

**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

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

## CONTENTS

1	INTRODUCTION.....	3
2	METHODS AND DISCUSSION.....	3
3	CONCLUSIONS.....	3
4	REFERENCES.....	4

## 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.

---

\*\*\* This document contains proprietary information that should not be released to the public

#### 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.

# Explore Litigation Insights

Docket Alarm provides insights to develop a more informed litigation strategy and the peace of mind of knowing you're on top of things.

## Real-Time Litigation Alerts



Keep your litigation team up-to-date with **real-time alerts** and advanced team management tools built for the enterprise, all while greatly reducing PACER spend.

Our comprehensive service means we can handle Federal, State, and Administrative courts across the country.

## Advanced Docket Research



With over 230 million records, Docket Alarm's cloud-native docket research platform finds what other services can't. Coverage includes Federal, State, plus PTAB, TTAB, ITC and NLRB decisions, all in one place.

Identify arguments that have been successful in the past with full text, pinpoint searching. Link to case law cited within any court document via Fastcase.

## Analytics At Your Fingertips



Learn what happened the last time a particular judge, opposing counsel or company faced cases similar to yours.

Advanced out-of-the-box PTAB and TTAB analytics are always at your fingertips.

## API

Docket Alarm offers a powerful API (application programming interface) to developers that want to integrate case filings into their apps.

## LAW FIRMS

Build custom dashboards for your attorneys and clients with live data direct from the court.

Automate many repetitive legal tasks like conflict checks, document management, and marketing.

## FINANCIAL INSTITUTIONS

Litigation and bankruptcy checks for companies and debtors.

## E-DISCOVERY AND LEGAL VENDORS

Sync your system to PACER to automate legal marketing.