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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: October 23, 2013

Reviewer: Vicky Borders-Hemphill, Pharm.D.
Division of Medication Error Prevention and Analysis

Acting Team Leader: Morgan Walker, Pharm.D.
Division of Medication Error prevention and Analysis

Drug Name and Strength: Targiniq ER
(Oxycodone Hydrochloride and Naloxone Hydrochloride)
Controlled-release Tablets
10 mg/5 mg, 20 mg/10 mg, 40 mg/20 mg

Application Type/Number: IND 070851/NDA 205777

Applicant/Sponsor: Purdue Pharma L.P.

OSE RCM #: 2013-1093

*** 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, Targiniq ER (oxycodone hydrochloride and naloxone hydrochloride controlled release tablets), 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

On May 2, 2013, Purdue Pharma L.P. submitted a request for proprietary name review for the name, Targiniq. On October 10, 2013, DMEPA communicated with Purdue Pharma L.P. via email to convey that the name Targiniq was found to be unacceptable during preliminary review due to the lack of a modifier appended to the name to indicate the “extended-release” properties of the drug. DMEPA had previously communicated this assessment to ONDQA via email on August 29, 2013 and they concurred. Purdue Pharma L.P. amended the proprietary name request to Targiniq ER for IND 70851, on October 16, 2013 and also submitted a proprietary name request for Targiniq ER to NDA 205777 on October 22, 2013.

1.2 PRODUCT INFORMATION

The following product information is provided in the May 2, 2013, request for proprietary name submission under IND 070851 for oxycodone hydrochloride/naloxone hydrochloride controlled release tablets as of date:

- Proprietary name: Targiniq
- Established name: oxycodone/naloxone controlled-release tablets
- Indication of Use: an opioid agonist/antagonist combination for the management of ^{(b) (4)} pain ^{(b) (4)} around-the-clock ^{(b) (4)}
- Route of administration: oral
- Dosage Form: controlled released tablets
- Strength: 10 mg/5 mg, 20 mg/10 mg, 40 mg/20 mg (2:1 ratio OXY/NAL)
- Dose: 1 tablet every 12 hours up to a ceiling of 80 mg/40 mg/day (40 mg/20 mg every 12 hours). Targiniq must be swallowed whole, and not broken or chewed.
- How Supplied and Container/Closure System: bottles
- Storage: Controlled room temperature Store at ^{(b) (4)}

2 RESULTS

The following sections provide the 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, Targiniq ER, is acceptable from a promotional perspective. DMEPA and the Division of

Anesthesia, Analgesia, and Addiction Products (DAAAP) 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*

This name does not contain a USAN stem.¹

2.2.2 *Components of the Proposed Proprietary Name*

This proprietary name is comprised of two components: 1) the proposed root name, Targiniq, and 2) a modifier, ER. The modifier ‘ER’ has been added to the proprietary name to highlight the extended release properties of the proposed drug product. We evaluate this modifier in section 2.2.6. This proprietary name does not contain any components that are misleading or can contribute to medication error.

2.2.3 *FDA Name Simulation Studies*

Targiniq

Seventy-three practitioners participated in DMEPA’s prescription studies. The interpretations did not overlap with any currently marketed products nor did the misinterpretations sound or look similar to any currently marketed products or any products in the pipeline. Fourteen of the participants interpreted the name correctly as “Targiniq”, with correct interpretations occurring in the inpatient and outpatient written studies. Voice prescription studies consisted of the correct phonetic interpretation but with an incorrect spelling such as: “Targaneac”, “Targanic”, Targiniq”, Targanique”, “Targeneek”, “Torginiq”.

Targiniq ER

Forty practitioners participated in DMEPA’s prescription studies. The interpretations did not overlap with any currently marketed products nor did the misinterpretations sound or look similar to any currently marketed products or any products in the pipeline. Seventeen of the participants interpreted the name correctly as “Targiniq ER”, with correct interpretations occurring in the inpatient and outpatient written studies. Voice study responses had the correct phonetic interpretation but with an incorrect spelling such as “Targinique ER”, Targanique ER”, “Targeniq ER”.

DMEPA considered various misinterpretations in our look-alike and sound-alike searches and analysis (see Appendix B). See Appendix C for the complete listing of interpretations from the verbal and written prescription studies.

¹ October 17, 2013 search of the United States Adopted Name (USAN) stems

2.2.4 Comments from Other Review Disciplines at Initial Review

In response to the OSE, May 15, 2013, e-mail, DAAAP did not have any comments or concerns relating to the proposed proprietary name at the initial phase of the review.

2.2.5 Failure Mode and Effects Analysis of Similar Names

Appendix B lists possible orthographic and phonetic misinterpretations of the letters appearing in the proposed proprietary name. These variations were used in the search for names similar to Targiniq ER.

Table 1a lists the names with potential orthographic, phonetic, or spelling similarity to the proposed proprietary name, Targiniq, identified by the primary reviewer, the Expert Panel Discussion (EPD), and other review disciplines, and the FDA Prescription Simulation. Our analysis of the thirty-two names contained in Table 1a contained in Table 1a found none to be confused with the proposed name. We expressed concerns with the lack of a modifier to denote the extended-release properties of this product, as discussed in Section 3.

Table 1b lists the names with potential orthographic, phonetic, or spelling similarity to the proposed proprietary name, Targiniq ER identified by the primary reviewer, the Expert Panel Discussion (EPD), other review disciplines, and the FDA Prescription Simulation. Our analysis of the eight names contained in Table 1b considered the information obtained in the previous sections along with their product characteristics. We determined all eight names will not pose a risk for confusion as described in Appendices D through E.

Table 1a: Collective List of Potentially Similar Names to Targiniq (DMEPA, EPD, Other Disciplines, FDA Name Simulation Studies, and ^{(b) (4)} External Name Study)					
Look Similar					
<i>Name</i>	<i>Source</i>	<i>Name</i>	<i>Source</i>	<i>Name</i>	<i>Source</i>
Invega	External	Tarceva	External	Tigan	external
Fergensol	FDA	Targiniq	FDA	^{(b) (4)}	FDA
Fulyzaq	FDA	^{(b) (4)}	FDA	Torse mide	FDA
Januvia	External	Tavist	External	Toviaz	external
Largon	FDA	Taztia	External	Tradjenta	FDA
Naloxone	External	Tequin	external	Zirgan	FDA
Tara fig	FDA	Terconazole	FDA	Zorprin	FDA
Sound Similar					
<i>Name</i>	<i>Source</i>	<i>Name</i>	<i>Source</i>	<i>Name</i>	<i>Source</i>
Angeliq	External	Tegrin	external	Vaniqa	external
Fentanyl	External	Tekturna	external		

Look and Sound Similar					
<i>Name</i>	<i>Source</i>	<i>Name</i>	<i>Source</i>	<i>Name</i>	<i>Source</i>
Actiq	External	Tagamet	External	Tasigna	Both
Pristiq	External	Targretin	Both	Tegretol	external

Table 1b: Collective List of Potentially Similar Names to Targiniq ER (DMEPA, EPD, Other Disciplines, FDA Name Simulation Studies)

Look Similar to Targiniq ER					
<i>Name</i>	<i>Source</i>	<i>Name</i>	<i>Source</i>	<i>Name</i>	<i>Source</i>
(b) (4)	FDA	Taclonex	FDA	Terbinex	FDA
(b) (4)	FDA	(b) (4)	FDA	(b) (4)	FDA
Look and Sound Similar to Targiniq ER					
<i>Name</i>	<i>Source</i>	<i>Name</i>	<i>Source</i>	<i>Name</i>	<i>Source</i>
Targin	FDA	Teargen /Teargen II	FDA		

2.2.6 Evaluation of the Modifier ER

We requested the Applicant include a modifier, “ER”, to highlight the extended-release properties of the product.²

According to ISMP’s List of Products with Drug Name Suffixes, the modifier “ER” has been used for other modified-release dosage formulations to distinguish the dosing schedule from currently marketed immediate release formulations, and has been used to signal “every 12 hour”, “twice daily”, “once daily”, and “three times daily” dosing schedules. This product is dosed every 12 hours; therefore, the use of the modifier “ER” is consistent with the dosing frequency associated with ER. We are not aware of any errors relating to misinterpretation of “ER”. Thus, we find the use of this modifier to be appropriate.

2.2.7 Communication of DMEPA’s Analysis at Midpoint of Review

DMEPA communicated our findings to DAAAP via e-mail on October 18, 2013. At that time we also requested additional information or concerns that could inform our review. Per e-mail correspondence from DAAAP on October 18, 2013, they stated no additional concerns with the proposed proprietary name, Targiniq ER.

3 CONCLUSIONS

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

If you have further questions or need clarifications, please contact Vaishali Jarral, OSE project manager, at 301-796-4248.

² Memorandum of Email Communication for IND 070851, Targiniq (Oxycodone Hydrochloride/Naloxone) Controlled Release Tablets dated October 10, 2013. DARRTS Advice/ Information Request.

3.1 COMMENTS TO THE APPLICANT

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

If any of the proposed product characteristics as stated in your May 2, 2013 submission are altered, the name must be resubmitted for review.

4 REFERENCES

1. *Micromedex Integrated Index*

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. *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.

10. *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.

11. *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.

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

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

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

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

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

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

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

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

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

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

17. Rx List (www.rxlist.com)

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

18. 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.

19. 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.³

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.

³ National Coordinating Council for Medication Error Reporting and Prevention. <http://www.nccmerp.org/about/MedErrors.html>. Last accessed 10/11/2007.

Typical product characteristics considered when identifying drug names that could potentially be confused with the proposed proprietary name include, but are not limited to; established name of the proposed product, proposed indication of use, dosage form, route of administration, strength, unit of measure, dosage units, recommended dose, typical quantity or volume, frequency of administration, product packaging, storage conditions, patient population, and prescriber population. DMEPA considers how these product characteristics may or may not be present in communicating a product name throughout the medication use system. Because drug name confusion can occur at any point in the medication use process, DMEPA considers the potential for confusion throughout the entire U.S. medication use process, including drug procurement, prescribing and ordering, dispensing, administration, and monitoring the impact of the medication.⁴

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).

⁴ Institute of Medicine. Preventing Medication Errors. The National Academies Press: Washington DC. 2006.

Table 2. Criteria Used to Identify Drug Names that Look- or Sound-Similar to a Proposed Proprietary Name.

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

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

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

1. Database and Information Sources

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

2. Expert Panel Discussion

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

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

3. FDA Prescription Simulation Studies

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

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

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

4. Comments from Other Review Disciplines

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

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

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

5. Safety Evaluator Risk Assessment of the Proposed Proprietary Name

The primary Safety Evaluator applies his/her individual expertise gained from evaluating medication errors reported to FDA, considers all aspects of the name that may be misleading or confusing, conducts a Failure Mode and Effects Analysis, and provides an overall decision on acceptability dependent on their risk assessment of name confusion. Failure Mode and Effects Analysis (FMEA) is a systematic tool for evaluating a process and identifying where and how it might fail.⁵ 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

⁵ Institute for Healthcare Improvement (IHI). Failure Mode and Effects Analysis. Boston. IHI:2004.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Appendix B: Letters with Possible Orthographic or Phonetic Misinterpretation

Letters in Name Targiniq ER or Targiniq XR	Scripted May Appear as	Spoken May Be Interpreted as
Capital 'T'	F, Z, J	D
Lower case "t"	r, f, x, A, l	d
Lower case 'a'	el, ci, cl, d, o, u	Any Vowel
Lower case "r"	s, n, e, v	
Lower case 'g'	q, j, s	k, j
Lower case 'i'	e, l	y
Lower case 'n'	m, u, x, r, h, s	dn, gn, kn, mn, pn
Lower case 'i'	e, l	y
Lower case 'q'	a, g, j, z	k
Capital "E"	C, f	
Capital "R"	B, Pr, K	
Capital "X"	d, f, K,P, t, U, V, Y	KS, KZ, S, Z
Letter strings in Name Targiniq	Scripted May Appear as	Spoken May Be Interpreted as
niq	imp	neat, neep, neet, nique, neck, neac, ny, neque
gi	gr	ga, ge, go, ki

Appendix C: Prescription Simulation Samples and Results

Figure 1. Targiniq Study (Conducted on June 7, 2013)

Handwritten Requisition Medication Order	Verbal Prescription
<p><u>Medication Order:</u> <i>Targiniq 10mg/5mg one tablet po every 12 hours</i></p>	<p>Targiniq 10 mg/5 mg Take one tablet every 12 hours Dispense # 20</p>
<p><u>Outpatient Prescription:</u> <i>Targiniq 10mg/5mg 1 tab q 12hr #20</i></p>	

Figure 2. Targiniq ER Study (Conducted on September 20, 2013)

Handwritten Requisition Medication Order	Verbal Prescription
<p><u>Medication Order:</u> <i>Targiniq ER 10mg/5mg 1 po q 12hr</i></p>	<p>Targiniq ER 10 mg/5 mg Take one tablet every 12 hours Dispense # 20</p>
<p><u>Outpatient Prescription:</u> <i>Targiniq ER 10mg/5mg Take one tablet po q 12hrs #20</i></p>	

FDA Prescription Simulation Responses. (Aggregate 1 Rx studies report)

Study Name: Targiniq
 191 People Received Study
 73 People Responded

Total	23	28	22	
INTERPRETATION	OUTPATIENT	VOICE	INPATIENT	TOTAL
FANGINIQ	1	0	0	1
FARGINIQ	2	0	0	2
FORGINIQ	1	0	0	1
JARGINIQ	2	0	0	2
LARGINIZ	1	0	0	1
TANGIMIG	0	0	1	1
TANGINIG	0	0	1	1
TANGINIY	0	0	1	1
TANGINIZ	0	0	1	1
TANQINIQ	0	0	1	1
TARGANEAC	0	1	0	1
TARGANIC	0	1	0	1
TARGANIK	0	1	0	1
TARGANIQ	0	1	0	1
TARGANIQUE	0	5	0	5
TARGANY	0	2	0	2
TARGARNIC	0	1	0	1
TARGENEEK	0	1	0	1
TARGENIC 10MG/5 MG	0	1	0	1
TARGENIQ	0	1	0	1
TARGENIQUE	0	4	0	4
TARGIMIG	0	0	1	1
TARGIMY	0	0	2	2
TARGINEEK	0	1	0	1
TARGINEQUE	0	1	0	1
TARGINIG	0	0	7	7
TARGINIQ	11	0	3	14
TARGINIQUE	0	2	0	2
TARGINQUE	0	1	0	1
TARGINY	0	0	1	1
TARGONIQUE	0	2	0	2
TARKINEEK	0	1	0	1
TARKINEK	0	1	0	1
TARQININQ	0	0	1	1
TARZINIZ	0	0	1	1
TORGINIQ	4	0	0	4
TORGINIQ 10 MG/5 MG	1	0	0	1
TRRGINIG	0	0	1	1

Study Name: Targiniq ER
 189 People Received Study
 40 People Responded

Total	14	11	15	
INTERPRETATION	OUTPATIENT	VOICE	INPATIENT	TOTAL
FARGINIQ ER	0	0	2	2
FARGISIQ ER	0	0	1	1
TARGADEQ ER	0	1	0	1
TARGAMINE ER	0	1	0	1
TARGANEK ER	0	1	0	1
TARGANIQUE ER	0	3	0	3
TARGENIQ ER	1	1	0	2
TARGENIQUE ER	0	3	0	3
TARGIMIQ	0	0	1	1
TARGIMIQ ER	0	0	1	1
TARGIMIZ	0	0	1	1
TARGINIG ER	1	0	1	2
TARGINIG ER	0	0	2	2
TARGINIQ ER	11	0	6	17
TARGINIQUE ER	0	1	0	1
TARGINQ ER	1	0	0	1

Appendix D.1: Proprietary names not likely to be confused or not used in usual practice settings for the reasons described.

No.	Proprietary Name	Active Ingredient	Similarity to Targiniq	Failure preventions
1	Fentanyl	active ingredient in Abstral , Actiq, Duragesic, Ionsys, Lazanda, Onsolis, Sublimaze, Subsys, Innovar, and generic formulation	Phonetic	Pair have sufficient phonetic differences
2	Invega	paliperidone	Orthographic	Pair have sufficient orthographic differences
3	Naloxone	active ingredient	Orthographic	Pair have sufficient orthographic differences
4	Tara fig	Common name for Kiwi fruit (Actinidia chinensis Planchon; kiwi fruit extract)	Orthographic	Product is not a drug. It is a food product and will not be written on a prescription
5	Targiniq	oxycodone hydrochloride/naloxone hydrochloride	Orthographic	Name being considered in review

No.	Proprietary Name	Active Ingredient	Similarity to Targiniq	Failure preventions
6				(b) (4)
7	Tegretol	carbamazepine	Orthographic and Phonetic	Pair have sufficient orthographic and phonetic differences
8	Tequin	gatifloxacin	Orthographic	Pair have sufficient orthographic differences
9	Terconazole	active ingredient in Terazol 3, Terazol 7, and generic formulation	Orthographic	Pair have sufficient orthographic differences
10	Tigan	trimethobenzamide hydrochloride	Orthographic	Pair have sufficient orthographic differences
11				(b) (4)
12	Torseמידe	Demadex	Orthographic	Pair have sufficient orthographic differences
13	Tradjenta	Linagliptin	Orthographic	Pair have sufficient orthographic differences

Appendix D.2: Proprietary names not likely to be confused or not used in usual practice settings for the reasons described.

No.	Proprietary Name	Active Ingredient	Similarity to Targiniq XR or ER	Failure preventions
1				(b) (4)
2	Targin	Oxycodone and naloxone	Orthographic and Phonetic	Canadian brand name for Oxycodone and naloxone by Purdue Pharma L.P.

No.	Proprietary Name	Active Ingredient	Similarity to Targiniq XR or ER	Failure preventions
3	(b) (4)			
4				

Appendix E.1: Risk of medication errors due to product confusion minimized by dissimilarity of names and/or use in clinical practice for reasons described.

<p>Targiniq (oxycodone hydrochloride/naloxone hydrochloride controlled-release tablets)</p> <p>Dosage Form: tablets</p> <p>Strengths: 10 mg/5 mg, 20 mg/10 mg, 40 mg/20 mg</p> <p>Usual Dose: one tablet every 12 hours up to 80 mg/40 mg/day (40 mg/20 mg q12h)</p> <p>Route of Administration: oral</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> <p>In the conditions outlined below, the following combination of factors are expected to minimize the risk of confusion between these two names</p>
<p>Actiq (fentanyl citrate) breakthrough cancer pain</p> <p>Strength:</p> <p>0.2 mg (200 mcg), 0.4 mg (400 mcg),</p> <p>0.6 mg (600 mcg), 0.8 mg (800 mcg),</p> <p>1.2 mg (1200 mcg), 1.6 mg (1600 mcg)</p> <p>Dosage form: transmucosal troche</p> <p>Dose: 200 mcg to 1200 mcg as needed for breakthrough pain episode; patient must wait at least 4 hours before treating another breakthrough episode</p> <p>Route of Administration: transmucosal</p>	<p><u>Orthographic similarity:</u></p> <p>Both names begin with letters that may appear similar when scripted (lower case “t” and “A”), and contain the suffix “iq”</p> <p><u>Phonetic similarity:</u></p> <p>Both names end with the letters “iq”</p> <p><u>Overlapping Product Characteristics:</u></p> <p>Strength: 20 mg vs. 200 mcg and 40 mg vs. 400 mcg</p>	<p><u>Orthographic differences:</u></p> <p>The names do not have the same length or shape as the infix “argin” in Targiniq confers elongation and has a downstroke letter “g”</p> <p><u>Phonetic differences:</u></p> <p>Targiniq has three syllables vs. Actiq has two syllables and “Targin” does not sound like “Ac”</p> <p><u>Product characteristic differences:</u></p> <p>Frequency: every 12 hours vs. as needed or at least every 4 hours</p>

<p>Targiniq (oxycodone hydrochloride/naloxone hydrochloride controlled-release tablets)</p> <p>Dosage Form: tablets</p> <p>Strengths: 10 mg/5 mg, 20 mg/10 mg, 40 mg/20 mg</p> <p>Usual Dose: one tablet every 12 hours up to 80 mg/40 mg/day (40 mg/20 mg q12h)</p> <p>Route of Administration: oral</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> <p>In the conditions outlined below, the following combination of factors are expected to minimize the risk of confusion between these two names</p>
<p>Angeliq (drospirinone/estradiol)</p> <p>Strengths: 0.25 mg/0.5 mg and 0.5 mg/1 mg</p> <p>Dosage form: tablet</p> <p>Dose: one tablet once daily</p> <p>Route of Administration: oral</p>	<p><u>Orthographic similarity:</u> Both names begin with letters that may appear similar when scripted (lower case “t” and “A”), and contain the suffix “iq”</p> <p><u>Phonetic similarity:</u> The infix and suffix “iniq” may sound similar to “eliq” and both names contain three syllables</p> <p><u>Overlapping Product Characteristics:</u> Strength: 5 mg vs. 0.5 mg and 10 mg vs. 1 mg Route of administration: oral</p>	<p><u>Orthographic differences:</u> The names do not have the same length or shape as the infix “argin” in Targiniq confers elongation and the infix “ngel” contains an upstroke letter “l”</p> <p><u>Phonetic differences:</u> “Tar” does not sound like “Ang”</p> <p><u>Product characteristic differences:</u> Frequency: every 12 hours vs. once daily</p>

<p>Targiniq (oxycodone hydrochloride/naloxone hydrochloride controlled-release tablets)</p> <p>Dosage Form: tablets</p> <p>Strengths: 10 mg/5 mg, 20 mg/10 mg, 40 mg/20 mg</p> <p>Usual Dose: one tablet every 12 hours up to 80 mg/40 mg/day (40 mg/20 mg q12h)</p> <p>Route of Administration: oral</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> <p>In the conditions outlined below, the following combination of factors are expected to minimize the risk of confusion between these two names</p>
<p>Fergensol (ferrous sulfate)</p> <p>Strength: 75 mg/0.6 mL (50 mL)</p> <p>Dosage form: drops</p> <p>Dose: 75 mg once daily</p> <p>Route of Administration: oral</p>	<p><u>Orthographic similarity:</u></p> <p>Both names contain prefixes (“targin” vs. “fergen” that may appear similar when scripted</p> <p><u>Overlapping Product Characteristics:</u></p> <p>Route of administration: oral</p>	<p><u>Orthographic differences:</u></p> <p>The suffix “iq” is not orthographically similar to “ol”</p> <p><u>Product characteristic differences:</u></p> <p>Frequency: every 12 hours vs. once daily</p> <p>Strength: Targiniq has multiple strengths which will need to be included on the prescription vs. Fergensol has a single strength and may be omitted. There is no numerical overlap or numerical similarity between the strengths.</p>

<p>Targiniq (oxycodone hydrochloride/naloxone hydrochloride controlled-release tablets)</p> <p>Dosage Form: tablets</p> <p>Strengths: 10 mg/5 mg, 20 mg/10 mg, 40 mg/20 mg</p> <p>Usual Dose: one tablet every 12 hours up to 80 mg/40 mg/day (40 mg/20 mg q12h)</p> <p>Route of Administration: oral</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> <p>In the conditions outlined below, the following combination of factors are expected to minimize the risk of confusion between these two names</p>
<p>Fulyzaq (crofelemer)</p> <p>Strength: 125 mg</p> <p>Dosage form: delayed release tablet</p> <p>Dose: One 125 mg delayed-release tablet taken orally twice a day</p> <p>Route of Administration: oral</p>	<p><u>Orthographic similarity:</u></p> <p>Both names begin with letters (“Ta” vs. “Fu”), contain a down stork letter (“g” vs. “y”) in the fourth position that may appear similar when scripted, and end with the letter “q”</p> <p><u>Overlapping Product Characteristics:</u></p> <p>Frequency: twice daily</p> <p>Route of administration: oral</p>	<p><u>Orthographic differences:</u></p> <p>The names are not shaped similarly as Fulyzaq has an upstroke letter “l” in the infix and the infix “ini” in Targiniq confers elongation</p> <p><u>Product characteristic differences:</u></p> <p>Strength: Targiniq has multiple strengths which will need to be included on the prescription vs. Fulyzaq has a single strength and may be omitted. There is no numerical overlap or numerical similarity between the strengths.</p>

<p>Targiniq (oxycodone hydrochloride/naloxone hydrochloride controlled-release tablets)</p> <p>Dosage Form: tablets</p> <p>Strengths: 10 mg/5 mg, 20 mg/10 mg, 40 mg/20 mg</p> <p>Usual Dose: one tablet every 12 hours up to 80 mg/40 mg/day (40 mg/20 mg q12h)</p> <p>Route of Administration: oral</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> <p>In the conditions outlined below, the following combination of factors are expected to minimize the risk of confusion between these two names</p>
<p>Januvia (sitagliptin phosphate)</p> <p>Strength: 25 mg, 50 mg, 100 mg</p> <p>Dosage form: tablet</p> <p>Dose: 100 mg once daily; CrCl \geq 30 to <50 mL/min: 50 mg once daily; CrCl <30 mL/min: 25 mg once daily</p> <p>Route of Administration: oral</p>	<p><u>Orthographic similarity:</u></p> <p>Both names begin with letters (“Tar” vs. “Jan”) and contain suffices (“niq” vs. “via”) that may appear similar when scripted</p> <p><u>Overlapping Product Characteristics:</u></p> <p>Route of administration: oral</p>	<p><u>Orthographic differences:</u></p> <p>Targiniq has a downstroke letter “g” and the infix “gi” confers elongation which helps to differentiate these names</p> <p><u>Product characteristic differences:</u></p> <p>Frequency: every 12 hours vs. once daily</p> <p>Strength: Both products have multiple strengths which will need to be included on the prescription. There is no numerical overlap or numerical similarity between the strengths.</p>
<p>Largon (propiomazine hydrochloride) anesthesia or labor</p> <p>Strength: 20 mg/mL</p> <p>Dosage form: injection</p> <p>Dose: 20 mg to 40 mg once for anesthesia or every three hours for labor</p> <p>Route of Administration: intramuscular or intravenous</p>	<p><u>Orthographic similarity:</u></p> <p>Both names contain letters (“Targin” vs. “Largon”) that may appear similar when scripted</p> <p><u>Overlapping Product Characteristics:</u></p> <p>Strength: 20 mg/10 mg vs. 20 mg/mL</p>	<p><u>Orthographic differences:</u></p> <p>The suffix (“iq”) in Targiniq confers elongation and helps to differentiate these names</p> <p><u>Product characteristic differences:</u></p> <p>Frequency: every 12 hours vs. once or every three hours</p> <p>Setting of Use: Outpatient retail or inpatient bedside vs. inpatient labor and delivery</p>

<p>Targiniq (oxycodone hydrochloride/naloxone hydrochloride controlled-release tablets)</p> <p>Dosage Form: tablets</p> <p>Strengths: 10 mg/5 mg, 20 mg/10 mg, 40 mg/20 mg</p> <p>Usual Dose: one tablet every 12 hours up to 80 mg/40 mg/day (40 mg/20 mg q12h)</p> <p>Route of Administration: oral</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> <p>In the conditions outlined below, the following combination of factors are expected to minimize the risk of confusion between these two names</p>
<p>Pristiq (desvenlafaxine succinate)</p> <p>Strength: 50 mg and 100 mg</p> <p>Dosage form: tablet, ER</p> <p>Dose: 50 mg to 100 mg once daily</p> <p>Route of Administration: oral</p>	<p><u>Orthographic similarity:</u></p> <p>Both names have letters (“g” vs. “s”) in the fourth position that may appear similar when scripted and contain the suffix “iq”</p> <p><u>Phonetic similarity:</u></p> <p>Both names end with the letters “iq”</p> <p><u>Overlapping Product Characteristics:</u></p> <p>Strength: 10 mg vs. 100 mg</p> <p>Route of administration: oral</p>	<p><u>Orthographic differences:</u></p> <p>The prefix “Tar” is not orthographically similar to “Pri”, Pristiq has an upstroke letter “t” in the infix and the infix “ini” in Targiniq confers elongation</p> <p><u>Phonetic differences:</u></p> <p>Targiniq contains three syllables vs. Pristiq contains two syllables and the prefix “Tar” does not sound like “Prist”</p> <p><u>Product characteristic differences:</u></p> <p>Frequency: every 12 hours vs. once daily</p>

<p>Targiniq (oxycodone hydrochloride/naloxone hydrochloride controlled-release tablets)</p> <p>Dosage Form: tablets</p> <p>Strengths: 10 mg/5 mg, 20 mg/10 mg, 40 mg/20 mg</p> <p>Usual Dose: one tablet every 12 hours up to 80 mg/40 mg/day (40 mg/20 mg q12h)</p> <p>Route of Administration: oral</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> <p>In the conditions outlined below, the following combination of factors are expected to minimize the risk of confusion between these two names</p>
<p>Tagamet (cimetidine)</p> <p>Strength: 200 mg (OTC), 300 mg, 400 mg, 800 mg or 300 mg/5 mL (oral solution), 300 mg/2 mL (solution for injection), 1200 mg/250 mL, 900 mg/250 mL, or 300 mg/50 mL in sodium chloride 0.9% solution for injection</p> <p>Dosage form: tablet, oral solution, and injection</p> <p>Dose: 200 mg once to relieve heartburn or 200 mg 30 minutes before eating food not to exceed two tablets in 24 hours; 300 mg four times daily, 400 mg to 800 mg twice daily, 400 mg to 800 mg at bedtime,</p> <p>300 mg intravenous or intramuscular every 6 hours (age 16 years+) or</p> <p>20 to 40 mg/kg/day in divided doses every 6 hours (age < 15 years; 45 kg = 225 mg to 450 mg every 6 hours)</p> <p>Route of Administration: oral, intravenous, intramuscular</p>	<p><u>Orthographic similarity:</u></p> <p>Both names begin with “Ta” and have a downstroke letter “g” in the infix</p> <p><u>Phonetic similarity:</u></p> <p>Both names contain prefixes and infixes that may sound similar (“Targi” vs. “Taga”)</p> <p><u>Overlapping Product Characteristics:</u></p> <p>Frequency: twice daily</p> <p>Strength: 20 mg vs. 200 mg and 40 mg vs. 400 mg</p>	<p><u>Orthographic differences:</u></p> <p>The letter “r” in Targiniq confers elongation in the prefix and the last letter in Tagamet is an upstroke letter “t” which may help differentiate these names</p> <p><u>Phonetic differences:</u></p> <p>The suffix “niq” does not sound like “met”</p> <p><u>Product characteristic differences:</u></p> <p>Dosage form: Targiniq has a single dosage form which may be omitted vs. Tagamet has multiple dosage forms which must be included on the prescription</p> <p>Route of administration: Targiniq has one route of administration which may be omitted from the prescription vs. Tagamet has several routes which must be included on the prescription</p>

<p>Targiniq (oxycodone hydrochloride/naloxone hydrochloride controlled-release tablets)</p> <p>Dosage Form: tablets</p> <p>Strengths: 10 mg/5 mg, 20 mg/10 mg, 40 mg/20 mg</p> <p>Usual Dose: one tablet every 12 hours up to 80 mg/40 mg/day (40 mg/20 mg q12h)</p> <p>Route of Administration: oral</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> <p>In the conditions outlined below, the following combination of factors are expected to minimize the risk of confusion between these two names</p>
<p>Tarceva (erlotinib hydrochloride) metastatic non-small cell lung cancer or pancreatic cancer</p> <p>Strength: 25 mg, 100 mg, 150 mg</p> <p>Dosage form: tablet</p> <p>Dose: 150 mg once daily or 100 mg once daily (reduce dose by 50 mg decrements when taking certain concomitant medications thus 50 mg once daily)</p> <p>Route of Administration: oral</p>	<p><u>Orthographic similarity:</u></p> <p>Both names begin with “Tar” and end with letters that may appear similar when scripted (“ni” vs. v”) and (“q” vs. “a”)</p> <p><u>Overlapping Product Characteristics:</u></p> <p>Route of administration: oral</p> <p>Strength: 10 mg vs. 100 mg</p>	<p><u>Orthographic differences:</u></p> <p>Targiniq contains a downstroke letter “g” in the infix and the infix “ini” in Targiniq confers elongation</p> <p><u>Product characteristic differences:</u></p> <p>Frequency: every 12 hours vs. once daily</p>

<p>Targiniq (oxycodone hydrochloride/naloxone hydrochloride controlled-release tablets)</p> <p>Dosage Form: tablets</p> <p>Strengths: 10 mg/5 mg, 20 mg/10 mg, 40 mg/20 mg</p> <p>Usual Dose: one tablet every 12 hours up to 80 mg/40 mg/day (40 mg/20 mg q12h)</p> <p>Route of Administration: oral</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> <p>In the conditions outlined below, the following combination of factors are expected to minimize the risk of confusion between these two names</p>
<p>Targretin (bexarotene)</p> <p>topical treatment of cutaneous lesions in patients with cutaneous T-cell lymphoma</p> <p>Strength: 75 mg and 1%</p> <p>Dosage form: capsule and gel</p> <p>Dose: initial dose of Targretin capsules is 300 mg/m²/day (0.88-1.12 m² = 300 mg, 1.13 - 1.37 m² = 375 mg, 1.38 - 1.62 m² = 450 mg, 1.63 - 1.87 m² = 525 mg, 1.88 - 2.12 m² = 600 mg, 2.13 - 2.37 m² = 657 mg, 2.38 - 2.62 m² = 750 mg) once daily or</p> <p>Topical: applied once every other day for the first week then increased at weekly intervals to once daily, then twice daily, then three times daily and finally four times daily according to individual lesion tolerance</p> <p>Route of Administration: oral and topical</p>	<p><u>Orthographic similarity:</u></p> <p>Both names begin with “Targ”</p> <p><u>Phonetic similarity:</u></p> <p>Both names begin with “Targ” and the infixes (“gi” vs. “gre”) may sound alike</p> <p><u>Overlapping Product Characteristics:</u></p> <p>Frequency: twice daily</p> <p>Route of administration: oral</p>	<p><u>Orthographic differences:</u></p> <p>The suffixes (“iniq” vs. retin”) are not orthographically similar</p> <p><u>Phonetic differences:</u></p> <p>The suffices (“iq” vs. “in”) do not sound alike and once the infix and suffix letters are combined (“giniq” vs. “gretin”), the endings do not sound alike</p> <p><u>Product characteristic differences:</u></p> <p>Strength: Both products have multiple strengths which will need to be included on the prescription. There is no numerical overlap or numerical similarity between the strengths.</p> <p>Dose: Targiniq dose may be expressed as one tablet vs. Targretin dose is weight based and must be included on the prescription or as an application using “apply”.</p> <p>Dosage form: Targiniq has a single dosage form which may be omitted vs. Targretin has two dosage forms which must be included on the prescription</p> <p>Route of administration: Targiniq has one route of administration which may be omitted from the prescription vs. Targretin has two routes which must be included on the prescription (if the dosage form was omitted)</p>

<p>Targiniq (oxycodone hydrochloride/naloxone hydrochloride controlled-release tablets)</p> <p>Dosage Form: tablets</p> <p>Strengths: 10 mg/5 mg, 20 mg/10 mg, 40 mg/20 mg</p> <p>Usual Dose: one tablet every 12 hours up to 80 mg/40 mg/day (40 mg/20 mg q12h)</p> <p>Route of Administration: oral</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> <p>In the conditions outlined below, the following combination of factors are expected to minimize the risk of confusion between these two names</p>
<p>Tasigna (nilotinib hydrochloride monohydrate)</p> <p>adult patients with newly diagnosed Philadelphia chromosome positive chronic myeloid leukemia (Ph+ CML) in chronic phase</p> <p>Strength: 150 mg and 200 mg</p> <p>Dosage form: capsule</p> <p>Dose: newly diagnosed: 300 mg twice daily; resistant or intolerant: 400 mg twice daily</p> <p>Route of Administration: oral</p>	<p><u>Orthographic similarity:</u></p> <p>Both names begin with letters (“Tar” vs. “Tas”) that may appear similar when scripted, contain a downstroke letter “g” in the infix, and end with letters (“q” vs. “a”) that may appear similar when scripted</p> <p><u>Phonetic similarity:</u></p> <p>Both names begin with “Ta”</p> <p><u>Overlapping Product Characteristics:</u></p> <p>Frequency: twice daily</p> <p>Strength: 20 mg vs. 200 mg</p> <p>Route of administration: oral</p>	<p><u>Orthographic differences:</u></p> <p>The infix “ini” in Targiniq confers elongation and the letter “g” are not in the same position of the name which helps to differentiate these names</p> <p><u>Phonetic differences:</u></p> <p>The infixes (“gin” vs. “ig”) and suffixes (“iq” vs. “na”) do not sound alike</p> <p><u>Product characteristic differences:</u></p> <p>Strength: Both products have multiple strengths which will need to be included on the prescription. There is no numerical overlap between the strengths.</p>

<p>Targiniq (oxycodone hydrochloride/naloxone hydrochloride controlled-release tablets)</p> <p>Dosage Form: tablets</p> <p>Strengths: 10 mg/5 mg, 20 mg/10 mg, 40 mg/20 mg</p> <p>Usual Dose: one tablet every 12 hours up to 80 mg/40 mg/day (40 mg/20 mg q12h)</p> <p>Route of Administration: oral</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> <p>In the conditions outlined below, the following combination of factors are expected to minimize the risk of confusion between these two names</p>
<p>Tavist Allergy (clemastine fumarate) allergic rhinitis</p> <p>Strength: 1.34 mg</p> <p>Dosage form: tablet</p> <p>Dose: one tablet every 12 hours or twice daily or two tablets twice daily for angioedema or urticaria</p> <p>Route of Administration: oral</p>	<p><u>Orthographic similarity:</u></p> <p>Both names begin with letters (“Tar” vs. “Tas”) that may appear similar when scripted</p> <p><u>Overlapping Product Characteristics:</u></p> <p>Frequency: twice daily</p> <p>Route of administration: oral</p>	<p><u>Orthographic differences:</u></p> <p>The suffixes (“iniq” vs. ist”) are not orthographically similar</p> <p><u>Product characteristic differences:</u></p> <p>Strength: Targiniq has multiple strengths which will need to be included on the prescription vs. Tavist has a single strength which may be omitted. There is no numerical overlap or numerical similarity between the strengths.</p>

<p>Targiniq (oxycodone hydrochloride/naloxone hydrochloride controlled-release tablets)</p> <p>Dosage Form: tablets</p> <p>Strengths: 10 mg/5 mg, 20 mg/10 mg, 40 mg/20 mg</p> <p>Usual Dose: one tablet every 12 hours up to 80 mg/40 mg/day (40 mg/20 mg q12h)</p> <p>Route of Administration: oral</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> <p>In the conditions outlined below, the following combination of factors are expected to minimize the risk of confusion between these two names</p>
<p>Taztia XT (diltiazem hydrochloride)</p> <p>Strength: 120 mg, 180 mg, 240 mg, 300 mg, 360 mg</p> <p>Dosage form: capsule, ER</p> <p>Dose: 120 mg to 360 mg once daily</p> <p>Route of Administration: oral</p>	<p><u>Orthographic similarity:</u></p> <p>Both names begin with letters “Ta”, contains letters (“g” vs. downstroke “z”) in the prefix that may appear similar when scripted</p> <p><u>Overlapping Product Characteristics:</u></p> <p>Route of administration: oral</p>	<p><u>Orthographic differences:</u></p> <p>The letter “r” in Targiniq’s prefix and the letters “ini” in the infix confer elongation. The suffixes (“iniq” vs. tia”) are not orthographically similar.</p> <p><u>Product characteristic differences:</u></p> <p>Frequency: every 12 hours vs. once daily</p> <p>Strength: Both products have multiple strengths which will need to be included on the prescription. There is no numerical overlap or numerical similarity between the strengths.</p>
<p>Toviaz (fesoterodine fumarate) overactive bladder</p> <p>Strength: 4 mg and 8 mg</p> <p>Dosage form: tablet, ER</p> <p>Dose: 4 mg once daily or 8 mg once daily</p> <p>Route of Administration: oral</p>	<p><u>Orthographic similarity:</u></p> <p>Both names begin with (“Tar” vs. “Tov”) and end with (“q” vs. downstroke letter “z”) letters that may appear similar when scripted</p> <p><u>Overlapping Product Characteristics:</u></p> <p>Strength: 40 mg vs. 4 mg</p> <p>Route of administration: oral</p>	<p><u>Orthographic differences:</u></p> <p>The infix letters “gini” confer elongation to the name Targiniq and has a downstroke letter “g” which affords different shape than “ia” in the infix/suffix of Toviaz</p> <p><u>Product characteristic differences:</u></p> <p>Frequency: every 12 hours vs. once daily</p>

<p>Targiniq (oxycodone hydrochloride/naloxone hydrochloride controlled-release tablets)</p> <p>Dosage Form: tablets</p> <p>Strengths: 10 mg/5 mg, 20 mg/10 mg, 40 mg/20 mg</p> <p>Usual Dose: one tablet every 12 hours up to 80 mg/40 mg/day (40 mg/20 mg q12h)</p> <p>Route of Administration: oral</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> <p>In the conditions outlined below, the following combination of factors are expected to minimize the risk of confusion between these two names</p>
<p>Vaniqa (eflornithine hydrochloride) unwanted facial hair</p> <p>Strength: 13.9%</p> <p>Dosage form: cream</p> <p>Dose: apply to affected areas of face and chin twice daily at least 8 hours apart</p> <p>Route of Administration: topical</p>	<p><u>Orthographic similarity:</u></p> <p>Both names contain letters in the second and third position (“ar” vs. “an”) that may appear similar when scripted</p> <p><u>Phonetic similarity:</u> Both names contain three syllables and the letters “iq”</p> <p><u>Overlapping Product Characteristics:</u></p> <p>Frequency: twice daily</p>	<p><u>Orthographic differences:</u></p> <p>The first letters “T” vs. “V”, and the suffices (“giniq” vs. “iqa”) are not orthographically similar</p> <p><u>Phonetic differences:</u></p> <p>The letters “iq” are sounded in the third syllable of Targiniq vs. the second syllable of Vaniqa; The prefix “Tar” vs. “Van”, the infix “gin” vs. “iq”, and the suffix “iq” vs. “a” do not sound similar</p> <p><u>Product characteristic differences:</u></p> <p>Strength: Targiniq has multiple strengths which will need to be included on the prescription vs. Vaniqa has a single strength which will be omitted. There is no numerical overlap or numerical similarity between the strengths.</p> <p>Dose: Targiniq dose may be expressed as one tablet vs. Vaniqa is dosed as an application using “apply”.</p>

<p>Targiniq (oxycodone hydrochloride/naloxone hydrochloride controlled-release tablets)</p> <p>Dosage Form: tablets</p> <p>Strengths: 10 mg/5 mg, 20 mg/10 mg, 40 mg/20 mg</p> <p>Usual Dose: one tablet every 12 hours up to 80 mg/40 mg/day (40 mg/20 mg q12h)</p> <p>Route of Administration: oral</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> <p>In the conditions outlined below, the following combination of factors are expected to minimize the risk of confusion between these two names</p>
<p>Zirgan (ganciclovir)</p> <p>Strength: 0.15%</p> <p>Dosage form: gel</p> <p>Dose: one drop into affected eye five times daily while awake or every three hours until corneal ulcer heals then 1 drop 3 times daily for 7 days</p> <p>Route of Administration: ophthalmic</p>	<p><u>Orthographic similarity:</u></p> <p>Both names contain letters (“Targin” vs. “Zirgan”) that may appear similar when scripted</p>	<p><u>Orthographic differences:</u></p> <p>The suffix (“iq”) in Targiniq confers elongation and helps to differentiate these names</p> <p><u>Product characteristic differences:</u></p> <p>Frequency: every 12 hours vs. five times daily or every three hours</p> <p>Strength: Targiniq has multiple strengths which will need to be included on the prescription vs. Zirgan has a single strength will be omitted. There is no numerical overlap or numerical similarity between the strengths.</p> <p>Dose: Targiniq dose may be expressed as one tablet vs. Zirgan is dosed using “instill” or “one drop” and must be included on the prescription.</p>

<p>Targiniq (oxycodone hydrochloride/naloxone hydrochloride controlled-release tablets)</p> <p>Dosage Form: tablets</p> <p>Strengths: 10 mg/5 mg, 20 mg/10 mg, 40 mg/20 mg</p> <p>Usual Dose: one tablet every 12 hours up to 80 mg/40 mg/day (40 mg/20 mg q12h)</p> <p>Route of Administration: oral</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> <p>In the conditions outlined below, the following combination of factors are expected to minimize the risk of confusion between these two names</p>
<p>Zorprin (aspirin)</p> <p>Strength: 800 mg</p> <p>Dosage form: tablet, ER</p> <p>Dose: one tablet every 8 hours not to exceed 3.9 grams/day</p> <p>Route of Administration: oral</p>	<p><u>Orthographic similarity:</u></p> <p>Both names contain letters (“Tar” vs. “Zor”) that may appear similar when scripted</p> <p><u>Overlapping Product Characteristics:</u></p> <p>Route of administration: oral</p>	<p><u>Orthographic differences:</u></p> <p>The suffices (“giniq” vs. “prin”) are not orthographically similar</p> <p><u>Product characteristic differences:</u></p> <p>Frequency: every 12 hours vs. every 8 hours</p> <p>Strength: Targiniq has multiple strengths which will need to be included on the prescription vs. Zorprin has a single strength will be omitted. There is no numerical overlap or numerical similarity between the strengths.</p>

Appendix E.2: Risk of medication errors due to product confusion minimized by dissimilarity of names and/or use in clinical practice for reasons described.

<p>Targiniq ER (oxycodone hydrochloride/naloxone hydrochloride controlled-release tablets)</p> <p>Dosage Form: tablets</p> <p>Strengths: 10 mg/5 mg, 20 mg/10 mg, 40 mg/20 mg</p> <p>Usual Dose: one tablet every 12 hours up to 80 mg/40 mg/day (40 mg/20 mg q12h)</p> <p>Route of Administration: oral</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> <p>In the conditions outlined below, the following combination of factors are expected to minimize the risk of confusion between these two names</p>
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(b) (4)

<p>Targiniq ER (oxycodone hydrochloride/naloxone hydrochloride controlled-release tablets)</p> <p>Dosage Form: tablets</p> <p>Strengths: 10 mg/5 mg, 20 mg/10 mg, 40 mg/20 mg</p> <p>Usual Dose: one tablet every 12 hours up to 80 mg/40 mg/day (40 mg/20 mg q12h)</p> <p>Route of Administration: oral</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> <p>In the conditions outlined below, the following combination of factors are expected to minimize the risk of confusion between these two names</p>
<p>Taclonex (betamethasone dipropionate/calcipotriene hydrate) for psoriasis</p> <p>Strength: 0.064%/0.005%</p> <p>Dosage form: ointment and suspension</p> <p>Dose: apply to affected areas once daily for up to 4 weeks for ointment and up to 8 weeks for suspension;</p> <p>Route of Administration: topical</p>	<p><u>Orthographic similarity:</u></p> <p>Both names contain prefix letters “Tar” vs. “Tac” that may appear similar when scripted.</p>	<p><u>Orthographic differences:</u></p> <p>The suffix “giniq” has the downstroke letter “g” which affords a different shape than the suffix “lonex” which has an upstroke letter “l” and elongates the name</p> <p><u>Product characteristic differences:</u></p> <p>Frequency: every 12 hours vs. once daily</p> <p>Strength: Targiniq ER has multiple strengths which must be included on the prescription vs. Taclonex has a single strength which may be omitted.</p> <p>Dose: Targiniq ER dose may be expressed as one tablet vs. Taclonex is dosed using “apply” or “use as directed” and must be included on the prescription.</p>

<p>Targiniq ER (oxycodone hydrochloride/naloxone hydrochloride controlled-release tablets)</p> <p>Dosage Form: tablets</p> <p>Strengths: 10 mg/5 mg, 20 mg/10 mg, 40 mg/20 mg</p> <p>Usual Dose: one tablet every 12 hours up to 80 mg/40 mg/day (40 mg/20 mg q12h)</p> <p>Route of Administration: oral</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> <p>In the conditions outlined below, the following combination of factors are expected to minimize the risk of confusion between these two names</p>
<p>Teargen / Teargen II artificial tear solution (dextran/hypromellose)</p> <p>Strength: 0.1% or 0.3%</p> <p>Dosage form: solution</p> <p>Dose: one drop into affected eye as needed</p> <p>Route of Administration: ophthalmic</p>	<p><u>Orthographic similarity:</u></p> <p>Both names contain prefix letters “Ta” vs. “Te” and suffix letters “gin” vs. “gen” that may appear similar when scripted.</p> <p><u>Phonetic similarity:</u></p> <p>Both names contain prefix letters “Tar” vs. “Tear” and suffix letters “gin” vs. “gen” that may sound similar.</p>	<p><u>Orthographic differences:</u></p> <p>The suffix “iq” elongates Targiniq</p> <p><u>Phonetic differences:</u></p> <p>Targiniq ER has three to five syllables (depending if the modifier is left off) vs. Teargen/Teargen II has two to three syllables</p> <p><u>Product characteristic differences:</u></p> <p>Frequency: every 12 hours vs. as needed</p> <p>Strength: Both products have multiple strengths which must be included on the prescription and there is no numerical overlap</p> <p>Dose: Targiniq ER dose may be expressed as one tablet vs. Teargen is dosed using “instill” or “drop” and must be included on the prescription.</p>

<p>Targiniq ER (oxycodone hydrochloride/naloxone hydrochloride controlled-release tablets)</p> <p>Dosage Form: tablets</p> <p>Strengths: 10 mg/5 mg, 20 mg/10 mg, 40 mg/20 mg</p> <p>Usual Dose: one tablet every 12 hours up to 80 mg/40 mg/day (40 mg/20 mg q12h)</p> <p>Route of Administration: oral</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> <p>In the conditions outlined below, the following combination of factors are expected to minimize the risk of confusion between these two names</p>
<p>Terbinex (terbinafine hydrochloride) antifungal onychomycosis</p> <p>Strength: 250 mg</p> <p>Dosage form: Bottle of 30 tablets packaged with 12 mL bottle of Eco Formula (hydroxypropyl chitosan 1% applied daily to enhance appearance of dystrophic nails)</p> <p>Dose: one tablet once daily for 6 weeks for fingernail and 12 weeks for toenail onychomycosis</p> <p>Route of Administration: oral</p>	<p><u>Orthographic similarity:</u></p> <p>Both names contain prefix letters “Tar” vs. “Ter” that may appear similar when scripted</p> <p><u>Overlapping Product Characteristics:</u></p> <p>Route of Administration: oral</p>	<p><u>Orthographic differences:</u></p> <p>The suffix “giniq” has the downstroke letters “g” and “q” which affords a different shape than the suffix “binex” which has an upstroke letter “b” and crosstroke letter “x”</p> <p><u>Product characteristic differences:</u></p> <p>Frequency: every 12 hours vs. once daily</p> <p>Strength: Targiniq ER has multiple strengths which must be included on the prescription vs. Terbinex has a single strength which may be omitted</p>

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

/s/

BRENDA V BORDERS-HEMPHILL
10/23/2013

MORGAN A WALKER
10/23/2013