CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

200603

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

Date:	October 21, 2010
Application Type/Number:	NDA 200603
Through:	Melina Griffis RPh, Team Leader 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):	Latuda (Lurasidone HCl) Tablets 40 mg, 80 mg, and 120 mg
Applicant/sponsor:	Sepracor, Inc
OSE RCM #:	2010-2142

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

CONTENTS

EXECUTIVE SUMMARY

This review summarizes the Division of Medication Error Prevention and Analysis' evaluation for the proposed proprietary name Latuda for Lurasidone HCl Tablets. The Division of Drug Marketing, Advertising and Communication identified no concerns from a promotional perspective, and DMEPA identified no concerns from a safety perspective that would render the name unacceptable. Thus, DMEPA finds the proposed proprietary name, Latuda, acceptable for this product.

We consider this a final review of the proposed proprietary name, Latuda. However, if the action on this NDA is delayed 90 days beyond the date of this review, the proposed proprietary name, Latuda, must be re-reviewed.

1 BACKGROUND

1.1 INTRODUCTION

This review responds to a request from Sepracor, Inc dated October 8, 2010, for an assessment of the proposed proprietary name, Latuda, regarding potential name confusion with other proprietary or established drug names in the usual practice settings as well as a promotional assessment of the name.

1.2 REGULATORY HISTORY

This product is a pending NDA with a PDUFA action date of October 30, 2010.

The Applicant submitted the proposed proprietary names (b) (4). DMEPA objected to these proposed names in OSE review #'s 2010-208 and 2010-1230, respectively.

Subsequently, the Applicant submitted the proposed name, (b) (4) September 2, 2010. DMEPA held a teleconference with the Applicant to notify them of the vulnerabilities to this proposed name on October 7, 2010. The Applicant agreed to withdraw the name (b) (4) and submit a request for review for the alternate proprietary name, Latuda.

1.3 PRODUCT INFORMATION

Latuda (Lurasidone hydrochloride) is an atypical antipsychotic agent indicated for the treatment of acute schizophrenia in adult patients. Latuda tablets will be available in three strengths (40 mg, 80 mg, and 120 mg). The usual dose is a 40 mg or 80 mg tablet by mouth daily with a meal. (b) (4) Each strength of Latuda will be packaged in bottles containing 30, 90 and 500 tablets as well as professional samples of 7 tablets on a blister card packaged 10 cards per carton and unit dose tablets in cartons of 100. Latuda tablets are stored at room temperature (25º 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 and 2.2 identify specific information associated with the methodology for the proposed proprietary name, Latuda.

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 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 Latuda, the DMEPA safety evaluators also considers the orthographic appearance of the name on lined and unlined orders. Specific attributes taken into consideration include the length of the name (six letters), upstrokes (three, capital letter 'L' and lower case 't' and 'd'), down strokes (none), cross strokes (one, lower case 't'), and dotted (none). Additionally, several letters in Latuda may be vulnerable to ambiguity when scripted (See Appendix B). As a result, the DMEPA safety evaluator also considers these alternate appearances when identifying drug names that may look similar to Latuda.

When searching to identify potential names that may sound similar to Latuda, the safety evaluators search for names with similar number of syllables (three), stresses (LAH-too-dah and lah-TOO-dah), and placement of vowel and consonant sounds. (See Appendix B) Names are often mispronounced and/or spoken with regional accents and dialects, so other potential pronunciations of the name are considered.

2.2 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. (See Appendix for samples and results)

3 RESULTS

The names identified from DMEPA's methods as potential sources for name confusion with Latuda are listed below.

3.1 DATA BASE AND INFORMATION SOURCES

The searches yielded a total of 38 names as having some similarity to the name Latuda.

Thirty-one of the names were thought to look like Latuda. These include: Labid, Lactase, Lactose, Lactulose, Latisse, Letairis, Lexiva, Lialda, Lidodan, Lofibra, Lortab, Lotemax, Lotrel, Lotrimin, Lotrisone, Lotronex, Lotusate, [redacted] (b) (4), Lunesta, Luride, Lutera,

[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)

Potaba, Sebulon, Sufenta, Talacen, Toradol, (b) (4) Xeloda, Zantac, (b) (4) Zoladex. One of the names, Lotussin, was thought to sound like Latuda. The remaining six names were thought to look and sound similar to Latuda: Latuda, (b) (4), Lotensin, Lusedra, Lysteda and Truvada.

Additionally, DMEPA staff did not identify any United States Adopted Names (USAN) stems in the proposed proprietary name, as of October 6, 2010.

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 Latuda.

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 PRESCRIPTION ANALYSIS STUDIES

A total of 25 practitioners responded to the study with no responses overlapping with an existing name. Eight of the participants interpreted the name correctly as "Latuda," with correct interpretation occurring in the outpatient study. The remainder of the written responses misinterpreted the drug name. In the verbal studies, three of the responses were correct, while the remaining responses were misspelled phonetic variations of the proposed name, Latuda. See Appendix C for the complete listing of interpretations from the verbal and written prescription studies.

3.4 COMMENTS FROM THE DIVISION OF PSYCHIATRY PRODUCTS (DPP)

DMEPA notified the Division of Psychiatry Products at a labeling meeting that we had no concerns with the proposed proprietary name, Latuda on October 4, 2010. The Division of Psychiatry Products provided no concerns with the proposed proprietary name, Latuda.

3.5 SAFETY EVALUATOR RISK ASSESSMENT

Independent searches by the primary Safety Evaluator resulted in no additional names which were thought to look or sound similar to Latuda.

The identified name Latuda is the proposed name for this product and was identified as a trademark licensed to Dainippon Sumitomo, an affiliated company to Sepracor. Therefore, we removed this name from further evaluation.

Thus, we evaluated a total of 37 names identified in section 3.1 above.

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

4 DISCUSSION

This proposed name, Latuda, 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 Psychiatry Products concurred with the findings of DDMAC's promotional assessment of the proposed name.

4.2 SAFETY ASSESSMENT

DMEPA evaluated 37 names for their potential similarity to the proposed name, Latuda. No other aspects of the name were considered to pose a potential for confusion.

Nine names were determined to not appear in usual clinical practice for the reasons described in Appendix D and thus eliminated from further evaluation.

Failure mode and effects analysis (FMEA) was applied to determine if the proposed proprietary name could potentially be confused with the 28 remaining names and lead to medication errors. This analysis determined that the name similarity between Latuda and all of these 28 identified names was unlikely to result in medication error for the reasons presented in Appendices E and F.

5 CONCLUSIONS

The Proprietary Name Risk Assessment indicates that the proposed name, Latuda, is not vulnerable to name confusion that could lead to medication errors, nor is it considered promotional. Thus, the Division of Medication Error Prevention and Analysis (DMEPA) has no objection to the proprietary name, Latuda, for this product at this time. The Applicant will be notified via letter.

We consider this a final review of the proposed proprietary name, Latuda. However, if the action on this NDA is delayed 90 days beyond the date of this review, the proposed proprietary name, Latuda, must be re-reviewed.

If you have further questions or need clarifications, please contact Sandra Griffith, project manager, at 301-796-2445.

5.1 COMMENTS TO THE APPLICANT

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

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

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/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 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 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

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

[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.

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.

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

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

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 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.

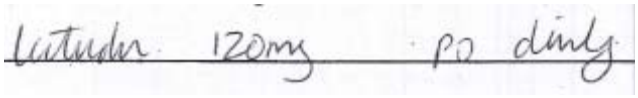
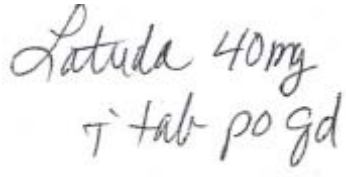
In the event that DMEPA objects to the use of the proposed proprietary name, based upon the potential for confusion with another proposed (but not yet approved) proprietary name, DMEPA will provide a contingency objection based on the date of approval. Whichever product, the Agency approves first has 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, Latuda	Scripted may appear as	Spoken may be interpreted as
Capital 'L'	C, I, T, or Z	'N'
lower case '1'	b, c, e, or i	'n'
lower case 'a'	c, 'ce,' 'ci,' e, o, or u	any vowel
lower case 't'	f, l, or r	'd'
lower case 'u'	a, 'ie,' n, o, or v	any vowel
lower case 'd'	'cl', l, or t	't'

Appendix C: Prescription study samples and results

Figure 1. Latuda Study (conducted on October 15, 2010)

HANDWRITTEN REQUISITION MEDICATION ORDER	VERBAL PRESCRIPTION
Medication Order : 	Latuda 120 mg po daily
Outpatient prescription: 	

FDA Prescription Study Responses.

Inpatient Medication Order	Outpatient Prescription	Voice Prescription
Latudor 120 mg	Latuda 40 mg	Latuda 120 mg
Latudor 120 mg	Latuda	Letuda
Latudoir	Latuda 40 mg	Letuda 120 mg
Lutudor	Latuda 40 mg	Latuta 120 mg
uninterpretable	Latuda	Latuda 120 mg
Lutudir 120mg Take by mouth daily.	Latuda 40	Latuta 120mg
Laturder 120 mg po daily	Latuda 40 mg	Latuda 120mg
Latudir	Latuda 40 mg	Letuda 120 mg
	Latruda 40 mg	

Appendix D: Proprietary names not used in usual clinical practice settings for the reasons described.

Proprietary Name	Active Ingredient	Similarity to	Failure preventions
Lotussin	Guaifenesin in combination with other active ingredients	Sound	Discontinued combination Guaifenesin containing products marketed outside the United States (United Kingdom, Ireland, and South Africa).
Lotusate	Tabutal	Look	Discontinued product with no generic equivalents. Withdrawn in 1997 not for safety reasons.
Lactose		Look	Not identified as a medication but an inactive ingredient used n the preparation of pharmaceuticals.
Labid	Theophylline ext release 250 mg tablet	Look	Discontinued branded generic with no equivalents marketed.

(b) (4)

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

Proprietary Name	Active Ingredient	Similarity to	Failure preventions
Lidodan	Lidocaine endotracheal spray	Look	Endotracheal spray marketed in Canada.
Sebulon	Pyrithione Zinc Shampoo	Look	Noted in identified database as not marketed in the US and noted as discontinued by manufacturer in another database.

Appendix E: 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.
Latuda (Lurasidone HCl)	40 mg, 80 mg, and 120 mg tablets		One tablet (40 or 80 mg) by mouth daily with food. (The dose may be increased to a maximum of 120 mg.) No titration is needed.	
Lactase (Oral enzyme supplement)	Look	3000 FCC and 9000 FCC *tablets*	*One* to three *tablets by mouth* with meals and snacks,	**Orthographic difference:** Latuda includes the letter 'd' which provides an additional upstroke appearing toward end of the name when scripted. **Strength:** 3000 FCC and 9000 FCC vs. 40 mg, 80 mg, and 120 mg **Frequency of use:** With meals or each time dairy products are consumed vs. daily,
Lactulose	Look	10 g/15 mL oral solution	*One* to three tablespoons (15 mL) to 45 mL) *by mouth daily* or three to four times daily.	**Orthographic difference:** Lactulose includes three additional letters (nine vs. six) providing additional length when scripted. **Strength:** 10 mg/15 mL (single strength which may be omitted) vs. 40 mg, 80 mg, and 120 mg **Dosage form:** oral liquid vs. tablet
Latisse (Bimatoprost)	Look	0.3 mg/mL ophthalmic solution	Apply nightly directly to the skin of the upper eyelid margin at the base of the eyelashes using the accompanying applicators	**Orthographic difference:** Latuda includes the letter 'd' which provides an additional upstroke appearing toward end of the name when scripted. **Strength:** 0.3 mg/mL (single strength which may be omitted) vs. 40 mg, 80 mg, and 120 mg **Dosage form and route of administration:** Ophthalmic solution vs. oral tablet.

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.
Latuda (Lurasidone HCl)	40 mg, 80 mg, and 120 mg tablets		One tablet (40 or 80 mg) by mouth daily with food. (The dose may be increased to a maximum of 120 mg.) No titration is needed.	
Letairis	Look	5 mg and 10 mg tablet	*One tablet by mouth daily*	**Orthographic difference:** Latuda includes the letter 'd' which may provide an additional upstroke in the name when scripted. Letairis include two additional letters (eight vs. six) providing added length to the name when scripted. **Strength:** 5 mg and 10 mg vs. 40 mg, 80 mg, and 120 mg
Lexiva (Fosamprenavir calcium)	Look	50 mg/mL oral suspension and 700 mg tablets	Therapy-Naive Adults: Two tablets (1,400 mg) by mouth twice daily; Two tablets 1,400 mg by mouth once daily plus ritonavir 200 mg once daily; Two tablets (1,400 mg) once daily plus ritonavir 100 mg by mouth once daily; One tablet (700 mg) twice daily plus ritonavir 100 mg twice daily. Protease Inhibitor-Experienced Adults: One tablet (700 mg) by mouth twice daily plus ritonavir 100 mg twice daily.	**Orthographic difference:** Latuda includes the letters 't' and 'd' which provide two additional upstrokes when scripted. **Strength:** 50 mg/mL and 700 mg vs. 40 mg, 80 mg, and 120 mg.
Lialda (Mesalamine)	Look	1.2 g *tablets*	Two to four tablets (2.4 g to 4.8 g) *by mouth daily* with food.	**Orthographic difference:** Latuda includes the letter 't' which may provide a cross stroke. The upstrokes provided by 'l' and 'd' appear adjacent in Lialda while the 't' and 'd' are separated by one letter in Latuda. **Dose:** two to four tablets vs. one tablets or 2.4 g to 4.8 g vs. 40 mg, 80 mg, or 120 mg.

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.
Latuda (Lurasidone HCl)	40 mg, 80 mg, and 120 mg tablets		One tablet (40 or 80 mg) by mouth daily with food. (The dose may be increased to a maximum of 120 mg.) No titration is needed.	
Lofibra (Fenofibrate)	Look	54 mg and 160 mg *tablets* 67 mg, 134 mg and 200 mg capsules	*One tablet or capsule by mouth daily*.	**Orthographic differences:** Lofibra includes an 'f' which may provide a down stroke when scripted. The 'b' in Lofibra makes the second and third upstrokes appear closer when scripted. **Strengths:** 54 mg, 160 mg, 67 mg, 134 mg and 200 mg vs. 40 mg, 80 mg, and 120 mg
Lortab (Hydrocodone Bitartrate and Acetaminophen)	Look	2.5 mg/500 mg 5 mg/500 mg 7.5 mg/500 mg and 10 mg/500 mg tablets and 7.5 mg/500 mg per 15 mL oral elixir	One to two *tablets by mouth* every four to six hours as needed for pain. (or liquid equivalent One to two tablespoonfuls)	**Orthographic difference:** Latuda includes the letter 'a' appearing at the end of the name providing an additional letter following the third upstroke. **Strengths:** 2.5 mg/500 mg, 5 mg/500 mg, 7.5 mg/500 mg, and 10 mg/500 mg, vs. 40 mg, 80 mg, and 120 mg **Frequency of use:** every four to six hours vs. daily.
Lotemax (Loteprednol)	Look	0.5% ophthalmic suspension	Instill one to two drops into affected eye four times daily (may be prescribe up to every hour))	**Orthographic difference: L**atuda includes the letter 'd' which provides an additional upstroke. **Strength:** 0.5% vs. 40 mg , 80 mg, and 120 mg. **Dosage form and route of administration:** Ophthalmic suspension vs. oral tablet.
Lotrel (Amlodipine Besylate and Benazepril HCl)	Look	2.5 mg/10 mg, 5 mg/10 mg, 5 mg/20 mg, 5 mg/*40 mg*, 10 mg/20 mg, 10 mg/*40 mg* capsules	*One capsule by mouth daily*	**Orthographic difference:** Latuda includes the letter 'a' appearing at the end of the name adding length and an additional letter following the third upstroke. **Strength:** The strength of Lotrel consists of both active ingredients thus both strengths must be expressed for a complete prescription. Although the 40 mg strength overlaps in both products, the 40 mg strength in Lotrel is preceded with an additional strength presentation (5 mg or 10 mg) not present in Latuda.

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.
Latuda (Lurasidone HCl)	40 mg, 80 mg, and 120 mg tablets		One tablet (40 or 80 mg) by mouth daily with food. (The dose may be increased to a maximum of 120 mg.) No titration is needed.	
Lotrimin Lotrimin AF (Clotrimazole)	Look	1% cream or topical solution	Apply a sufficient quantity to cover affected area twice daily.	**Orthographic difference:** Latuda includes the letter 'd' which provides an additional upstroke. Lotrimin includes two additional letters (eight vs. six) providing added length to the name when scripted. Lotrimin may be written with a modifier. **Strength:** 1% (single strength which may be omitted) vs. 40 mg, 80 mg, and 120 mg **Dosage form and route of administration:** topical cream and topical solution vs. oral tablet.
Lotrisone (Clotrimazole and Betamethasone Dipropionate)	Look	1 %/0.05% cream or lotion	Apply sparingly (a small amount) to affected area twice daily.	**Orthographic difference:** Latuda includes the letter 'd' which provides an additional upstroke. Lotrisone includes three additional letters (nine vs. six) providing added length to the name when scripted. **Strength:** 1%/0.05% (single strength which may be omitted) vs. 40 mg, 80 mg, and 120 mg **Dosage form and route of administration:** topical cream and topical lotion vs. oral tablet.
Lotronex (Alosetron)	Look	0.5 mg and 1 mg *tablets*	*One tablet by mouth* twice daily.	**Orthographic difference:** Latuda includes the letter 'd' which provides an additional upstroke. Lotronex includes two additional letters (eight vs. six) providing added length to the name when scripted.. **Strength:** 0.5 mg and 1 mg vs. 40 mg, 80 mg, and 120 mg **Frequency of use:** twice daily vs. once daily. Lotronex use includes a REMS which provides for prescriptions for Lotronex to include a blue RX sticker to notify pharmacists the prescriber is certified to prescribe this product.

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.
Latuda (Lurasidone HCl)	40 mg, 80 mg, and 120 mg tablets		One tablet (40 or 80 mg) by mouth daily with food. (The dose may be increased to a maximum of 120 mg.) No titration is needed.	
Lunesta (Eszopiclone)	Look	1 mg, 2 mg, and 3 mg *tablets*	*One tablet by mouth* at bedtime for sleep	**Orthographic difference:** Latuda includes two letters providing upstrokes compared to only a 't' in Lunesta. **Strengths:** 1 mg, 2 mg, and 3 mg vs. 40 mg, 80 mg, and 120 mg**.**
Luride (Sodium Fluoride)	Look	0.25 mg, 0.5 mg, 1 mg chewable tablets and 0.5 mg/mL drips	Chew and swallow *one tablet daily.*	**Orthographic difference:** Latuda includes a 't' which provides a cross stroke and an additional upstroke in the middle of the name. **Strength:** 0.25 mg, 0.5 mg and 1 mg vs. 40 mg, 80 mg, and 120 mg Luride is indicated for use in pediatric patients while Latuda is only indicated in adults.
Lusedra (Fospropofol Disodium)	Look and Sound	1050 mg/30 mg vial (35 mg/mL)	Initial dose: 6.5 mg/kg intravenously once. not to exceed 16.5 mL. Supplemental doses 1.6 mg/kg intravenously Dose ranges from 3 mL to 4 mL	**Orthographic difference:** Latuda includes a 't' in the third position providing an additional upstroke and a possible cross stroke not seen in Lusedra. **Phonetic difference:** The second syllable in each name begins with a different sounding consonant ('tt' vs. 'ss'). **Strength:** 1050 mg/30 mL vs. 40 mg, 80 mg, or 120 mg**.** **Dosage form and route of administration:** injection given intravenously vs. oral tablet.
Lutera (Ethinyl Estradiol and Levonorgestrel)1	Look	0.02 mg/0.1 mg *tablets*	*One tablet by mouth daily.*	**Orthographic difference:** Latuda includes the letter 'd' which may provide an additional upstroke in the name. **Strength:** 0.02 mg/0.1 mg (single strength which may be omitted) vs. 40 mg, 80 mg and 120 mg

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.
Latuda (Lurasidone HCl)	40 mg, 80 mg, and 120 mg tablets		One tablet (40 or 80 mg) by mouth daily with food. (The dose may be increased to a maximum of 120 mg.) No titration is needed.	
Lysteda (Tranexamic Acid	Look and Sound	650 mg *tablets*	Two tablets (1300 mg) *by mouth* three times daily during menses.	**Orthographic difference:** Lysteda includes the letter 'y' which may provide a down stroke when scripted and an 's' adding a letter between the 'L' and 't'. **Phonetic difference:** The first syllable in Lysteda ends with an 'ss' sound not heard in the name Latuda. **Strength:** 650 mg (single strength which may be omitted) vs. 40 mg, 80 mg, or 120 mg. **Dose:** two tablets vs. one tablet **Frequency of use**: three times daily vs. once a day.
Potaba Aminobenzoate Potassium	Look	500 mg *tablets* and capsules and 2 g packets	Three *tablet*s or capsules by mouth with meals or snacks.	**Orthographic difference:** Potaba begins with 'P' compared to a 'L' **Strength:** 500 mg and 2 g vs. 40 mg, 80 mg, and 120 mg **Dose:** 1.5 to 2 grams vs. 40 mg, 80 mg, and 120 mg **Frequency of use:** three times daily vs. daily
Sufenta (Sufentanil Citrate)	Look	50 mcg/mL, 100 mcg/2 mL, and 250 mcg/5 mL ampules	As genera; anesthesia : Adult 8-10 mcg/kg total in increments of 0.5 mcg/kg - 10 mcg/kg intravenously; adjuvant 2-8 mcg/kg intravenously in 10-25 mcg increments or as cont infusion	**Orthographic difference:** Sufenta begins with an 'S' rather than an 'L.' **Dosage form and route of administration:** injection administered intravenously vs. oral tablet. Sufenta is limited to use by anesthesiology for procedures.
Talacen (Pentazocine HCl and Acetaminophen)	Look	25 mg/650 mg *tablets*	One tablet every four to six hours as needed for pain.	**Orthographic difference:** Latuda includes the letter 'd' which provides an additional upstroke. **Strength**: 25 mg/650 mg (single strength which may be omitted) vs. 40 mg , 80 mg, and 120 mg.

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.
Latuda (Lurasidone HCl)	40 mg, 80 mg, and 120 mg tablets		One tablet (40 or 80 mg) by mouth daily with food. (The dose may be increased to a maximum of 120 mg.) No titration is needed.	
Toradol (Ketorolac Tromethamine)	Look	10 mg *tablets* 15 mg/ml, 30 mg/mL, and 60 mg/2 mL injection	*One tablet* by mouth every four to six hours as needed for up to five days. 30 mg intravenously or intramuscularly every six hours for up to five days. (first dose may be 60 mg.)	**Orthographic difference:** The upstrokes in Toradol appear in the fifth and seventh (or final) positions compared to the third and fifth positions in Latuda. **Strength:** 10 mg, 15 mg/ mL, 30 mg/mL and 60 mg/ mL vs. 40 mg, 80 mg, and 120 mg **Frequency of use:** every four or six hours vs. daily
Truvada (emtricitabine and tenofovir disoproxil fumarate)	Look and sound	200 mg/300 mg tablet	*One tablet by mouth daily*	**Orthographic difference:** Latuda includes the letter 't' which provides an additional upstroke and a cross stroke. **Phonetic difference:** The first and second syllables begin with different sound consonants. 'Tr' vs. 'L' in the first syllable . 'V' vs. 't' starts the second syllable. **Strength:** 200 mg/300 mg (single strength which may be omitted.) vs. 40 mg, 80 mg, or 120 mg.
Xeloda (Capecitabine)	Look	150 mg and 500 mg *tablets*	2500 mg/m^2/day divided and given two doses per day for two weeks. or 2000 mg/m^2/day divided into two doses per day fir two weeks average person BSA is approximately 1.73mg/m2 2000 mg/m^2/day dose of Xeloda equals 3500 mg may be given as four tablets 2000 mg by mouth in the morning and three tablets (1500 mg) by mouth in the evening. 2500 mg/m^2/day dose of Xeloda equals 4000 mg as for tablets (2000 mg) by mouth twice daily.	**Orthographic difference:** Xeloda begins with an 'X' rather than an 'L.' **Strength:** 150 mg and 500 mg vs. 40 mg, 80 mg, and 120 mg Xeloda is an oral chemotherapy agent with a complicated dosing regimen which is likely to require a combination of strengths to make a dose.

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.
Latuda (Lurasidone HCl)	40 mg, 80 mg, and 120 mg tablets		One tablet (40 or 80 mg) by mouth daily with food. (The dose may be increased to a maximum of 120 mg.) No titration is needed.	
Zantac (Ranitidine HCl)	Look	75 mg, 150 mg and 300 mg *tablets* 25 and 150 mg effervescent tablet; 15 mg/mL oral solution; 50 mg/50 mL premixed bag, 50 mg/2 mL and 150 mg/6 mL vials	Adults: Oral: *One tablet* (75 mg to 150 mg) by mouth twice daily. or *One tablet* (300 mg) *by mouth daily*. Injection: 50 mg intravenously or intramuscularly every 6 to 8 hours. Pediatric: Oral: 2- 4 mg/kg/dose by mouth twice a day. Injection: 2-4 mg/kg/day divided every 6 to 8 hours.	**Orthographic difference:** Latuda includes the letter 'd' which provides an additional upstroke appearing towards the end of the name. **Strength of oral solid dosage forms:** 25 mg , 75 mg, 150 mg, and 300 mg vs. 40 mg, 80 mg and 120 mg. **Dose in adult population:** 75 mg, 150 mg and 300 mg vs. 40 mg. 80 mg, and 120 mg
				(b) (4)
Zoladex (Goserelin Acetate)	Look	3.6 mg and 10.8 mg implant in a prefilled syringe	Inject the contents of one syringe subcutaneously monthly (3.6 mg) or every three months (10.8 mg).	**Strength:** 3.6 mg and 10.8 mg vs. 40 mg, 80 mg, and 120 mg **Dosage form and route of administration:** subcutaneous implant in a prefilled syringe vs. oral tablet. **Frequency use of use:** monthly and every three months (making it likely to be ordered as a single dose) vs. daily.

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

Proposed name: **Latuda** **(Lurasidone HCl)**	**Strength:** **40 mg, 80 mg, and 120 mg**	**Usual dose:** **One tablet (40 or 80 mg) by mouth daily with food. (The dose may be increased to a maximum of 120 mg.) No titration is needed.**
Failure Mode: Name confusion	**Causes (could be multiple)**	**Prevention of Failure Mode;(name confusion)**
Lotensin (Benazepril HCl) 5 mg, 10 mg, 20 mg and 40 mg tablets Usual dose: One tablet (any strength) by mouth daily	Orthographic similarity: Both names begin with three letters that appear similar when scripted (Lot- vs. Lat-). Phonetic similarity: Both names contain three syllable and the first two start with the same consonant sounds ('LL' and 't') Both products are available as oral tablets taken once daily and share a common strength	Orthographic and phonetic differences minimize the risk for medication error. Rationale The orthographic differences stem from the fact Lotensin includes eight letters and appears longer when scripted. Latuda includes the letter 'd' which provides an additional upstroke. The phonetic difference stems from the fact the second and third syllable in Lotensin contain consonants not heard in Latuda. The second syllable of Lotensin ends with an 'nn' sound while there is no ending consonant sound in Latuda. The third begins with an 'ss' sound and also ends with a 'nn' sound while the third syllable of Latuda begins with a 'dd' sound.

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