CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

0201280Orig1s000

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:	January 30, 2012
Reviewer:	Yelena Maslov, Pharm.D., Safety Evaluator Division of Medication Error Prevention and Analysis
Team Leader	Irene Chan, Pharm.D., BCPS, Team Leader Division of Medication Error Prevention and Analysis
Division Director	Carol Holquist, R.Ph., Director Division of Medication Error Prevention and Analysis
Drug Name and Strength:	Korlym (Mifepristone) Tablets, 300 mg
Application Type/Number:	NDA 202107
Applicant/sponsor:	Corcept Therapeutics, Inc.
OSE RCM #:	2011-4120

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CONTENTS

1 INTRODUCTION

This re-assessment of the proposed proprietary name, Korlym, 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, Korlym, acceptable in OSE Review RCM #2011-2647 dated October 20, 2011.

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 RCM #2011-2647. Since none of the proposed product characteristics were altered we did not re-evaluate previous names of concern. The searches of the databases yielded one new name (b) (4) thought to look or sound similar to Korlym and represent a potential source of drug name confusion. Failure mode and effects analysis was applied to determine if the proposed proprietary name could potentially be confused with (b) (4) and lead to medication errors. This analysis determined that the name similarity between Korlym and the identified name was unlikely to result in medication error for the reasons presented in Appendix A.

Additionally, DMEPA searched the USAN stem list to determine if the name contains any USAN stems as of the last USAN updates. The Safety Evaluator did not identify any United States Adopted Names (USAN) stems in the proposed proprietary name, as of January 4, 2012. The Office of Prescription Drug Promotion (OPDP) re-reviewed the proposed name on December 1, 2011 and had no concerns regarding the proposed name from a promotional perspective.

3 CONCLUSIONS

The re-evaluation of the proposed proprietary name, Korlym, did not identify any vulnerabilities that would result in medication errors with the additional name noted in this review. Thus, DMEPA has no objection to the proprietary name, Korlym, 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 Metabolism and Endocrinology Products (DMEP) 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 Ermias Zerislassie, OSE project manager, at 301-796-0097.

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4 REFERENCES

1. ***Maslov, Yelena. Proprietary Name Review for Korlym, OSE Review #2011-2647***

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.

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

Proprietary Name	Active Ingredient	Similarity to Korlym	Failure Preventions
	(b) (4)	Looks alike	The product was approved on June 10, 2011 under the proprietary name, Potiga. Additionally, the established name was also changed to Ezogabine.

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/s/

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01/30/2012

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02/02/2012

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:	October 19, 2011
Reviewer:	Yelena Maslov, Pharm.D., Safety Evaluator Division of Medication Error Prevention and Analysis
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Division Director	Carol Holquist, R.Ph., Director Division of Medication Error Prevention and Analysis
Drug Name and Strength:	Korlym (Mifepristone) Tablets, 300 mg
Application Type/Number:	NDA 202107
Applicant/sponsor:	Corcept Therapeutics, Inc.
OSE RCM #:	2011-2647

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CONTENTS

1 INTRODUCTION

This review evaluates the proposed proprietary name, Korlym, 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. The proposed product characteristics are provided in Section 1.2.

1.1 REGULATORY HISTORY

This review responds to a request from Corcept Therapeutcis, dated July 28, 2011, for an assessment of the proposed proprietary name, Korlym, regarding potential name confusion with other proprietary or established drug names in the usual practice setting. The name, Korlym, is the third proposed proprietary name for Mifepristone Tablets, 300 mg. The first proposed proprietary name, Corlux, was found unacceptable by DMEPA in OSE Review #2010-1719, dated December 28, 2010, while the product was in IND stage of development (IND 076480). The name was found unacceptable due to vulnerability to name confusion with Cortef and Avelox, based on orthographic similarities and shared product characteristics. The second name, (b) (4), was found unacceptable by DMEPA in OSE Review #2011-1353, dated July 14, 2011. (b) (4) [redacted].

1.2 PRODUCT INFORMATION

Korlym (Mifepristone) Tablets is a cortisol receptor blocking agent indicated to treat the clinical and metabolic effects of hypercortisolism in patients with endogenous Cushing's syndrome. The recommended dose of Korlym is 300 mg to 1200 mg (1-4 tablets) administered orally once daily. It will be available in a single strength of 300 mg packaged in bottles of 28 and 280 counts. (b) (4) [redacted].

2 RESULTS

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

2.1 PROMOTIONAL ASSESSMENT

DDMAC determined the proposed name is acceptable from a promotional perspective. DMEPA and the Division of Metabolism and Endocrinology Products (DMEP) concurred with the findings of DDMAC's promotional assessment of the proposed name.

2.2 SAFETY ASSESSMENT

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

2.2.1 United States Adopted Names (USAN) SEARCH

The United States Adopted Name (USAN) stem search conducted on August 16, 2011, identified that a USAN stem is not present in the proposed proprietary name.

2.2.2 Components of the Proposed Proprietary Name

The proposed name is a single word that does not contain any components (i.e., modifier, dosage form, frequency, indications, etc.) that can contribute to medication error.

2.2.3 FDA Name Simulation Studies

Forty practitioners participated in DMEPA's prescription studies. Twenty-three practitioners interpreted the proposed name, 'Korlym' correctly with correct interpretations occurring with inpatient (n=10) and outpatient (n=13) prescription studies. The remaining seventeen practitioners misinterpreted the name. The most common misinterpretation occurred with the 14 voice study participants misinterpreting the letter 'K' as the letter 'C'. See Appendix C for the complete listings of interpretations from the verbal and written prescription studies.

2.2.4 Comments from Other Review Disciplines

In response to the OSE email, dated August 11, 2011, DMEP did not forward any comments or concerns relating to the proposed name at the initial phase of the name review.

2.2.5 Failure Mode and Effects Analysis of Similar Names

Table 1 (page 5) lists the names with orthographic, phonetic, or spelling similarity to the proposed proprietary name, Korlym. These names were identified by the primary reviewer and the Expert Panel Discussion (EPD), and other disciplines. Table 1 (next page) also included the names identified by external name study conducted by the Drug Safety Institute, Inc. (DSI) that were not previously identified by DMEPA and require further evaluation.

Table 1: Collective List of Potentially Similar Names (DMEPA, EPD, other disciplines, and DSI)

Look Similar		Sound Similar		Look and Sound Similar	
Name	***Source***	***Name***	***Source***	***Name***	***Source***
Kelnor	EPD	Cordran	EPD	Corlopam	DSI
Kalanji	EPD	Corlex	EPD	Cromolyn	DSI and EPD
Cortan	EPD	Corsym	EPD	Delsym	DSI
Kariva	EPD			K-Dur	DSI
Ku-zyme	EPD			Keralyt	DSI and EPD
Korlyum	EPD			Kerlix	DSI
Cortrosyn	EPD			Kerlon	DSI and EPD
Kenalog	EPD			Konsyl	DSI and EPD
Kinevac	EPD			Orlaam	DSI
(b) (4)	EPD			Crolom	EPD
Corlux***	EPD			Cotrim	EPD
Colcrys	EPD				
Kantrex	Primary Reviewer				
Kinlytic	Primary Reviewer				
Nardil	Primary Reviewer				
Rondec	Primary Reviewer				
(b) (4)					

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

DMEPA communicated these findings to the Division of Metabolism and Endocrinology Products (DMEP) via e-mail on September 2, 2011. At that time we also requested additional information or concerns that could inform our review. Per e-mail correspondence from the Division of Metabolism and Endocrinology Products (DMEP) on September 14, 2011, stated they have no additional concerns with the proposed proprietary name, Korlym.

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3 CONCLUSIONS

DMEPA concludes the proposed proprietary name, Korlym, is acceptable from both a promotional and safety perspective. The Applicant will be notified of this finding via letter.

3.1 COMMENTS TO THE APPLICANT

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

The proposed proprietary name, Korlym, must be re-reviewed 90 days prior to approval of the NDA. If we find the name unacceptable following the re-review, we will notify you.

If any of the proposed product characteristics as stated in your submission, dated July 28, 2011, are altered prior to approval of marketing application, DMEPA rescinds this finding and the name must be resubmitted for review. The conclusions upon re-review are subject to change.

4 REFERENCES

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

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

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

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

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

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

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. ***Electronic online version of the FDA Orange Book (http://www.fda.gov/cder/ob/default.htm)***

   The FDA Orange Book provides a compilation of approved drug products with therapeutic equivalence evaluations.

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

   USPTO provides information regarding patent and trademarks.

9. ***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.

10. ***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.

11. ***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.

12. ***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.

13. ***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.

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

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

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

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

16. ***Medical Abbreviations Book***

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

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 DDMAC. DDMAC 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. DDMAC 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 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.

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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.

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

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

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*
	Similar spelling	Identical prefix Identical infix Identical suffix	• Names may appear similar in print or electronic media and lead to drug name

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

Look-alike		Length of the name Overlapping product characteristics	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 (DDMAC). 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 DDMAC'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 characteristics listed in Appendix B1 of this review. The Safety Evaluator then analyzes the proposed proprietary name in the context of the usual practice setting and works to identify potential failure modes and the effects associated with the failure modes.

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

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

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

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. DDMAC finds the proposed proprietary name misleading from a promotional perspective, and the Review Division concurs with DDMAC'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, Korlym	Scripted May Appear as	Spoken May Be Interpreted as
Capital 'K'	'R', 'X', 'N', 'V', 'U'	'C', 'Q'
Lower case 'k'	'r', 'x', 'n'	'c', 'q'
lower case 'o'	a, c u, or v	any vowel
lower case 'r'	n, s, t, or v	'w'
lower case 'l'	'b', 't', 'e', 'i'	'n'
lower case 'y'	'p', 'g', 'v'	'e', 'i', 'u'
lower case 'm'	'n', 'w', 'vi, 'eu', 'ni', 'rn'	'n'

Appendix C: Prescription Simulation Samples and Results

Figure 1. Korlym Study (Conducted on 08/12/2011)

Handwritten Requisition Medication Order	Verbal Prescription
Medication Order: Korlym 2 tablets po qd	Korlym #30 1 po qd
Outpatient Prescription: Korlym #3 1 tab po qd	

FDA Prescription Simulation Responses.

Inpatient Medication Order	Outpatient Prescription	Voice Prescription
Korlym	Korlym	Coralin
Korlym	Korlym	Cordone
Korlym	Korlym	Corlan
Korlym	Korlym	Corlan
Korlym	Korlym	Corlin
Korlym	Korlym	Corlin
Korlym	Korlym	Corlin
Korlyn	Korlym	Corlin
Korlyn	Korlym	Corlin
Korlynn	Korlym	Corlin
Korlym	Korlym	Corline
Korlym	Korlym	Corlun
Korlym	Korlym	Corlyn
		Corlyn

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

Name of the Product	Similarity to Korlym	Failure preventions
Kinevac (Sincaline)	Looks alike	Lacks sufficient orthographic similarity
K-Dur (Potassium Chloride)	Looks alike and sounds alike	Lacks sufficient orthographic or phonetic similarity
Corlex	Sounds alike	The name was identified in Facts and Comparisons database. However, no product characteristics are available from any of the databases in Reference Section 4.
Cortan	Looks alike	The name was identified in POCA database. However, no product characteristics are available from any of the databases in Reference Section 4.

Kalanji	Looks alike	A plant with terminal, grayish-blue flowers and is not a drug product. Dosing guidelines for the plant are not established.
Cotrim (Sulfamethoxazole and Trimethoprim)	Looks alike and sounds alike	International name for Sulfamethoxazole and Trimethoprim
Corsym (Chlorpheniramine Polistirex and Phenylpropanolamine Polistirex)	Sounds alike	The products is discontinued without a generic equivalent
Orlaam (Levomethadyl)	Looks alike and sounds alike	The product is discontinued without a generic equivalent
Kolyum (Potassium Chloride) Powder for Solution, 29mEq/5 mL	Looks alike	The product is discontinued without a generic equivalent
Ku-zume (Amylase, lipase, protease)	Looks alike	The product is discontinued without a generic equivalent
[redacted]		(b) (4)
Corlux*** (Mifepristone)	Looks alike	Previously proposed name for Mifepristone (NDA 202107). The name was found unacceptable by DMEPA is OSE Review #2010-1719, dated December 28, 2010
[redacted]		(b) (4)

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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: **Korlym** **(Mifepristone) Tablets**	**Strength:** **300 mg**	**Usual dose:** **Take 300 mg to 1200 mg orally once daily (1 tablet to 4 tablets orally once daily)**
Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion	**Causes (could be multiple)**	**Prevention of Failure Mode**
Kelnor 1/35 (Ethynodiol Diacetate and Ethinyl Estradiol) Tablets, 1 mg/0.035 mg Usual Dose Take 1 tablet orally once daily	Orthographic Both names start with the letter 'K' and share the letter 'l' in similar positions. Dosage Form Both products are tablets Strength Both products are single strength; thus, the strength may be omitted. Route of Administration Oral Usual Dosage 1 tablet Frequency of Administration Once daily	Orthographic The name Korlym contains 2 upstrokes and 1 down stroke vs. the name Kelnor contains 2 upstrokes and no down strokes. Additionally, the letter string 'lym' in Korlym lacks orthographic similarity to the letter string 'nor' in Kelnor when scripted.

Kariva (Decogestrel and Ethinyl Estradiol) Tablets, 0.15 mg/0.01 mg Usual Dose Take 1 tablet orally once daily	Orthographic The letter string 'Kor' in Korlym may appear similar to the corresponding letter string 'Kar' in Kariva when scripted. Dosage Form Both products are tablets Strength Both products are single strength; thus, the strength may be omitted. Route of Administration Oral Usual Dosage 1 tablet Frequency of Administration Once daily	Orthographic The name Korlym contains 2 upstrokes and 1 down stroke vs. the name Kariva contains 1 upstroke and no down strokes. Additionally, The letter string 'lym' in Korlym lacks orthographic similarity to the letter string 'iva' when scripted.
Cortrosyn (Cosyntropin) Powder for Injection, 0.25 mg Usual Dose 0.25 mg intravenously over 6 hours. Children and Infants 0.015 mg/kg/dose	Orthographic Both names contain 2 upstrokes and 1 down stroke. Additionally, both names share the letter string 'or' in similar positions and the letter 'l' in Korlym may appear similar to the corresponding letter 't' in Cortrosyn when scripted. Strength Both products are single strength; thus, the strength may be omitted.	Orthographic The name Cortrosyn is longer than then name Korlym (9 letters vs. 6 letters). Additionally, the letter 'K' and the letter string 'ym' in Korlym lack orthographic similarity to the corresponding letter 'C' and the letter string 'rosyn' in Cortrosyn. Frequency of Administration Once daily vs. once

Kenalog (Triamconolone Acetonide) Cream: 0.1% and 0.5% Lotion: 0.1% Ointment: 0.1% <u>Usual Dose</u> Apply cream, lotion, or ointment two to four times daily Topical Spray: 0.147 mg/g <u>Usual Dose</u> Spray three to four times to affected area once daily Dental Paste: 0.1% <u>Usual Dose</u> Press a small dab (about ¼ inch) to the lesion until a thin film develops one daily at bedtime Kenalog-10 Suspension for Injection, 50 mg/5 mL (10 mg/mL) Kenalog-40 Suspension for Injection 200 mg/5 mL and 40 mg/mL <u>Usual Dose</u> 40 mg to 80 mg intramuscularly, repeat every 4 weeks as needed.	<u>Orthographic</u> Both names start with the letter 'K' and contains 2 upstrokes and 1 down stroke. Additionally, the letter string 'or' in Korlym may appear similar to the corresponding letter string 'en' in Kenalog when scripted. <u>Strength</u> Both products are single strength; thus, the strength may be omitted. (i.e., lotion, ointment, topical spray, dental paste) <u>Frequency of Administration</u> Once daily (for dental paste)	<u>Orthographic</u> Although both names have two upstrokes and one down stroke, the 2 upstroke and 1 down stroke are located in different positions of the names. Additionally, the letter string 'ym' in Korlym lacks orthographic similarity to the corresponding letter string 'og'. <u>Dosage Form</u> Tablet vs. cream, lotion, ointment, topical spray. Thus, although most products are available in single strength, the dosage form must be specified. <u>Route of Administration</u> Oral vs. topical

Kantrex* (Kanamycin Sulfate) Injection, 1g/3 mL *Although the proprietary name is discontinued, the generic products are available <u>Usual Dose</u> 10 mg/kg/day to 15 mg/kg/day intravenously or intramuscularly in two divided doses for 5 to 7 days per week. After 2 to 4 months reduce the frequency to two to three times a week.	<u>Orthographic</u> The letter string 'Korl' may appear similar to the corresponding letter string 'Kant' when scripted. <u>Strength</u> Both products are single strength; thus, the strength may be omitted. <u>Overlap in Usual Dose</u> Korlym can be dosed at 300 mg,600 mg, 900 mg, and 1200 mg and Kantrex can have an achievable dose of 300 mg, 600 mg, 900 mg, and 1200 mg	<u>Orthographic</u> The name Korlym contains 2 upstrokes and 1 down stroke vs. the name Katrex contains two upstrokes and no down strokes. Additionally, the letter string 'ym' in Korlym lacks orthographic similarity to the corresponding letter string 'ex' in Kantex. <u>Route of Administration</u> Oral vs. intravenous or intramuscular <u>Frequency of Administration</u> Once daily vs. twice daily
Kinlytic (Urokinase) Injection, 250,000 units <u>Usual Dose</u> 4400 units/kg intravenously over 10 minutes, followed by continuous intravenous infusion of 4400 units/kg/hour for 12 to 72 hours.	<u>Orthographic</u> The letter string 'Korly' may appear similar to the corresponding letter string 'Kinly'. <u>Strength</u> Both products are single strength; thus, the strength may be omitted. <u>Strength</u> Both products are single strength; thus, the strength may be omitted.	<u>Orthographic</u> The name Korlym contains 2 upstrokes and 1 down stroke vs. the name Kinlytic contains 3 upstrokes and 1 down stroke. Additionally, the letter 'm' in Korlym lacks orthographic similarity to the corresponding letter string 'tic' in Kinlytic. <u>Usual Dose</u> 300 mg to 1200 mg vs. 4400 units/kg <u>Frequency of Administration</u> Once daily vs. continuous infusion not to exceed 72 hours.

Nardil (Phenelzine Sulfate) Tablets, 15 mg Usual Dose 15 mg (1 tablet) orally once daily to every other day	Orthographic The letter string 'Korl' may appear similar to the letter string 'Nard' when scripted. Dosage Form Both products are tablets Strength Both products are single strength; thus, the strength may be omitted. Route of Administration Oral Usual Dosage 1 tablet Frequency of Administration Once daily	Orthographic The name Korlym contains 2 upstrokes and 1 down stroke vs. the name Nardil contains 3 upstrokes and no down strokes. Additionally, the letter string 'ym' in Korlym lacks orthographic similarity to the corresponding letter string 'il' in Nardil.
Rondec* (Chlorpheniramine Maleate and Phenylephrine HCl) Oral Solution (Drops), 1 mg/3.5 mg per mL, Usual Dose 1 mL to 2 mL every 4 to 6 hours. Rondec (Brompheniramine Maleate ad Pseudoephedrine HCl) Oral Syrup, 4 mg/45 mg per 5 mL Usual Dose 5 mL to 20 mg every 12 hours. *Although the proprietary name is discontinued, multiple generic products are available.	Orthographic The letter string 'Korl' may appear similar to the corresponding letter string 'Rond' when scripted. Strength Both products are single strength; thus, the strength may be omitted. Route of Administration Oral	Orthographic The name Korlym contains 2 upstrokes and 1 down stroke vs. the name Rondec contains 2 upstrokes and no down strokes. Additionally, the letter string 'ym' in Korlym lacks orthographic similarity to the corresponding letter string 'ec' in Rondec. Dosage Form Tablet vs. drops or syrup. Thus, either the strength of the products must be specified or the dosage form. Frequency of Administration Once daily vs. 4 to 6 hours or 12 hours

Corlopam (Fenoldopam Mesylate) Injection, 20 mg/2 mL and 10 mg/mL <u>Usual Dose</u> 0.1 mcg/kg/min intravenously and titrated upwards up to the maximum dose of 1.6 mcg/kg/min as a continuous infusion for up to 48 hours in adults and up to 4 hours in pediatric patients.	<u>Orthographic</u> Both names contain 2 upstrokes and 1 down stroke. Additionally, both names share the letter string 'orl'. <u>Phonetic</u> The letter strings 'Korly' and 'ym' is phonetically similar to the letter string 'Corlo' and 'am'. <u>Strength</u> Both products are single strength; thus, the strength may be omitted.	<u>Orthographic</u> The name Corlopam longer than the name Korlym (8 letters vs. 6 letters) and wider letters 'a' and 'm'. Additionally, the letter 'K' and the letter string 'ym' in Korlym lack orthographic similarity to the corresponding letter 'C' and the letter string 'opam' in Corlopam. <u>Phonetic</u> Korlym contains 2 syllables vs. Corlopam contains 3 syllables. Additionally, the name Corlopam contains the letter 'p' <u>Usual Dose</u> 300 mg to 1200 mg vs. 0.1 mcg/kg/min to 1.6 mcg/kg/min.
Cromolyn Inhalation Solution, 20 mg/2 mL <u>Usual Dose</u> Inhale 20 mg orally via nebulizer four times per day at regular intervals. Cromolyn Nasal Spray, 5.2 mg per actuation <u>Usual Dose</u> 1 spray in each nostril 3 to 4 times per day, may be increased to 6 times a day as needed Cromolyn Ophthalmic Solution, 4% <u>Usual Dose</u> 1 drop to 2 drops in each eye 4 to 6 times per day	<u>Orthographic</u> Both names contain 2 upstrokes and 1 down stroke. Additionally, the letter string 'lym' in Korlym appears similar to the corresponding letter string 'lyn' in Cromolyn. <u>Phonetic</u> The letter strings 'Kor' and 'lym' in Korlym are phonetically similar to the corresponding letter strings 'Cro' and 'lyn' in Cromolyn. <u>Strength</u> Both products are single strength; thus, the strength may be omitted.	<u>Orthographic</u> The name Cromolyn is longer than the name Korlym (8 letters vs. 6 letters). Additionally, the letter 'K' lacks orthographic similarity to the corresponding letter string 'C' when scripted. <u>Phonetic</u> Korlym contains 2 syllables vs. Cromoyn contains 3 syllables. Additionally, the name Cromolyn contains a letter string 'mo'. <u>Dosage Form</u> Tablets vs. inhalation solution, nasal spray, or ophthalmic solution. Thus, either the dose form, strength, or directions would appear on an order for Cromolyn. <u>Frequency of Administration</u> Once daily vs. 3 to 4 times a day or 4 to 6 times a day (ophthalmic solution)

Delsym (Dextromethorphan) Suspension, 30 mg <u>Usual Dose</u> Take 1 teaspoonful every 12 hours Delsym Pediatric Nighttime Cough and Cold (Phenylephrine HCl and Diphenhydramine HCl) 5 mg/12.5 mg per 5 mL <u>Usual Dose</u> Take 1 to 2 teaspoonfuls at night Delsym Adult Nighttime Cough and Cold (Acetaminophen, Dextromethorphan, and Doxylamine) Suspension, 500 mg/15 mg/6.25 mg per 5 mL <u>Usual Dose</u> Take 1 to 2 teaspoonfuls at night Delsym Adult Nighttime Multi-Symptom (Acetaminophen, Dextromethorphan, and Doxylamine, Phenylephrine) Suspension, 325 mg/10 mg/6.25 mg/ 5 mg per 5 mL <u>Usual Dose</u> Take 1 to 2 teaspoonfuls at night	<u>Orthographic</u> Both names contain 2 upstrokes and 1 down stroke. Additionally, the letter string 'lym' in Korlym may appear similar to the corresponding letter string 'lsym' in Delsym. <u>Phonetic</u> Both names share the letter 'l' and the letter string 'ym' <u>Strength</u> Both products are single strength; thus, the strength may be omitted. <u>Route of Administration</u> Oral <u>Frequency of Administration</u> Once daily (Delsym Nighttime)	<u>Orthographic</u> The letter string 'Kor' lacks orthographic similarity to the letter string 'De'. <u>Phonetic</u> The the letter string 'Kor' lack phonetic similarity to letter string 'De' and the letter 's.

Keralyt (Salicylic Acid) Topical Gel, 3% and 6% <u>Usual Dose</u> Apply to affected are at night and wash off in the morning. May apply twice daily Shampoo and Gel kit: 6% and 6% <u>Usual Dose</u> First apply gel, then wash hair with Shampoo. Gel: Apply to scalp, leave on for 10 to 20 minutes initially, gradually increasing to up to an hour as treatment progresses. Rinse thoroughly with Keralyt Shampoo. Shampoo: Apply to wet hair, lather, leave for several minutes, then rinse thoroughly.	<u>Orthographic</u> Both names share the letter 'K' and the letter string 'ly'. Additionally, the letter string 'or' in Korlym may appear similar to the letter string 'er' when scripted. <u>Phonetic</u> Both names share the letter string 'ly'. Additionally, the letter string 'Kor' is phonetically similar to the letter string 'Ker' <u>Frequency of Administration</u> Once daily	<u>Orthographic</u> The name Korlym contains 2 upstrokes and 1 down stroke vs. the name Keralyt contains 3 upstrokes and 1 down stroke. Additionally, the letter 'm' in Korlym lacks orthographic similarity to the letter 't' in Keralyt. <u>Phonetic</u> The letter 'm' in Korlym lacks phonetic similarity to the letter 't' in Keralyt. Additionally, the letter 'a' in Keralyt lacks phonetic similarity to the name Korlym. <u>Route of Administration</u> Oral vs. topical
Kerlix Gauzes and Bandages. <u>Usual Dose</u> Use as needed	<u>Orthographic</u> The letter string 'Korl' may appear similar to the corresponding letter string 'Kerl' in Kerlix when scripted. <u>Phonetic</u> Both names share the letter 'K'. Additionally, the letter string 'orly' in Korlym is phonetically similar to the letter string 'erli' in Kerlix. <u>Strength</u> Both products are single strength; thus, the strength may be omitted. <u>Frequency of Administration</u> Once daily	<u>Orthographic</u> The name Korlym contains 2 upstrokes and 1 down stroke vs. the name Kerlix contains 2 upstrokes and no down strokes. Additionally, the letter string 'ym' in Korlym lacks orthographic similarity to the letter string 'ix' in Kerlix when scripted. <u>Phonetic.</u> The letter 'x' in Korlym lack phonetic similarity to the corresponding letter 'x' in Kerlix. <u>Route of Administration</u> Oral vs. topical

Kerlone (Betaxolol)Tablets, 10 mg and 20 mg Usual Dose 10 mg to 20 mg orally once daily	Orthographic The letter string 'Korl' and the letter 'm' in Korlym may appear similar to the corresponding letter strings 'Kerl' and 'ne' in Kerlone when scripted. Phonetic The letter string 'Korl' in Korlym is phonetically similar to the letter string 'kerl' in Kerlone. Dosage Form Tablets Route of Administration Oral	Orthographic The name Korlym contains 2 upstrokes and 1 down stroke vs. the name Kerlone contains 2 upstrokes and no down strokes. Additionally, the letter 'y' in Korlym lacks orthographic similarity to the corresponding letter 'o' in Kerlone. Strength and Dose 300 mg, 600 mg, 900 mg, 1200 mg vs. 10 mg and 20 mg
Konsyl Family brand name includes several products containing psyllium, cvitamins, minerals, isoflavone Multiple names such as: Konsyl Balance Konsyl Easy Mix Konsyl Orange Konsyl Original Formula Konsyl-D Konsyl Bladder Control Available as powder for oral suspension and capsules Usual Dose Once daily to three times daily depending on the formulation and indication.	Orthographic Both names contains 2 upstrokes and 1 down stroke. Additionally, both names share the letter 'y' in similar positions and the letter string 'Kor' may appear similar to the corresponding letter string 'Kon' when scripted. Phonetic Both names share the letter string 'Ko' Dosage Form Both products can be solid dosage form: tablets vs. capsules Strength Both products are single strength; thus, the strength may be omitted. Route of Administration Oral Frequency of Administration Both products can be administered once daily	Orthographic Although both names contain 2 upstrokes and 1 down stroke, the second upstroke is located in different positions of the names. Additionally, the letter 'l' and the letter 'm' in Korlym lack orthographic similarity to the corresponding letters 's' and 'l' in Konsyl. Phonetic The letter string 'rlym' in Korlym lacks phonetic similarity to the letter string 'nsyl' in Konsyl. Name Since Konsyl is a family brand name, the name of the product has to be specified.

Crolom (Cromolyn Sodium) Ophthalmic Solution, 4% Usual Dose 1 drop to 2 drops in each eye 4 to 6 times per day	Orthographic Both names share the letters ‘l’ and ‘m’. Phonetic The letter string ‘Kor’ may be misinterpreted as the letter string ‘Cor’ and vice versa. Additionally, the letter string ‘lym’ in Korlym is phonetically similar to the letter string ‘lom’ in Crolom. Strength Both products are single strength; thus, the strength may be omitted.	Orthographic The name Korlym contains 2 upstrokes and 1 down stroke vs. the name Crolom contains 2 upstrokes and no down strokes. Additionally, the letter ‘K’ and the letter ‘y’ lack orthographic similarity to the letter ‘C’ and the second letter ‘o’ in Crolom. Route of Administration Oral vs. ophthalmic Frequency of Administration Once daily vs. 4 to 6 times a day
Colcrys (Colchicine) Tablets, 0.6 mg Usual Dose 1 tablet once daily to twice daily	Orthographic Both names share two upstrokes and 1 down stroke. Additionally, both names share letters ‘o’ and ‘y’ in similar positions. Dosage Form Both products are tablets Route of Administration Oral Strength Both products are single strength, thus, the strength on the prescription may be omitted Frequency of Administration Both products can be administered once daily.	Orthographic Although both names share 2 upstrokes, the second upstroke (i.e., letter ‘l’ in each name) is located in different positions, thus, the names are differently shaped. Additionally, the letters ‘K’ and ‘m’ in Korlym lack orthographic similarity to the corresponding the letters ‘C’ and ‘s’ when scripted.

Cordran (Flurandrenolide) Lotion, 0.05% Cordran SP Cream, 0.05% <u>Usual Dose</u> Apply sparingly two to three times per day to affected area. Cordran Impgregnated dressing (Tape), 4 mcg <u>Usual Dose</u> Apply to clean area every 12 hours to 24 hours	<u>Phonetic</u> The letter string ‘Kor’ and the letter ‘m’ in Korlym is phonetically similar to the letter string ‘Cor’ and the letter ‘n’ in Cordran. <u>Strength</u> Both products are available in a single strength. Thus, strength can be omitted. <u>Frequency of Administration</u> Both products may be administered once daily.	<u>Phonetic</u> The letter string ‘ly’ in Korlym lacks phonetic similarity to the letter string ‘dra’ in Cordran. <u>Dosage Form</u> Although all of the products are single strength, the dosage form must be specified, because Cordran is available in three dosage forms: Lotion, Cream, or Tape.

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Department of Health and Human Services
Public Health Service
Food and Drug Administration
Center for Drug Evaluation and Research
Office of Surveillance and Epidemiology

Proprietary Name Review

Date:	July 13, 2011
Application Type/Number:	NDA 202107
Reviewer(s):	Yelena Maslov, Pharm.D., Safety Evaluator Division of Medication Error Prevention and Analysis
Team Leader	Zachary Oleszczuk, Pharm.D., Team Leader Division of Medication Error Prevention and Analysis
Division Director	Carol Holquist, R.Ph., Director Division of Medication Error Prevention and Analysis
Drug Name(s):	(b) (4) (Mifepristone) Tablets, 300 mg
Applicant/sponsor:	Corcept Therapeutics, Inc
OSE RCM #:	#2011-1353

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