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RESEARCH**

APPLICATION NUMBER:
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PROPRIETARY NAME REVIEW(S)

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

Proprietary Name Review

Date: June 3, 2013

Reviewer: Loretta Holmes, BSN, PharmD
Division of Medication Error Prevention and Analysis

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Drug Name and Strengths: Fetzima (Levomilnacipran) Extended-release Capsules
20 mg, 40 mg, 80 mg, and 120 mg

Application Type/Number: NDA 204168

Applicant: Forest Laboratories, Inc.

OSE RCM #: 2013-659

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

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1 INTRODUCTION

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

1.1 REGULATORY HISTORY

The name (b) (4) was initially proposed for this NDA. (b) (4) was evaluated in OSE Review 2012-2332, dated October 25, 2012, and determined to be unacceptable (b) (4). The Applicant subsequently submitted the name, (b) (4) for our evaluation. In OSE Review 2012-2846, dated February 14, 2013, the name (b) (4) was found unacceptable (b) (4).

1.2 PRODUCT INFORMATION

The following product information is provided in the March 11, 2013 proprietary name submission.

- Active Ingredient: Levomilnacipran
- Indication of Use: Treatment of Major Depressive Disorder (MDD)
- Route of Administration: Oral
- Dosage Form: Extended-release Capsules
- Dose and Frequency of Administration: Initiate at 20 mg once daily for 2 days and then increase to 40 mg once daily. Based on efficacy and tolerability, the dose may be increased in increments of 40 mg at intervals of 2 or more days. The maximum recommended dose is 120 mg once daily. For patients with mild renal impairment (creatinine clearance 60 to 89 mL/min), the maintenance dose should not exceed 80 mg once daily. For patients with severe renal impairment (creatinine clearance of 15 to 29 mL/min), the maintenance dose should not exceed 60 mg once daily. Fetzima should be swallowed whole. Do not open, chew or crush the capsule. Fetzima can be taken with or without food.
- How Supplied: See tables below for retail and professional sample packaging configurations
- Storage: Store at 25°C (77°F); excursions permitted between 15°C and 30°C (59°F and 86°F)
- Container and Closure Systems: HDPE bottles (b) (4)
- Intended Pronunciation of the Proposed Proprietary Name: fet-ZEE-muh
- Derivation of the Proposed Proprietary Name: The name Fetzima is not derived from any one particular concept.

Table 1: Retail Bottles and Hospital Unit Dose (HUD) Configurations	
Capsule Strength	Retail Package Configurations
20 mg	Bottle / 30 count
	Hospital Unit Dose (Blister) / 10 x 10
40 mg	Bottle / 30 count
	Bottle / 90 count
	Hospital Unit Dose (Blister) / 10 x 10
80 mg	Bottle / 30 count
	Bottle / 90 count
	Hospital Unit Dose (Blister) / 10 x 10
120 mg	Bottle / 30 count
	Bottle / 90 count
	Hospital Unit Dose (Blister) / 10 x 10

Table 2: Retail Titration Pack Configurations (b) (4)	
Capsule Strength	Package Configuration
2x 20 mg	Titration Pack/Starter Kit
26x 40 mg	

(b) (4)

(b) (4)

(b) (4)

2 RESULTS

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

2.1 PROMOTIONAL ASSESSMENT

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

2.2 SAFETY ASSESSMENT

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

2.2.1 United States Adopted Names (USAN) SEARCH

The April 26, 2013 search of the United States Adopted Name (USAN) stems did not identify that a USAN stem is present in the proposed proprietary name.

2.2.2 Components of the Proposed Proprietary Name

The Applicant indicated in their submission that the proposed name, Fetzima, is not derived from any one particular concept. This proprietary name is comprised of a single word that does not contain any components (i.e., a modifier, route of administration, dosage form, etc.) that are misleading or can contribute to medication error.

2.2.3 FDA Name Simulation Studies

Sixty-two practitioners participated in DMEPA's prescription studies. The interpretations did not overlap with currently marketed products nor did they appear or sound similar to any currently marketed products or pending products. Nine practitioners in the verbal study interpreted the beginning letter "F" as the letter "S", two interpreted it as the letter "C", one as the letter "X", and another as the letter "Z". There were also multiple verbal and written interpretations of the letters "ima" (e.g., "uma", "una", "ura", and "mna"). See Appendix C for the complete listing of interpretations from the verbal and written prescription studies. We considered these interpretations in our analysis of the proposed proprietary name.

2.2.4 Failure Mode and Effects Analysis of Similar Names

Appendix B lists possible orthographic and phonetic misinterpretations of the letters appearing in the proposed proprietary name, Fetzima. Table 4 lists the names with orthographic, phonetic, or spelling similarity to the proposed proprietary name, Fetzima, identified by the primary reviewer, the Expert Panel Discussion (EPD) and the (b) (4) external name study.

Table 4: Collective List of Potentially Similar Names from DMEPA, EPD, and the External Name Study

(b) (4)

Look Similar (n=31)					
<i>Name</i>	<i>Source</i>	<i>Name</i>	<i>Source</i>	<i>Name</i>	<i>Source</i>
Fe-Tinic	EPD Panel	Tekturna	EPD Panel	Relenza	EPD Panel
Fetrin	EPD Panel	Tekalmo	EPD Panel	Robaxin	EPD Panel
Rezira	EPD Panel	Fulyzaq	EPD Panel	Rotarix	EPD Panel
Testim	EPD Panel	(b) (4)	EPD Panel	Fentora	EPD Panel
Fexmid	EPD Panel	Fergon	EPD Panel	Tetcaine	EPD Panel
Falmina	EPD Panel	Metvixia	EPD Panel	Teflaro	EPD Panel
Letrozole	EPD Panel	Feigen	EPD Panel	Fatsia	EPD Panel
Tri-Luma	EPD Panel	Tetanus Toxoid	EPD Panel	Amitiza	(b) (4)
Folivane-F Folivane-OB	EPD Panel	Fentanyl	(b) (4)	Frova	(b) (4)
Felodipine	(b) (4)	Teczem	(b) (4)	Zefazone	Primary Safety Evaluator
Pentazine	Primary Safety Evaluator				
Sound Similar (n=6)					
<i>Name</i>	<i>Source</i>	<i>Name</i>	<i>Source</i>	<i>Name</i>	<i>Source</i>
(b) (4)	EPD Panel	Pexeva	EPD Panel	Zyprexa	(b) (4)
Ezetimibe	(b) (4)	Fexofenadine	(b) (4)	Fanapt	(b) (4)
Look and Sound Similar (n=5)					
<i>Name</i>	<i>Source</i>	<i>Name</i>	<i>Source</i>	<i>Name</i>	<i>Source</i>
Feldene	EPD Panel (b) (4)	Zetia	(b) (4)	Sustiva	EPD Panel (b) (4)
Femara	(b) (4)	Forteo	(b) (4)		

Our analysis of the 42 names contained in Table 4 considered the information obtained in the previous sections along with their product characteristics. We determined all 42 names will not pose a risk for confusion as described in Appendices D through E.

2.2.5 Communication of DMEPA's Final Decision to Other Disciplines

DMEPA communicated our findings to the Division of Psychiatry Products via e-mail on May 2, 2013. At that time we also requested additional information or concerns that could inform our review. Per e-mail correspondence from the Division of Psychiatry Products on May 9, 2013, they stated no additional concerns with the proposed proprietary name, Fetzima.

3 CONCLUSIONS

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

If you have further questions or need clarifications, please contact Louis Flowers, OSE Project Manager, at 301-796-3158.

3.1 COMMENTS TO THE APPLICANT

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

If any of the proposed product characteristics as stated in your March 11, 2013 submission are altered, the name must be resubmitted for review.

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

4 REFERENCES

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

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

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

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

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

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

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

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

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

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

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

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

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

USPTO provides information regarding patent and trademarks.

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

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

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

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

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

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

11. Access Medicine (www.accessmedicine.com)

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

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

USAN Stems List contains all the recognized USAN stems.

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

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

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

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

15. Medical Abbreviations (www.medilexicon.com)

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

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

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

17. Walgreens (www.walgreens.com)

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

18. Rx List (www.rxlist.com)

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

19. Dogpile (www.dogpile.com)

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

20. Natural Standard (<http://www.naturalstandard.com>)

Natural Standard is a resource that aggregates and synthesizes data on complementary and alternative medicine.

APPENDICES

Appendix A

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

The safety assessment is conducted by DMEPA. DMEPA staff search a standard set of databases and information sources to identify names that are similar in pronunciation, spelling, and orthographically similar when scripted to the proposed proprietary name. Additionally, we consider inclusion of USAN stems or other characteristics that when incorporated into a proprietary name may cause or contribute to medication errors (i.e., dosing interval, dosage form/route of administration, medical or product name abbreviations, names that include or suggest the composition of the drug product, etc.). DMEPA defines a medication error as any preventable event that may cause or lead to inappropriate medication use or patient harm while the medication is in the control of the health care professional, patient, or consumer.²

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

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

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

Typical product characteristics considered when identifying drug names that could potentially be confused with the proposed proprietary name include, but are not limited to; established name of

² National Coordinating Council for Medication Error Reporting and Prevention.
<http://www.nccmerp.org/about/MedErrors.html>. Last accessed 10/11/2007.

the proposed product, proposed indication of use, dosage form, route of administration, strength, unit of measure, dosage units, recommended dose, typical quantity or volume, frequency of administration, product packaging, storage conditions, patient population, and prescriber population. DMEPA considers how these product characteristics may or may not be present in communicating a product name throughout the medication use system. Because drug name confusion can occur at any point in the medication use process, DMEPA considers the potential for confusion throughout the entire U.S. medication use process, including drug procurement, prescribing and ordering, dispensing, administration, and monitoring the impact of the medication.³

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		
	<i>Potential Causes of Drug Name Similarity</i>	<i>Attributes Examined to Identify Similar Drug Names</i>	<i>Potential Effects</i>
Look-alike	Similar spelling	Identical prefix Identical infix Identical suffix Length of the name Overlapping product characteristics	<ul style="list-style-type: none"> Names may appear similar in print or electronic media and lead to drug name confusion in printed or electronic communication Names may look similar when scripted and lead to drug name confusion in written communication

³ Institute of Medicine. Preventing Medication Errors. The National Academies Press: Washington DC. 2006.

	Orthographic similarity	Similar spelling Length of the name/Similar shape Upstrokes Down strokes Cross-strokes Dotted letters Ambiguity introduced by scripting letters Overlapping product characteristics	<ul style="list-style-type: none"> Names may look similar when scripted, and lead to drug name confusion in written communication
Sound-alike	Phonetic similarity	Identical prefix Identical infix Identical suffix Number of syllables Stresses Placement of vowel sounds Placement of consonant sounds Overlapping product characteristics	<ul style="list-style-type: none"> Names may sound similar when pronounced and lead to drug name confusion in verbal communication

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

1. Database and Information Sources

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

2. Expert Panel Discussion

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

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

3. FDA Prescription Simulation Studies

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

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

4. Comments from Other Review Disciplines

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

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

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

5. Safety Evaluator Risk Assessment of the Proposed Proprietary Name

The primary Safety Evaluator applies his/her individual expertise gained from evaluating medication errors reported to FDA, considers all aspects of the name that may be misleading or confusing, conducts a Failure Mode and Effects Analysis, and provides an overall decision on acceptability dependent on their risk assessment of name confusion. Failure Mode and Effects Analysis (FMEA) is a systematic tool for evaluating a process and identifying where and how it might fail.⁴ 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 has not been marketed, the primary Safety Evaluator anticipates the use of the product in the usual practice settings by considering the clinical and product characteristics listed in Section 1.2 of this review. The Safety Evaluator then analyzes the proposed proprietary name in the context of the usual practice setting and works to identify potential failure modes and the effects associated with the failure modes.

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

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

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

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

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

The answer to this question is a central component of the Safety Evaluator’s overall risk assessment of the proprietary name. If the Safety Evaluator determines through FMEA that the name similarity would not ultimately be a source of medication errors in the usual practice setting, the primary

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

Safety Evaluator eliminates the name from further analysis. However, if the Safety Evaluator determines through FMEA that the name similarity could ultimately cause medication errors in the usual practice setting, the Safety Evaluator will then recommend the use of an alternate proprietary name.

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

- a. OPDP finds the proposed proprietary name misleading from a promotional perspective, and the Review Division concurs with OPDP's findings. The Federal Food, Drug, and Cosmetic Act provides that labeling or advertising can misbrand a product if misleading representations are made or suggested by statement, word, design, device, or any combination thereof, whether through a PROPRIETARY name or otherwise [21 U.S.C 321(n); See also 21 U.S.C. 352(a) & (n)].
- b. DMEPA identifies that the proposed proprietary name is misleading because of similarity in spelling or pronunciation to another proprietary or established name of a different drug or ingredient [CFR 201.10.(C)(5)].
- c. FMEA identifies the potential for confusion between the proposed proprietary name and other proprietary or established drug name(s), and demonstrates that medication errors are likely to result from the drug name confusion under the conditions of usual clinical practice.
- d. The proposed proprietary name contains an USAN (United States Adopted Names) stem.
- e. DMEPA identifies a potential source of medication error within the proposed proprietary name. For example, the proprietary name may be misleading or, inadvertently, introduce ambiguity and confusion that leads to errors. Such errors may not necessarily involve confusion between the proposed drug and another drug product but involve a naming characteristic that when incorporated into a proprietary name may be confusing, misleading, cause or contribute to medication errors.

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

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

The threshold set for objection to the proposed proprietary name may seem low to the Applicant/Sponsor. However, the safety concerns set forth in criteria a through e above are supported either by FDA regulation or by external healthcare authorities, including the Institute of Medicine (IOM), World Health Organization (WHO), the Joint Commission, and the Institute for Safe Medication Practices (ISMP). These organizations have examined medication errors resulting

from look- or sound-alike drug names, confusing, or misleading names and called for regulatory authorities to address the issue prior to approval. Additionally, DMEPA contends that the threshold set for the Proprietary Name Risk Assessment is reasonable because proprietary drug name confusion is a predictable and preventable source of medication error that, in many instances, the Agency and/or Sponsor can identify and rectify prior to approval to avoid patient harm.

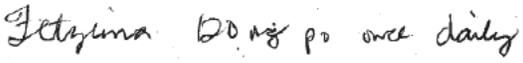
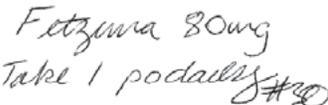
Furthermore, post-marketing experience has demonstrated that medication errors resulting from drug name confusion are notoriously difficult to rectify post-approval. Educational and other post-approval efforts are low-leverage strategies that have had limited effectiveness at alleviating medication errors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

Appendix B: Letters with Possible Orthographic or Phonetic Misinterpretation

Letters in Name, Fetzima	Scripted May Appear as	Spoken May Be Interpreted as
F	P, I, L, T, Z	C, Pf, Ph, S, X, Z, V, Fh
f	p, t, l	c, pf, ph, s, x, z, v, fh
e	a, c, i, l, o, p	Any vowel, ai
t	b, f, l, r, x	d
z	c, e, g, j, n, m, q, r, s, v, y	c, s, x
i	e, l, j, r	Any vowel
m	rn, rv, rr, nn, n, nr, in, v, w, wi, vi, onc, z	
a	el, ci, cl, d, o, u	Any vowel
Letter strings		
Fe	H	Fa, Fai, Fei, Feh
et	d	at
im	an, un	em

Appendix C: Prescription Simulation Samples and Results

Figure 1. Fetzima Study (Conducted on April 1, 2013)

Handwritten Requisition Medication Order	Verbal Prescription
<u>Inpatient Medication Order:</u> 	Fetzima 80 mg Take one po daily Disp. #30
<u>Outpatient Prescription:</u> 	

FDA Prescription Simulation Responses (Aggregate 1 Rx Studies Report)

192 People Received Study 62 People Responded				
Study Name: Fetzima				
Total	21	16	25	
INTERPRETATION	INPATIENT	VOICE	OUTPATIENT	TOTAL
CETZIMA	0	2	0	2
FENTVIMA	0	1	0	1
FETIMRA	1	0	0	1
FETZEMA	1	1	0	2
FETZERMA	1	0	0	1
FETZERVA	1	0	0	1
FETZIMA	2	1	18	21
FETZIMNA	0	0	1	1
FETZINA	0	0	1	1
FETZINRA	2	0	0	2

FETZRINA	0	0	1	1
FETZUMA	4	0	0	4
FETZUNA	5	0	0	5
FETZURA	3	0	0	3
FETZURRA	1	0	0	1
SETEMA	0	1	0	1
SETFEMA	0	1	0	1
SETSIMA	0	1	0	1
SETVIMA	0	1	0	1
SETXIMA	0	1	0	1
SETZEMA	0	2	0	2
SETZIMA	0	2	0	2
TETZUMA	0	0	1	1
XETZIMA	0	1	0	1
ZETZIMA	0	1	0	1

Appendix D: Proprietary names not likely to be confused or not used in usual practice settings for the reasons described.

No.	Drug Name	Active Ingredient(s)	Similarity to Fetzima	Failure preventions
1.	Testim	Testosterone	Look	The pair have sufficient orthographic and/or phonetic differences.
2.	Letrozole	Letrozole	Look	The pair have sufficient orthographic differences.
3.	Folivane-F Folivane-OB	<u>Folivane-F:</u> Ascorbate, Ferrous Fumarate, Folic Acid, Niacin, Polysaccharide-Iron Complex <u>Folivane-OB</u> Ascorbate, Biotin, Calcium Pantothenate, Copper, Cyanocobalamin, Ferrous Fumarate, Folic Acid, Magnesium, Manganese, Niacin, Polysaccharide-Iron Complex, Pyridoxine, Riboflavin, Thiamine Mononitrate, Zinc	Look	The pair have sufficient orthographic differences
4.	Tekturna	Aliskiren Fumarate	Look	The pair have sufficient orthographic differences.
5.	Tekamlo	Aliskiren Hemifumarate and Amlodipine Besylate	Look	The pair have sufficient orthographic differences
6.	Fulyzaq	Crofelemer	Look	The pair have sufficient orthographic differences.
7.	Fergon	Ferrous Gluconate	Look	The pair have sufficient orthographic differences
8.	Metvixia	Methyl Aminolevulinate	Look	The pair have sufficient orthographic differences.
9.	Fe-Tinic 150 Fe-Tinic 150 Forte	<u>Fe-Tinic 150:</u> Ascorbic Acid, Calcium Threonate, Ferrous Asparto Glycinate, Polysaccharide-Iron Complex, Succinic acid <u>Fe-Tinic 150 Forte:</u> Calcium Ascorbate with ascorbic acid metabolites, Calcium Threonate, Cyanocobalamin, Ferrous Asparto Glycinate, Folic Acid, Polysaccharide-Iron Complex, Succinic acid	Look	The pair have sufficient orthographic differences.
10.	Felodipine	Felodipine	Look	The pair have sufficient orthographic differences
11.	Tetanus Toxoid	Tetanus Toxoid Adsorbed	Look	The pair have sufficient orthographic differences.

No.	Drug Name	Active Ingredient(s)	Similarity to Fetzima	Failure preventions
12.	Relenza	Zanamivir	Look	The pair have sufficient orthographic differences
13.	Robaxin	Methocarbamol	Look	The pair have sufficient orthographic differences.
14.	Rotarix	Rotavirus Vaccine, Live, Oral	Look	The pair have sufficient orthographic differences
15.	Fentora	Fentanyl Citrate	Look	The pair have sufficient orthographic differences.
16.	Teflaro	Ceftaroline Fosamil	Look	The pair have sufficient orthographic differences.
17.	Feigen	Also known as "Fig" Scientific name: Ficus carica	Look	The pair have sufficient orthographic differences
18.	Teczem	Diltiazem Maleate and Enalapril Maleate	Look	The pair have sufficient orthographic differences.
19.	Amitiza	Lubiprostone	Look	The pair have sufficient orthographic differences
20.	Fentanyl	Fentanyl/Fentanyl Citrate	Look	The pair have sufficient orthographic differences.
21.	Frova	Frovatriptan Succinate	Look	The pair have sufficient orthographic differences
22.	(b) (4)			
23.	Pexeva	Paroxetine Mesylate	Sound	The pair have sufficient phonetic differences.
24.	Ezetimibe	Ezetimibe	Sound	The pair have sufficient phonetic differences.
25.	Fanapt	Iloperidone	Sound	The pair have sufficient phonetic differences.
26.	Fexofenadine	Fexofenadine Hydrochloride	Sound	The pair have sufficient phonetic differences.
27.	Zyprexa	Olanzapine	Sound	The pair have sufficient phonetic differences.
28.	Zetia	Ezetimibe	Look and Sound	The pair have sufficient orthographic and phonetic differences.
29.	Femara	Letrozole	Look and Sound	The pair have sufficient orthographic and phonetic differences

No.	Drug Name	Active Ingredient(s)	Similarity to Fetzima	Failure preventions
30.	Forteo	Teriparatide (Recombinant)	Look and Sound	The pair have sufficient orthographic and phonetic differences
31.	Sustiva	Efavirenz	Look and Sound	The pair have sufficient orthographic and phonetic differences
32.	(b) (4)			
33.	Fatsia	Also known as “Devils Club” Scientific name: Oplopanax horridus	Look	This name was identified as an ingredient in some other products. There were no products identified that have the name “Fatsia”. Unlikely to be ordered by prescription.

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

	Proposed name: Fetzima (Levomilnacipran) Extended-release Capsules	Strengths: 20 mg, 40 mg, 80 mg, and 120 mg	Usual Dose: 20 mg orally once daily for 2 days and then increase to 40 mg once daily. Based on efficacy and tolerability, the dose may be increased in increments of 40 mg at intervals of 2 or more days. The maximum recommended dose is 120 mg once daily. <u>Renal adjustment:</u> Creatinine clearance 60 to 89 mL/min: maintenance dose should not exceed 80 mg once daily Creatinine clearance 15 to 29 mL/min: maintenance dose should not exceed 60 mg once daily.
	Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion	Causes (could be multiple)	Prevention of Failure Mode
34.	Fexmid (Cyclobenzaprine Hydrochloride) Tablets <u>Strength:</u> 7.5 mg <u>Dosage:</u> 7.5 mg orally three times per day	<u>Orthographic:</u> The prefixes “Fetzi” vs. “Fexmi” look similar when written. <u>Route of administration:</u> Both products are administered orally. <u>Dosage form:</u> Both products are solid oral dosage forms	<u>Orthographic:</u> The suffixes “ma” vs. “d” look different. <u>Strength:</u> 20 mg, 40 mg, 80 mg, and 120 mg (multiple strengths) vs. 7.5 mg (single strength) Fetzima is available in multiple strengths so the strength would have to be specified on a prescription whereas Fexmid is available in a single strength so the strength would not have to be specified. Additionally, the products do not have overlapping strengths.
35.	Falmina (Ethinyl Estradiol and Levonorgestrel) Tablets <u>Strength:</u> 20 mcg/0.1 mg <u>Dosage:</u> 1 tablet orally once daily	<u>Orthographic:</u> Both names contain seven letters. The prefixes (“Fetz” vs. “Falm”) and suffixes (“ima” vs. “ina”) look similar when written. <u>Route of administration:</u> Both products are administered orally. <u>Dosage form:</u> Both products are solid oral dosage forms <u>Strength:</u> The products have numerical overlap in strength (i.e., 20 mg vs. 20 mcg/0.1 mg)	<u>Strength:</u> Fetzima is available in multiple strengths so the strength would have to be specified on a prescription whereas Falmina is available in a single strength so the strength would not have to be specified. Additionally, if the strength was specified on a prescription for Falmina, it is unlikely a prescriber would specify only the 20 mcg Ethinyl Estradiol strength and not the 0.1 mg Levonorgestrel strength.

	Proposed name: Fetzima (Levomilnacipran) Extended-release Capsules	Strengths: 20 mg, 40 mg, 80 mg, and 120 mg	Usual Dose: 20 mg orally once daily for 2 days and then increase to 40 mg once daily. Based on efficacy and tolerability, the dose may be increased in increments of 40 mg at intervals of 2 or more days. The maximum recommended dose is 120 mg once daily. <u>Renal adjustment:</u> Creatinine clearance 60 to 89 mL/min: maintenance dose should not exceed 80 mg once daily Creatinine clearance 15 to 29 mL/min: maintenance dose should not exceed 60 mg once daily.
	Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion	Causes (could be multiple)	Prevention of Failure Mode
36.	Tri-Luma (Fluocinolone Acetonide, Hydroquinone, and Tretinoin) Cream <u>Strength:</u> 0.1%/4%/0.05% <u>Dosage:</u> Apply a thin film to the affected area(s) at bedtime	<u>Orthographic:</u> The beginning letters “F” vs. “T” look similar when written. When Tri-Luma is written as a single word (Triluma), the infix letters (“et” vs. “il”) look similar. Additionally, the suffixes “ma” are identical. <u>Frequency of administration:</u> Both products are administered once daily.	<u>Orthographic:</u> Triluma contains the additional letter “r” in the prefix, which lengthens the prefix and gives it a different appearance. <u>Strength:</u> Fetzima is available in multiple strengths so the strength would have to be specified on a prescription whereas Tri-Luma is available in a single strength so the strength would not have to be specified. Although there is numerical similarity between 40 mg of Fetzima and the 4% strength of the Hydroquinone component of Tri-Luma, if the strength was specified on a prescription for Tri-Luma, it is unlikely a prescriber would specify only the 4% Hydroquinone strength and not the strengths of the other two ingredients.

	<p>Proposed name: Fetzima (Levomilnacipran) Extended-release Capsules</p>	<p>Strengths: 20 mg, 40 mg, 80 mg, and 120 mg</p>	<p>Usual Dose: 20 mg orally once daily for 2 days and then increase to 40 mg once daily. Based on efficacy and tolerability, the dose may be increased in increments of 40 mg at intervals of 2 or more days. The maximum recommended dose is 120 mg once daily. <u>Renal adjustment:</u> Creatinine clearance 60 to 89 mL/min: maintenance dose should not exceed 80 mg once daily Creatinine clearance 15 to 29 mL/min: maintenance dose should not exceed 60 mg once daily.</p>
	<p>Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion</p>	<p>Causes (could be multiple)</p>	<p>Prevention of Failure Mode</p>
37.	<p>Feldene (Piroxicam) Capsules</p> <p><u>Strengths:</u> 10 mg and 20 mg</p> <p><u>Dosage:</u> 10 mg orally twice daily or 20 mg orally once daily</p>	<p><u>Orthographic:</u> The prefixes “Fet” vs. “Fel” look similar when written. The suffixes “ima” vs. “ene” look similar when written.</p> <p><u>Phonetic:</u> The prefixes “Fe” vs. “Fe” sound similar.</p> <p><u>Strength, route of administration, dose, and frequency of administration:</u> Both products are available in a 20 mg strength and can be administered 20 mg orally once daily</p>	<p><u>Orthographic:</u> Feldene contains the upstroke letter “d” in the fourth position whereas Fetzima contains the letter “z” in that position. The letters “d” vs. “z” look different when scripted.</p> <p><u>Phonetic:</u> Fetzima contains three syllables whereas Feldene contains two which helps to differentiate the names phonetically. The second syllables “-zi-” vs. “-dene” sound different.</p>

	<p>Proposed name: Fetzima (Levomilnacipran) Extended-release Capsules</p>	<p>Strengths: 20 mg, 40 mg, 80 mg, and 120 mg</p>	<p>Usual Dose: 20 mg orally once daily for 2 days and then increase to 40 mg once daily. Based on efficacy and tolerability, the dose may be increased in increments of 40 mg at intervals of 2 or more days. The maximum recommended dose is 120 mg once daily. <u>Renal adjustment:</u> Creatinine clearance 60 to 89 mL/min: maintenance dose should not exceed 80 mg once daily Creatinine clearance 15 to 29 mL/min: maintenance dose should not exceed 60 mg once daily.</p>
	<p>Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion</p>	<p>Causes (could be multiple)</p>	<p>Prevention of Failure Mode</p>
38.	<p>Zefazone (Cefmetazole Sodium) for Injection</p> <p><u>Strengths:</u> 1 g/vial and 2 g/vial</p> <p><u>Dosage:</u> 2 g intravenously every 6 hours; every 8 hours; every 12 hours; every 24 hours; or every 48 hours depending on the indication and patient’s renal function</p> <p>Zefazone is a discontinued product. The NDA was withdrawn by the Commissioner effective 09/17/01 (not for safety reasons). The dosing information was obtained from: http://reference.medscape.com/drug/zefazone-cefmetazole-342495 which is not one of our usual drug information sources. There are no generics available in the marketplace.</p>	<p><u>Orthographic:</u> The prefixes “Fet” vs. “Zef” look similar when written. The suffixes “zima” vs. “zone” look similar when written.</p> <p><u>Numerical similarity between doses:</u> 20 mg vs. 2 g</p> <p><u>Frequency of administration:</u> Both products can be administered once daily</p>	<p><u>Orthographic:</u> The letter “a” comes between the letters “f” and “z” in Zefazone, lengthening the infix.</p>

	Proposed name: Fetzima (Levomilnacipran) Extended-release Capsules	Strengths: 20 mg, 40 mg, 80 mg, and 120 mg	Usual Dose: 20 mg orally once daily for 2 days and then increase to 40 mg once daily. Based on efficacy and tolerability, the dose may be increased in increments of 40 mg at intervals of 2 or more days. The maximum recommended dose is 120 mg once daily. <u>Renal adjustment:</u> Creatinine clearance 60 to 89 mL/min: maintenance dose should not exceed 80 mg once daily Creatinine clearance 15 to 29 mL/min: maintenance dose should not exceed 60 mg once daily.
	Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion	Causes (could be multiple)	Prevention of Failure Mode
39.	<p>Pentazine (Promethazine Hydrochloride) Syrup Injection</p> <p><u>Strength:</u> <i>Syrup:</i> 6.25 mg/5 mL <i>Injection:</i> 50 mg/mL</p> <p><u>Dosage:</u> <i>Syrup:</i> Dose range 6.25 mg to 50 mg orally; frequency: once; every 4-6 hours as needed; three times per day; four times per day <i>Injection:</i> Dose range: 6.25 mg to 50 mg intravenously or intramuscularly; frequency: once, every 4 hours as needed</p> <p>1 mg/kg intramuscularly or intravenously (maximum of 25 mg per dose)</p> <p><i>Pentazine is a discontinued product; however, generics are available.</i></p>	<p><u>Orthographic:</u> The prefixes “Fe” vs. “Pe” look similar when written. Both names contain the upstroke letter “t”. The suffixes “zime” vs. “zine” look nearly identical.</p> <p><u>Dose:</u> The potential exists for doses to overlap between the products (e.g., 20 mg or 40 mg)</p>	<p><u>Orthographic:</u> The prefix for Pentazine contains an additional letter “n” preceding the letter “t” lengthening the prefix compared to Fetzima. Additionally, the letter “t” in Pentazine is followed by the letter “a”, lengthening the infix compared to Fetzima.</p>

	Proposed name: Fetzima (Levomilnacipran) Extended-release Capsules	Strengths: 20 mg, 40 mg, 80 mg, and 120 mg	Usual Dose: 20 mg orally once daily for 2 days and then increase to 40 mg once daily. Based on efficacy and tolerability, the dose may be increased in increments of 40 mg at intervals of 2 or more days. The maximum recommended dose is 120 mg once daily. <u>Renal adjustment:</u> Creatinine clearance 60 to 89 mL/min: maintenance dose should not exceed 80 mg once daily Creatinine clearance 15 to 29 mL/min: maintenance dose should not exceed 60 mg once daily.
	Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion	Causes (could be multiple)	Prevention of Failure Mode
40.	Rezira (Hydrocodone Bitartrate and Pseudoephedrine Hydrochloride) Oral Solution <u>Strength:</u> 5 mg/60 mg per 5 mL <u>Dose:</u> 5 mL orally every 4-6 hours as needed	<u>Orthographic:</u> The prefixes “Fe” vs. “Re” look similar when written. Both names contain the infix letters “zi” and end with the letter “a”.	<u>Orthographic:</u> Fetzima contains the upstroke letter “t” whereas Rezira does not contain any upstroke letters. <u>Strength:</u> 20 mg, 40 mg, 80 mg, and 120 mg (multiple strengths) vs. 5 mg/60 mg (single strength) Fetzima is available in multiple strengths so the strength would have to be specified on a prescription whereas Rezira is available in a single strength so the strength would not have to be specified. Additionally, the products do not have overlapping strengths. <u>Dose:</u> 20 mg, 40 mg, 80 mg, and 120 mg vs. 5 mL

	Proposed name: Fetzima (Levomilnacipran) Extended-release Capsules	Strengths: 20 mg, 40 mg, 80 mg, and 120 mg	Usual Dose: 20 mg orally once daily for 2 days and then increase to 40 mg once daily. Based on efficacy and tolerability, the dose may be increased in increments of 40 mg at intervals of 2 or more days. The maximum recommended dose is 120 mg once daily. <u>Renal adjustment:</u> Creatinine clearance 60 to 89 mL/min: maintenance dose should not exceed 80 mg once daily Creatinine clearance 15 to 29 mL/min: maintenance dose should not exceed 60 mg once daily.
	Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion	Causes (could be multiple)	Prevention of Failure Mode
41.	Fetrin (Ascorbic Acid 60 mg, Cyanocobalamin 5 mcg, Ferrous Fumarate 200 mg) Extended-release Capsules <u>Dosage:</u> Dosage information not available in our usual drug information databases; however, similar products are usually dosed 1 capsule orally once daily.	<u>Orthographic:</u> Both names begin with the letters “Fet”. The infix letters “zim” vs. “rin” look similar when written.	<u>Strength:</u> 20 mg, 40 mg, 80 mg, and 120 mg (multiple strengths) vs. 60 mg/5 mcg/200 mg (single strength) Fetzima is available in multiple strengths so the strength would have to be specified on a prescription whereas Fetrin is available in a single strength so the strength would not have to be specified. Although there is numerical similarity between 20 mg of Fetzima and the 200 mg strength of the Ferrous Fumarate component of Fetrin, if the strength was specified on a prescription for Fetrin, it is unlikely a prescriber would specify only the 200 mg Ferrous Fumarate strength and not the strengths of the other two ingredients.
42.	Tetacaine (Tetracaine Hydrochloride) Ophthalmic Solution <u>Strength:</u> 0.5% <u>Dosage:</u> 1 or 2 drops every 5 to 10 minutes for 1 to 5 doses	<u>Orthographic:</u> The beginning letters “F” vs. “T” and the infix letters “etz” vs. “etc” look similar when written. The ending letters “ima” vs. “ine” look similar. <u>Dose:</u> There is numerical similarity between doses (i.e., 20 mg vs. 2 drops), but the units “mg” vs. “drops” can prevent the error.	<u>Frequency of administration:</u> Once daily vs. every 5 to 10 minutes <u>Dose:</u> Although there is numerical similarity between doses (i.e., 20 mg vs. 2 drops), the units “mg” vs. “drops” are different and can help to prevent the error.

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/s/

LORETTA HOLMES
06/03/2013

IRENE Z CHAN
06/04/2013

CAROL A HOLQUIST
06/04/2013

**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: February 14, 2013

Reviewer: Loretta Holmes, BSN, PharmD
Division of Medication Error Prevention and Analysis

Team Leader: Irene Z. Chan, PharmD, BCPS
Division of Medication Error Prevention and Analysis

Associate Director: Kellie Taylor, PharmD, MPH
Division of Medication Error Prevention and Analysis

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

Drug Name and Strengths: (b) (4) (Levomilnacipran Hydrochloride)
Extended-release Capsules
20 mg, 40 mg, 80 mg, and 120 mg

Application Type/Number: NDA 204168

Applicant: Forest Laboratories Inc.

OSE RCM #: 2012-2846

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LORETTA HOLMES
02/14/2013

IRENE Z CHAN
02/14/2013

CAROL A HOLQUIST on behalf of KELLIE A TAYLOR
02/14/2013
Signing on behalf of Kellie Taylor

CAROL A HOLQUIST
02/14/2013

**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
Division of Medication Error Prevention and Analysis**

Proprietary Name Review

Date: October 25, 2012

Reviewer: Loretta Holmes, BSN, PharmD
Division of Medication Error Prevention and Analysis

Team Leader Irene Z. Chan, PharmD, BCPS
Division of Medication Error Prevention and Analysis

Drug Name and Strength: (b) (4) (Levomilnacipran Hydrochloride)
Extended-release Capsules
20 mg, 40 mg, 80 mg, and 120 mg

Application Type/Number: NDA 204168

Applicant: Forest Laboratories, Inc.

OSE RCM #: 2012-2332

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LORETTA HOLMES
10/25/2012

IRENE Z CHAN
10/25/2012