CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

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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

Date:	May 1, 2012
Reviewer(s):	Reasol S. Agustin, PharmD Division of Medication Error and Prevention Analysis
Acting Team Leader	Yelena Maslov, PharmD Division of Medication Error and Prevention Analysis
Division Director	Carol Holquist, RPh Division of Medication Error and Prevention Analysis
Drug Name and Strength:	Belviq (Lorcaserin) Tablets, 10 mg
Application Type/Number:	NDA 22529
Applicant/Sponsor:	Arena Pharmaceuticals Inc
OSE RCM #:	2012-333

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

CONTENTS

1 INTRODUCTION

This review evaluates the proposed proprietary name, Belviq, 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 Applicant submitted a request for an assessment of the proposed proprietary name, Belviq for Lorcaserin Hydrochloride tablets, 10 mg, NDA 022529 on February 2, 2012. The name Belviq is the third proposed name for this product. Additionally, the Applicant also submitted container labels and carton labeling on December 23, 2011, for the proposed proprietary name, Belviq, which will be reviewed by DMEPA under a separate cover in OSE Review #2012-172.

The first proposed proprietary name, Lorqess, submitted to IND 069888 on August 31, 2009, was found unacceptable by DMEPA in OSE Review #2009-1601, dated February 12, 2010 because of orthographic similarity and shared product characteristics with another proposed proprietary name, Loryna, for a pending Application. The second proposed proprietary name, (b) (4) submitted to IND 069888 on July 12, 2011, was found unacceptable by DMEPA in OSE Review #2011-2253, dated December 19, 2011 because of orthographic similarity and shared product characteristics with the currently marketed products (b) (4)

1.2 PRODUCT INFORMATION

The following product information is provided in the February 2, 2012 proprietary name submission.

- Active Ingredient: Lorcaserin
- Indication of Use: For the management of obesity including weight loss and the maintenance of weight loss in conjunction with a reduced-calorie diet and a program of regular exercise.
- Route of Administration: Oral
- Dosage Form: Tablets
- Strength: 10 mg
- Dose and Frequency: 10 mg by mouth twice daily
- How Supplied: Packaged in bottles of 100 tablets and sample blister card of 10 tablets per carton
- Storage: Store at 15°- 30°C (59°- 86°F) [See USP Controlled Room Temperature]. Protect from heat and moisture
- Container and Closure Systems:
  - Bottle of 100: 60 cc HDPE, round, (b) (4) Child-resistant closure (CRC), (b) (4)
  - Blister card: (b) (4) heat seal coated foil backing material

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 Metabolism and Endocrinology Products (DMEP) concurred with the findings of OPDP's promotional assessment of the proposed name.

2.2 SAFETY ASSESSMENT

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

2.2.1 United States Adopted Names (USAN) SEARCH

On March 1, 2012, the United States Adopted Name (USAN) stem search identified that a USAN stem is not present in the proposed proprietary name.

2.2.2 Components of the Proposed Proprietary Name

The Applicant indicated in their submission that the proposed name, Belviq, is was not derived from any one particular concept and has no intended meaning. This proprietary name is comprised of a single word that does not contain any components (i.e. a modifier, route of administration, dosage form, etc.) that are misleading or can contribute to medication error.

2.2.3 FDA Name Simulation Studies

Thirty-three practitioners participated in DMEPA's prescription studies. The interpretations did not overlap with or appear or sound similar to any currently marketed products. Four of the 15 inpatient participants responded correctly and the most common misinterpretation occurred with 5 participants misinterpreting the letter 'v' for 'e' in 'Bel*V*iq'. None of the 10 voice participants responded correctly and the most common misinterpretation occurred with participants misinterpreting the letter 'q' for 'c' and 'g' in 'Belvi*Q*.' Seven out of 8 outpatient participants responded correctly to Belviq and one misinterpretation occurred with a participant misinterpreting the letter 'q' for 'g' in 'Belvi*Q*.' See Appendix C for the complete listing of interpretations from the verbal and written prescription studies.

See Appendix C for the complete listing of interpretations from the verbal and written prescription studies.

2.2.4 Comments from Other Review Disciplines

In response to the OSE, March 2, 2012 e-mail, the Division of Metabolism and Endocrinology Products (DMEP) did not forward any comments or concerns relating to the proposed name at the initial phase of the proprietary name review.

2.2.5 Failure Mode and Effects Analysis of Similar Names

Appendix B lists possible orthographic and phonetic misinterpretations of the letters appearing in the proposed proprietary name, Belviq. Table 1 lists the names with orthographic, phonetic, or

spelling similarity to the proposed proprietary name, Belviq identified by the primary reviewer, the Expert Panel Discussion (EPD), and other review disciplines. Table 1 also includes the names identified from the FDA Prescription Simulation or by Drug Safety Institute, Inc. (DSI) not identified by DMEPA and require further evaluation.

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

Look Similar					
Name	***Source***	***Name***	***Source***	***Name***	***Source***
Benicar	FDA	Pristiq	FDA	Luxiq	FDA
Benicar HCT	FDA	Relief-SF	FDA	Mobic	FDA
Del-Vi-A	FDA	Relief-PE	FDA	Balmex	FDA
Reluri	FDA	Kalmz	FDA	Rebif	FDA
Rulox	FDA	Multaq	FDA	Zolvit	FDA
Baciim	FDA	Benziq LS	FDA	Halog	FDA
Relpax	FDA	Balziva	FDA/External	Actiq	FDA/External
Beldin	FDA/External	Bricanyl	External	Bilivist	External
Del-Aqua	External	Bentyl	External	Angeliq	External
Benylin	External				
Sound Similar					
Gelnique	FDA				
Look and Sound Similar					
Belviq	FDA	Bellviq	FDA	Belvir	FDA
Belix	FDA/External	Benziq	FDA/External		

Our analysis of the 34 names contained in Table 1 considered the information obtained in the previous sections along with their product characteristics. We determined 34 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 Metabolism and Endocrinology Products (DMEP) via e-mail on March 28, 2012. 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 April 2, 1012, they stated no additional concerns with the proposed proprietary name, Belviq.

3 CONCLUSIONS

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

If you have further questions or need clarifications, please contact Ermias Zerislassie, OSE project manager, at 301-796-0097

3.1 COMMENTS TO THE APPLICANT

We have completed our review of the proposed proprietary name, Belviq, and have concluded that this name is acceptable. However, if any of the proposed product characteristics as stated in your February 2, 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.

4 REFERENCES

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

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

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

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

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

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

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

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

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

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

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

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

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

   USPTO provides information regarding patent and trademarks.

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

   Clinical Pharmacology contains full monographs for the most common drugs in clinical use, plus mini monographs covering investigational, less common, combination, nutraceutical and nutritional products. It also provides a keyword search engine.

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

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

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

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

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

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

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

    USAN Stems List contains all the recognized USAN stems.

13. ***Red Book (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 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

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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.

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).

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

Type of Similarity	**Considerations when Searching the Databases**		
	Potential Causes of Drug Name Similarity	*Attributes Examined to Identify Similar Drug Names*	*Potential Effects*
Look-	Similar spelling	Identical prefix Identical infix Identical suffix Length of the name Overlapping product characteristics	• Names may appear similar in print or electronic media and lead to drug name confusion in printed or electronic communication • Names may look similar when scripted and lead to drug name confusion in written communication

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

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

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

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

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

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

> ***"Could the confusion of the drug names conceivably result in medication errors in the usual practice setting?"***

The answer to this question is a central component of the Safety Evaluator's overall risk assessment of the proprietary name. If the Safety Evaluator determines through FMEA that the

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

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.

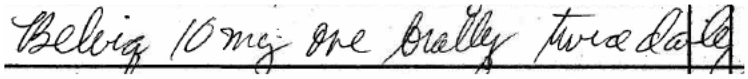
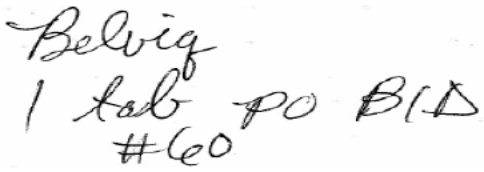
Furthermore, post-marketing experience has demonstrated that medication errors resulting from drug name confusion are notoriously difficult to rectify post-approval. Educational and other post-approval efforts are low-leverage strategies that have had limited effectiveness at alleviating medication errors 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, Belviq	**Scripted may appear as**	**Spoken may be interpreted as**
'B'	R, P, D, M	P, D, V
Lowercase 'b'	l, h, k	p,v,d
lowercase 'e'	a, c, i, l, o, u, p	Any vowel
lowercase 'l'	b, e, s, A, P, i	
lowercase 'v'	r, u	f
lowercase 'i'	e	Any vowel
lowercase 'q'	g, j, z	k

Appendix C: Prescription Simulation Samples and Results

Figure 1. Belviq Study (Conducted on February 21, 2012)

Handwritten Requisition Medication Order	Verbal Prescription
Medication Order: 	Belviq One tablet by mouth twice daily #60
Outpatient Prescription: 	

FDA Prescription Simulation Responses (Aggregate 1 Rx Studies Report)

84 People Received Study

33 People Responded

Study Name: Belviq

INTERPRETATION	INPATIENT	VOICE	OUTPATIENT	TOTAL
BELBIQ	2	0	0	2
BELEIQ	5	0	0	5
BELREQ	1	0	0	1
BELVIC	0	3	0	3
BELVICK	0	1	0	1
BELVIG	2	3	1	6
BELVIQ	4	0	7	11
BEVIQ	1	0	0	1
VALVIC	0	2	0	2
VALVIK	0	1	0	1
TOTAL	**15**	**10**	**8**	**33**

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 Belviq	Failure preventions
Belviq	Lorcaserin HCl	Look and Sound	The subject of this review
Benicar Benicar HCT	Olmesartan Medoxomil Olmesartan Medoxomil and Hydrochlorothiazide	Look	The pair have sufficient orthographic differences
Benylin	Diphenhydramine HCl Diphenhydramine HCl and Pseudoephedrine	Look	The pair have sufficient orthographic differences
Bricanyl	Terbutaline Sulfate	Look	The pair have sufficient orthographic differences
Angeliq	Drospirenone/Estradiol	Look	The pair have sufficient orthographic differences
Baciim	Bacitracin	Look	The pair have sufficient orthographic differences
Bentyl	Dicyclomine HCl	Look	The pair have sufficient orthographic differences
Bilivist	Iopodate sodium	Look	The pair have sufficient orthographic differences
Del-Aqua	Benzoyl peroxide	Look	The pair have sufficient orthographic differences
Gelnique	Oxybutinin Chloride	Sound	The pair have sufficient phonetic differences
Bellviq	Pharmaceutical preparations for human use, to treat or prevent obesity, for weight management, weight loss and the maintenance of weight loss.	Look and Sound	Name identified in Saegis and USPTO databases. The name is trademarked in USPTO and appears in Saegis by the same manufacturer of the proposed product, Belviq: Arena Pharmaceuticals. Unable to find product characteristics in any other commonly used drug databases referenced in section 4.
Belvir	N/A	Look and Sound	Name identified in Saegis database. Unable to find product characteristics in any other commonly used drug databases referenced in section 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.

Proposed name: ***Belviq*** ***(Lorcaserin HCl)*** **Dosage form and Strength(s):** ***Oral tablet: 10 mg*** **Usual dose:** ***One tablet by mouth twice daily***	**Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of name confusion** **Causes (could be multiple)**	**Prevention of Failure Mode** **In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names**
Del-vi-a (Vitamin A Palmitate) Dosage form and strength: Oral Capsule: 25,000 Units Usual dose: One capsule by mouth daily	**Orthographic similarity:** The letter 'B' and 'D' appear orthographically similar when scripted and both names contain the letter string 'elvi' when Delvia is written without hyphenation. **Strength:** Both are available as single strengths and may be omitted from a prescription. **Dosage form and route of administration:** Both are oral dosage forms.	**Orthographic difference:** Belviq contains a downstroke 'q' at the end on the name which is absent in Del-vi-a giving the names different shapes.
Pristiq (Desvenlafaxine Succinate) Dosage form and strength: Extended-release oral tablets: 50 mg, 100 mg Usual dose: One tablet by mouth daily	**Orthographic similarity:** Both names end in the letter string 'iq' Additionally, the beginning letter strings ('Be' vs. 'Pri') may appear similar when scripted. **Dosage form and route of administration:** Both are oral tablets.	**Orthographic difference:** Belviq contains an upstroke 'l' in the third position vs, Pristiq contains a cross stroke 't' in the fourth position. **Strength:** Single vs. multiple. Belviq is available in single strength and may be omitted from a prescription vs. an order for Pristiq will require strength as it is available in multiple strengths. There is numerical overlap between the two strengths during prescription writing *(10 mg vs. 100 mg)*

Proposed name: ***Belviq*** ***(Lorcaserin HCl)*** **Dosage form and Strength(s):** ***Oral tablet: 10 mg*** **Usual dose:** ***One tablet by mouth twice daily***	**Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of name confusion** **Causes (could be multiple)**	**Prevention of Failure Mode** **In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names**
Belix (Diphenhydramine HCl) Dosage form and strength: Oral solution: l2.5 mg/5 mL Usual dose: 25 to 50 mg (10 to 20 mL) by mouth every 4 to 6 hours. 50 mg (20 mL) by mouth at bedtime	**Orthographic similarity:** Both names begin with the letter string 'Bel' **Strength:** Both are available as single strengths and may be omitted from a prescription. **Dosage form and route of administration:** Both are oral dosage forms.	**Orthographic difference:** Belviq contains a downstroke 'q' at the end on the name which is absent in Belix giving the names different shapes.
Relief-SF (Acetaminophen, Chlorpheniramine, and Pseudoephedrine) Dosage form and strength: Oral caplet: 500 mg/2mg/30 mg Usual dose: One to two caplets by mouth every 6 hours **Relief PE** (Acetaminophen, Chlorpheniramine, and Phenylephrine) Dosage form and strength: Oral caplet: 500 mg/2mg/5 mg Usual dose: One to two caplets by mouth every 6 hour to 12 hours.	**Orthographic similarity:** The letter 'B' and 'R' appear orthographically similar when scripted and both names contain the letter string 'el' **Strength:** Both are available as single strengths and may be omitted from a prescription. **Dosage form and route of administration:** Both are oral dosage forms.	**Orthographic difference:** The names Relief contains a modifier, SF vs. PE that should be specified on the order. **Frequency:** Belviq is prescribed as twice daily (BID) vs. Relief-SF is prescribed every 6 hours.

Proposed name: ***Belviq*** ***(Lorcaserin HCl)*** **Dosage form and Strength(s):** ***Oral tablet: 10 mg*** **Usual dose:** ***One tablet by mouth twice daily***	**Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of name confusion** **Causes (could be multiple)**	**Prevention of Failure Mode** **In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names**
Kalmz (Fructose, Dextrose, and Phosphoric Acid) Dosage form and strength: Oral solution: 1.87 gm/1.87 gm/ 21.5 gm per 5 mL Usual dosage: 15-30 mL; repeat dose every 15 minutes until distress subsides; do not take for more than 1 hour (5 doses)	**Orthographic similarity:** The letter strings 'bel' and 'kel' appear orthographically similar when scripted. Also, both names end in a downstroke 'q' and 'z' **Strength:** Both are available as single strengths and may be omitted from a prescription. **Dosage form and route of administration:** Both are oral dosage forms.	**Frequency:** Belviq is taken twice daily (BID) vs. Kalmz is taken one-time then repeat every 15 minutes. **Dosing:** One tab vs. 15 mL or 30 mL
Multaq (Dronedarone HCl) Dosage form and strength: Oral tablet: 400 mg Usual dose: One tablet by mouth twice daily	**Orthographic similarity:** The letter strings 'Bel' and 'Mul' appear orthographically similar when scripted. Also, both names end in a downstroke 'q' **Strength:** Both are available as single strengths and may be omitted from a prescription. **Dosage form and route of administration:** Both are oral dosage forms.	**Orthographic difference:** Multaq contains a cross stroke 't' in the fourth position which is absent in Belviq giving the names different shapes.

Proposed name: ***Belviq*** ***(Lorcaserin HCl)*** **Dosage form and Strength(s):** ***Oral tablet: 10 mg*** **Usual dose:** ***One tablet by mouth twice daily***	**Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of name confusion** **Causes (could be multiple)**	**Prevention of Failure Mode** **In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names**
Benziq **Benziq LS** (Benzoyl Peroxide) Dosage form and strength: External Gel: 5.25% LS: External gel: 2.75% Wash: External liquid: 5.25% Usual dose for Gel: Apply or use once or twice daily Usual Dose For Wash: Wash affected area once to twice daily.	**Orthographic similarity:** Both names begin with the letter string 'Be' and end with the letter string 'iq'	**Orthographic difference:** Belviq contains an upstroke 'l' which is absent in Benziq giving the names different shapes. **Strength:** Single vs. multiple. Belviq is available in single strength and may be omitted from a prescription vs. an order for Benziq will require strength, modifier, or a dosage form as it is available in multiple strengths for both Gel and Wash. There is no numerical overlap between the two strengths during prescription writing. **Dosing:** One tablets vs. apply to affected area or wash affected area. **Dosage form:** Benziq is available in two dosage forms (external gel and Wash), Thus, a modifer, a dosage form, strength, or directions must be specified on the prescription.

Proposed name: ***Belviq*** ***(Lorcaserin HCl)*** **Dosage form and Strength(s):** ***Oral tablet: 10 mg*** **Usual dose:** ***One tablet by mouth twice daily***	**Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of name confusion** **Causes (could be multiple)**	**Prevention of Failure Mode** **In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names**
Luxiq (Betamethasone Valerate) Dosage form and strength: External Foam 0.12% Usual dose: Apply twice daily (once in the morning and once in the evening)	**Orthographic similarity:** Both names end in the letter string 'iq' **Strength:** Both are available as single strengths and may be omitted from a prescription. **Frequency:** Both are prescribed twice daily.	**Orthographic difference:** The letters 'B' and 'L' appear orthographically different when scripted. Belviq contains an upstroke 'l' in the third position which is absent is Luxiq giving the names different shapes.
Halog (Halcinonide) Dosage form and strength: External ointment and cream: 0.1% Usual dosage: Apply the cream or ointment to the affected area 2 to 3 times daily	**Orthographic similarity:** The letter strings 'bel' and 'hal' appear orthographically similar when scripted. Also, both names end in a downstroke 'q' and 'g' **Strength:** Both are available as single strengths and may be omitted from a prescription.	**Orthographic difference:** The letter strings 'vi' and 'o' appear orthographically different when scripted. **Dosing:** One tablets vs. apply to affected area or wash affected area.

Proposed name: ***Belviq*** ***(Lorcaserin HCl)*** **Dosage form and Strength(s):** ***Oral tablet: 10 mg*** **Usual dose:** ***One tablet by mouth twice daily***	**Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of name confusion** **Causes (could be multiple)**	**Prevention of Failure Mode** **In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names**
Reluri (Guiafenesin/Phenylephrine) Dosage form and strength: Oral tablet: 1200mg/30 mg Usual dose: One tablet by mouth every 12 hours	**Orthographic similarity:** The letter 'B' and 'R' appear orthographically similar when scripted. Both names contain the letter string 'el' and 'v' and 'u' also appear orthographically similar when scripted. **Strength:** Both are available as single strengths and may be omitted from a prescription. **Frequency:** Both are taken twice daily **Dosage form and route of administration:** Both are oral tablets.	**Orthographic difference:** Belviq contains a downstroke 'q' at the end of the name which is absent in Reluri giving the names different shapes.
Beldin (Diphenhydramine HCl) Dosage form and strength: Oral solution: l2.5 mg/5 mL Usual dose: 25 to 50 mg (10 to 20 mL) by mouth every 4 to 6 hours. 50 mg (20 mL) by mouth at bedtime	**Orthographic similarity:** Both names begin with the letter string 'Bel' **Strength:** Both are available as single strengths and may be omitted from a prescription. **Dosage form and route of administration:** Both are oral dosage forms.	**Orthographic difference:** Beldin contains an upstroke 'd' in the fourth position which is absent in Belviq and Belviq contains a downstroke 'q' at the end of the name which is absent in Beldin giving the names different shapes. **Frequency:** Belviq is taken twice daily (BID) vs. Beldin is taken every 4 to 6 hours or at bedtime (QHS)

Proposed name: ***Belviq*** ***(Lorcaserin HCl)*** **Dosage form and Strength(s):** ***Oral tablet: 10 mg*** **Usual dose:** ***One tablet by mouth twice daily***	**Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of name confusion** **Causes (could be multiple)**	**Prevention of Failure Mode** **In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names**
Balziva (Ethinyl estradiol and Norethindrone) Dosage form and strength: Oral tablets: 0.035 mg/0.4 mg Usual dose: One tablet by mouth once daily	**Orthographic similarity:** Both names begin with the letter 'B' and the letter string 'el' and 'al' appears orthographically similar when scripted. **Strength:** Both are available as single strengths and may be omitted from a prescription. **Dosage form and route of administration:** Both are oral tablets.	**Orthographic difference:** Belviq contains a downstroke 'q' at the end of the name which is absent in Balziva giving the names different shapes. Additionally, the letter 'q' in Belviq lacks orthographic similarity to the letter string 'va' in Balziva.
Zolvit (Hydrocodone/Acetaminophen) Dosage form and strength: Oral solution: 10 mg/300 mg per 15 ml Usual dose: Take 3.75 to 15 mL (3/4 to 3 teaspoonful) by mouth every 4 to 6 hours as needed for pain	**Orthographic similarity:** Both names contain the letter string 'lvi' in similar positions. **Strength:** Both are available as single strengths and may be omitted from a prescription. **Dosage form and route of administration:** Both are oral dosage forms.	**Orthographic difference:** The letter 'Z' and 'B' appear orthographically different when scripted. Also, Belviq contains a downstroke 'q' while Zolvit contains a cross stroke 't' in the last position. **Frequency:** Belviq is taken twice daily (BID- scheduled) vs. Zolvit is taken every 4 to 6 hours as needed

Proposed name: ***Belviq*** ***(Lorcaserin HCl)*** **Dosage form and Strength(s):** ***Oral tablet: 10 mg*** **Usual dose:** ***One tablet by mouth twice daily***	**Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of name confusion** **Causes (could be multiple)**	**Prevention of Failure Mode** **In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names**
Actiq (Fentanyl Citrate) Dosage form and strength: Buccal Lollipop: 200 mcg, 400 mcg, 600 mcg, 800 mcg, 1200 mcg, 1600 mcg Usual dose: 200 mcg to 1600 mcg 1 to 4 times daily	**Orthographic similarity:** Both names end in the letter string 'iq. Additionally, both names contain 2 upstrokes in 1st and 3rd positions and downs troke in the last position of the names.	**Orthographic difference:** The letter 'A' and 'B' appear orthographically different when scripted. . **Strength:** Single vs. multiple. Belviq is available in single strength and may be omitted from a prescription vs. an order for Actiq will require strength as it is available in multiple strengths. There is no numerical overlap between the two strengths during prescription writing.
Mobic (Meloxicam) Dosage Strength: Oral tablet: 7.5 mg, 15 mg Oral suspension: 7.5 mg/5 mL Usual dosage: Adults: 7.5 to 15 mg once daily Children: 1.5 mg to 7.5 mg once daily	**Orthographic similarity:** The letter strings 'Bel' and 'Mob' appear orthographically similar when scripted. **Dosage form and route of administration:** Both are oral dosage forms.	**Orthographic difference:** Belviq contains a downstroke 'q' at the end on the name which is absent in Mobic giving the names different shapes. **Strength:** Single vs. multiple. Belviq is available in single strength and may be omitted from a prescription vs. an order for Mobic will require strength as it is available in multiple strengths. There is no numerical overlap between the two strengths during prescription writing.

Proposed name: ***Belviq*** ***(Lorcaserin HCl)*** **Dosage form and Strength(s):** ***Oral tablet: 10 mg*** **Usual dose:** ***One tablet by mouth twice daily***	**Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of name confusion** **Causes (could be multiple)**	**Prevention of Failure Mode** **In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names**
Relpax (Eletriptan HBr) Dosage form and strength: Oral tablets: 20 mg, 40 mg Usual dose: One tablet (20 or 40 mg) as a single dose; if the headache improves but then returns, a repeat dose may be taken at least 2 hours after the initial dose	**Orthographic similarity:** The letter 'B' and 'R' appear orthographically similar when scripted and both names contain the letter string 'el' **Dosage form and route of administration:** Both are oral tablets.	**Orthographic difference:** Belviq contains a downstroke 'q' at the end on the name which is absent in Relpax. Also, Relpax contains a downstroke in the fourth position which is absent in Belviq giving the names different shapes. **Strength:** Single vs. multiple. Belviq is available in single strength and may be omitted from a prescription vs. an order for Relpax will require strength as it is available in multiple strengths. There is no numerical overlap between the two strengths during prescription writing *(10 mg vs. 20 mg and 40 mg)* **Frequency:** Belviq is taken twice daily (BID-scheduled) vs. Relpax is taken at onset of headache and may repeat after two hours (as needed).

Proposed name: ***Belviq*** ***(Lorcaserin HCl)*** **Dosage form and Strength(s):** ***Oral tablet: 10 mg*** **Usual dose:** ***One tablet by mouth twice daily***	**Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of name confusion** **Causes (could be multiple)**	**Prevention of Failure Mode** **In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names**
Balmex (Zinc Oxide) Dosage form and strength: External cream Usual dose: Apply liberally as needed	**Orthographic similarity:** Both names begin with the letter 'B' and the letter string 'el' and 'al' appears orthographically similar when scripted. **Strength:** Both are available as single strengths and may be omitted from a prescription.	**Orthographic difference:** Belviq contains a downstroke 'q' which is absent in Balmex giving the names different shapes. Additionally, the ending letter strings of the names 'viq' and 'mex' lack orthographic similarity when scripted.
Rebif (Interferon Beta-1a) Dosage form and strength: Subcutaneous solution: 22 mcg/0.5 mL, 44 mcg/0.5 mL Usual dose: 22 or 44 mcg injected subcutaneously 3 times per week	**Orthographic similarity:** The letter string 'Bel' and 'Reb' appear orthographically similar when scripted	**Strength:** Single vs. multiple. Belviq is available in single strength and may be omitted from a prescription vs. an order for Pristiq will require strength as it is available in multiple strengths. There is no numerical overlap between the two strengths during prescription writing. **Frequency:** Belviq is taken twice daily (BID) vs. Rebif is given 3 times per week.

Proposed name: ***Belviq*** ***(Lorcaserin HCl)*** **Dosage form and Strength(s):** ***Oral tablet: 10 mg*** **Usual dose:** ***One tablet by mouth twice daily***	**Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of name confusion** **Causes (could be multiple)**	**Prevention of Failure Mode** **In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names**
Rulox (Aluminum Hydroxide Magnesium Hydroxide, and Simethicone) Dosage form and strength: Oral suspension: 500 mg/450 mg/40 mg per 5 mL Usual dose: Adults: 10 to 20 mL (2 to 4 teaspoonfuls) by mouth between meals, at bedtime Children: 5 to 15 mL (1 to 3 teaspoonfuls) by mouth every 3 to 6 hours, or 1 to 3 hours after meals and at bedtime	**Orthographic similarity:** The letter strings "Rul' and 'Bel' appear orthographically similar when scripted. **Strength:** Both are available as single strengths and may be omitted from a prescription. **Dosage form and route of administration:** Both are oral dosage forms.	**Orthographic difference:** Belviq contains a downstroke 'q' at the end on the name which is absent in Rulox giving the names different shapes.

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

/s/

YELENA L MASLOV on behalf of REASOL AGUSTIN
05/01/2012

YELENA L MASLOV
05/01/2012

CAROL A HOLQUIST
05/02/2012

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

Date:	February 12, 2010
To:	Mary Parks, MD, Director Division of Metabolism and Endocrinology Products
Through:	Melina Griffis RPh, Team Leader Denise Toyer, PharmD, Deputy Director Carol Holquist, RPh, Director Division of Medication Error Prevention and Analysis (DMEPA)
From:	Richard Abate, RPh, MS, Safety Evaluator Division of Medication Error Prevention and Analysis (DMEPA)
Subject:	Proprietary Name Review
Drug Name(s):	Lorqess (Lorcaserin Hydrochloride) Tablets
Application Type/Number:	IND 069888
Sponsor:	Arena Pharmaceuticals, Inc.
OSE RCM #:	2009-1601

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CONTENTS

EXECUTIVE SUMMARY

Lorqess is the proposed proprietary name for Lorcaserin Hydrochloride Tablets. This proposed name was evaluated from a safety and promotional perspective based on the product characteristics provided by the Sponsor. We sought input from pertinent disciplines involved with the review of this application and considered it accordingly. The results of our assessment found the proposed name, Lorqess, is potentially vulnerable to name confusion that could lead to medication error with another proposed proprietary name for a pending application with the Agency, Loryna*** (ANDA 079221). At this time the acceptability of the proposed proprietary name, Lorqess, is dependent on which application is approved first. If Lorqess is approved for marketing first, we will request the Applicant for Loryna*** seek an alternative name for that product.

The proposed proprietary name, Lorqess, must be re-reviewed upon submission of the NDA and 90 days before approval of the NDA. Additionally, if any of the proposed product characteristics as stated in this review are altered, DMEPA rescinds this finding and the name must be resubmitted for review. The conclusions upon re-review are subject to change.

1 BACKGROUND

1.1 INTRODUCTION

This review is in response to a request from Arena Pharmaceuticals on August 18, 2009, for an assessment of the proposed proprietary name, Lorqess, regarding potential name confusion with other proprietary or established drug names in the usual practice settings. The Sponsor submitted an external study in support of their proposed proprietary name.

1.2 PRODUCT INFORMATION

Lorqess is the proposed proprietary name for Locaserin Hydrochloride tablets currently being evaluated under an Investigational New Drug (IND) for the management of obesity including weight loss and the maintenance of weight loss in conjunction with a reduced-calorie diet and a program of regular exercise. Lorqess will be available as a 10 mg tablet to be taken orally twice a day. Lorqess is proposed to be packaged in bottles of 100 tablets and sample blister cards containing 10 tablets. Both will be stored at room temperature (15º-30º C).

2 METHODS AND MATERIALS

Appendix A describes the general methods and materials used by the Division of Medication Error Prevention and Analysis (DMEPA) when conducting a proprietary name risk assessment for all proprietary names. Sections 2.1, 2.2, and 2.3 identify specific information associated with the methodology for the proposed proprietary name, Lorqess.

2.1 SEARCH CRITERIA

For this review, particular consideration was given to drug names beginning with the letter 'L' when searching to identify potentially similar drug names, as 75% of the confused drug names

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reported by the USP-ISMP Medication Error Reporting Program involve pairs beginning with the same letter.[1,2]

To identify drug names that may look similar to Lorqess, the DMEPA staff also considers the orthographic appearance of the name on lined and unlined orders. Specific attributes taken into consideration include the length of the name (seven letters), upstrokes (one, capital letter 'L' or lower case 'l'), down strokes (one, lower case 'q'), cross strokes (none), and dotted (none). The name Lorqess includes the letter 'q' without the letter 'u.' However, as the letter 'q' is usually followed by the letter 'u' in the English language, practitioners are likely to write Lorqess with the letter 'u' after the letter 'q' (i.e., Lorquess). Therefore, DMEPA evaluated the name Lorqess with and without the letter 'u' added. Additionally, several letters in Lorqess may be vulnerable to ambiguity when scripted (See Appendix B). As a result, the DMEPA staff also considers these alternate appearances when identifying drug names that may look similar to Lorqess.

When searching to identify potential names that may sound similar to Lorqess, the DMEPA staff search for names with similar number of syllables (Two), stresses (LOR-kess or lor-KESS), and placement of vowel and consonant sounds. (See Appendix B) Additionally, the DMEPA staff considers that pronunciation of parts of the name can vary such as "-qess" may be mispronounced as "-quess." The Sponsor's intended pronunciation (lor-KESS) was also taken into consideration, as it was included in the Proprietary Name Review Request. Moreover, names are often mispronounced and/or spoken with regional accents and dialects, so other potential pronunciations of the name are considered.

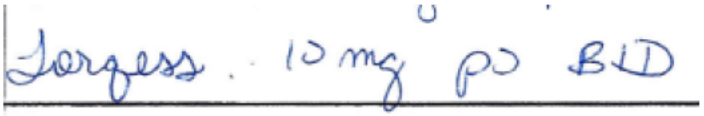
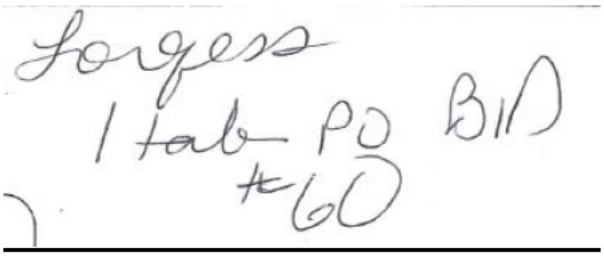
2.2 FDA PRESCRIPTION ANALYSIS STUDIES

In order to evaluate the potential for misinterpretation of the proposed proprietary name in handwriting and verbal communication of the name, the following inpatient medication order, outpatient and verbal prescription was communicated during the FDA prescription studies.

[1] Institute for Safe Medication Practices. Confused Drug name List (1996-2006). Available at http://www.ismp.org/Tools/confuseddrugnames.pdf

[2] Kondrack, G and Dorr, B. Automatic Identification of Confusable Drug Names. Artificial Intelligence in Medicine (2005)

Figure 1. Lorqess Study (conducted on September 14, 2009)

HANDWRITTEN REQUISITION MEDICATION ORDER	VERBAL PRESCRIPTION
Medication Order :   	Lorqess 10 mg Dispense #60 One tablet po bid

2.3 External Proprietary Name Risk Assessment

For this product, the Sponsor submitted an external evaluation of the proposed proprietary name. The Division of Medication Error Prevention and Analysis conducts an independent analysis and evaluation of the data provided, and responds to the overall findings of the assessment. When the external proprietary name risk assessment identifies potentially confusing names that were not captured in DMEPA's database searches or in the Expert Panel Discussion, these names are included in the Safety Evaluator's Risk Assessment and analyzed independently by the Safety Evaluator to determine if the potentially confusing name could lead to medication errors in usual practice settings. After the Safety Evaluator has determined the overall risk associated with proposed name, the Safety Evaluator compares the findings of their overall risk assessment with the findings of the proprietary name risk assessment submitted by the Sponsor. The Safety Evaluator then determines whether the Division's risk assessment concurs or differs with the findings. When the proprietary name risk assessments differ, the Division of Medication Error Prevention and Analysis provides a detailed explanation of these differences.

3 RESULTS

3.1 Database and Information Sources

The searches yielded a total of twenty-two names as having some similarity to the name Lorqess.

Seventeen of the names were thought to look like Lorqess. These include: Corfen DM, Corgard, Corque, Fergon, Lagesic, Lapase, Largon, (b) (4)***, Lopressor, Loprox, Lortuss DM, Lortuss HC, Loryna***, Lupron, Tequin, Zagam, and Ziagen. Two of the names were thought to sound

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like Lorqess. These include: Clorpres and Low-quel. The remaining three names were thought to look and sound similar to Lorqess: Lorcet, Lorcet HD and Lucassin***.

Additionally, DMEPA staff did not identify any United States Adopted Names (USAN) stems in the proposed proprietary name, as of December 18, 2009.

3.2 EXPERT PANEL DISCUSSION

The Expert Panel reviewed the pool of names identified by DMEPA staff (See Section 3.1 above) and noted no additional names thought to have orthographic or phonetic similarity to Lorqess.

DDMAC had no concerns regarding the proposed name from a promotional perspective, and did not offer any additional comments relating to the proposed name.

3.3 FDA PRESCRIPTION ANALYSIS STUDIES

A total of eighteen practitioners responded with one of the responses overlapping with an existing name (Lortab), which will be included in the Safety Evaluator Assessment. Five of the participants interpreted the name correctly as "Lorqess," with correct interpretation occurring in the inpatient written studies. The remainder of the written responses misinterpreted the drug name. In the verbal studies, all responses were misspelled phonetic variations of the proposed name, Lorqess. See Appendix B for the complete listing of interpretations from the verbal and written prescription studies.

3.4 EXTERNAL STUDY

In the proposed name risk assessment submitted by the Sponsor, (b) (4) identified no names thought to have some potential for confusion with the name Lorqess. Thus, their conclusion stated, "Lorqess has low vulnerability from the safety standpoint."

3.5 SAFETY EVALUATOR RISK ASSESSMENT

Independent searches by the primary Safety Evaluator resulted in five additional names which were thought to look or sound similar to Lorqess and represent a potential source of drug name confusion.

The names identified to have look-alike similarities are Lorazepam, Lovaza, Zorprin, and Zortress***. The name, Klorvess, was identified to have sound-alike similarities. Thus, we evaluated a total of 28 names: one identified from the FDA Prescription Analysis Studies, five identified by the primary safety evaluator and 22 identified in section 3.1 above.

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3.6 COMMENTS FROM THE DIVISION OF METABOLISM AND ENDOCRINOLOGY PRODUCTS (DMEP)

3.6.1 Initial Phase of Review

In response to the OSE Date, September 28, 2009 e-mail, Division of Metabolism and Endocrinology Products (DMEP) did not forward any comments and/or concerns on the proposed name at the initial phase of the name review.

3.6.2 Midpoint of Review

DMEPA notified the Division of Metabolism and Endocrinology Products via e-mail that we had concerns with the proposed proprietary name, Lorqess, on December 28, 2009. Per e-mail correspondence from the Division of Metabolism and Endocrinology Products on January 5, 2010, they indicated they concur with our assessment of the proposed proprietary name, Lorqess.

4 DISCUSSION

This proposed name, Lorqess, was evaluated from a safety and promotional perspective. Furthermore, input from pertinent disciplines involved with the review of this application was considered accordingly.

4.1 PROMOTIONAL ASSESSMENT

DDMAC had no concerns regarding the proposed name from a promotional perspective, and did not offer any additional comments relating to the proposed name. DMEPA and the Division of Metabolic and Endocrinology Products concurred with the findings of DDMAC's promotional assessment of the proposed name.

4.2 SAFETY ASSESSMENT

DMEPA evaluated 28 names for their potential similarity to the proposed name, Lorqess. No other aspects of the name were considered to pose potential confusion with the name.

Failure mode and effect analysis (FMEA) was applied to determine if the proposed proprietary name could potentially be confused with the 28 names and lead to medication errors. This analysis determined that the name similarity between Lorqess and twenty-seven of the 28 identified names was unlikely to result in medication error for the reasons presented in Appendices D through H.

The remaining name Loryna*** (ANDA 079221), which is currently under review by the Agency was found to be vulnerable to confusion with Lorqess.

*4.2.1 Look-Alike Similarity to Loryna****

The orthographic similarity of Lorqess and Loryna*** stems from the fact that both names begin with the same three letters 'Lor' and the fourth letter in each name provides a down stroke in the same position ('q' vs. 'y'). Additionally, the names contain a similar number of letters (seven vs. six) providing a similar length to the names. (See samples below.)

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

In addition, the shared product characteristics between Lorqess and Loryna*** add to user confirmation bias that may result in medication error. Both Lorqess and Loryna*** are available as a single strength oral tablet. Post-marketing surveillance of medication errors demonstrates prescribers may omit the strength of products when writing prescriptions for medications available in a single strength. Loryna*** is an oral contraceptive that is likely to be ordered in number of months with the directions for use of "As directed." Thus, DMEPA believes that the orthographic similarity would lead to prescription written for "Loryna*** 1 month supply as directed" may be misinterpreted as " Lorqess one month supply as directed" and the pharmacist would dispense 60 tablets of Lorqess. Alternatively, should the prescriber put the quantity of Loryna*** (#28) as directed, the pharmacist would likely dispense 28 tablets of Lorqess for a two week supply of this medication.

4.2.2 External Name Study

We note our assessment differs from the conclusions of (b) (4) external name review. However, the name we found likely to be confused with Lorqess is a product still under review by the Agency and not publicly available.

5 CONCLUSIONS AND RECOMMENDATIONS

The Proprietary Name Risk Assessment findings indicate that the proposed name, Lorqess, is not promotional but is vulnerable to name confusion that could lead to medication errors with Loryna*** a proposed proprietary name of a pending ANDA (079221) under review with the Agency. Therefore , at this time, the acceptability of the proposed proprietary name, Lorqess, is dependent upon which application is approved first.

The proposed proprietary name, Lorqess, must be re-reviewed upon submission of the NDA and 90 days before approval of the NDA. Additionally, if any of the proposed product characteristics as stated in this review are altered, DMEPA rescinds this finding and the name must be resubmitted for review. The conclusions upon re-review are subject to change.

If you have further questions or need clarifications, please contact Margarita Tossa, project manager, at 301-796-4053.

5.1 COMMENTS TO THE SPONSOR

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

5.1.1 Proprietary Name

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

Lorqess must be resubmitted and re-reviewed at the time of the NDA submission. If we find the name unacceptable following the re-review or the other application is approved prior to yours, we will notify you and request an alternative name be submitted for your application.

6 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. Stat!Ref (www.statref.com)

Stat!Ref contains full-text information from approximately 30 texts; it includes tables and references. Among the database titles are: Handbook of Adverse Drug Interactions, Rudolphs Pediatrics, Basic Clinical Pharmacology, and Dictionary of Medical Acronyms Abbreviations.

13. USAN Stems (http://www.ama-assn.org/ama/pub/category/4782.html)

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 potential for confusion between the proposed proprietary name and the proprietary and established names of drug products existing in the marketplace and those pending IND, NDA, BLA, and ANDA products currently under review by the Center. DMEPA defines a medication error as any preventable event that may cause or lead to inappropriate medication use or patient harm while the medication is in the control of the health care professional, patient, or consumer. [3]

For the proposed proprietary name, DMEPA staff search a standard set of databases and information sources to identify names with orthographic and phonetic similarity and hold a Center for Drug Evaluation and Research (CDER) Expert Panel discussion to gather professional opinions on the safety of the proposed proprietary name. DMEPA staff also conducts internal CDER prescription analysis studies. When provided, DMEPA considers external prescription analysis study results and incorporate into the overall risk assessment.

The Safety Evaluator assigned to the Proprietary Name Risk Assessment is responsible for considering the collective findings, and provides an overall risk assessment of the proposed proprietary name. DMEPA bases

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

the overall risk assessment on the findings of a Failure Mode and Effects Analysis (FMEA) of the proprietary name, and focuses on the avoidance of medication errors.

FMEA is a systematic tool for evaluating a process and identifying where and how it might fail. [4] DMEPA uses FMEA to analyze whether the drug names identified with orthographic or phonetic similarity to the proposed proprietary name could cause confusion that subsequently leads to medication errors in the clinical setting. 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.

In addition, the product characteristics provide the context for the verbal and written communication of the drug names and can interact with the orthographic and phonetic attributes of the names to increase the risk of confusion when there is overlap or, in some instances, decrease the risk of confusion by helping to differentiate the products through dissimilarity. Accordingly, the DMEPA staff considers the product characteristics associated with the proposed drug 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.

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. Because drug name confusion can occur at any point in the medication use process, DMEPA staff 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.[5] DMEPA provides the product characteristics considered for this review in section one.

The Division of Medication Error Prevention and Analysis considers the spelling of the name, pronunciation of the name when spoken, and appearance of the name when scripted. DMEPA also compares the spelling of the proposed proprietary name with the proprietary and established name of existing and proposed drug products because similarly in spelled names may have greater likelihood to sound similar to one another when spoken or look similar to one another when scripted. DMEPA staff also examines the orthographic appearance of the proposed name using a number of different handwriting samples. Handwritten communication of drug names has a long-standing association with drug name confusion. Handwriting can cause similarly and even dissimilarly spelled drug name pairs to appear very similar to one another. The similar appearance of drug names when scripted has led to medication errors. The DMEPA staff applies expertise gained from root-cause analysis of such 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). In addition, the DMEPA staff 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. 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.

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

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

Table 1. Criteria used to identify drug names that look- or sound-similar to a proposed proprietary name.

Type of similarity	**Considerations when searching the databases**		
	Potential causes of drug name similarity	*Attributes examined to identify similar drug names*	*Potential Effects*
Look-alike	Similar spelling	Identical prefix Identical infix Identical suffix Length of the name Overlapping product characteristics	• Names may appear similar in print or electronic media and lead to drug name confusion in printed or electronic communication • Names may look similar when scripted and lead to drug name confusion in written communication
	Orthographic similarity	Similar spelling Length of the name 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, the DMEPA staff also 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 staff conducts searches of 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 using the criteria outlined in Section 2.1. Section 6 provides a standard description of the databases used in the searches. To complement the process, the DMEPA staff use 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, the DMEPA staff review 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.

2. CDER Expert Panel Discussion

DMEPA conducts an Expert Panel Discussion to gather CDER professional opinions on the safety of the proposed product and the proposed proprietary name. 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). 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 DMEPA staff to the Expert Panel for consideration. Based on the clinical and professional experiences of the Expert Panel members, the Panel may recommend the addition of 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 Analysis 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 the 123 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 send their interpretations of the orders via e-mail to DMEPA.

4. Comments from the OND review Division or Generic drugs

DMEPA requests the Office of New Drugs (OND) or Office of Generic Drugs (OGD) Regulatory Division responsible for the application for their comments or concerns with the proposed proprietary name and 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 or 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 concur/not concur with DMEPA's final decision.

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, conducts a Failure Mode and Effects Analysis, and provides an overall 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.[6] 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 Section one. 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?"***

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. 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.

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 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

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

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.

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 is likely to recommend that the Sponsor select an alternative proprietary name and submit the alternate name to the Agency for DMEPA to 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 Sponsor. However, the safety concerns set forth in criteria a through e 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 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 a 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. . (See Section 4 for limitations of the process).

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 is likely to recommend that the Sponsor select an alternative proprietary name and submit the alternate name to the Agency for DMEPA to 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.

Appendix B: Letters with possible orthographic or phonetic misinterpretation

Letters in Name, Lorqess	Scripted may appear as	Spoken may be interpreted as
Capital 'L'	I, T, or Z	'N'
lower case '1'	b, c, e, or i	'n'
lower case 'o'	a, c u, or v	any vowel
lower case 'r'	n, s, t, or v	'w'
lower case 'q' usually followed by a 'u'	g, p, y, or z -	'k' 'kw'
lower case 'e'	c, i, or l	any vowel
lower case 's' as grouping 'ss'	a, n, or r m	'c' or followed by a silent 'e'

Appendix C: **FDA Prescription Study Responses.**

Inpatient Medication Order	Outpatient Prescription	Voice Prescription
Lorqess	Lorgess	Lorkess
Tergess	Lorqess	lorkess
Lorqess	Lorgess	Lorcast
Lorgess	Lorfess	Lorques
	Lorqess	Lortab
	Loqess	
	Lorgess	
	Lorgess	
	Lorqess	

Appendix D: Discontinued products with no available generics

Proprietary Name	Active Ingredient	Similarity to Lorqess
Corque	Clioquinol and hydrocortisone	Look
Tequin	Gatifloxacin	Look
Zagam	Sparfloxacin	Look
Lapase	Lipase, protease and amylase	Look
Largon	Propiomazine HCl	Look

Appendix E: Proposed Alternate Proprietary name for product under review by Agency

Proprietary Name	Similarity to Lorqess
(b) (4) ***	Look

Appendix F: Branded generic which is no longer marketed

Proprietary Name	Active Ingredient	Similarity to Lorqess	Failure preventions
Low-quel	Diphenoxylate HCl and Atropine Sulfate	Look and Sound	Branded generic equivalent for Lomotil which was withdrawn from the Agency in 1995.

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

Appendix G: Risk of name confusion minimized by preventions listed. (Potential contributing causes highlighted by *italics*)

Product name with potential for confusion	Similarity to Proposed Proprietary Name	Strength	Usual Dose (if applicable)	Failure Mode of name confusion prevented by the combination of stated product characteristics as well as orthographic and/or phonetic differences as described.
Lorqess **(Lorcaserin)**		**10 mg** **(Strength may be omitted during the prescription or procurement steps of medication use process for single strength products.)**	**One tablet by mouth twice daily**	
Clorpres (Chlorthalidone and Clonidine HCl)	Look and sound	15 mg/0.1 mg, 15 mg/0.2 mg, and 15 mg/0.3 mg tablets	*One tablet* (any strength) by mouth once daily or *twice daily*.	**Orthographic differences:** Clorpres includes two upstrokes at the beginning of the name provided by 'Cl' rather than one. **Phonetic differences:** The 'kuh' sound begins the first syllable in Clorpess vs. the second in Lorqess; The second syllable in Clorpres begins with a 'p.' **Clorpres is a combination product with multiple strengths, none of which overlap with the proposed product.**
Corfem DM (Chlorpheniramine, Phenylephrine HCl, and Dextromethorphan HBr)	Look	4mg/10 mg/15 mg per 5 mL oral liquid *(Single Strength)*	Adult: *One* teaspoonful (5 mL) by mouth every four to six hours as needed. Pediatric : (6 to 12 years): One half teaspoonful (2.5 mL) by mouth every four to six hours.	**Orthographic differences:** The 'f' provides an up stroke and potentially a cross stroke in the name where there is a down stroke in the proposed name. **Dosage form:** oral liquid vs. tablet **Frequency of administration:** every four to six hours vs. twice daily
Corgard (Nadolol)	Look	20 mg, 40 mg, 80 mg tablets	*One tablet* (20 mg, 40 mg, or 80 mg) by mouth daily	**Orthographic difference:** The letter 'd' provides an upstroke at the end of the name. **Corgard is available in multiple strengths of which none overlap with the proposed product.** Lorqess may achieve 20 mg with two tablets. Lorqess does not have a dose other than 10 mg under evaluation. **Frequency of administration:** Once daily vs. twice daily.

Product name with potential for confusion	Similarity to Proposed Proprietary Name	Strength	Usual Dose (if applicable)	Failure Mode of name confusion prevented by the combination of stated product characteristics as well as orthographic and/or phonetic differences as described.
Lorqess **(Lorcaserin)**		**10 mg** **(Strength may be omitted during the prescription or procurement steps of medication use process for single strength products.)**	**One tablet by mouth twice daily**	
Fergon (Ferrous gluconate)	Look	240 mg tablet (containing 27 mg of iron) *(Single Strength)*	*One tablet* (240 mg) *by mouth* daily with food	**Orthographic difference:** The beginning letter 'F' provides a cross stroke not seen in Lorqess. **Frequency of administration:** Once daily vs. twice daily.
Klorvess (Potassium Chloride)	Sound	20 mEq effervescent granules per packet *(Single strength product)*	One or two (20 mEq to 40 mEq) packet diluted in eight ounces of water or juice by mouth daily.	**Phonetic differences:** The first syllable starts with the 'kuh' sound and the second syllable starts with a 'v' sound. **Dosage form:** Effervescent granules require manipulation prior to administration.
Lopressor (metoprolol tartrate)	Look	50 mg and *100 mg* tablets 5 mg/5 mL ampuls	*One* or two *tablets* (50 mg to 200 mg) *by mouth twice daily* or One tablet by mouth every six hours. One ampule (5 mg) intravenously every two to three minutes for three doses.	**Orthographic differences:** Lopressor is longer by two letters and these letters, '-or' appear at the end of the name.
Loprox (Ciclopirox)	Look	0.77 % cream, gel, and topical suspension 1% shampoo	Cream, gel and topical suspension: Apply topically to affected area *twice daily*. Shampoo: Apply as shampoo to hair twice a week	**Strength and units:** 0.77% or 1 % vs. 10 mg **Dosage form:** cream, gel, shampoo, and topical suspension vs. tablet. **Route of administration:** topical vs. oral
Lorazepam (established name for Ativan)	Look	0.5 mg, 1 mg and 2 mg tablets, 2 mg/mL oral concentrate, 2 mg/mL, 20 mg/10 mL, 4 mg/mL, and 40 mg/10 mL	Preanesthetic: 0.05 mg/kg up to 4 mg intramuscularly one time or 0.044 mg/kg up to 2 mg intravenously once. Status epilepticus: 4 mg intravenously once, may repeat. Anxiety: 0.5 mg, 1 mg, or 2 mg (*one* or	**Orthographic differences:** Lorazepam contains two additional letters and may contain two down strokes. **Dosage forms:** multiple (injection, oral concentrate as well as shared form tablet) vs. single **Two of the dosage forms are available in multiple strengths.**

Product name with potential for confusion	Similarity to Proposed Proprietary Name	Strength	Usual Dose (if applicable)	Failure Mode of name confusion prevented by the combination of stated product characteristics as well as orthographic and/or phonetic differences as described.
Lorqess **(Lorcaserin)**		**10 mg** **(Strength may be omitted during the prescription or procurement steps of medication use process for single strength products.)**	**One tablet by mouth twice daily**	
		injection	two *tablets*) by mouth or intravenously *twice daily* or three times daily.	
Lorcet (Hydrocodone bitartrate and acetaminophen) Lorcet HD	Sound	HD-5 mg/500 mg capsule (discontinued with generic equivalents marketed) PLUS-7.5 mg/ 650 mg capsule 10/650 - 10 mg/ 650 mg capsule	HD *One* or two capsules *by mouth* every six hours. Plus and 10/650: *One* capsule by mouth every four to six hours.	**Phonetic differences:** The second syllable of Lorcet begins with the 'ss' sound and ends with the 't' vs. Lorqess which begins with the 'kuh' sound and ends with the 'ss' sound. **Lorcet is a combination product with multiple strengths. Need to use a strength or modifier for a complete prescription.** **Frequency of administration:** every four or six hours vs. twice daily.
Lortuss DM (Brompheniramine maleate, Dextromethorphan HBr, and Phenylephrine HCl) (Discontinued unapproved product with similar generic equivalents on the market)	Look and sound	2 mg/15 mg/ 7.5 mg per 5 mL *(Single Strength)*	Adults: Two teaspoonfuls (10 mL) by mouth every six hours Pediatric (6- 12 years): One teaspoonful (5 mL) by mouth every six hours	**Orthographic differences:** Upstroke rather than down stroke in the center of the name. **Dosage form:** Oral liquid vs. tablet. **Dose units:** mLs or teaspoonfuls vs. tablets. **Frequency of use :** every six hours vs. twice daily. Root name with multiple modifiers.
Lortuss HC Hydrocodone bitartrate and Phenylephrine HCl) (Discontinued unapproved product)	Look and sound	3.75 mg/7.5 mg per 5 mL *(Single Strength)*	Adults: *One* teaspoonfuls (5 mL) by mouth every four hours Pediatric (6- 12 years): One half teaspoonful (2.5 mL) by mouth every four hours	**Orthographic differences:** Upstroke rather than down stroke in the center of the name. **Dosage form:** Oral liquid vs. tablet. **Dose units:** mLs or teaspoonfuls vs. tablets. **Frequency of use :** every four hours vs. twice daily. Root name with multiple modifiers

Product name with potential for confusion	Similarity to Proposed Proprietary Name	Strength	Usual Dose (if applicable)	Failure Mode of name confusion prevented by the combination of stated product characteristics as well as orthographic and/or phonetic differences as described.
Lorqess **(Lorcaserin)**		**10 mg** **(Strength may be omitted during the prescription or procurement steps of medication use process for single strength products.)**	**One tablet by mouth twice daily**	
Lovaza (Omega-3-Acid Ethyl Esters)	Look	1 gram capsules *(Single Strength)*	Two capsules (2 grams) by mouth *twice daily.* Four Capsules (4 grams) by mouth daily.	**Orthographic differences:** The down strokes in these names appear at differing locations making the ending of each name appear different. ('-aza' vs. '-qess') **Dose**: Two or four capsules vs. one tablet
Lucassin[***] (Terlipressin)	Sound compared to the proposed proprietary name, Look and sound compared to the established name,	0.85 mg/ vial *(Single Strength)*	Treatment of hepatorenal syndrome type I One vial (0.85 mg) intravenous push every six hours.	**Dose:** 0.85 mg vs. 10 mg **Dosage form:** powder for injection in a vial vs. tablet **Route of administration:** intravenous vs. oral **Frequency of use:** every six hours vs. twice daily. **Lucassin is limited to critically ill patients with Hepatorenal syndrome and will only be used in critical care units in inpatient settings.** **Storage conditions:** refrigerated vs. room temperature. Product received a Complete response letter from the Agency November 2009.

[***] **This is proprietary and confidential information that should not be released to the public.**[***]

Product name with potential for confusion	Similarity to Proposed Proprietary Name	Strength	Usual Dose (if applicable)	Failure Mode of name confusion prevented by the combination of stated product characteristics as well as orthographic and/or phonetic differences as described.
Lorqess **(Lorcaserin)**		**10 mg** **(Strength may be omitted during the prescription or procurement steps of medication use process for single strength products.)**	**One tablet by mouth twice daily**	
Lupron (Leuprolide Acetate)	Look	Lupron: 14 mg/2.8 mL (5 mg/ml) vial in a 2 week kit. Lupron Depot: 3.75 mg, and 7.5 mg prefilled syringe Lupron Depot-3: 11.25 mg and 22.5 mg prefilled syringe Lupron Depot-4: 30 mg prefilled syringe Lupron Depot-PED: 7.5 mg, 11.25 mg and 15 mg prefilled syringe	Lupron: Inject 1 mg (0.2 mL) subcutaneously once a day. Lupron Depot: Inject *one* syringe intramuscularly once a month. Lupron Depot 3: Inject *one* syringe intramuscularly every three months Lupron Depot -4: Inject *one* syringe intramuscularly every four months Lupron Depot –PEDS: Inject *one* syringe intramuscularly monthly	**Lupron is available in multiple strengths, none of which overlap with the proposed product.** **Dosage Form:** Injectable (vial and prefilled syringes) vs. tablets **Route of administration:** subcutaneous or intramuscular vs. oral **Frequency of use:** daily, monthly, every three months or every four months.
Ziagen (abacavir)	Look	300 mg tablets 20 mg/mL oral solution	HIV injection in combination with other antiretrovirals Adults: *One tablet* (300 mg) *by mouth twice daily.* Pediatric (3 months to 16 years) 8 mg/kg)	**Orthographic differences: The second and third letters 'ia' appear different when compared to 'or.'** **Ziagen is limited to a very specific patient population (HIV patients).** **Strength:** Ziagen is available in two dosage forms, each with a different strength. Lorqess is available in one strength (10 mg) which cannot achieve the usual adult dose of Ziagen (300 mg) in the usual number of oral solids (one half to three) to form a dose.

Appendix H: Products with similar strengths and product characteristics requiring more detailed Failure mode prevention analysis and description.

Proposed name: **Lorqess** **(Lorcaserin)**	**Strength:** **10 mg tablets**	**Usual dose:** **One tablet by mouth twice daily**
Failure Mode: Name confusion	**Causes (could be multiple)**	**Prevention of Failure Mode;(name confusion)**
Zorprin (Aspirin) 800 mg tablets	Orthographic similarity: Both names contain seven letters; The beginning three letters appear similar when scripted ('Lor-' vs. Zor-); and the fourth letter in both names provides a down stroke (p vs. q) Both products are available in a single strength which may be omitted during the prescribing or procurement steps of the medication use process. Both products are available as tablets. Both are available in bottles containing 100 tablets.	Product characteristics and the low use of Zorprin minimize the potential for medication errors in usual practice settings. Rationale: Zorprin is a high dose aspirin product taken three or four times daily for arthritic conditions. Zorprin is an unapproved medication which has minimal use per preliminary drug-use data. Lorqess is for obesity and taken twice daily.
Lagesic (Acetaminophen and Phenyltoloxamine) 600 mg/66 mg extended-release tablets	Orthographic similarity: Both names contain seven letters; Both names begin with the same letter 'L;' both names contain a letter that appear similar when scripted and provide a down stroke (g vs. q) in the middle of the name; and this letter is followed by the same letter pair '-es-' in	Orthographic differences and the low use of Lagesic minimize the potential for medication error in usual practice settings. Rationale: Orthographic differences stem from the fact the last two letters of Lagesic '-ic' may appear different when compared to the '-s' of Lorqess. Lagesic is an unapproved medication which has minimal use per preliminary drug-use data.

	both names. Both products are available in a single strength which may be omitted during the prescribing or procurement steps of the medication use process. Both products are available as tablets which may be taken twice daily (or every twelve hours) and thus may be ordered in the same quantity. Both are available in bottles containing 100 tablets.	
Lortab (Hydrocodone bitartrate and Acetaminophen) 5: 5mg/500 mg 7.5:7.5 mg/500 mg, and 10: 10 mg/500 mg tablets	Phonetic similarity: Both have two syllables and the first syllable is the same, "Lor-." Both are oral tablets are available the same numeric strength 10. (10 mg and 10 as the modifier.) Both are available in bottles containing 100 tablets. One respondent on the verbal Rx Study heard this drug name when the proposed name was spoken.	Phonetic differences and product characteristics minimize the potential for medication error in usual practice settings. Rationale: Phonetic differences stem from the fact the second syllable begin with ('t' in Lortab vs. 'k' in Lorqess) and end with differing consonant sounds ('buh' vs. 'ss') Lortab is a combination opioid-analgesic which is a CIII controlled substance. The dose is usually one or two tablets every six hours as needed for pain. Lorqess is not a controlled substance which is taken twice daily as a routine medication.
Zortress[***] (Everolimus) 0.25 mg, 0.5 mg. 0.75 mg (b) (4)	Orthographic similarity: Both names begin a letter grouping that appear similar when	Orthographic differences minimize the potential for medication error in usual practice settings. Rationale: Orthographic differences stem from the fact Zortress[***]

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	scripted, (Zor- vs. Lor-) and both names end with the same letter grouping (-ess).	contains the letter 't' in the center of the name providing an upstroke as well as a cross stroke where in the same fourth position in Lorqess appears a 'q' which provides a down stroke.
	(b) (4)	
	Both products are oral tablets taken twice daily.	

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Application Type/Number	Submission Type/Number	Submitter Name	Product Name
IND-69888	ORIG-1	ARENA PHARMCEUTICALS	LORCASERIN HYDROCLORIDE

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

/s/

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