CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

204592Orig1s000

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:	September 5, 2013
Reviewer(s):	Vicky Borders-Hemphill, Pharm.D. Division of Medication Error Prevention and Analysis
Team Leader	Jamie Wilkins Parker, Pharm.D. Division of Medication Error Prevention and Analysis
Drug Name and Strength(s):	Zorvolex (Diclofenac acid) Capsules, 18 mg and 35 mg
Application Type/Number:	NDA 204592
Applicant/Sponsor:	Iroko Pharmaceuticals, LLC
OSE RCM #:	2013-1067

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

CONTENTS

1 INTRODUCTION

This re-assessment of the proposed proprietary name, Zorvolex 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, Zorvolex, acceptable in OSE Review #2013-343 dated April 26, 2013.

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 #2013-343. 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. The searches of the databases yielded no new names, thought to look or sound similar to Zorvolex and represent a potential source of drug name confusion

Additionally, DMEPA searched the United States Adopted Names (USAN) list to determine if the name contains any USAN stems as of the last USAN updates. The Safety Evaluator did not identify any USAN stems in the proposed proprietary name, as of September 5, 2013.

3 CONCLUSIONS

The re-evaluation of the proposed proprietary name, Zorvolex, did not identify any vulnerabilities that would result in medication errors with any additional names. Thus, DMEPA has no objection to the proprietary name, Zorvolex, 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, then the Division of Analgesia, Anesthesia, and Addiction 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 Vaishali Jarral, OSE project manager, at 301-796-4248.

4 REFERENCES

1. OSE Reviews

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.

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

BRENDA V BORDERS-HEMPHILL
09/05/2013

JAMIE C WILKINS PARKER
09/06/2013

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:	April 26, 2013
Reviewer(s):	Vicky Borders-Hemphill, Pharm.D. Division of Medication Error Prevention and Analysis
Team Leader	Jamie Wilkins Parker, Pharm.D. Division of Medication Error Prevention and Analysis
Division Director:	Carol Holquist, RPh Division of Medication Error Prevention and Analysis
Drug Name and Strength(s):	Zorvolex (Diclofenac acid) Capsules, 18 mg and 35 mg
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CONTENTS

1 INTRODUCTION

This review evaluates the proposed proprietary name, Zorvolex, 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 February 4, 2013, Proprietary name submission and March 6, 2013 labeling submission:

- Active Ingredient: Diclofenac acid
- Indication of Use: for the treatment of mild to moderate acute pain in adults
- Route of administration: Oral
- Dosage form: Capsule
- Strength: 18 mg or 35 mg
- Dose and Frequency of administration: 18 mg or 35 mg by mouth three times daily taken on an empty stomach (b) (4)
- How Supplied: each strength in bottles of 30 capsules, bottles of 90 capsules, and blister of 3 capsules
- Storage: 25°C (77°F), with excursions permitted to 15 to 30°C (59-86°F)

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 Anesthesia, Analgesia, and Addiction Products (DAAAP) 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

On February 11, 2013 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 stated the name did not have any intended meaning or derivation. This proprietary name is comprised of a single/multiple word(s) that does not contain any

components (i.e. a modifier, route of administration, dosage form, etc.) that is misleading or can contribute to medication error.

2.2.4 FDA Name Simulation Studies

Eighty Nine (89) practitioners participated in DMEPA's prescription studies. Thirty Nine (39) of the participants interpreted the name correctly as 'Zorvolex', with correct interpretation occurring in the inpatient and outpatient written studies and voice prescription. Misinterpretations occurred with expected orthographically and phonetically similar letter strings. None of the misinterpreted names overlap with marketed products. See Appendix C for the complete listing of interpretations from the verbal and written prescription studies.

2.2.5 Comments from Other Review Disciplines

In response to the OSE, April 25, 2013 e-mail, the Division of Anesthesia, Analgesia, and Addiction Products (DAAAP) did not forward any comments or concerns relating to the proposed name at the initial phase of the proprietary name review.

2.2.6 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, Zorvolex. Table 1 lists the names with orthographic, phonetic, or spelling similarity to the proposed proprietary name, Zorvolex, identified by the primary reviewer, the Expert Panel Discussion (EPD), and other review disciplines. The February 4, 2013, proprietary name submission cover letter refers to an external name study conducted by (b) (4) that was submitted to the IND 103880 on September 23, 2011. This external name study was previously evaluated in DMEPA review dated March 16, 2012 (OSE review #2011-3627).

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

Look Similar					
Name	***Source***	***Name***	***Source***	***Name***	***Source***
Concerta	FDA	Tobradex	FDA	Zinacef	FDA
Coricidin	FDA	Tornalate	FDA	Zometa	FDA
Corvita	FDA	Zamdray	FDA	Zonalon	FDA
Corvite	FDA	Zariviz	FDA	Zonatuss	FDA
Dovonex	FDA	Zarontin	FDA	Zorbtive	FDA
Fosamax	FDA	Zenatane	FDA	Zorcala	FDA
Lovenox	FDA	Zicadia	FDA	Zortress	FDA
Norel EX	FDA				
Sound Similar					
Norflex	FDA	Zanaflex	FDA	Zostavax	FDA
Sorilux	FDA	Zervalx	FDA	Zovirax	FDA
Xopenex	FDA	Zoladex	FDA		
Look and Sound Similar					
Parvolex	FDA				

Our analysis of the 31 names contained in Table 1 considered the information obtained in the previous sections along with their product characteristics. We determined that all 31 names will not pose a risk for confusion as described in Appendices D through E.

2.2.7 Communication of DMEPA's Final Decision to Other Disciplines

DMEPA communicated our findings to the Division of Analgesia, Anesthesia, and Addiction Products (DAAAP) via e-mail on April 25, 2013. At that time we also requested additional information or concerns that could inform our review. Per e-mail correspondence from the Division of Analgesia, Anesthesia, and Addiction Products (DAAAP)) on April 26, 2013, they stated no additional concerns with the proposed proprietary name, Zorvolex.

3 CONCLUSIONS

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

If you have further questions or need clarifications, please contact Teena Thomas, OSE project manager, at 301-796-0549.

3.1 COMMENTS TO THE APPLICANT

We have completed our review of the proposed proprietary name, Zorvolex, and have concluded that this name is acceptable. The proposed proprietary name must be re-reviewed 90 days prior to approval of NDA 204592. The results are subject to change. If any of the proposed product characteristics as stated in your February 4, 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 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

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[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**		
	Potential Causes of Drug Name Similarity	*Attributes Examined to Identify Similar Drug Names*	*Potential Effects*
Look-alike	Similar spelling	Identical prefix Identical infix Identical suffix Length of the name Overlapping product characteristics	• 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	• 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	• 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 gather 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.

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 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 Zorvolex,	Scripted May Appear as	Spoken May Be Interpreted as
Capital 'Z'	B, C, f, L, M, T, S, V, Y, c, e, g, n, q, r	'c', 's', 'x'
lower case 'z'	b, c, e, g, n, m, q, r, s, v	'c', 's', 'x'
lower case 'o'	Q, a, c, e, u	'Oh'
lower case 'r'	B, Pr, K, s, n, e, ,v	'WR'
lower case 'v'	r, u	'f'
lower case 'o'	Q, a, c, e, u	'Oh'
lower case 'l'	Z, S, T, b,e, A, P, i	'w'
lower case 'e'	C, f, a, i, o, l, p	Any Vowel and 'y'
Lower case 'x'	d, f, K,P, t, U, V, Y, a, n, r	'ks', 'kz', 's', 'z'
Letter strings in Name Zorvolex	**Scripted May Appear as**	**Spoken May Be Interpreted as**
rv	w, ni, nu	
olex	dex	
zorvo	zorio, zorno, zoro, zorva, zorvo, zovo, zos	sorbo, zobo, zorba, zorbi, zorbo, zorva, zorbor
lex	lax, laz, lox	let, lets, lax

Appendix C: Prescription Simulation Samples and Results

Figure 1. Zorvolex Study (Conducted on February 26, 2013)

Handwritten Requisition Medication Order	Verbal Prescription
Medication Order: Zorvolex 35mg 1 po tid	Zorvolex 18 mg 1 capsule po tid dispense # 90

Outpatient Prescription: Zorvolex 18mg 1 po TID #90	

FDA Prescription Simulation Responses. (Aggregate 1 Rx studies report)

Study Name: Zorvolex
192 People Received
89 People Responded

Total	**30**	**31**	**28**	
INTERPRETATION	**INPATIEN**	**VOICE**	**OUTPATIEN**	**TOTA**
???	0	1	0	1
SORBOLET	0	1	0	1
ZORBALET	0	3	0	3
ZORBALEX	0	3	0	3
ZORBILET	0	1	0	1
ZORBOLET	0	2	0	2
ZORBORLEX	0	1	0	1
ZORIOLAX	0	0	1	1
ZORNOLEX	0	0	1	1
ZOROLAX	0	0	1	1
ZORVALET	0	2	0	2
ZORVALETS	0	1	0	1
ZORVALEX	2	6	0	8
ZORVOLAX	0	0	16	16
ZORVOLAZ	0	0	1	1
ZORVOLEX	27	10	2	39
ZORVOLOX	0	0	6	6
ZOVOLEX	1	0	0	1

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 Zorvolex	Failure preventions
Lovenox	Enoxaparin	Orthographic	The name pair have sufficient orthographic differences and differences in product characteristics as stated in OSE review #2011-3627
Norflex	Orphenadrine	Phonetic	The name pair have sufficient phonetic differences and differences in product characteristics as stated in OSE review #2011-3627
Parvolex	Acetylcysteine	Orthographic and Phonetic	International product marketed in Canada
Tobradex	Tobramycin and Dexamethasone	Orthographic	The name pair have sufficient orthographic differences and differences in product characteristics as stated in OSE review #2011-3627
Tornalate	bitolterol mesylate	Orthographic	NDA 018770 and NDA 019548 withdrawn FR effective 12-7-2007
Xopenex	Levalbuterol	Phonetic	The name pair have sufficient phonetic differences and differences in product characteristics as stated in OSE review #2011-3627
Zanaflex	Tizanidine	Phonetic	The name pair have sufficient phonetic differences and differences in product characteristics as stated in OSE review #2011-3627
Zariviz	cefotaxime	Orthographic	International Brand Name for Cefotaxime
Zarontin	Ethosuximide	Orthographic	The name pair have sufficient orthographic differences and differences in product characteristics as stated in OSE review #2011-3627
Zinacef	Cefuroxime sodium	Orthographic	The name pair have sufficient orthographic differences.
Zoladex	Goserelin acetate	Phonetic	The name pair have sufficient phonetic differences and differences in product characteristics as stated in OSE review #2011-3627
Zorbtive	somatropin	Orthographic	The name pair have sufficient orthographic differences.

Proprietary Name	Active Ingredient	Similarity to Zorvolex	Failure preventions
(b) (4)	calipotriene	Orthographic	The product is approved with the name Sorilux (December 2010). (b) (4)
Zonatuss	Benzonatate	Orthographic	The name pair have sufficient orthographic differences and differences in product characteristics as stated in OSE review #2011-3627
Zortress	everolimus	Orthographic	The name pair have sufficient orthographic differences and differences in product characteristics as stated in OSE review #2011-3627
Zostavax	Zoster Vaccine	Phonetic	The name pair have sufficient phonetic differences and differences in product characteristics as stated in OSE review #2011-3627

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 and Dosage form: Zorvolex (Diclofenac) capsules **Strength:** 18 mg and 35 mg **Usual dose:** 18 mg three times daily; or 35 mg three times daily. (54 mg to 105 mg/day) **Package size:** Bottles of 30 capsules, Bottles of 90 capsules, Blisters of 3 capsules **Route of Administration**: oral	Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion Causes (could be multiple)	Prevention of Failure Mode In the conditions outlined below, the following combination of factors are expected to minimize the risk of confusion between these two names
Concerta (methylphenidate) **Strength:** 18 mg, 27 mg, 36 mg, and 54 mg **Dosage form:** tablets **Dose:** 18 mg, 36 mg, 54 mg, or 72 mg once daily **Route of Administration:** oral	Orthographic similarity: Both names begin with letters that may be similarly scripted (Z vs. C). The letter string 'orvo' in Zorvolex infix appears orthographically similar to the letter string 'once' in Concerta infix when scripted. Product characteristic similarities: **Dose:** Zorvolex 18 mg and 54 mg vs. Concerta 18 mg and 54 mg **Strength:** Zorvolex 18 mg and 35 mg vs. Concerta 18 mg and 36 mg **Route of Administration:** oral	Orthographic differences: The letter string "lex" in Zorvolex suffix is not orthographically similar to the letter string "rta" in Concerta suffix Product characteristic differences: **Frequency:** Zorvolex three times daily vs. Concerta once daily

Proposed name and Dosage form: Zorvolex (Diclofenac) capsules **Strength:** 18 mg and 35 mg **Usual dose:** 18 mg three times daily; or 35 mg three times daily. (54 mg to 105 mg/day) **Package size:** Bottles of 30 capsules, Bottles of 90 capsules, Blisters of 3 capsules **Route of Administration**: oral	Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion Causes (could be multiple)	Prevention of Failure Mode In the conditions outlined below, the following combination of factors are expected to minimize the risk of confusion between these two names
Coricidin (chlorpheniramine/acetaminophen) **Strength:** 2 mg/30 mg/325 mg **Dosage form:** tablet **Dose:** Adults and ages 12 yrs+: 2 tablets every 4 to 6 hours, not more than 12 tablets in 24 hours; Ages 6yrs to 12 yrs: 1 tablet every 4 to 6 hours, not more than 5 tablets in 24 hours **Route of Administration:** oral	Orthographic similarity: Both names begin with letters that may be similarly scripted (Z vs. C). The letter string 'orv' in Zorvolex infix appears orthographically similar to the letter string 'ori' in Coricidin infix when scripted. The letter string 'lex' in Zorvolex suffix appears orthographically similar to the letter string 'din' in Coricidin suffix when scripted. Product characteristic similarities: **Route of Administration:** oral	Orthographic differences: The letter string 'ci' in Coricidin infix when scripted appears orthographically elongated compared to the letter 'o' in Zorvolex infix Product characteristic differences: **Strength:** Zorvolex has two strengths (18 mg and 35 mg) which must be written on the prescription vs. Coricidin has a single strength which may be omitted from the prescription **Frequency:** Zorvolex three times daily vs. Coricidin every 4 to 6 hours

Proposed name and Dosage form: Zorvolex (Diclofenac) capsules **Strength:** 18 mg and 35 mg **Usual dose:** 18 mg three times daily; or 35 mg three times daily. (54 mg to 105 mg/day) **Package size:** Bottles of 30 capsules, Bottles of 90 capsules, Blisters of 3 capsules **Route of Administration**: oral	Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion Causes (could be multiple)	Prevention of Failure Mode In the conditions outlined below, the following combination of factors are expected to minimize the risk of confusion between these two names
Corvita (multivitamin and multimineral with iron) **Strength:** multi-strength **Dosage form:** tablet **Dose:** one tablet once daily **Route of Administration:** oral	<u>Orthographic similarity:</u> Both names begin with letters that may be similarly scripted (Z vs. C). The letter string 'orv' in Zorvolex is similar to the letter string 'orv' in Corvita. The letter string 'ol' in Zorvolex appears orthographically similar to the letter string 'it' in Corvita when scripted. <u>Product characteristic similarities:</u> **Route of Administration:** oral	<u>Orthographic differences:</u> The ending letter string "ex" in Zorvolex appears orthographically elongated compared to the last letter "a" in Corvita. <u>Product characteristic differences:</u> **Strength:** Zorvolex has two strengths (18 mg and 35 mg) which must be written on the prescription vs. Corvita has a single strength which may be omitted from the prescription **Frequency:** Zorvolex three times daily vs. Corvita once daily

Proposed name and Dosage form: Zorvolex (Diclofenac) capsules **Strength:** 18 mg and 35 mg **Usual dose:** 18 mg three times daily; or 35 mg three times daily. (54 mg to 105 mg/day) **Package size:** Bottles of 30 capsules, Bottles of 90 capsules, Blisters of 3 capsules **Route of Administration**: oral	Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion Causes (could be multiple)	Prevention of Failure Mode In the conditions outlined below, the following combination of factors are expected to minimize the risk of confusion between these two names
Corvite (multivitamin and multimineral with iron) **Strength:** multi-strength **Dosage form:** tablet **Dose:** one tablet once daily **Route of Administration:** oral	<u>Orthographic similarity:</u> Both names begin with letters that may be similarly scripted (Z vs. C). The letter string 'orv' in Zorvolex is similar to the letter string 'orv' in Corvite. <u>Product characteristic similarities:</u> **Route of Administration:** oral	<u>Orthographic differences:</u> The ending letter string "ex" in Zorvolex appears orthographically elongated compared to the last letter "e" in Corvite. <u>Product characteristic differences:</u> **Strength:** Zorvolex has two strengths (18 mg and 35 mg) which must be written on the prescription vs. Corvite has a single strength which may be omitted from the prescription **Frequency:** Zorvolex three times daily vs. Corvite once daily

Proposed name and Dosage form: Zorvolex (Diclofenac) capsules **Strength:** 18 mg and 35 mg **Usual dose:** 18 mg three times daily; or 35 mg three times daily. (54 mg to 105 mg/day) **Package size:** Bottles of 30 capsules, Bottles of 90 capsules, Blisters of 3 capsules **Route of Administration**: oral	Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion Causes (could be multiple)	Prevention of Failure Mode In the conditions outlined below, the following combination of factors are expected to minimize the risk of confusion between these two names
Dovonex (calcipotriene) **Strength:** 0.005% **Dosage form:** cream, ointment, scalp solution **Package size:** Cream: 60 gram tube, 120 gram tube, Ointment: 60 gram tube, 120 gram tube, Scalp solution: 60 mL bottle **Dose:** Cream: Apply a thin film to the affected area twice daily for up to 8 weeks Ointment: Apply a thin film to the affected area once or twice daily for up to 8 weeks Scalp Solution: Comb hair to remove scaly debris, and after suitably parting apply scalp solution twice daily **Route of Administration:** topical	Orthographic similarity: The suffix of both names contains the letter string "ex".	Orthographic differences: The letter beginning "Z" in Zorvolex is not orthographically similar to the letter "D" in Dovonex. The letter string 'orvo' in Zorvolex infix appears orthographically elongated compared to the letter string 'ovo' in Dovonex infix when scripted. The letter "l" in the suffix of Zorvolex is not orthographically similar to the letter "n" in the suffix of Dovonex Product characteristic differences: **Strength:** Zorvolex has two strengths (18 mg and 35 mg) which must be written on the prescription vs. Dovonex has a single percentage strength which may be omitted from the prescription **Frequency:** Zorvolex three times daily vs. Dovonex two times daily

Proposed name and Dosage form: Zorvolex (Diclofenac) capsules **Strength:** 18 mg and 35 mg **Usual dose:** 18 mg three times daily; or 35 mg three times daily. (54 mg to 105 mg/day) **Package size:** Bottles of 30 capsules, Bottles of 90 capsules, Blisters of 3 capsules **Route of Administration**: oral	Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion Causes (could be multiple)	Prevention of Failure Mode In the conditions outlined below, the following combination of factors are expected to minimize the risk of confusion between these two names
Fosamax (alendronate) **Strength:** 10 mg, 40 mg, 5 mg, 35 mg, 70 mg **Dosage form:** tablet and oral solution **Dose:** 5 mg once daily, 10 mg once daily, 70 mg once weekly, 35 mg once weekly, 40 mg once daily **Route of Administration:** oral	<u>Orthographic similarity:</u> Both names begin with letters that may be similarly scripted (Z vs. F) and the letter string 'Zorv' in Zorvolex prefix is similar to the letter string 'Fosa' in Fosamax prefix. The suffix of both names contains letter strings that may appear similar when scripted, "ex" in Zorvolex vs. "ax" in Fosamax. <u>Product characteristic similarities:</u> **Dose:** Zorvolex 35 mg vs. Fosamax 35 mg **Strength:** Zorvolex 35 mg vs. Fosamax 35 mg **Route of Administration:** oral	<u>Orthographic differences:</u> The letter string "ol" in Zorvolex is not orthographically similar to the letter "m" in Fosamax <u>Product characteristic differences:</u> **Frequency:** Zorvolex three times daily vs. Fosamax once daily or once weekly with days supply or quantity on the prescription

Proposed name and Dosage form: Zorvolex (Diclofenac) capsules **Strength:** 18 mg and 35 mg **Usual dose:** 18 mg three times daily; or 35 mg three times daily. (54 mg to 105 mg/day) **Package size:** Bottles of 30 capsules, Bottles of 90 capsules, Blisters of 3 capsules **Route of Administration**: oral	Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion Causes (could be multiple)	Prevention of Failure Mode In the conditions outlined below, the following combination of factors are expected to minimize the risk of confusion between these two names
Norel EX (guaifenesin/phenylephrine) **Strength:** 800 mg/40 mg **Dosage form:** tablet **Dose:** 1 tablet every 12 hours, not to exceed 2 tablets in 24 hours **Route of Administration:** oral	<u>Orthographic similarity:</u> Both names begin with letters that may be similarly scripted (Z vs. N). If Norel Ex were to be scripted to appear as a single word, then the suffix of both names contains the letter string "lex".	<u>Orthographic differences:</u> The letter string 'orvo' in Zorvolex appears orthographically elongated compared to the letter string 'ore' in Norel Ex when scripted. <u>Product characteristic differences:</u> **Strength:** Zorvolex has two strengths (18 mg and 35 mg) which must be written on the prescription vs. Norel Ex has a single strength which may be omitted from the prescription **Frequency:** Zorvolex three times daily vs. Norel Ex every 12 hours

Proposed name and Dosage form: Zorvolex (Diclofenac) capsules **Strength:** 18 mg and 35 mg **Usual dose:** 18 mg three times daily; or 35 mg three times daily. (54 mg to 105 mg/day) **Package size:** Bottles of 30 capsules, Bottles of 90 capsules, Blisters of 3 capsules **Route of Administration**: oral	Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion Causes (could be multiple)	Prevention of Failure Mode In the conditions outlined below, the following combination of factors are expected to minimize the risk of confusion between these two names
Sorilux (Calcipotriene) **Strength:** 0.005% **Dosage form:** Foam **Package size:** 60 gram and 120 gram can **Usual Dose:** Apply a thin layer to the affected areas twice daily **Route of Administration:** topical	<u>Orthographic similarity:</u> Both names begin with letters that may be similarly scripted (Z vs. S). The letter string 'lex' in Zorvolex suffix appears orthographically similar to the letter string 'lex' in Sorilux suffix when scripted.	<u>Orthographic differences:</u> The letter string 'orvo' in Zorvolex appears orthographically elongated compared to the letter string 'oro' in Sorilux when scripted. <u>Product characteristic differences:</u> **Strength:** Zorvolex has two strengths (18 mg and 35 mg) which must be written on the prescription vs. Sorilux has a single percentage strength which may be omitted from the prescription **Frequency:** Zorvolex three times daily vs. Sorilux two times daily

Proposed name and Dosage form: Zorvolex (Diclofenac) capsules **Strength:** 18 mg and 35 mg **Usual dose:** 18 mg three times daily; or 35 mg three times daily. (54 mg to 105 mg/day) **Package size:** Bottles of 30 capsules, Bottles of 90 capsules, Blisters of 3 capsules **Route of Administration**: oral	Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion Causes (could be multiple)	Prevention of Failure Mode In the conditions outlined below, the following combination of factors are expected to minimize the risk of confusion between these two names
Zamdray (lumiracoxib) **Strength:** 100 mg **Dosage form:** tablet **Dose:** one tablet once daily **Route of Administration:** oral	<u>Orthographic similarity:</u> Both names begin with the letter "Z". The letter string 'orv' in Zorvolex may appear orthographically similar to the letter string 'am' in Zamdray when scripted. The letter string 'ol' in Zorvolex appears orthographically similar to the letter "d" in Zamdray when scripted.	<u>Orthographic differences:</u> The letter string 'ex' in Zorvolex is not orthographically similar to the letter string "ray" in Zamdray when scripted. <u>Product characteristic differences:</u> **Strength:** Zorvolex has two strengths (18 mg and 35 mg) which must be written on the prescription vs. Zamdray has a single strength which may be omitted from the prescription **Frequency:** Zorvolex three times daily vs. Zamdray once daily

Proposed name and Dosage form: Zorvolex (Diclofenac) capsules **Strength:** 18 mg and 35 mg **Usual dose:** 18 mg three times daily; or 35 mg three times daily. (54 mg to 105 mg/day) **Package size:** Bottles of 30 capsules, Bottles of 90 capsules, Blisters of 3 capsules **Route of Administration**: oral	Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion Causes (could be multiple)	Prevention of Failure Mode In the conditions outlined below, the following combination of factors are expected to minimize the risk of confusion between these two names
Zenatane (isotretinoin) **Strength:** 10 mg, 20 mg, 40 mg **Dosage form:** capsule **Dose:** 0.5 mg/kg to 1 mg/kg/day or 10 mg-100 mg given in 2 divided doses Max dose 2 mg/kg/day. **Route of Administration:** oral	<u>Orthographic similarity:</u> Both names begin with the letter "Z" and the letter string 'Zor' in Zorvolex may appear orthographically similar to the letter string 'Zen' in Zenatane when scripted. The letter string 'ol' in Zorvolex may appear orthographically similar to the letter "at" in Zenatane when scripted.	<u>Orthographic differences:</u> The letter string 'ex' in Zorvolex is not orthographically similar to the letter string "ana" in Zenatane when scripted. <u>Product characteristic differences:</u> **Strength:** Zorvolex has two strengths (18 mg and 35 mg) which must be written on the prescription vs. Zenatane has three strengths which must be written on the but there are no overlapping strengths **Frequency:** Zorvolex three times daily vs. Zenatane in two divided dose

Proposed name and Dosage form: Zorvolex (Diclofenac) capsules **Strength:** 18 mg and 35 mg **Usual dose:** 18 mg three times daily; or 35 mg three times daily. (54 mg to 105 mg/day) **Package size:** Bottles of 30 capsules, Bottles of 90 capsules, Blisters of 3 capsules **Route of Administration**: oral	Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion Causes (could be multiple)	Prevention of Failure Mode In the conditions outlined below, the following combination of factors are expected to minimize the risk of confusion between these two names
Zervalx (levomefolate) **Strength:** 1 mg **Dosage form:** tablet **Dose:** 7.5 mg to 15 mg once daily; 25 mg once daily (off label use) **Route of Administration:** oral	<u>Orthographic similarity:</u> Both names begin with the letter "Z". The letter string 'orvo' in Zorvolex appears orthographically similar to the letter string 'erva' in Zervalx when scripted. <u>Phonetic similarities:</u> Both names begin with phonetically similar prefixes "Zorv" vs. "Zerv"	<u>Orthographic differences:</u> The letter string 'lex' in Zorvolex appears orthographically elongated compared to the letter string "lx" in Zervalx when scripted. <u>Phonetic differences:</u> The infix letter "o" in Zorvolex may be pronounced as a long "o" using the standard American English pronunciation affording the name three syllables (Zorv-, -Oh-, -lex) vs. two syllables in Zervalx (Zerv-alks) <u>Product characteristic differences:</u> **Strength:** Zorvolex has two strengths (18 mg and 35 mg) which must be written on the prescription vs. Zervalx has a single strength which may be omitted from the prescription **Frequency:** Zorvolex three times daily vs. Zervalx once daily

Proposed name and Dosage form: Zorvolex (Diclofenac) capsules **Strength:** 18 mg and 35 mg **Usual dose:** 18 mg three times daily; or 35 mg three times daily. (54 mg to 105 mg/day) **Package size:** Bottles of 30 capsules, Bottles of 90 capsules, Blisters of 3 capsules **Route of Administration**: oral	Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion Causes (could be multiple)	Prevention of Failure Mode In the conditions outlined below, the following combination of factors are expected to minimize the risk of confusion between these two names
Zicadia (azimilide) **Strength:** 75 mg **Dosage form:** tablet **Dose:** one tablet once daily **Route of Administration:** oral	<u>Orthographic similarity:</u> Both names begin with the letter "Z". The letter string 'ol' in Zorvolex appears orthographically similar to the letter "d" in Zicadia when scripted. The suffix letter string "ex" in Zorvolex may appear orthographically similar to the suffix letter string "ia" in Zicadia when scripted.	<u>Orthographic differences:</u> The letter string 'orv' in Zorvolex infix is not orthographically similar to the letter string 'ica' in Zicadia infix when scripted. <u>Product characteristic differences:</u> **Strength:** Zorvolex has two strengths (18 mg and 35 mg) which must be written on the prescription vs. Zicadia has a single strength which may be omitted from the prescription **Frequency:** Zorvolex three times daily vs. Zicadia once daily

Proposed name and Dosage form: Zorvolex (Diclofenac) capsules **Strength:** 18 mg and 35 mg **Usual dose:** 18 mg three times daily; or 35 mg three times daily. (54 mg to 105 mg/day) **Package size:** Bottles of 30 capsules, Bottles of 90 capsules, Blisters of 3 capsules **Route of Administration**: oral	Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion Causes (could be multiple)	Prevention of Failure Mode In the conditions outlined below, the following combination of factors are expected to minimize the risk of confusion between these two names
Zometa (zolendronic acid) **Strength:** 4 mg **Dosage form:** powder for injection solution for injection **Dose:** 4 mg intravenously over a minimum of 15 minutes every 3 to 4 weeks **Route of Administration:** intravenous	Orthographic similarity: Both names begin with the letter "Z". The letter string 'orvo' in Zorvolex appears orthographically similar to the letter string 'ome' in Zometa when scripted.	Orthographic differences: The letter string 'lex' in Zorvolex suffix appears orthographically elongated compared to the letter string "ta" in Zometa suffix when scripted. Product characteristic differences: **Strength:** Zorvolex has two strengths (18 mg and 35 mg) which must be written on the prescription vs. Zometa has a single strength which may be omitted from the prescription **Frequency:** Zorvolex three times daily vs. Zometa once every 3 to 4 weeks

Proposed name and Dosage form: Zorvolex (Diclofenac) capsules **Strength:** 18 mg and 35 mg **Usual dose:** 18 mg three times daily; or 35 mg three times daily. (54 mg to 105 mg/day) **Package size:** Bottles of 30 capsules, Bottles of 90 capsules, Blisters of 3 capsules **Route of Administration**: oral	Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion Causes (could be multiple)	Prevention of Failure Mode In the conditions outlined below, the following combination of factors are expected to minimize the risk of confusion between these two names
Zonalon (Doxepin) **Strength:** 5% **Dosage form:** Cream **Package size:** 30 gram tube and 45 gram tube **Usual Dose:** Apply a thin film to affected area 4 times/day **Route of Administration:** Topical	<u>Orthographic similarity:</u> Both names begin with the letter "Z". The letter string 'lex' in Zorvolex suffix appears orthographically similar to the letter string 'lon' in Zonalon suffix when scripted.	<u>Orthographic differences:</u> The letter string 'orvo' in Zorvolex appears orthographically elongated compared to the letter string "ona" in Zonalon when scripted. <u>Product characteristic differences:</u> **Strength:** Zorvolex has two strengths (18 mg and 35 mg) which must be written on the prescription vs. Zonalon has a single percentage strength which may be omitted from the prescription **Frequency:** Zorvolex three times daily vs. Zonalon four times daily

Proposed name and Dosage form: Zorvolex (Diclofenac) capsules **Strength:** 18 mg and 35 mg **Usual dose:** 18 mg three times daily; or 35 mg three times daily. (54 mg to 105 mg/day) **Package size:** Bottles of 30 capsules, Bottles of 90 capsules, Blisters of 3 capsules **Route of Administration**: oral	Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion Causes (could be multiple)	Prevention of Failure Mode In the conditions outlined below, the following combination of factors are expected to minimize the risk of confusion between these two names
Zovirax (acyclovir) **Strength and Dosage form:** 200 mg capsule, 200 mg/5 mL oral suspension, 400 mg and 800 mg tablet, 1000 mg and 500 mg powder for solution for injection, 50 mg/ mL solution for injection, 5% topical cream (5 gram tube) and topical ointment (30 gram tube) **Dose and Route of Administration:** **oral:** 800 mg four times daily, 800 mg every 4 hours, 800 mg two times daily, 800 mg once daily, 600 mg once daily, 200 mg every 4 hours or five times daily, 400 mg two times daily, 400 mg **three times daily**, 200 mg **three times daily,** 200 mg five times daily, Pediatric 20 mg/kg per dose four times daily (for 29 kg child: 580 mg four times daily); **topical:** cream: apply 5 times per day for 4 days ointment apply to affected area every 3 hours 6 times per day for 7 days **intravenous:** 5 mg/kg every 8 hours (70 kg adult: 350 mg every 8 hours; 29 kg child: 145 mg every 8 hours), 10 mg/kg every 8 hours (70 kg adult: 700 mg every 8 hours; 29 kg child: 290 mg every 8 hours) or 20 mg/kg every 8 hours (29 kg child: 580 mg every 8 hours)	Orthographic similarity: Both names begin with the letter "Z" and the letter string 'Zorv' in Zorvolex may appear orthographically similar to the letter string 'Zov' in Zovirax when scripted. The suffix of both names contains the letter strings that may appear similar when scripted "ex" in Zorvolex vs. "ax" in Zovirax. Phonetic similarities: Both names begin with phonetically similar prefixes "Zorv" vs. "Zov" and similar suffixes "ex" vs. "ax". Both names contain three syllables.	Orthographic differences: The letter string 'ol' in Zorvolex infix is not orthographically similar to the letter string "ir" in Zovirax infix when scripted. Phonetic differences: The infix letter "o" in Zorvolex may be pronounced as a long "o" using the standard American English pronunciation (Zorv-, -Oh-, -lex) vs. the infix letter "i" in Zovirax which has the consonant letter *r* following and pronounced similar to the "ir" in the words *stir* and *girl*) Product characteristic differences: **Strength:** Zorvolex has two strengths (18 mg and 35 mg) vs. Zovirax 200 mg, 200 mg/5 mL, 400 mg, 800, 1000 mg, 500 mg, 50 mg/ mL, 5% **Frequency:** Zorvolex three times daily vs. Zovirax every 8 hours, four times daily, five times daily, two times daily, once daily

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This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

BRENDA V BORDERS-HEMPHILL
04/26/2013

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