CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

202811Orig1s000

PROPRIETARY NAME REVIEW(S)

Department of Health and Human Services
Public Health Service
Food and Drug Administration
Center for Drug Evaluation and Research
Office of Surveillance and Epidemiology
Office of Medication Error Prevention and Risk Management

Proprietary Name Review--Final

Date:	August 10, 2012
Acting Team Leader:	Jamie Wilkins Parker, Pharm.D. Division of Medication Error Prevention and Analysis
Drug Name(s) and Strength(s):	Linzess (Linaclotide) Capsules, 145 mcg and 290 mcg
Application Type/Number:	NDA 202811
Applicant/sponsor:	Ironwood Pharmaceuticals, Inc.
OSE RCM #:	2011-4209

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CONTENTS

1 INTRODUCTION

This re-assessment of the proposed proprietary name, Linzess is written in response to the anticipated approval of this NDA within 90 days from the date of this review. DMEPA found the proposed name, *Linzess*, acceptable in OSE Review #2011-3177 dated November 16, 2011.

2 METHODS AND DISCUSSION

For re-assessments of proposed proprietary names, DMEPA searches a standard set of databases and information sources (see section 4) to identify names with orthographic and phonetic similarity to the proposed name that have been approved since the previous OSE proprietary name review. For this review we used the same search criteria described in OSE Review #2011-3177. We note that none of the proposed product characteristics were altered. However, we evaluated the previously identified names of concern considering any lessons learned from recent post-marketing experience, which may have altered our previous conclusion regarding the acceptability of the proposed proprietary name. The searches of the databases yielded no new names thought to look or sound similar to Linzess and represent a potential source of drug name confusion.

Additionally, DMEPA searched the USAN stem list to determine if the name contains any USAN stems as of the last USAN updates. The Safety Evaluator did not identify any United States Adopted Names (USAN) stems in the proposed proprietary name, as of August 10, 2012. The Office of Prescription Drug Promotion OPDP re-reviewed the proposed name on March 8, 2012 and had no concerns regarding the proposed name from a promotional perspective.

3 CONCLUSIONS

The re-evaluation of the proposed proprietary name, Linzess, did not identify any vulnerabilities that would result in medication errors with any additional name(s) noted in this review. Thus, DMEPA has no objection to the proprietary name, Linzess, for this product at this time.

DMEPA considers this a final review; however, if approval of the NDA is delayed beyond 90 days from the date of this review, the Division of Gastroenterology and Inborn Errors Products should notify DMEPA because the proprietary name must be re-reviewed prior to the new approval date.

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

4 REFERENCES

1. **OSE Reviews:** Wilkins Parker, J. *Linzess.* RCM 2011-3177. November 16, 2011.

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

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

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

   USAN Stems List contains all the recognized USAN stems.

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

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

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

/s/

JAMIE C WILKINS PARKER
08/10/2012

Department of Health and Human Services
Public Health Service
Food and Drug Administration
Center for Drug Evaluation and Research
Office of Surveillance and Epidemiology
Office of Medication Error Prevention and Risk Management

Proprietary Name Review

Date:	November 16, 2011
Reviewer(s):	Jamie Wilkins Parker, Pharm.D. Division of Medication Error Prevention and Analysis
Team Leader	Carlos Mena-Grillasca, RPh Division of Medication Error Prevention and Analysis
Division Director	Carol A. Holquist, RPh Division of Medication Error Prevention and Analysis
Drug Name(s) and Strengths:	Linzess (Linaclotide) Capsules 145 mcg and 290 mcg
Application Type/Number:	NDA 202811
Applicant/sponsor:	Ironwood Pharmaceuticals, Inc.
OSE RCM #:	2011-3177

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CONTENTS

1 INTRODUCTION

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

1.1 PRODUCT INFORMATION

Linzess (linaclotide) is a selective GC-C receptor agonist with a proposed indication of the treatment of irritable bowel syndrome with constipation (IBS-C) and chronic constipation. The usual recommended dose of Linzess is 145 or 290 mcg taken orally once daily on an empty stomach. Linzess will be available as (b) (4) gelatin capsules imprinted with "FL 145" for the 145 mcg strength and "FL 290" for the 290 mcg strength. Linzess will be packaged in bottles containing 30 capsules, with the middle NDC numbers differing for each strength. Linzess should be stored between 59ºF and 86 ºF, and should remain in the original container (should not be subdivided or repackaged).

2 RESULTS

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

2.1 PROMOTIONAL ASSESSMENT

DDMAC determined the proposed name is acceptable from a promotional perspective. DMEPA and the Division of Gastroenterology and Inborn Errors Products (DGIEP) concurred with the findings of DDMAC's promotional assessment of the proposed name.

2.2 SAFETY ASSESSMENT

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

2.2.1 United States Adopted Names (USAN) SEARCH

The United States Adopted Name (USAN) stem search conducted on October 20, 2011 identified that a USAN stem is not present in the proposed proprietary name.

2.2.2 Components of the Proposed Proprietary Name

The proposed 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 is misleading or can contribute to medication error.

2.2.4 FDA Name Simulation Studies

Thirty nine practitioners participated in DMEPA's prescription studies with no responses overlapping with an existing drug name. See Appendix C for the complete listing of interpretations from the verbal and written prescription studies. Fourteen out of thirty nine participants interpreted the name correctly in both written studies.

2.2.5 Comments from Other Review Disciplines

In response to the OSE, September 1, 2011 e-mail, the Division of Gastroenterology and Inborn Errors Products (DGIEP) did not forward any comments or concerns relating to the proposed name at the initial phase of the name review.

2.2.6 Failure Mode and Effects Analysis of Similar Names

Table 1 lists the names with orthographic, phonetic, or spelling similarity to the proposed proprietary name, Linzess (see Appendix B). These names were identified by the primary reviewer, the Expert Panel Discussion (EPD), other review disciplines. Table 1 also included the names identified by Ironwood Pharmaceuticals that were not previously identified by DMEPA and require further evaluation.

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

Look Similar		**Sound Similar**		**Look and Sound Similar**	
Name	***Source***	***Name***	***Source***	***Name***	***Source***
Lidex	Both	Clindesse	External	Lantus	Both
Arzerra	FDA	Clindets	Both		
Linjeta***	FDA	Zinacef	FDA		
Cimzia	FDA				
Combipres	FDA				
Cuvposa	FDA				
Isentress	FDA				
Levemir	FDA				
Lorquess***	FDA				
Linezolid	FDA				
Lumigan	FDA				
Latisse	FDA				
Loryna	FDA				
Leucine	FDA				
Lessina	FDA				
(b) (4)	FDA				

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Lincocin	FDA				
(b) (4)	FDA				
Luvertis	FDA				
Lindane	FDA				
Nesina***	FDA				
Saizen	FDA				
Semprex-D	FDA				
Serzone	FDA				
Zirgan	FDA				
Ziagen	FDA				
Zortress	FDA				

Our analysis of the thirty one names contained in Table 1 considered the information obtained in the previous sections along with the product characteristics. We determined that none of the names will pose a risk for confusion as described in Appendices D and E.

DMEPA communicated these findings to the Division of Gastroenterology and Inborn Errors Products (DGIEP) via e-mail on October 19, 2011. At that time we also requested additional information or concerns that could inform our review. Per e-mail correspondence from the Division of Gastroenterology and Inborn Errors Products (DGIEP) on October 20, 2011, they stated no additional concerns with the proposed proprietary name, Linzess.

3 CONCLUSIONS

DMEPA concludes the proposed proprietary name is acceptable from both a promotional and safety perspective. However, 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.

Additionally, the proposed proprietary name must be re-reviewed 90 days prior to approval of the NDA.

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

3.1 COMMENTS TO THE APPLICANT

We have completed our review of the proposed proprietary name, Linzess, and have concluded that it is acceptable. The proposed proprietary name, Linzess, will be re-

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reviewed 90 days prior to the approval of the NDA. If we find the name unacceptable following the re-review, we will notify you.

If **any** of the proposed product characteristics as stated in your August 22, 2011, submission are altered prior to approval of the marketing application, the proprietary name should be resubmitted for review. If you have any questions regarding the contents of this letter or any other aspects of the proprietary name review process, contact Nitin Patel, Safety Regulatory Project Manager in the Office of Surveillance and Epidemiology, at (301) 796-5412. For any other information regarding this application contact the Office of New Drugs (OND) Regulatory Project Manager Brian Strongin at (301) 796-1008.

4 REFERENCES

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

   USPTO provides information regarding patent and trademarks.

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

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

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

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

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

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

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

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

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

    USAN Stems List contains all the recognized USAN stems.

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

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

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

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

16. ***Medical Abbreviations Book***

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

APPENDICES

Appendix A

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

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

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

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

DMEPA uses the clinical expertise of its staff to anticipate the conditions of the clinical setting where the product is likely to be used based on the characteristics of the proposed product. DMEPA considers the product characteristics associated with the proposed product throughout the risk assessment because the product characteristics of the proposed may provide a context for communication of the drug name and ultimately determine the use of the product in the *usual* clinical practice setting.

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

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

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

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

Type of Similarity	**Considerations when Searching the Databases**		
	Potential Causes of Drug Name Similarity	*Attributes Examined to Identify Similar Drug Names*	*Potential Effects*
	Similar spelling	Identical prefix Identical infix Identical suffix	• Names may appear similar in print or electronic media and lead to drug name

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

Look-alike		Length of the name Overlapping product characteristics	confusion in printed or electronic communication • Names may look similar when scripted and lead to drug name confusion in written communication
	Orthographic similarity	Similar spelling Length of the name/Similar shape Upstrokes Down strokes Cross-strokes Dotted letters Ambiguity introduced by scripting letters Overlapping product characteristics	• Names may look similar when scripted, and lead to drug name confusion in written communication
Sound-alike	Phonetic similarity	Identical prefix Identical infix Identical suffix Number of syllables Stresses Placement of vowel sounds Placement of consonant sounds Overlapping product characteristics	• Names may sound similar when pronounced and lead to drug name confusion in verbal communication

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

1. Database and Information Sources

DMEPA searches the internet, several standard published drug product reference texts, and FDA databases to identify existing and proposed drug names that may sound-alike or look-alike to the proposed proprietary name. A standard description of the databases used in the searches is provided in the reference section of this review. To complement the process, the DMEPA uses a computerized method of identifying phonetic and orthographic similarity between medication names. The program, Phonetic and Orthographic Computer Analysis (POCA), uses complex algorithms to select a list of names from a database that have some similarity (phonetic, orthographic, or both) to the

trademark being evaluated. Lastly, DMEPA reviews the USAN stem list to determine if any USAN stems are present within the proprietary name. The individual findings of multiple safety evaluators are pooled and presented to the CDER Expert Panel. DMEPA also evaluates if there are characteristics included in the composition that may render the name unacceptable from a safety perspective (abbreviation, dosing interval, etc.).

2. Expert Panel Discussion

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

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

3. FDA Prescription Simulation Studies

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

In order to evaluate the potential for misinterpretation of the proposed proprietary name in handwriting and verbal communication of the name, inpatient medication orders and/or outpatient prescriptions are written, each consisting of a combination of marketed and unapproved drug products, including the proposed name. These orders are optically scanned and one prescription is delivered to a random sample of participating health professionals via e-mail. In addition, a verbal prescription is recorded on voice mail. The voice mail messages are then sent to a random sample of the participating health professionals for their interpretations and review. After receiving either the written or verbal prescription orders, the participants record their interpretations of the orders which are recorded electronically.

4. Comments from Other Review Disciplines

DMEPA requests the Office of New Drugs (OND) and/or Office of Generic Drugs (OGD), ONDQA or OBP for their comments or concerns with the proposed proprietary name, ask for any clinical issues that may impact the DMEPA review during the initial phase of the name review. Additionally, when applicable, at the same time DMEPA

requests concurrence/non-concurrence with DDMAC's decision on the name. The primary Safety Evaluator addresses any comments or concerns in the safety evaluator's assessment.

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

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

5. Safety Evaluator Risk Assessment of the Proposed Proprietary Name

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

In order to perform an FMEA of the proposed name, the primary Safety Evaluator must analyze the use of the product at all points in the medication use system. Because the proposed product is has not been marketed, the primary Safety Evaluator anticipates the use of the product in the usual practice settings by considering the clinical and product characteristics listed in Appendix B1 of this review. The Safety Evaluator then analyzes the proposed proprietary name in the context of the usual practice setting and works to identify potential failure modes and the effects associated with the failure modes.

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

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

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

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

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

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

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

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

a. DDMAC finds the proposed proprietary name misleading from a promotional perspective, and the Review Division concurs with DDMAC's findings. The Federal Food, Drug, and Cosmetic Act provides that labeling or advertising can misbrand a product if misleading representations are made or suggested by statement, word, design, device, or any combination thereof, whether through a PROPRIETARY name or otherwise [21 U.S.C 321(n); See also 21 U.S.C. 352(a) & (n)].

b. DMEPA identifies that the proposed proprietary name is misleading because of similarity in spelling or pronunciation to another proprietary or established name of a different drug or ingredient [CFR 201.10.(C)(5)].

c. FMEA identifies the potential for confusion between the proposed proprietary name and other proprietary or established drug name(s), and demonstrates that medication errors are likely to result from the drug name confusion under the conditions of usual clinical practice.

d. The proposed proprietary name contains an USAN (United States Adopted Names) stem.

e. DMEPA identifies a potential source of medication error within the proposed proprietary name. For example, the proprietary name may be misleading or, inadvertently, introduce ambiguity and confusion that leads to errors. Such errors may not necessarily involve confusion between the proposed drug and another drug product but involve a naming characteristic that when incorporated into a proprietary name, may be confusing, misleading, cause or contribute to medication errors.

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

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

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

Furthermore, post-marketing experience has demonstrated that medication errors resulting from drug name confusion are notoriously difficult to rectify post-approval. Educational and other post-approval efforts are low-leverage strategies that have had limited effectiveness at alleviating medication errors involving drug name confusion. Sponsors have undertaken higher-leverage strategies, such as drug name changes, in the past but at great financial cost to the Sponsor and at the expense of the public welfare, not to mention the Agency's credibility as the authority responsible for approving the error-prone proprietary name. Moreover, even after Sponsors' have changed a product's proprietary name in the post-approval phase, it is difficult to eradicate the original proprietary name from practitioners' vocabulary, and as a result, the Agency has continued to receive reports of drug name confusion long after a name change in some instances. Therefore, DMEPA believes that post-approval efforts at reducing name confusion errors should be reserved for those cases in which the potential for name confusion could not be predicted prior to approval.

Appendix B: Letters with Possible Orthographic or Phonetic Misinterpretation

Letters in Name, NAME	Scripted May Appear as	Spoken May Be Interpreted as
Capital 'L'	Z, S, T, J	'N'
lower case '1'	b, e, A, or i	'n'
lower case 'i'	a, e	any vowel
lower case 'n'	m, u, x, r, h, s	'gn', 'dn', 'kn', 'mn', 'pn'
lower case 'z'	c, e, g, n, m, q, r, s, v, p	'c', 's', 'x'
lower case 'e'	a, i, l, p	any vowel
lower case 's' as grouping 'ss'	a, n, or r m	'c' or followed by a silent 'e' 'z'

Appendix C: Prescription Simulation Samples and Results

Figure 1. Linzess Study (Conducted on September 9, 2011)

Handwritten Requisition Medication Order	Verbal Prescription
Medication Order: Linzess 290 mg 1 capsule PO qd	Linzess 145 mg Take one cap orally every day Dispense #30
Outpatient Prescription: Linzess 145 mg 1 po qd #30	

FDA Prescription Simulation Responses.

INPATIENT	STRENGTH	VOICE	STRENGTH	OUTPATIENT	STRENGTH
LINLESS	290mg	LINCEF	145mg	LIN?ESS	145 mg
LINLESS	290 mg	LINCEF	145 mg	LINFESS	145mg
LINLESS	290mg	LINDSEFF	145 mg	LINLESS	145 mg
LINLESS	290mg	LINSESS	145 mg	LINSESS	145 mg
LINLESS	290 mg	LINSEST	145 mg	LINTESS	145 mg
LINLESS	290mg	LINZEF	145 mg	LINZESS	145mg
LINLESS	290 mg	LINZEF	140mg	LINZESS	145 mg
LINTESS	290 mg	LINZEF		LINZESS	145mg
LINZESS	290mg	LINZESS	145 mg	LINZESS	145 mg
LINZESS	290 mg.	LINZEV	140 mg	LINZESS	145mg
LINZESS	290 mg	LYNSAS	145 mg		
LINZESS	290mg	LYNZES	145 mg		
LINZESS	290 mg				
LINZESS	290mg				
LINZESS	290 mg				
LINZESS	290 mg				
LINZESS	290mg				

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 Linzess	Failure preventions
Lidex	Fluocinonide	Orthographic	Product lacks convincing orthographic similarities to Linzess
Zinacef	Cefuroxime	Phonetic	Product lacks convincing phonetic similarities to Linzess
Combipres	Chlorthalidone and Clonidine	Orthographic	Product lacks convincing orthographic similarities to Linzess
Lorqess***	Lorcaserin HCl	Orthographic	Proposed proprietary name denied by DMEPA for orthographic similarity to the name Loryna, which will be evaluated in this review.
Linezolid	Established name for Zyvox	Orthographic	Product lacks convincing orthographic similarities to Linzess
Leucine	Leucine	Orthographic	Leucine is an essential amino acid, preliminary drug use data shows no prescribing of Leucine
Nesina***	Alogliptin	Orthographic	Product lacks convincing orthographic similarities to Linzess

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

Appendix E: Products with orthographic, phonetic and/or multiple differentiating product characteristics minimize the risk for medication errors

Proposed name: Linzess (Linaclotide) **Strength(s) and Dosage form: 145 mcg, 290 mcg capsules** **Usual dose: 145 or 290 mcg by mouth once daily, depending on indication.**	**Causes of Failure Mode Resulting in Medication Error: Incorrect Product Ordered/ Selected/Dispensed or Administered Because of Name confusion**	**Prevention of Failure Mode: Orthographic/Phonetic/Product Characteristic Differences**
Levemir (Insulin detemir) - 100 units/mL solution -Individualized insulin dosing	**Orthographic name similarity** - Both names are similarly shaped when the 'z' in Linzess is scripted without a downstroke -Both names contain seven letters -Both medications can be taken once daily	**Product characteristic differences** - Dosage form (capsule vs. solution for injection) -Route of administration (oral vs. subcutaneous) - Strength (multiple strengths vs. single concentration solution) -Dose (capsule or mcg vs. units)
Isentress (Raltegravir) -400 mg tablet -400 mg by mouth twice daily	**Orthographic name similarity** -When scripted with the first letter ('L') in the lower case, the first letters of the names are similarly shaped. (Lower case L vs. Upper case I). Both names also contain a cross stroke if the 'z' in Linzess is scripted in that manner. Both names end in the letters 'ess'. **Product characteristics** -Route of administration (oral)	**Orthographic differences** Linzess contains seven letters whereas Isentress contains nine, therefore appearing shorter when scripted. Isentress also contains an upstroke, which is absent in Linzess. **Product characteristic differences** - Frequency of administration (once daily vs. twice daily) -Strength (multiple strengths vs. single strength which therefore will not be required on a prescription, and there is no overlap in strength.)

Proposed name: Linzess (Linaclotide) **Strength(s) and Dosage form: 145 mcg, 290 mcg capsules** **Usual dose: 145 or 290 mcg by mouth once daily, depending on indication.**	**Causes of Failure Mode Resulting in Medication Error: Incorrect Product Ordered/ Selected/Dispensed or Administered Because of Name confusion**	**Prevention of Failure Mode: Orthographic/Phonetic/Product Characteristic Differences**
Lumigan (Bimatoprost Opthalmic Solution) -0.01% and 0.03% ophthalmic solution -1 drop into affected eye(s) once daily in the evening	**Orthographic name similarity** - Both names begin with a similarly shaped letter string (Lin vs. Lum) and contain a downstroke	**Product Characteristic Differences** -Strength (145 and 290 mcg capsules vs. 0.01% and 0.03% solution) -Dosage form (capsules vs. ophthalmic solution) -Route of administration (oral vs. ophthalmic)
Cimzia (Certolizumab pegol) -400 mg kit powder for injection, 200 mg/mL syringe for injection -Chron's Disease: 400 mg subcutaneously at weeks 0, 2, and 4, then 400 mg subcutaneously every 4 weeks. Rheumatoid Arthritis: 400 mg at weeks 0, 2, and 4 then 200 mg every other week	**Orthographic name similarity** -Both names begin with similarly shaped letter strings 'Lin' vs. 'Cim' and have a z as the fourth letter in the name.	**Product Characteristic differences** -Strength (145 and 290 mcg capsules vs. 200 mg/mL and 400 mg solutions and powder for injection) -Dosage form (oral capsule vs. solution and powder for injection) -Frequency (daily vs. every 2 to 4 weeks) -Route of administration (oral vs. subcutaneous)

Proposed name: Linzess (Linaclotide) **Strength(s) and Dosage form: 145 mcg, 290 mcg capsules** **Usual dose: 145 or 290 mcg by mouth once daily, depending on indication.**	**Causes of Failure Mode Resulting in Medication Error: Incorrect Product Ordered/ Selected/Dispensed or Administered Because of Name confusion**	**Prevention of Failure Mode: Orthographic/Phonetic/Product Characteristic Differences**
Zirgan (Ganciclovir Opthalmic Gel) -0.15% Opthalmic gel -1 drop into affected eye 5 times a day (approx every 3 hours while awake) until corneal ulcer heals, then 1 drop into the affected eye 3 times per day for 7 days	**Orthographic name similarity** -Both names contain a downstroke, and are similarly shaped when scripted	**Product Characteristic differences** -Dosage Form (capsule vs. ophthalmic gel) -Route of administration (oral vs. ophthalmic) -Frequency (once daily vs. 3-5 times per day) -Strength (145 and 290 mcg vs. single strength which therefore will not be required on a prescription. None of the strengths overlap.)
Ziagen (Abacavir) -300 mg tablet, 20 mg/mL oral solution -Adult: 300 mg by mouth twice daily or 600 mg once daily. Pediatric: 8 mg/kg by mouth twice daily to a maximum dose of 300 mg twice daily. Average dose for a 7 year old child (based upon a weight of 19 kg) is 152 mg twice daily.	**Orthographic name similarity** -Both names contain a downstroke, and are similarly shaped when scripted **Product characteristics** -Route of administration (oral) **Dose** -Potential dose overlap for pediatric doses if a child weighs 18.12 kg (145 mg dose) or 36.25 kg (290 mg dose)	**Orthographic differences** Linzess can be scripted without a downstroke 'z' in the fourth position, whereas Ziagen contains a constant downstroke in the name. **Product Characteristic differences** -Strength (145 and 290 mcg vs. 300 mg or 20 mg/mL)

Proposed name: Linzess (Linaclotide) **Strength(s) and Dosage form: 145 mcg, 290 mcg capsules** **Usual dose: 145 or 290 mcg by mouth once daily, depending on indication.**	**Causes of Failure Mode Resulting in Medication Error: Incorrect Product Ordered/ Selected/Dispensed or Administered Because of Name confusion**	**Prevention of Failure Mode: Orthographic/Phonetic/Product Characteristic Differences**
Zortress (Everolimus) -0.25 mg, 0.5 mg, 0.75 mg tablet -0.75 mg by mouth every 12 hours, with adjustment to target of 3-9 ng/mL blood concentrations	**Orthographic name similarity** -Both names are similarly shaped when the 'z' in Linzess is scripted with a cross stroke. -Both names contain seven letters and end in the letter string 'ess'. **Product characteristics** -Route of administration (oral)	**Orthographic Differences** Linzess does not contain an upstroke whereas Zortress contains an upstroke in the fourth position. **Product Characteristic differences** -Strength (145 and 290 mcg vs. 0.25, 0.5, 0.75 mg, none of which overlap) -Frequency (once daily vs. every 12 hours)
Lessina (Levonorgestrel/Ethinyl Estradiol) -0.1 mg/ 0.2 mg single strength tablets -One tablet by mouth once daily	**Orthographic name similarity** -Both names begin with the letter L, contain seven letters, and are similarly shaped when the 'z' in Linzess is not scripted as a downstroke **Product characteristics** -Route of administration (oral) -Frequency (once daily) **Dose** -1 capsule/tablet	**Orthographic Differences** Linzess can be scripted with a downstroke 'z', which will help differentiate the names. The endings 'ina' vs. 'ess' may also look different when scripted. **Product characteristic differences:** -Strength (145 and 290 mcg capsules vs. single strength tablets which would not be required to be written on a prescription. None of the strengths overlap.) -Preliminary drug use data shows low prescribing of the name, Lessina.

Proposed name: Linzess (Linaclotide) **Strength(s) and Dosage form: 145 mcg, 290 mcg capsules** **Usual dose: 145 or 290 mcg by mouth once daily, depending on indication.**	**Causes of Failure Mode Resulting in Medication Error: Incorrect Product Ordered/ Selected/Dispensed or Administered Because of Name confusion**	**Prevention of Failure Mode: Orthographic/Phonetic/Product Characteristic Differences**
Lincocin (Lincomycin) -300 mg/mL solution for injection -Intravenous/ Intramuscular: 600-1000 mg every 8-24 hours. Pediatric: 10-20 mg/kg/day divided doses every 8-12 hours. Average dose for a 7 year old child (based upon a weight of 19 kg) is 190-380 mg twice daily.	**Orthographic name similarity** -Both names begin with the letter L, and are similarly shaped when the 'z' in Linzess is not scripted as a downstroke	**Product characteristic differences** -Route (oral vs. intravenous or intramuscular which needs to be specified on the order) -Frequency (once daily vs. every 8-24 hours) -Dosage form (oral capsule vs. injection) -Strength (145 and 290 mcg capsules vs. single strength which would not be required to be written on a prescription. None of the strengths overlap.)
Luvertis (Lutropin alfa) -75 unit powder for injection -75 units subcutaneously once daily	**Orthographic similarities** - Both names begin with the letter L, and are similarly shaped when the 'z' in Linzess is not scripted as a downstroke **Product characteristics** Frequency (once daily)	**Orthographic difference** Linzess contains a potential cross stroke in the fourth position, if the z is scripted in such a manner, however Luvertis contains a cross stroke in the sixth position, thus giving the names different shapes when scripted. **Product characteristic differences** -Dosage Form (oral capsule vs. powder for injection) -Route (oral vs. subcutaneous) -Dose (145 and 290 mcg (1 capsule) vs. 75 units)

Proposed name: Linzess (Linaclotide) **Strength(s) and Dosage form: 145 mcg, 290 mcg capsules** **Usual dose: 145 or 290 mcg by mouth once daily, depending on indication.**	**Causes of Failure Mode Resulting in Medication Error: Incorrect Product Ordered/ Selected/Dispensed or Administered Because of Name confusion**	**Prevention of Failure Mode: Orthographic/Phonetic/Product Characteristic Differences**
Lindane -0.1% cream, lotion - Scabies: Apply a thin layer all over body, for 8-12 hours, then wash off Lice: Place 15-30mL to dry hair, leave in place for 4 minutes, lather then rinse.	**Orthographic similarities** - Both names begin with the letter L, and are similarly shaped when the 'z' in Linzess is not scripted as a downstroke	**Orthographic differences** Linzess does not contain any upstrokes in the name, whereas Lindane contains an upstroke in the fourth position. **Product characteristic differences** -Strength (145 and 290 mcg vs. 0.1% single strength which would not be required to be written on a prescription. None of the strengths overlap.) -Frequency (once daily vs. one time use) -Dosage Form (oral capsule vs. cream, lotion) -Route of administration (oral vs. topical)
Serzone (Nefazodone) -50 mg, 100 mg, 150 mg, 200 mg, 250 mg tablet -50-300 mg by mouth twice daily	**Orthographic similarities** -Both names are similarly shaped, contain seven letters, and a 'z' in the fourth position. **Product characteristics** -Route of administration (oral) **Dose** 1 tablet/capsule	**Product characteristic differences** -Strength (145 and 290 mcg vs. 50 mg, 100 mg, 150 mg, 200 mg, 250 mg) -Frequency (once daily vs. twice daily)

Proposed name: Linzess (Linaclotide) **Strength(s) and Dosage form: 145 mcg, 290 mcg capsules** **Usual dose: 145 or 290 mcg by mouth once daily, depending on indication.**	**Causes of Failure Mode Resulting in Medication Error: Incorrect Product Ordered/ Selected/Dispensed or Administered Because of Name confusion**	**Prevention of Failure Mode: Orthographic/Phonetic/Product Characteristic Differences**
Semprex-D (Acravistine and Pseudoephedrine) -8 mg/60 mg capsule -1 capsule by mouth every 4-6 hours -The product does not exist without a modifier. Semprex-D is the only available product in the product line.	**Orthographic similarities** -Both names are similarly shaped, contain seven letters, and a downstroke in the fourth position, when the modifier is not used with Semprex-D. **Product characteristics** -Route of administration (oral)	**Orthographic differences** Linzess does not contain a modifier, whereas Semprex-D contains a modifier, and does not exist without the modifier, thus adding length to the name. **Product characteristic differences** -Strength (145 and 290 mcg vs. single strength which would not be required to be written on a prescription. None of the strengths overlap.) -Frequency (once daily vs. every 4-6 hours)

Proposed name: Linzess (Linaclotide) **Strength(s) and Dosage form: 145 mcg, 290 mcg capsules** **Usual dose: 145 or 290 mcg by mouth once daily, depending on indication.**	**Causes of Failure Mode Resulting in Medication Error: Incorrect Product Ordered/ Selected/Dispensed or Administered Because of Name confusion**	**Prevention of Failure Mode: Orthographic/Phonetic/Product Characteristic Differences**
Saizen (Somatropin rh-GH) -5 mg powder for injection, 8.8 mg Click Easy Cartridge powder for injection, 8.8 mg powder for injection -0.005-0.01 mg/kg subcutaneously per day. Average dose for a 77 kg adult is 0.36-0.77 mg per day. Pediatric: 0.18 mg/kg/week subcutaneously or intramuscularly divided either 3 times per week or 6 times per week. Average dose for a 7 year old child (based upon a weight of 19 kg) is 3.42 mg per week, or 1.14 mg three times per week, or 0.57 mg six times per week.	**Orthographic similarities** -Both names are similarly shaped, and contain a 'z' in the fourth position.	**Product characteristic differences** -Strength (145 and 290 mcg vs. 5 mg and 8.8 mg) -Route (oral vs. subcutaneous or intramuscular, which needs to be specified on the order)

Proposed name: Linzess (Linaclotide) **Strength(s) and Dosage form: 145 mcg, 290 mcg capsules** **Usual dose: 145 or 290 mcg by mouth once daily, depending on indication.**	**Causes of Failure Mode Resulting in Medication Error: Incorrect Product Ordered/ Selected/Dispensed or Administered Because of Name confusion**	**Prevention of Failure Mode: Orthographic/Phonetic/Product Characteristic Differences**
Latisse (bimatoprost) -0.03% solution -apply 1 drop to each eye at night using the supplied applicator along the upper eyelid margin at the base of the eyelashes	**Orthographic similarities** -Both names are similarly shaped, contain seven letters, and if the z in Linzess is written with a cross stroke, both have cross strokes in the infix of the name **Product Characteristics:** Frequency (once daily)	**Orthographic differences** Linzess does not contain an upstroke in the name whereas Latisse contains an upstroke in the third position. **Product characteristic differences** -Strength (145 and 290 mcg vs. single strength which would not be required to be written on a prescription. None of the strengths overlap.) -Route (oral vs. topical) -Dosage Form (capsule vs. solution)
Cuvposa (Glycopyrrolate) -1 mg/5 mL solution -0.02 mg/kg by mouth three times daily. Average adult dose (77 kg) is 1.54 mg three times daily	**Orthographic similarities** -Both names are similarly shaped, contain seven letters, and if the z in Linzess is scripted as a downstroke, both names contain a downstroke in the 4th position. **Product Characteristics:** Route of administration (oral)	**Product characteristic differences** -Strength (145 and 290 mcg vs. single strength solution which would not be required to be written on a prescription. None of the strengths overlap.) -Dosage Form (capsule vs. solution) -Frequency (once daily vs. three times daily)

Proposed name: Linzess (Linaclotide) **Strength(s) and Dosage form: 145 mcg, 290 mcg capsules** **Usual dose: 145 or 290 mcg by mouth once daily, depending on indication.**	**Causes of Failure Mode Resulting in Medication Error: Incorrect Product Ordered/ Selected/Dispensed or Administered Because of Name confusion**	**Prevention of Failure Mode: Orthographic/Phonetic/Product Characteristic Differences**
Loryna (Drospirenone and Ethinyl Estradiol) -3 mg/0.02 mg tablets -one tablet by mouth daily	**Orthographic similarities** -Both names are similarly shaped, and if the z in Linzess is scripted as a downstroke, both names contain a downstroke in the 4th position. **Product Characteristics:** Route of administration (oral) Frequency (once daily)	**Product characteristic differences** -Strength (145 mcg and 290 mcg vs. single strength which would not be required to be written on a prescription. None of the strengths overlap.) Preliminary drug use data shows no prescribing of the name Loryna.
Arzerra (ofatumumab) -100 mg/5 mL solution for injection -300 mg per day via intravenous infusion initially, then 2000 mg intravenously once weekly for 7 doses, then 4 weeks later 2000 mg via intravenous infusion once every 4 weeks for 4 doses. 12 total doses over 24 weeks.	**Orthographic similarities** -Both names are similarly shaped, and contain the letter z in a similar location within the name	**Product characteristic differences** -Dose (145 and 290 mcg (1 capsule) vs. 300 mg or 2000 mg) -Route of administration (oral vs. intravenous) -Dosage Form (oral capsule vs. injection)

Proposed name: Linzess (Linaclotide) **Strength(s) and Dosage form: 145 mcg, 290 mcg capsules** **Usual dose: 145 or 290 mcg by mouth once daily, depending on indication.**	**Causes of Failure Mode Resulting in Medication Error: Incorrect Product Ordered/ Selected/Dispensed or Administered Because of Name confusion**	**Prevention of Failure Mode: Orthographic/Phonetic/Product Characteristic Differences**
Lantus (Insulin Glargine) -100 units/mL solution -Individualized insulin therapy	**Orthographic similarities** -Both names are similarly shaped, contain seven letters, and if the z in Linzess is written with a cross stroke, both have cross strokes in the infix of the name **Frequency** -Both medications can be prescribed for once daily use	**Orthographic differences** Linzess does not contain an upstroke in the name whereas Lantus contains an upstroke in the fourth position. **Product characteristic differences** -Strength (145 and 290 mcg vs. single strength solution which would not be required to be written on a prescription. None of the strengths overlap.) -Dose (capsules or mcg vs. units)
Clindets (Clindamycin Phosphate) -1% topical pledget (small, flat, absorbent pad) -Apply twice daily	**Phonetic similarities** -Both names contain the letter string "lin" in the beginning of the name, as well as similar sounding letter strings at the end of the name "ess" vs. "ets"	**Orthographic differences** Linzess does not contain an upstroke in the name whereas Clindets contains upstrokes in the second, fifth, and seventh positions. **Product characteristic differences** -Strength (145 and 290 mcg vs. single strength pledget which would not be required to be written on a prescription. None of the strengths overlap.) -Dosage Form (capsule vs. Topical pledget) -Route of administration (oral vs. topical) -Frequency (once daily vs. twice daily)

Proposed name: Linzess (Linaclotide) **Strength(s) and Dosage form: 145 mcg, 290 mcg capsules** **Usual dose: 145 or 290 mcg by mouth once daily, depending on indication.**	**Causes of Failure Mode Resulting in Medication Error: Incorrect Product Ordered/ Selected/Dispensed or Administered Because of Name confusion**	**Prevention of Failure Mode: Orthographic/Phonetic/Product Characteristic Differences**
Clindesse (Clindamycin) -2% vaginal cream -1 applicatorful intravagnally as a single dose at any time of the day	**Phonetic similarities** -Both names contain the letter string "lin" in the beginning of the name, as well as similar sounding letter strings at the end of the name "ess" vs. "esse"	**Orthographic differences** Linzess does not contain an upstroke in the name whereas Clindesse contains upstrokes in the second and fifth positions. **Product characteristic differences** -Strength (145 and 290 mcg vs. single strength cream which would not be required to be written on a prescription. None of the strengths overlap.) -Dosage Form (capsule vs. cream) -Route of administration (oral vs. intravaginal) -Frequency (once daily vs. one time use)

Proposed name: Linzess (Linaclotide) **Strength(s) and Dosage form: 145 mcg, 290 mcg capsules** **Usual dose: 145 or 290 mcg by mouth once daily, depending on indication.**	**Causes of Failure Mode Resulting in Medication Error: Incorrect Product Ordered/ Selected/Dispensed or Administered Because of Name confusion**	**Prevention of Failure Mode: Orthographic/Phonetic/Product Characteristic Differences**
(b) (4)		

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

Proposed name: Linzess (Linaclotide) **Strength(s) and Dosage form: 145 mcg, 290 mcg capsules** **Usual dose: 145 or 290 mcg by mouth once daily, depending on indication.**	**Causes of Failure Mode Resulting in Medication Error: Incorrect Product Ordered/ Selected/Dispensed or Administered Because of Name confusion**	**Prevention of Failure Mode: Orthographic/Phonetic/Product Characteristic Differences**
Linjeta[***] (b) (4) (b) (4)	**Orthographic similarities** Both names begin with the letter string 'Lin' followed by a downstroke (j vs z)	**Orthographic differences** Linzess contains no upstrokes in the name whereas Linjeta contains an upstroke in the sixth position, therefore giving the names different shapes when scripted. **Product characteristic differences** -Strength (145 mcg and 290 mcg vs. (b) (4) (b) (4)
(b) (4)		

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/s/

JAMIE C WILKINS PARKER
11/16/2011

CAROL A HOLQUIST
11/17/2011