

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:

203634Orig1s000

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: December 10, 2012

Reviewer: Denise V. Baugh, PharmD, BCPS
Division of Medication Error Prevention and Analysis

Team Leader: Lubna Merchant, PharmD, M.S.
Division of Medication Error Prevention and Analysis

Drug Name: Uceris (Budesonide) Extended-release Tablets

Strength: 9 mg

Application Type/Number: NDA 203634

Applicant/Sponsor: Santarus

OSE RCM #: 2012-1834

*** 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, Uceris, 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, *Uceris*, acceptable in OSE Review # 2012-235 dated April 16, 2012 and in OSE Review # 2012 1004 dated July 24, 2012.

2 METHODS AND DISCUSSION

For re-assessments of proposed proprietary names, DMEPA searches a standard set of databases and information sources (see section 4) to identify names with orthographic and phonetic similarity to the proposed name that have been approved since the previous OSE proprietary name review. For this review we used the same search criteria described in OSE Review# 2012-235. 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 Uceris and represent a potential source of drug name confusion.

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 December 10, 2012. The Office of Prescription Drug Promotion OPDP re-reviewed the proposed name on October 18, 2012 and had no concerns regarding the proposed name from a promotional perspective.

3 CONCLUSIONS

The re-evaluation of the proposed proprietary name, Uceris did not identify any vulnerability that would result in medication errors with any additional names. Thus, DMEPA has no objection to the proprietary name, Uceris, 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 Gastrointestinal and Inborn Errors (DGIEP) 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 Phong (Pete) Do, OSE Project Manager, at 301-796-4795.

4 REFERENCES

1. OSE Reviews

Maslov, Y. OSE Review# 2011-1309: Proprietary Name Review for Uceris. October 11, 2011.

Crandall Tobenkin, A. OSE Review # 2012-235: Proprietary Name Review for Uceris. April 16, 2012.

Baugh, D. OSE Review # 2012-1004: Proprietary name Review (Final) for Uceris. July 24, 2012.

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

Drugs@FDA contains most of the drug products approved since 1939. The majority of labels, approval letters, reviews, and other information are available for drug products approved from 1998 to the present. Drugs@FDA contains official information about FDA approved [brand name](#), [generic drugs](#), [therapeutic biological products](#), [prescription](#) and [over-the-counter](#) human drugs and [discontinued drugs](#) and “[Chemical Type 6](#)” approvals.

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

USAN Stems List contains all the recognized USAN stems.

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

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

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

/s/

DENISE V BAUGH
12/10/2012

ZACHARY A OLESZCZUK on behalf of LUBNA A MERCHANT
12/11/2012

**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--Final

Date: July 24, 2012

Reviewer: Denise V. Baugh, PharmD, BCPS
Division of Medication Error Prevention and Analysis

Team Leader: Lubna Merchant, PharmD, M.S.
Division of Medication Error Prevention and Analysis

Drug Name: Uceris (Budesonide) Extended-release Tablets

Strength: 9 mg

Application Type/Number: NDA 203634

Applicant/Sponsor: Santarus

OSE RCM #: 2012-1004

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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, Uceris, 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, *Uceris*, acceptable in OSE Review # 2012-235 dated April 16, 2012.

2 METHODS AND DISCUSSION

For re-assessments of proposed proprietary names, DMEPA searches a standard set of databases and information sources (see section 4) to identify names with orthographic and phonetic similarity to the proposed name that have been approved since the previous OSE proprietary name review. For this review we used the same search criteria described in OSE Review 2012-235. 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 Uceris and represent a potential source of drug name confusion.

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 July 22, 2012. The Office of Prescription Drug Promotion OPDP re-reviewed the proposed name on July 19, 2012 and had no concerns regarding the proposed name from a promotional perspective.

3 CONCLUSIONS

The re-evaluation of the proposed proprietary name, Uceris, did not identify any vulnerability that would result in medication errors. Thus, DMEPA has no objection to the proprietary name, Uceris, 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 Gastrointestinal and Inborn Errors Products (DGEIP) 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 Nitin Patel, OSE project manager, at 301-796-5412.

4 REFERENCES

1. OSE Reviews

Maslov, Y. OSE Review# 2011-1309: Proprietary Name Review for Uceris. October 11, 2011.

Crandall Tobenkin, A. OSE Review # 2012-235: Proprietary Name Review for Uceris. April 16, 2012.

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

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

USAN Stems List contains all the recognized USAN stems.

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/s/

DENISE V BAUGH
07/24/2012

LUBNA A MERCHANT
07/25/2012

**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: April 16, 2012

Reviewer: Anne Crandall Tobenkin, PharmD
Division of Medication Error Prevention and Analysis

Team Leader: Lubna Merchant, PharmD, M.S.
Division of Medication Error Prevention and Analysis

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

Drug Name(s): Uceris (Budesonide) Extended-release Tablets

Strength: 9 mg

Application Type/Number: NDA 203634

Applicant/Sponsor: Santarus

OSE RCM #: 2012-235

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CONTENTS

1	INTRODUCTION.....	1
1.1	Regulatory History.....	1
1.2	Product Information.....	1
2.2	Safety Assessment.....	1
2	CONCLUSIONS.....	3
2.1	Comments to the Applicant.....	4
3	REFERENCES.....	5
	APPENDICES.....	8

1 INTRODUCTION

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

1.1 REGULATORY HISTORY

The proposed name, Uceris, was found acceptable by DMEPA in OSE review # 2011-1309 during the IND phase of the Application. Subsequently, the application converted to an NDA and the proposed name was re-submitted for review. No product characteristics have been modified since the previous review was completed.

1.2 PRODUCT INFORMATION

The following product information is provided in the January 19, 2012 proprietary name submission.

- Active Ingredient: Budesonide
- Indication of Use: Remission in patients with active mild to moderate ulcerative colitis
- Route of Administration: Oral
- Dosage Form: Tablets
- Strength: 9 mg (single strength)
- Dose and Frequency: One tablet by mouth once daily
- How Supplied: Bottles of 30
- Storage: USP controlled room temperature
- Container and Closure Systems: Child-resistant safety cap

2. RESULTS

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

2.1 PROMOTIONAL ASSESSMENT

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

2.2 SAFETY ASSESSMENT

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

2.2.1 United States Adopted Names (USAN) SEARCH

The February 23, 2011 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 proposed product is an extended-release formulation of Budesonide. The proposed name, Uceris, does not contain a modifier that communicates the extended-release nature of the drug product. Our analysis noted that another Budesonide product, Entocort EC, utilizes a modifier. We considered whether this name should also have a modifier appended to the name as both Uceris and Entocort EC share overlapping characteristics in that they share similar frequency of administration (once daily), dose (9mg), and indication. However, the strengths are different, along with the release mechanism. Because both products are taken once daily and there is no currently marketed immediate release formulation of Budesonide, it is unlikely that confusion would occur with this product prompting a clinician to prescribe or administer it more than once daily. Therefore, we determined a modifier is not necessary for Uceris.

2.2.4 FDA Name Simulation Studies

Thirty five practitioners participated in DMEPA's prescription studies. The interpretations did not overlap with any currently marketed products. Common misinterpretations in the written studies include; 'l' for 'c' and 'n' for 'r'. Common misinterpretation in the verbal study included; 'Eu' for 'U', 's' for 'c', 'a' for 'e' and 'u' for 'i'. 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, February 10, 2012, e-mail, the Division of Gastroenterology and Inborn Error Products (DGEIP) 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

Table 1, on the page 3, lists the names with orthographic similarity to the proposed proprietary name, Uceris identified by the primary reviewer, the Expert Panel Discussion (EPD), and other review disciplines.

Table 1: Collective List of Potentially Similar Names (DMEPA and EPD)

Names that are orthographically similar to Uceris		
Urese	Vicerex	Acilac
Narcan	Vancor	Errin
Eraxis	Iressa	Vascor
Vermox	Ureacin	Lucentis
Cialis	Acanya	Acular
Acerola	Urelle	Urocit
Uribel	(b) (4)	Yasmin
Oasis	Leena	(b) (4)
(b) (4)	Duexis	Arava
Univasc	Amicar	Amrix
Aceon	Avonex	Avinza

Our analysis of the 33 names contained in Table 1 considered the information obtained in the previous sections along with their product characteristics. We determined that all 33 names will not pose a risk for confusion as described in Appendix D through E.

2.2.7 Communication of DMEPA's Final Decision to Other Disciplines

DMEPA communicated our findings to the Division of Gastrointestinal and Inborn Errors Products (DGEIP) via e-mail on March 30, 2012. At that time we also requested additional information or concerns that could inform our review. Per e-mail correspondence from the DGEIP on , they stated no additional concerns with the proposed proprietary name, Uceris.

2 CONCLUSIONS

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

If you have further questions or need clarifications, please contact Nitin Patel, OSE project manager, at 301-796-5412.

2.1 COMMENTS TO THE APPLICANT

We have completed our review of the proposed proprietary name, Uceris, and have concluded that this name is acceptable. However, if any of the proposed product characteristics as stated in your January 19, 2012 submission are altered, DMEPA rescinds this finding and the name must be resubmitted for review.

Additionally, the proposed proprietary name must be re-reviewed 90 days prior to approval of the NDA. The conclusions upon re-review are subject to change.

3 REFERENCES

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

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

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

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

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

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

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

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

5. ***Division of Medication Errors Prevention and Analysis proprietary name consultation requests***

This is a list of proposed and pending names that is generated by the Division of Medication Error Prevention and Analysis from the Access database/tracking system.

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

Drugs@FDA contains most of the drug products approved since 1939. The majority of labels, approval letters, reviews, and other information are available for drug products approved from 1998 to the present. Drugs@FDA contains official information about FDA approved brand name, generic drugs, therapeutic biological products, prescription and over-the-counter human drugs and discontinued drugs and “Chemical Type 6” approvals.

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

USPTO provides information regarding patent and trademarks.

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

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

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

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

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

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

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

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

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

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

USAN Stems List contains all the recognized USAN stems.

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

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

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

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

15. *Medical Abbreviations (www.medilexicon.com)*

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

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

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

17. *Walgreens (www.walgreens.com)*

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

18. Rx List (www.rxlist.com)

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

19. Dogpile (www.dogpile.com)

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

APPENDICES

Appendix A

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

The safety assessment is conducted by DMEPA. DMEPA staff search a standard set of databases and information sources to identify names that are similar in pronunciation, spelling, and orthographically similar when scripted to the proposed proprietary name. Additionally, we consider inclusion of USAN stems or other characteristics that when incorporated into a proprietary name may cause or contribute to medication errors (i.e., dosing interval, dosage form/route of administration, medical or product name abbreviations, names that include or suggest the composition of the drug product, etc.). DMEPA defines a medication error as any preventable event that may cause or lead to inappropriate medication use or patient harm while the medication is in the control of the health care professional, patient, or consumer.¹

Following the preliminary screening of the proposed proprietary name, DMEPA gathers to discuss their professional opinions on the safety of the proposed proprietary name. This meeting is commonly referred to the Center for Drug Evaluation and Research (CDER) Expert Panel discussion. DMEPA also considers other aspects of the name that may be misleading from a safety perspective. DMEPA staff conducts a prescription simulation studies using FDA health care professionals. When provided, DMEPA considers external proprietary name studies conducted by or for the Applicant/Sponsor and incorporates the findings of these studies into the overall risk assessment.

The DMEPA primary reviewer assigned to evaluate the proposed proprietary name is responsible for considering the collective findings, and provides an overall risk assessment of the proposed proprietary name. DMEPA bases the overall risk assessment on the findings of a Failure Mode and Effects Analysis (FMEA) of the proprietary name and misleading nature of the proposed proprietary name with a focus on the avoidance of medication errors.

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

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

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

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

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

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

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

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

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

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

1. Database and Information Sources

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

2. Expert Panel Discussion

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

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

3. FDA Prescription Simulation Studies

Three separate studies are conducted within the Centers of the FDA for the proposed proprietary name to determine the degree of confusion of the proposed proprietary name with marketed U.S. drug names (proprietary and established) due to similarity in visual appearance with handwritten prescriptions or verbal pronunciation of the drug name. The studies employ healthcare professionals (pharmacists, physicians, and nurses), and attempts to simulate the prescription ordering process. The primary Safety Evaluator uses the results to identify orthographic or phonetic vulnerability of the proposed name to be misinterpreted by healthcare practitioners.

In order to evaluate the potential for misinterpretation of the proposed proprietary name in handwriting and verbal communication of the name, inpatient medication orders and/or outpatient prescriptions are written, each consisting of a combination of marketed and unapproved drug products, including the proposed name. These orders are optically

scanned and one prescription is delivered to a random sample of participating health professionals via e-mail. In addition, a verbal prescription is recorded on voice mail. The voice mail messages are then sent to a random sample of the participating health professionals for their interpretations and review. After receiving either the written or verbal prescription orders, the participants record their interpretations of the orders which are recorded electronically.

4. Comments from Other Review Disciplines

DMEPA requests the Office of New Drugs (OND) and/or Office of Generic Drugs (OGD), ONDQA or OBP for their comments or concerns with the proposed proprietary name, ask for any clinical issues that may impact the DMEPA review during the initial phase of the name review. Additionally, when applicable, at the same time DMEPA requests concurrence/non-concurrence with OPDP's decision on the name. The primary Safety Evaluator addresses any comments or concerns in the safety evaluator's assessment.

The OND/OGD Regulatory Division is contacted a second time following our analysis of the proposed proprietary name. At this point, DMEPA conveys their decision to accept or reject the name. The OND or OGD Regulatory Division is requested to provide any further information that might inform DMEPA's final decision on the proposed name.

Additionally, other review disciplines opinions such as ONDQA or OBP may be considered depending on the proposed proprietary name.

5. Safety Evaluator Risk Assessment of the Proposed Proprietary Name

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

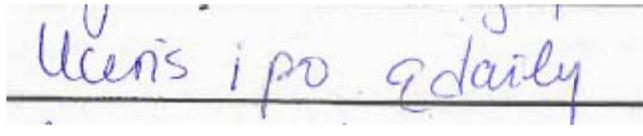
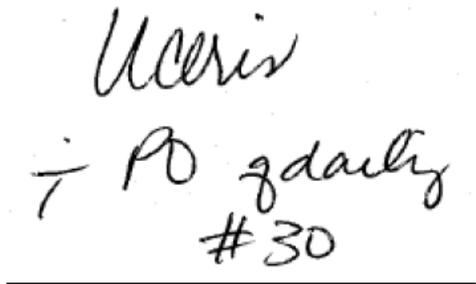
past but at great financial cost to the Sponsor and at the expense of the public welfare, not to mention the Agency’s credibility as the authority responsible for approving the error-prone proprietary name. Moreover, even after Sponsors’ have changed a product’s proprietary name in the post-approval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

Appendix B: Letters with Possible Orthographic or Phonetic Misinterpretation

Letters in Name, Uceris	Scripted May Appear as	Spoken May Be Interpreted as
U	A, O, L, V, N	“Yu”, “Eu”
u	a	
c	a, e, l,	“z”, “s”
e	a, c, i, l, o	
r	s, n, v, e,	
i	l, e,	y
s	n, r	z

Appendix C: Prescription Simulation Samples and Results

Figure 1. Prescription Simulation Study (Conducted on February 10, 2012)

Handwritten Requisition Medication Order	Verbal Prescription
<p><u>Medication Order:</u></p> 	<p>Uceris One tablet by mouth once daily</p>
<p><u>Outpatient Prescription:</u></p> 	

FDA Prescription Simulation Responses

Inpatient	Outpatient	Voice
UCERIS	UCERIS	EUSERIS
UCINS	UCERIS	USARUS
UCERIS	UCERIS	USERIS
UCERIS	UCERIS	USERUS
UCERIS	UCERIS	EUCERIS
UCENS	UCERIS	UCERIS
ULENS	UCERIS	EUCERIS
ULCERIS	UCERIS	UCERIS
UCERIS	UCERIS	URARIS
UCENS	UCERIS	EUSARIS
	UCERIS	EUSARIS
	UCERIS	
	UCERIS	
	UCERIS	

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 Uceris	Failure preventions
Urese	Benzthiazide	Orthographic	Product withdrawn from market in 1997. No generics available. Unable to determine if withdrawn for safety reasons. Also, NDA 12128 is referred to as proprietary name, "Favone" in DARRTS. Unable to find frequency of administration
Vicerex	n/a	Orthographic	"Male enhancement supplement", unlikely to be written on a prescription.
(b) (4)			
(b) (4)			
(b) (4)			

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

<p>Proposed name: Uceris (Budesonide) Strength: 9 mg Usual dose and frequency: One tablet by mouth once daily</p>	<p>Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion Causes (could be multiple)</p>	<p>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</p>
<p>Iressa (Gefitinib) - 250 mg oral tablet - One tablet by mouth once daily</p>	<p>Orthographic similarity - Both names are similar in length - Both names have no upstrokes or downstrokes after the first letter</p> <p>Overlapping product characteristics - Strength (both single strength) - Frequency of administration (once daily) - Route of administration (oral)</p>	<p>Orthographic differences - the suffix, 'ris' in Uceris does not resemble the suffix 'ssa' in Iressa when scripted</p> <p>Product characteristic differences - none</p>
<p>Acilac (Lactulose) Discontinued, generic available - 10 g/15 mL oral solution - 15 mL to 30 mL by mouth daily, up to 60 mL per day</p>	<p>Orthographic similarity - 'U' and 'A' appear similar when scripted - Both names are similar in length</p> <p>Overlapping product characteristics - Frequency of administration (once daily)</p>	<p>Orthographic differences - Uceris does not have an upstroke in the middle of the name vs. Acilac has an upstroke in the middle of the name</p> <p>Product characteristic differences - Dose (one capsule or 9 mg vs. 15 mL or one tablespoon)</p>
<p>Narcan (Nalaxone) Discontinued, generic available - 0.02 mg/mL, 0.4 mg/mL, 1 mg/mL - 0.1 mg to 2 mg intravenously, subcutaneously, or intramuscularly, can repeat every 2 to 3 minutes, up to 10 mg</p>	<p>Orthographic similarity - Both names are similar in length - Both names have no upstrokes or downstrokes after the first letter</p> <p>Overlapping product characteristics - none</p>	<p>Orthographic differences - none</p> <p>Product characteristic differences - Dose (one capsule or 9 mg vs. 0.1 mg to 2 mg) - Frequency of administration (once daily vs. one time and can be repeated based on response) - Route of administration (oral vs. intravenous, subcutaneous, intramuscular)</p>

<p>Proposed name: Uceris (Budesonide)</p> <p>Strength: 9 mg</p> <p>Usual dose and frequency: One tablet by mouth once daily</p>	<p>Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion Causes (could be multiple)</p>	<p>Prevention of Failure Mode:</p> <p>In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names</p>
<p>Vancor (Vancomycin) Discontinued, generic available</p> <ul style="list-style-type: none"> - 500 mg, 1 g per vial - 250 mg to 1500 mg intravenously once or twice daily 	<p>Orthographic similarity</p> <ul style="list-style-type: none"> - ‘V’ and ‘N’ appear similar when scripted - Both names are similar in length - Both names have no upstrokes or downstrokes after the first letter <p>Overlapping product characteristics</p> <ul style="list-style-type: none"> - Frequency of administration (once daily) 	<p>Orthographic differences</p> <ul style="list-style-type: none"> - none <p>Product characteristic differences</p> <ul style="list-style-type: none"> - Dose (one capsule or 9 mg vs. 250 mg to 1500 mg)
<p>Errin (Nnorethindrone)</p> <ul style="list-style-type: none"> - 0.35 mg oral tablet, 28 day pack - One tablet by mouth once daily or as directed 	<p>Orthographic similarity</p> <ul style="list-style-type: none"> - Both names are similar in length - Both names have no upstrokes or downstrokes after the first letter <p>Overlapping product characteristics</p> <ul style="list-style-type: none"> - Frequency of administration (once daily) - Route of administration (oral) - Dosage form (oral solid; capsule, tablet) - Strength (both single strength) 	<p>Orthographic differences</p> <ul style="list-style-type: none"> - ‘U’ and ‘E’ do not appear similar when scripted and there are no name pairs that begin with these letters on the ISMP confused name list <p>Product characteristic differences</p> <ul style="list-style-type: none"> - none
<p>Eraxis (Anidulafungin)</p> <ul style="list-style-type: none"> - 50 mg, 100 mg per vial - 200 mg load dose intravenously followed by 100 mg qdaily or 100 mg load dose followed by 50 mg once daily 	<p>Orthographic similarity</p> <ul style="list-style-type: none"> - Both names are similar in length - Both names have no upstrokes or downstrokes after the first letter <p>Overlapping product characteristics</p> <ul style="list-style-type: none"> - Frequency of administration (once daily) 	<p>Orthographic differences</p> <ul style="list-style-type: none"> - ‘E’ and ‘U’ do not appear similar when scripted and there are no name pairs that begin with these letters on the ISMP confused name list <p>Product characteristic differences</p> <ul style="list-style-type: none"> - Dose (one capsule or 9 mg vs. 50 mg, 100 mg, 200 mg) - Infusion time (oral medication vs. minimum of 45 minute infusion time due to adverse events associated with rapid infusion)

<p>Proposed name: Uceris (Budesonide)</p> <p>Strength: 9 mg</p> <p>Usual dose and frequency: One tablet by mouth once daily</p>	<p>Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion Causes (could be multiple)</p>	<p>Prevention of Failure Mode:</p> <p>In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names</p>
<p>Vascor (Bepidil)</p> <ul style="list-style-type: none"> - Discontinued per FR in 2007. No generics available - 200 mg, 300 mg, 400 mg oral tablet 	<p>Orthographic similarity</p> <ul style="list-style-type: none"> - ‘U’ and ‘V’ appear similar when scripted - Both names are similar in length - Both names have no upstrokes or downstrokes after the first letter <p>Overlapping product characteristics</p> <ul style="list-style-type: none"> - Frequency of administration (once daily) - Route of administration (oral) - Dosage form (tablet) 	<p>Orthographic differences</p> <ul style="list-style-type: none"> - none <p>Product characteristic differences</p> <ul style="list-style-type: none"> - Strength (9 mg, single strength, not required on prescription vs. 200 mg, 300 mg, 400 mg)
<p>Vermox (Mebendazole)</p> <p>Discontinued</p> <ul style="list-style-type: none"> - 100 mg oral tablet - One tablet by mouth once or twice daily for one or three days 	<p>Orthographic similarity</p> <ul style="list-style-type: none"> - Both names are similar in length - Both names have no upstrokes or downstrokes after the first letter <p>Overlapping product characteristics</p> <ul style="list-style-type: none"> - Strength (both single strength) - Frequency of administration (once daily) - Route of administration (oral) 	<p>Orthographic differences</p> <ul style="list-style-type: none"> - Ending, ‘ris’ in Uceris does not resemble ending ‘mox’ in Vermox when scripted <p>Product characteristic differences</p> <ul style="list-style-type: none"> - none
<p>Ureacin (Urea)</p> <ul style="list-style-type: none"> - 10%, 20% topical lotion - Apply once to three times daily 	<p>Orthographic similarity</p> <ul style="list-style-type: none"> - Both names begin with ‘U’ - Both names have no upstrokes or downstrokes after the first letter <p>Overlapping product characteristics</p> <ul style="list-style-type: none"> - Frequency of administration (once daily) 	<p>Orthographic differences</p> <ul style="list-style-type: none"> - Uceris has six narrow letters and appears shorter when scripted vs. Ureacin which has seven letters <p>Product characteristic differences</p> <ul style="list-style-type: none"> - Strength (9 mg, single strength, not required on prescription vs. 10%, 20%)

<p>Proposed name: Uceris (Budesonide)</p> <p>Strength: 9 mg</p> <p>Usual dose and frequency: One tablet by mouth once daily</p>	<p>Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion Causes (could be multiple)</p>	<p>Prevention of Failure Mode:</p> <p>In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names</p>
<p>Lucentis (Ranibizumab)</p> <ul style="list-style-type: none"> - 0.2 mL (10 mg/mL) injection - 0.05 mL intravitreally once a month or every 3 months 	<p>Orthographic similarity</p> <ul style="list-style-type: none"> - ‘L’ and ‘U’ appear similar when scripted <p>Overlapping product characteristics</p> <ul style="list-style-type: none"> - none 	<p>Orthographic differences</p> <ul style="list-style-type: none"> - Uceris has six letters vs. Lucentis has eight letters making it appear longer - Uceris has no upstrokes or cross-strokes vs. Lucentis has an upstroke and cross-stroke towards the end of the name <p>Product characteristic differences</p> <ul style="list-style-type: none"> - Frequency of administration (once daily vs. once a month or every 3 months) - Setting of use (home or hospital vs. injected by ophthalmologist) - Dose (9 mg or 1 capsule vs. 0.05 mL)
<p>Cialis (Tadalafil)</p> <ul style="list-style-type: none"> - 2.5 mg, 5 mg, 10 mg, 20 mg oral tablets - One tablet by mouth prior to activity or as directed 	<p>Orthographic similarity</p> <ul style="list-style-type: none"> - Both names are similar in length <p>Overlapping product characteristics</p> <ul style="list-style-type: none"> - Route of administration (oral) - Dosage form (tablets) 	<p>Orthographic differences</p> <ul style="list-style-type: none"> - ‘C’ and ‘U’ do not appear similar when scripted and there are no name pairs that begin with these letters on the ISMP confused name list - Uceris has no upstrokes in the middle of the name vs. Cialis has an upstroke in the middle of the name <p>Product characteristic differences</p> <ul style="list-style-type: none"> - Strength (9 mg, single strength, not required on prescription vs. 2.5 mg, 5 mg, 10 mg, 20 mg) - Frequency of administration (once daily vs. as needed, prior to sexual activity)
<p>Acanya (Clindamycin and Benzoyl peroxide)</p> <ul style="list-style-type: none"> - 1.2%/2.5% topical gel - Apply a pea-sized amount to the face once daily 	<p>Orthographic similarity</p> <ul style="list-style-type: none"> - ‘A’ and ‘U’ appear similar when scripted - Both names are similar in length <p>Overlapping product characteristics</p> <ul style="list-style-type: none"> - Strength (both single strength) - Frequency of administration (once daily) 	<p>Orthographic differences</p> <ul style="list-style-type: none"> - Uceris has no downstroke vs. Acanya has a downstroke in the name giving it a different shape <p>Product characteristic differences</p> <ul style="list-style-type: none"> - Dose (9 mg or one capsule vs. pea-sized amount or small amount)

<p>Proposed name: Uceris (Budesonide)</p> <p>Strength: 9 mg</p> <p>Usual dose and frequency: One tablet by mouth once daily</p>	<p>Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion Causes (could be multiple)</p>	<p>Prevention of Failure Mode:</p> <p>In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names</p>
<p>Acular (Ketorolac)</p> <ul style="list-style-type: none"> - 0.5% ophthalmic solution - One drop to the affected eye(s) four times daily 	<p>Orthographic similarity</p> <ul style="list-style-type: none"> - ‘A’ and ‘U’ appear similar when scripted - Both names are similar in length <p>Overlapping product characteristics</p> <ul style="list-style-type: none"> - Strength (both single strength) - Dose (‘one’) - Frequency of administration (QD and QID resemble one another when scripted) 	<p>Orthographic differences</p> <ul style="list-style-type: none"> - Uceris has no upstrokes in the middle of the name vs. Acular has an upstroke in the middle of the name <p>Product characteristic differences</p> <ul style="list-style-type: none"> - none
<p>Acerola (Ascorbic acid)</p> <ul style="list-style-type: none"> - 500 mg (chewable) oral tablet - One tablet by mouth as directed 	<p>Orthographic similarity</p> <ul style="list-style-type: none"> - ‘A’ and ‘U’ appear similar when scripted - Both names are similar in length <p>Overlapping product characteristics</p> <ul style="list-style-type: none"> - Strength (both single strength) - Route of administration (oral) - Frequency of administration (once daily) 	<p>Orthographic differences</p> <ul style="list-style-type: none"> - Acerola has an upstroke in the middle of the name vs. Uceris has no upstroke <p>Product characteristic differences</p> <ul style="list-style-type: none"> - none
<p>Urelle (Hyoscyamine, Methenamine, Methylene Blue, Phenyl salicylate, Sodium phosphate)</p> <ul style="list-style-type: none"> - 0.12 mg/81 mg/ 10.8 mg/32.4 mg/ 40.8 mg oral tablet - One tablet by mouth four times daily 	<p>Orthographic similarity</p> <ul style="list-style-type: none"> - Both names begin with ‘U’ - Both names are similar in length <p>Overlapping product characteristics</p> <ul style="list-style-type: none"> - Strength (both single strength) - Route of administration (oral) - Dosage form (oral solid) - Frequency of administration (QD and QID resemble one another when scripted) 	<p>Orthographic differences</p> <ul style="list-style-type: none"> - Uceris does not have an upstroke in the middle of the name vs. Urelle has two upstrokes in the middle of the name <p>Product characteristic differences</p> <ul style="list-style-type: none"> - none

<p>Proposed name: Uceris (Budesonide)</p> <p>Strength: 9 mg</p> <p>Usual dose and frequency: One tablet by mouth once daily</p>	<p>Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion Causes (could be multiple)</p>	<p>Prevention of Failure Mode:</p> <p>In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names</p>
<p>Urocit (K) (Potassium citrate)</p> <ul style="list-style-type: none"> - 10 mEq, 15 mEq oral tablet - 10 mEq to 30 mEq by mouth one to three times daily 	<p>Orthographic similarity</p> <ul style="list-style-type: none"> - Both names begin with ‘U’ - Both names are similar in length <p>Overlapping product characteristics</p> <ul style="list-style-type: none"> - Frequency of administration (once daily) - Route of administration (oral) - Dosage form (tablet) 	<p>Orthographic differences</p> <ul style="list-style-type: none"> - Uceris does not have an upstroke or cross-stroke at the end of the name vs. Urocit ends with a cross-stroke and upstroke <p>Product characteristic differences</p> <ul style="list-style-type: none"> - Strength (single strength, 9 mg, not required on prescription vs. 10 mEq or 15 mEq)
<p>Uribel (Hyoscyamine, Methenamine, Methylene Blue, Phenyl salicylate, Sodium phosphate)</p> <ul style="list-style-type: none"> - 0.12 mg/118 mg/10 mg/36 mg/40.8 mg oral capsule - One capsule by mouth four times daily 	<p>Orthographic similarity</p> <ul style="list-style-type: none"> - Both names begin with ‘U’ - Both names are similar in length <p>Overlapping product characteristics</p> <ul style="list-style-type: none"> - Route of administration (oral) - Dosage form (oral solid; tablet, capsule) - Frequency of administration (QD and QID resemble one another when scripted) 	<p>Orthographic differences</p> <ul style="list-style-type: none"> - Uceris has no upstrokes in the middle or ending of the name vs. Uribel has an upstroke in the middle and the end of the name <p>Product characteristic differences</p> <ul style="list-style-type: none"> - none
<p>Yasmin (Drospirenone and Ethinyl Estradiol)</p> <ul style="list-style-type: none"> - 3 mg/0.03 mg oral tablet, 28 day pack - One tablet by mouth once daily or as directed 	<p>Orthographic similarity</p> <ul style="list-style-type: none"> - Both Yasmin and Uceris have no upstrokes or downstrokes <p>Overlapping product characteristics</p> <ul style="list-style-type: none"> - Strength (both single strength) - Frequency of administration (once daily) - Route of administration (oral) 	<p>Orthographic differences</p> <ul style="list-style-type: none"> - The prefix “Uce” and “Yas” appear different when scripted <p>Product characteristic differences</p> <ul style="list-style-type: none"> - none

<p>Proposed name: Uceris (Budesonide)</p> <p>Strength: 9 mg</p> <p>Usual dose and frequency: One tablet by mouth once daily</p>	<p>Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion Causes (could be multiple)</p>	<p>Prevention of Failure Mode:</p> <p>In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names</p>
<p>Oasis Tears (Glycerin)</p> <ul style="list-style-type: none"> - 0.2% ophthalmic solution - one drop into the affected eye(s) as needed 	<p>Orthographic similarity</p> <ul style="list-style-type: none"> - Both names are similar in length - Both names has no upstrokes or downstrokes <p>Overlapping product characteristics</p> <ul style="list-style-type: none"> - Strength (both single strength) - Dose ('one') 	<p>Orthographic differences</p> <ul style="list-style-type: none"> - none <p>Product characteristic differences</p> <ul style="list-style-type: none"> - Frequency of administration (once daily vs. around the clock, as needed)
<p>Leena (Norethindrone and Ethinyl Estradiol)</p> <ul style="list-style-type: none"> - 0.5 mg/0.035 mg and 1 mg/0.035 mg oral tablet, 28 day pack - One tablet by mouth once daily 	<p>Orthographic similarity</p> <ul style="list-style-type: none"> - Both names are similar length - Both names have no upstrokes or downstrokes after the first letter <p>Overlapping product characteristics</p> <ul style="list-style-type: none"> - Strength (both single strength) - Frequency of administration (once daily) - Route of administration (oral) 	<p>Orthographic differences</p> <ul style="list-style-type: none"> - 'L' and 'U' do not appear similar when scripted and there are no name pairs that begin with these letters on the ISMP confused name list - The suffix "ris" does not resemble the suffix "ena" when scripted <p>Product characteristic differences</p> <ul style="list-style-type: none"> - none
<p>Duexis (Ibuprofen and Famotidine)</p> <ul style="list-style-type: none"> - 800 mg/26.6 mg oral tablet - One tablet by mouth three times daily as needed 	<p>Orthographic similarity</p> <ul style="list-style-type: none"> - Both names are similar in length - Both names have no upstrokes or downstrokes after the first letter <p>Overlapping product characteristics</p> <ul style="list-style-type: none"> - Route of administration (oral) - Strength (both single strength) - Dosage form (tablet) 	<p>Orthographic differences</p> <ul style="list-style-type: none"> - 'D' and 'U' do not appear similar when scripted and there are no name pairs that begin with these letters on the ISMP confused name list <p>Product characteristic differences</p> <ul style="list-style-type: none"> - Frequency of administration (once daily, around the clock vs. three times daily as needed)

<p>Proposed name: Uceris (Budesonide)</p> <p>Strength: 9 mg</p> <p>Usual dose and frequency: One tablet by mouth once daily</p>	<p>Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion Causes (could be multiple)</p>	<p>Prevention of Failure Mode:</p> <p>In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names</p>
<p>Arava (Leflunomide)</p> <ul style="list-style-type: none"> - 10 mg, 20 mg, 100 mg oral tablets - Loading dose of 100 mg by mouth once daily for 3 days followed by 10 mg or 20 mg by mouth once daily 	<p>Orthographic similarity</p> <ul style="list-style-type: none"> - ‘A’ and ‘U’ appear similar when scripted - Both names have no upstrokes or downstrokes after the first letter <p>Overlapping product characteristics</p> <ul style="list-style-type: none"> - Frequency of administration (once daily) - Route of administration (oral) - Dosage form (tablets) 	<p>Orthographic differences</p> <ul style="list-style-type: none"> - The suffix “ris” does not resemble the suffix “ava” when scripted <p>Product characteristic differences</p> <ul style="list-style-type: none"> - Strength (9 mg, single strength, not required on prescription vs. 10 mg, 20 mg, 100 mg)
<p>Univasc (Moexipril)</p> <ul style="list-style-type: none"> - 7.5 mg, 15 mg oral tablet - 7.5 mg to 30 mg by mouth once or twice daily 	<p>Orthographic similarity</p> <ul style="list-style-type: none"> - Both names begin with ‘U’ - Both names have no upstrokes or downstrokes after the first letter <p>Overlapping product characteristics</p> <ul style="list-style-type: none"> - Frequency of administration (once daily) - Route of administration (oral) - Dosage form (tablet) 	<p>Orthographic differences</p> <ul style="list-style-type: none"> - Uceris has six narrow letters and appears shorter when scripted vs. Univasc which has seven letters which are wider <p>Product characteristic differences</p> <ul style="list-style-type: none"> - Strength (9 mg, single strength, not required on prescription vs. 7.5 mg, 15 mg)
<p>Amicar (Aminocaproic acid)</p> <ul style="list-style-type: none"> - 500 mg, 1000 mg oral tablets - 0.25 g/mL oral solution - 5 g or 20 mL by mouth for acute bleeding syndrome followed by a g or 5 mL per hour for 8 hours or until bleeding is controlled 	<p>Orthographic similarity</p> <ul style="list-style-type: none"> - ‘A’ and ‘U’ appear similar when scripted - Both names have no upstrokes or downstrokes after the first letter <p>Overlapping product characteristics</p> <ul style="list-style-type: none"> - Route of administration (oral) - Dosage form (tablet) 	<p>Orthographic differences</p> <ul style="list-style-type: none"> - none <p>Product characteristic differences</p> <ul style="list-style-type: none"> - Dose (one tablet vs. 5 or 10 tablets or 10 mL to 20 mL) - Frequency of administration (once daily or once followed by every hour)

<p>Proposed name: Uceris (Budesonide)</p> <p>Strength: 9 mg</p> <p>Usual dose and frequency: One tablet by mouth once daily</p>	<p>Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion Causes (could be multiple)</p>	<p>Prevention of Failure Mode:</p> <p>In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names</p>
<p>Amrix (Cylcobenzaprine)</p> <ul style="list-style-type: none"> - 15 mg, 30 mg extended-release capsules - 15 mg to 30 mg by mouth once daily 	<p>Orthographic similarity</p> <ul style="list-style-type: none"> - ‘A’ and ‘U’ appear similar when scripted - Both names have no upstrokes or downstrokes after the first letter <p>Overlapping product characteristics</p> <ul style="list-style-type: none"> - Frequency of administration (once daily) - Route of administration (oral) - Dosage form (oral solid; capsule, tablet) 	<p>Orthographic differences</p> <ul style="list-style-type: none"> - none <p>Product characteristic differences</p> <ul style="list-style-type: none"> - Strength (9 mg, single strength, not required on prescription vs. 15 mg, 30 mg)
<p>Aceon (Perindopril)</p> <ul style="list-style-type: none"> - 2 mg, 4 mg, 8 mg oral tablets - 2 mg to 8 mg once or twice daily 	<p>Orthographic similarity</p> <ul style="list-style-type: none"> - ‘A’ and ‘U’ appear similar when scripted - Both names have no upstrokes or downstrokes after the first letter <p>Overlapping product characteristics</p> <ul style="list-style-type: none"> - Frequency of administration (once daily) - Route of administration (oral) - Dosage form (tablet) 	<p>Orthographic differences</p> <ul style="list-style-type: none"> - none <p>Product characteristic differences</p> <ul style="list-style-type: none"> - Strength (9 mg, single strength, not required on prescription vs. 2 mg, 4 mg, 8 mg)
<p>Avonex (Interferon beta-1a)</p> <ul style="list-style-type: none"> - 30 mcg prefilled syringe or vial - 30 mcg intramuscularly once weekly 	<p>Orthographic similarity</p> <ul style="list-style-type: none"> - ‘A’ and ‘U’ appear similar when scripted - Both names have no upstrokes or downstrokes after the first letter <p>Overlapping product characteristics</p> <ul style="list-style-type: none"> - Strength (both single strength) 	<p>Orthographic differences</p> <ul style="list-style-type: none"> - none <p>Product characteristic differences</p> <ul style="list-style-type: none"> - Frequency of administration (once daily vs. once weekly)

<p>Proposed name: Uceris (Budesonide)</p> <p>Strength: 9 mg</p> <p>Usual dose and frequency: One tablet by mouth once daily</p>	<p>Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion Causes (could be multiple)</p>	<p>Prevention of Failure Mode:</p> <p>In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names</p>
<p>Avinza (Morphine)</p> <ul style="list-style-type: none"> - 30 mg, 45 mg, 60 mg, 75 mg, 90 mg, 120 mg extended-release capsule - One capsule once daily 	<p>Orthographic similarity</p> <ul style="list-style-type: none"> - ‘A’ and ‘U’ appear similar when scripted - Both names have no upstrokes or downstrokes after the first letter <p>Overlapping product characteristics</p> <ul style="list-style-type: none"> - Frequency of administration (once daily) - Route of administration (oral) - Dosage form (oral solid; capsule, tablet) - Numerical similarity (9 mg vs. 90 mg) 	<p>Orthographic differences</p> <ul style="list-style-type: none"> - The suffix “ris” does not resemble the suffix “nza” when scripted <p>Product characteristic differences</p> <ul style="list-style-type: none"> - none

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/s/

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