Oral Suspension	Strength: 50 mg per mL	Usual dose:
			Begin with a 12.5 mg dose once or twice daily. Increase the dose with daily dosage increments of 25 mg to 50 mg per day, if well tolerated, to achieve a target dose of 300 mg to 450 mg per day by the end of 2 weeks. Subsequent dosage increases should be made no more than once or twice weekly in increments not to exceed 100 mg. Dosing should not exceed 900 mg per day. Cautious titration and a divided dosage schedule are necessary to minimize the risks of hypotension, seizure and sedation.
	Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion	Causes (could be multiple)	Prevention of Failure Mode
25	BenzaClin (Benzoyl Peroxide and Clindamycin Phosphate) Gel <u>Strength:</u> 5%/1% <u>Dosage:</u> Apply a sufficient amount to the affected area(s) twice daily	<u>Orthographic:</u> The beginning letters of the names may look similar when written “VersaCl” vs. “BenzaCl” (“B” written in lower case and “z” written without a downstroke).	<u>Dose:</u> 12.5 mg to 450 mg vs. apply a sufficient amount (or “use as directed”)
26	Visicol (Sodium Phosphate Monobasic Monohydrate and Sodium Phosphate Dibasic Anhydrous) Tablets <u>Strength:</u> 1.5 g <u>Dosage:</u> 40 tablets (60 g of sodium phosphate) with a total of 3.6 quarts of clear liquids in the following manner: the evening before the procedure, take 3 tablets (the last dose will be 2 tablets) with 8 ounces of clear liquids every 15 minutes for a total of 20 tablets. On the day of the procedure, starting 3 to 5 hours before the procedure, take 3 tablets (the last dose will be 2 tablets) with 8 ounces of clear liquids every 15 minutes for a total of 20 tablets.	<u>Phonetic:</u> Both names contain three syllables and all three syllables have phonetic similarity between the names (“Ver-” vs. “Vis-”); (“-sa-” vs. “-si-”); and (“cloz-” vs. “-col”)	<u>Dosage:</u> 12.5 mg to 450 mg vs. 2 or 3 tablets (or “use as directed”)

	Proposed name: VersaCloz (Clozapine) Oral Suspension	Strength: 50 mg per mL	Usual dose: Begin with a 12.5 mg dose once or twice daily. Increase the dose with daily dosage increments of 25 mg to 50 mg per day, if well tolerated, to achieve a target dose of 300 mg to 450 mg per day by the end of 2 weeks. Subsequent dosage increases should be made no more than once or twice weekly in increments not to exceed 100 mg. Dosing should not exceed 900 mg per day. Cautious titration and a divided dosage schedule are necessary to minimize the risks of hypotension, seizure and sedation.
	Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion	Causes (could be multiple)	Prevention of Failure Mode
27	Vaseretic (Enalapril Maleate and Hydrochlorothiazide) Tablets <u>Strengths:</u> 5 mg/12.5 mg 10 mg/25 mg <u>Dosage:</u> 1 or 2 tablets daily; maximum dose 20 mg/50 mg	<u>Orthographic:</u> Both names contain 9 letters. The beginning letters (“Vers” vs. “Vas”) may look similar when written.	<u>Orthographic:</u> The suffixes look different when written (“aCloz” vs. “eretic”). <u>Strength:</u> 50 mg/mL (single strength) vs. 5 mg/12.5 mg and 10 mg/25 mg VersaCloz is available in a single strength so the strength could be omitted from a prescription whereas Vaseretic is available in two strengths so the strength would have to be specified.
28	Vasocidin (Prednisolone Sodium Phosphate and Sodium Sulfacetamide) Ophthalmic Solution <u>Strength:</u> 0.25%/10% <u>Dosage:</u> 1 to 3 drops into the affected eye(s) every 1 to 4 hours during the day and at bedtime	<u>Orthographic:</u> Both names contain 9 letters. The beginning letters may look similar when written (“Versac” vs. “Vasoc”). <u>Dosage:</u> The doses of the products may have numerical overlap (e.g., 1 mL vs. 1 drop; 2 mL vs. 2 drops; and 3 mL vs. 3 drops)	<u>Orthographic:</u> The suffixes look different (“loz” vs. “idin”). <u>Unit of measure:</u> mg or mL vs. drops

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/s/

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