

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:

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PROPRIETARY NAME REVIEW(S)

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

Proprietary Name Review Memorandum

Date: June 18, 2012

Reviewer: Manizheh Siahpoushan, PharmD
Division of Medication Error Prevention and Analysis

Team Leader Zachary Oleszczuk, PharmD
Division of Medication Error Prevention and Analysis

Drug Name: Myrbetriq (Mirabegron) Extended-release Tablets
25 mg and 50

Application Type/Number: NDA 202611

Applicant: Astellas Pharma, Inc.

OSE RCM #: 2012-948-1

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

1 INTRODUCTION

This memorandum evaluates Astellas Pharma's request for change in pronunciation of the proposed proprietary name, Myrbetriq (Mirabegron) Extended-release Tablets, 25 mg and 50 mg. The proposed name, Myrbetriq (meer-beh-trick) was found acceptable in OSE Review #2012-948 dated June 8, 2012. The Applicant is proposing a new pronunciation for the proposed name, Myrbetriq ('meer-beh-treek') No other product characteristics (i.e. spelling) are altered.

2 METHODS AND MATERIALS REVIEWED

The proposed new pronunciation, 'meer-beh-treek', for the proposed proprietary name, Myrbetriq was submitted via an email communication on June 13, 2012. We compared this pronunciation to the names identified and evaluated in OSE Review #2012-948, dated June 8, 2012, to assess whether the change in pronunciation of Myrbetriq would alter our previous conclusion regarding the acceptability of the proposed proprietary name.

3 CONCLUSIONS

The re-evaluation of the proposed proprietary name, Myrbetriq, did not identify any vulnerabilities that would result in medication errors considering we evaluated this name with multiple pronunciations during our previous review.

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/s/

MANIZHEH SIAHPOUSHAN
06/14/2012

ZACHARY A OLESZCZUK
06/18/2012

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

Proprietary Name Review

Date: June 11, 2012

Reviewer: Manizheh Siahpoushan, PharmD
Division of Medication Error Prevention and Analysis

Team Leader: Zachary Oleszczuk, PharmD
Division of Medication Error Prevention and Analysis

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

Drug Name and Strength(s): Myrbetriq (Mirabegron) Extended-release Tablets
25 mg and 50 mg

Application Type/Number: NDA 202611

Applicant/Sponsor: Astellas Pharma, Inc.

OSE RCM #: 2012-948

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1 INTRODUCTION

This review evaluates the proposed proprietary name, Myrbetriq, 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 April 17, 2012, Astellas Pharma Global Development submitted a request to the Agency for an assessment of the proposed proprietary name Myrbetriq under NDA 202611. This is the fifth proposed proprietary name submitted for this product. DMEPA concluded the following for the previous proposed proprietary name submissions by the Applicant for this product:

- The proposed proprietary name (b) (4) (IND 069416) was found unacceptable in OSE Review #2009-1305, dated December 8, 2009 due to likelihood of name confusion with (b) (4).
- The proposed proprietary name (b) (4) (IND 069416) was found unacceptable in OSE Review #2010-436, dated August 10, 2010 due to likelihood of name confusion with (b) (4), and again in OSE Review #2011-238, dated July 15, 2011 (request for reconsideration (b) (4) and proposing the 25 mg and 50 mg strengths).
- The proposed proprietary name (b) (4) (NDA 202611) was found unacceptable in OSE Review #2011-3947, dated December 16, 2011 due to likelihood of name confusion with (b) (4).
- The proposed proprietary name, (b) (4) (NDA 202611) was found unacceptable due to orthographic similarity and shared product characteristics with the marketed product, (b) (4). DMEPA communicated the results of our assessment of the proposed name with the Applicant on March 28, 2012 in a teleconference. The Applicant agreed to withdraw the proposed proprietary name, (b) (4) and submit alternate names for review.

1.2 PRODUCT INFORMATION

The following product information is provided in the April 17, 2012 proprietary name submission.

- Active Ingredient: Mirabegron
- Indication of Use: Treatment of overactive bladder
- Route of Administration: Oral
- Dosage Form: Extended-release Tablets
- Strength: 25 mg and 50 mg
- Dose and Frequency: 25 mg orally once daily with or without food. Based on individual patient efficacy and tolerability, the dose may be increased to 50 mg

once daily. The daily dose should not exceed 25 mg once daily in patients with severe renal impairment or moderate hepatic impairment.

- How Supplied: Three commercial sizes of 30- and 90-count bottles and 10-count blister package will be available. Additionally, a 7-count blister sample package will also be available
- Storage: USP Room Temperature Storage

2 RESULTS

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

2.1 PROMOTIONAL ASSESSMENT

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

2.2 SAFETY ASSESSMENT

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

2.2.1 United States Adopted Names (USAN) SEARCH

On April 25, 2012 the United States Adopted Name (USAN) stem search, identified that a USAN stem is not present in the proposed proprietary name.

2.2.2 Components of the Proposed Proprietary Name

In the April 17, 2012 submission, the Applicant states that the string “ ‘*Bet-* ‘ was selected for its association with *Beta-3 adrenoceptor agonist, which is the underlying mechanism of action of the product.*” This statement is true and therefore, DMEPA does not have a concern with inclusion of the string ‘bet’ in the middle of the name in this instance. Additionally, neither OPDP nor DRUP cited concerns with this naming strategy during review.

We did not identify other components (i.e. a modifier, route of administration, dosage form, etc.) of the name that were thought to be misleading or contribute to medication error.

2.2.3 FDA Name Simulation Studies

Twenty-three practitioners participated in DMEPA's prescription studies. The interpretations did not overlap with or appear or sound similar to any currently marketed products. Two of the 23 participants interpreted the name correctly as ‘Myrbetriq’. All of the participants in the voice prescription studies (7 participants) misinterpreted the letter ‘q’ as the letter ‘c’ or the letter string ‘-ck’ and the letter ‘y’ as the letter ‘e’. Seven participants in the inpatient prescription studies misinterpreted the letter ‘i’ as the letter ‘e’. See Appendix C for the complete listing of interpretations from the verbal and written prescription studies.

2.2.4 Comments from Other Review Disciplines

In response to the OSE, April 26, 2012 e-mail, the Division of Reproductive and Urologic Products (DRUP) forwarded one comment regarding the difficulty in pronunciation of the proposed name due to the presence of multiple consonant sounds during the initial phase of the proprietary name review. They did not forward any other concerns with the proposed name. DMEPA considered the Division's comment when evaluating the proposed name. When analyzing a proposed proprietary name, we consider the spelling of the name, pronunciation of the name when spoken, and appearance of the name when scripted, as well as comparing the pronunciation of 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 also considers the Applicant's intended pronunciation of the proprietary name as well as a variety of pronunciations that could occur in the English language because the Applicant has little control over how the name will be spoken in clinical practice.

In an email correspondence to address the Division's concerns, DMEPA explained that various interpretations of how the name, Myrbetriq, may be pronounced or spelled were considered in our evaluation of the name. Even though the possibility of misinterpretation of the pronunciation and spelling of the proposed name exists, we believe the proposed name's unique structure (i.e. spelling, the use of the upstrokes and downstrokes) can minimize the risk of medication errors. Additionally, as with all the names for the newly approved products, healthcare practitioners and patients can be educated through advertisements, Patient Information leaflets (include drug name pronunciation), and database sources such as Drug Facts and Comparisons, regarding the correct pronunciation of the name.

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, Myrbetriq. Table 1 lists the names with orthographic, phonetic, or spelling similarity to the proposed proprietary name, Myrbetriq, identified by the primary reviewer (PR) and the Expert Panel Discussion (EPD). Table 1 also includes the names identified by ^{(b) (4)} not identified by DMEPA and require further evaluation.

Table 1: Collective List of Potentially Similar Names (DMEPA, EPD, and External Name Study (b) (4))

Look Similar					
<i>Name</i>	<i>Source</i>	<i>Name</i>	<i>Source</i>	<i>Name</i>	<i>Source</i>
Myozyme	EPD	Gelnique	(b) (4) (b) (4)	Miralax	(b) (4)
Myobloc	EPD	Mylotarg	EPD	Myfedrine	EPD
Myambutol	EPD	Mycobutin	EPD	(b) (4)	EPD
Mycitracin	EPD	Mycolog II	EPD	Mytelase	EPD
Mylanta	EPD	Nystatin	EPD	Myleran	EPD
Mirapex	EPD	Miraphen	EPD	Mircette	EPD
Miraluma	EPD	Myphetane	EPD	Moxatag	PR
Aquatag	PR	Mydriacyl	PR	Megatope	PR
(b) (4)	PR	Multaq	PR	Mustargen	PR
Sound Similar					
Betrixaban	(b) (4)	Toviaz	(b) (4)		
Look and Sound Similar					
Myrbetriq	EPD	Myfortic	EPD		

Our analysis of the 31 names contained in Table 1 considered the information obtained in the previous sections along with their product characteristics. We determined 31 names will not pose a risk for confusion as described in Appendix D through E.

2.2.7 Communication of DMEPA’s Final Decision to Other Disciplines

DMEPA communicated our findings to the Division of Reproductive and Urologic Products via e-mail on May 8, 2012. At that time we also requested additional information or concerns that could inform our review. Per e-mail correspondence from the Division of Reproductive and Urologic Products on May 8, 2012, they stated a concern with possible mispronunciation or misspelling of the proposed proprietary name. See Section 3 Discussion for more information.

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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 Shawnetta Jackson, OSE project manager, at 301-796-4952.

4 COMMENTS TO THE APPLICANT

We have completed our review of the proposed proprietary name, Myrbetriq, and have concluded that this name is acceptable. However, if any of the proposed product characteristics as stated in your April 17, 2012 submission are altered, DMEPA rescinds this finding and the name must be resubmitted for review.

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

5 REFERENCES

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

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

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

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

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

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

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

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

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

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

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

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

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

USPTO provides information regarding patent and trademarks.

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

Clinical Pharmacology contains full monographs for the most common drugs in clinical use, plus mini monographs covering investigational, less common,

combination, nutraceutical and nutritional products. It also provides a keyword search engine.

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

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

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

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

11. Access Medicine (www.accessmedicine.com)

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

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

USAN Stems List contains all the recognized USAN stems.

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

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

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

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

15. Medical Abbreviations (www.medilexicon.com)

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

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

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

17. Walgreens (www.walgreens.com)

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

18. Rx List (www.rxlist.com)

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

19. Dogpile (www.dogpile.com)

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

APPENDICES

Appendix A

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

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

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

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

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

¹ 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.²

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

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

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

Type of Similarity	Considerations when Searching the Databases		
	<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.³ When applying FMEA to assess the risk of a proposed proprietary name, DMEPA seeks to evaluate the potential for a proposed proprietary name to be confused with another drug name because of name confusion and, thereby, cause errors to occur in the medication use system. FMEA capitalizes on the predictable and preventable nature of medication errors associated with drug name confusion. FMEA allows the Agency to identify the potential for medication errors due to orthographically or phonetically similar drug names prior to approval, where actions to overcome these issues are easier and more effective than remedies available in the post-approval phase.

In order to perform an FMEA of the proposed name, the primary Safety Evaluator must analyze the use of the product at all points in the medication use system. Because the proposed product is has not been marketed, the primary Safety Evaluator anticipates the use of the product in the usual practice settings by considering the clinical and product

³ 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

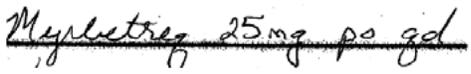
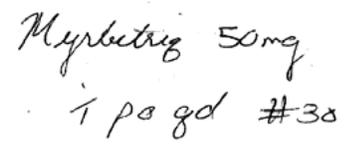
past but at great financial cost to the Sponsor and at the expense of the public welfare, not to mention the Agency’s credibility as the authority responsible for approving the error-prone proprietary name. Moreover, even after Sponsors’ have changed a product’s proprietary name in the post-approval 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, Myrbetriq	Scripted May Appear as	Spoken May Be Interpreted as
Capital ‘M’	‘N’, ‘W’, ‘V’, ‘ss’	‘e’, ‘i’, ‘u’
Lower case ‘m’	‘mn’, ‘m’, ‘vi’, ‘wi’, ‘n’, ‘v’, ‘w’, ‘onc’, ‘z’	
Lower case ‘y’	‘f’, ‘p’, ‘u’, ‘v’, ‘x’, ‘Z’	
Lower case ‘r’	‘s’, ‘n’, ‘e’, ‘v’	‘wr’
Lower case ‘b’	‘l’, ‘h’, ‘k’, ‘t’	‘p’, ‘v’, ‘d’
Lower case ‘e’	‘a’, ‘i’, ‘l’, ‘o’, ‘u’, ‘p’	Any vowel
Lower case ‘t’	‘r’, ‘f’, ‘x’, ‘A’, ‘b’	‘d’
Lower case ‘i’	‘e’, ‘l’	Any vowel
Lower case ‘q’	‘g’, ‘j’, ‘z’	‘k’

Appendix C: Prescription Simulation Samples and Results

Figure 1. Myrbetriq Study (Conducted on 4/27/12)

Handwritten Requisition Medication Order	Verbal Prescription
<p><u>Medication Order:</u> </p>	<p>Myrbetriq 50 mg 1 tablet by mouth once daily. #30</p>
<p><u>Outpatient Prescription:</u> </p>	

FDA Prescription Simulation Responses (Aggregate 1 Rx Studies Report)

84 People Received Study
 23 People Responded

Study Name: Myrbetriq

Total	8	7	8	
INTERPRETATION	INPATIENT	VOICE	OUTPATIENT	TOTAL
MERBECTRIC	0	1	0	1
MERBETRIC	0	3	0	3
MERBETRICK	0	1	0	1
MERPETRIC	0	1	0	1
MOVETRIC	0	1	0	1
MYRBECTRIQ	0	0	1	1
MYRBETRAQ	1	0	0	1
MYRBETREQ	7	0	0	7
MYRBETRIQ	0	0	2	2
MYRBITRIQ	0	0	4	4
MYRLECTRIG	0	0	1	1

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

Proprietary Name	Active Ingredient	Similarity to Myrbetriq	Failure preventions
Betrixaban	An investigational drug	Sound (b) (4)	The name pair has sufficient orthographic and /or phonetic differences.
Gelnique	Oxybutynin Chloride	Look (b) (4)	The name pair has sufficient orthographic and /or phonetic differences.
Miralax	Polyethylene Glycol	Look (b) (4)	The name pair has sufficient orthographic and /or phonetic differences.
Toviaz	Fesoterodine Fumarate	Sound (b) (4)	The name pair has sufficient orthographic and /or phonetic differences.
Mylotarg	Gemtuzumab Ozogamicin	Look	Withdrawn FR effective November 22, 2011 for safety reasons.*
(b) (4)	Mirabegron	Look	Alternate name for the same product under evaluation in this review. Name was turned down in OSE Review #2011- 3947, dated December 16, 2011 due to orthographic similarity and shared product characteristics to (b) (4).
Mircette	Desogestrel and Ethinyl Estradiol	Look	The name pair has sufficient orthographic and /or phonetic differences.
Mirapex	Pramipexole Dihydrochloride	Look	The name pair has sufficient orthographic and /or phonetic differences.
Miraphen PE	Guifenesin and Phenylephrine Hydrochloride	Look	The name pair has sufficient orthographic and /or phonetic differences.
Miraluma	Technetium TC-99M Sestamibi Kit	Look	The name pair has sufficient orthographic and /or phonetic differences.

Proprietary Name	Active Ingredient	Similarity to Myrbetriq	Failure preventions
Myozyme	Alglucosidase Alpha	Look	The name pair has sufficient orthographic and /or phonetic differences.
Myleran	Busulfan	Look	The name pair has sufficient orthographic and /or phonetic differences.
Moxatag	Amoxicillin	Look	The name pair has sufficient orthographic and /or phonetic differences.
Aquatag	Benzthiazide	Look	The name pair has sufficient orthographic and /or phonetic differences.
Mydriacyl	Tropicamide	Look	The name pair has sufficient orthographic and /or phonetic differences.
Megatope	Iodinated I131 Albumin	Look	The name pair has sufficient orthographic and /or phonetic differences.
(b) (4)	Metreleptin	Look	The name pair has sufficient orthographic and /or phonetic differences.
Multaq	Dronedarone	Look	The name pair has sufficient orthographic and /or phonetic differences.
Mustargen	Mechlorethamine Hydrochloride	Look	The name pair has sufficient orthographic and /or phonetic differences.
Mycitracin	Bacitracin, Neomycin Sulfate, and Polymyxin B Sulfate	Look	Withdrawn FR effective 12/13/93 due to pediatric safety issues.
Myrbetriq	Mirabregon	Look and sound	Proprietary name under evaluation in this review.

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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.

<p>Proposed name: Myrbetriq (Mirabegron)</p> <p>Dosage Form(s): Extended-release Tablets</p> <p>Strength(s): 25 mg and 50 mg</p> <p>Usual Dose: 25 mg (or one tablet) orally once daily. Dose may be increased to 50 mg once daily. Severe renal or moderate hepatic impairment: 25 mg (or one tablet) orally 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> <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>Myfedrine (Pseudoephedrine Hydrochloride) Solution 30 mg/5 mL</p> <p>Usual Dose: 15 mg to 60 mg (or ½ teaspoonful to 2 teaspoonfuls) orally every 4 to 6 hours</p>	<p>Orthographic: Both names consist of 9 letters, begin with the letter string ‘My-’, share the letter string ‘-ri-’ and the letter ‘e’ in similar positions in each name, and share similar letters in similar positions (‘b’ vs. ‘f’ and ‘t’ vs. ‘d’) when scripted.</p> <p>Route of Administration: Oral</p> <p>Frequency of Administration: ‘QD’ may be misinterpreted as ‘QID’ or vice versa.</p> <p>Achievable Product Strength: 25 mg</p> <p>Partial Numerical Overlap in the Usual Dose: One tablet vs. one teaspoonful</p>	<p>Orthographic: The letter ‘q’ at the end of the name, Myrbetriq (vs. the letter string ‘-ne’ in Myfedrine) provides a different shape for this name and can help differentiate Myrbetriq and Myfedrine when scripted.</p>

<p>Proposed name: Myrbetriq (Mirabegron)</p> <p>Dosage Form(s): Extended-release Tablets</p> <p>Strength(s): 25 mg and 50 mg</p> <p>Usual Dose: 25 mg (or one tablet) orally once daily. Dose may be increased to 50 mg once daily. Severe renal or moderate hepatic impairment: 25 mg (or one tablet) orally 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> <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>Myambutol (Ethambutol Hydrochloride) Tablets, 100 mg and 400 mg</p> <p>Usual Dose: Daily therapy: 15-25 mg/kg (maximum dose: 1.6 g) 40-55 kg: 800 mg 56-75 kg: 1200 mg 76-90 kg: 1600 mg Twice weekly directly observed therapy: 50 mg/kg (maximum dose: 4 g) 40-55 kg: 2000 mg 56-75 kg: 2800 mg 76-90 kg: 4000 mg Three times/week: 25-30 mg/kg (maximum dose: 2.4 g) 40-55 kg: 1200 mg 56-75 kg: 2000 mg 76-90 kg: 2400 mg Pediatric dosing: 15-25 mg/kg/day</p>	<p>Orthographic: Both names consist of 9 letters, begin with the letter string 'My-', share the letter 'b' in a similar position (4th vs. 5th) in each name, and share a similar letter string in a similar position in each name ('-et-' vs. '-ut-') when scripted.</p> <p>Route of Administration: Oral</p> <p>Dosage Form: Tablets</p> <p>Overlap in the Frequency of Administration: Once daily</p> <p>Possible Numerical Overlap in the Usual Dose: One tablet</p>	<p>Orthographic: The ending letter string '-riq' in Mirbetriq (vs. '-ol' in Myambutol), and the additional letter 'm' between the letter string 'My-' and the letter 'b' in Myambutol (vs. only the letter 'r' in Myrbetriq) provide different shapes for the two names and can help differentiate Myrbetriq and Myambutol when scripted.</p> <p>Strength: 25 mg and 50 mg vs. 100 mg and 400 mg</p>

<p>Proposed name: Myrbetriq (Mirabegron)</p> <p>Dosage Form(s): Extended-release Tablets</p> <p>Strength(s): 25 mg and 50 mg</p> <p>Usual Dose: 25 mg (or one tablet) orally once daily. Dose may be increased to 50 mg once daily. Severe renal or moderate hepatic impairment: 25 mg (or one tablet) orally 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> <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>Mycobutin (Rifabutin) Capsules 150 mg</p> <p>Usual Dose: 300 mg once daily or 150 mg twice daily. Infants and children: 5 to 20 mg/kg once daily or 2 to 3 times weekly.</p>	<p>Orthographic: Both names consist of 9 letters, begin with the letter string 'My-', share similar letters in the same position ('r' vs. 'c'), share the letter 'b' in similar positions (4th vs. 5th), and share similar letter strings in similar positions ('-et-' vs. '-ut-') when scripted.</p> <p>Route of Administration: Oral</p> <p>Dosage Form: Solid oral</p> <p>Overlap in the Frequency of Administration: Once daily</p> <p>Overlap in the Usual Dose: One (tablet vs. capsule)</p>	<p>Orthographic: The ending letter string '-riq' (vs. '-in' in Mycobutin), and the additional letter 'o' between the letter string 'My-' and the letter 'b' in Mycobutin (vs. only the letter 'r' in Myrbetriq) provide different shapes for each name and can help differentiate Myrbetriq and Mycobutin when scripted.</p> <p>Strength: 25 mg and 50 mg vs. 150 mg</p>

<p>Proposed name: Myrbetriq (Mirabegron)</p> <p>Dosage Form(s): Extended-release Tablets</p> <p>Strength(s): 25 mg and 50 mg</p> <p>Usual Dose: 25 mg (or one tablet) orally once daily. Dose may be increased to 50 mg once daily. Severe renal or moderate hepatic impairment: 25 mg (or one tablet) orally 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> <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>Mycolog II (Nystatin and Triamcinolone Acetonide) Ointment, 0.1%</p> <p>(Name is discontinued, but the generic equivalents are available.)</p> <p>Usual Dose: Apply a thin film sparingly to the affected area(s) twice daily.</p>	<p>Orthographic: Both names begin with the letter string 'My-', share similar letters in similar positions ('r' vs. 'c', 'b' vs. 'l', 'e' vs. 'o'), and end with letters that appear similar when scripted ('q' vs. 'g').</p> <p>Partial Overlap in the usual Dose: One (tablet vs. application)</p>	<p>Orthographic: The letter string '-tri-' in Mirbetriq provides a different shape and length for this name and can help differentiate Myrbetriq and Mycolog when scripted.</p> <p>Strength: 25 mg and 50 mg vs. single strength</p>
<p>Mytelase (Ambenonium Chloride) Caplets, 10 mg</p> <p>Usual Dose: Myasthenia gravis: 5 to 25 mg 3 to 4 times per day; adjust dose every 1 to 2 days as needed depending on patient response; some patients may require as much as 50 to 75 mg per dose.</p>	<p>Orthographic: Both names begin with the letter string 'My-', share the letter 'e' in a similar position in each name (5th vs. 4th), and share similar letters in similar positions ('b' vs. 't' and 't' vs. 'l') when scripted.</p> <p>Route of Administration: Oral</p> <p>Frequency of Administration: 'QD' may be misinterpreted as 'QID' or vice versa.</p> <p>Dosage Form: Solid oral</p> <p>Overlap in the Usual Dose: 25 mg or 50 mg</p>	<p>Orthographic: The ending letter 'q' in Myrbetriq (vs. 'e' in Mytelase) provides a different shape for this name and can help differentiate Myrbetriq and Mytelase when scripted.</p> <p>Strength: 25 mg and 50 mg vs. single strength (10 mg)</p>

<p>Proposed name: Myrbetriq (Mirabegron)</p> <p>Dosage Form(s): Extended-release Tablets</p> <p>Strength(s): 25 mg and 50 mg</p> <p>Usual Dose: 25 mg (or one tablet) orally once daily. Dose may be increased to 50 mg once daily. Severe renal or moderate hepatic impairment: 25 mg (or one tablet) orally 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> <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>Nystatin Tablets, 500,000 units Oral Suspension, 100,000 units/mL Powder, 50 or 500 million units</p> <p>Usual Dose: Tablets: 1 to 2 tablets orally every 8 hours Oral suspension: Adults: Swish and swallow 400,000 to 600,000 (or 4 to 6 mL) orally 4 times daily. Infants and children: 2 to 6 mL 4 times daily. Powder: 1/8 teaspoonful (500,000 units) to equal approximately half a cup of water</p>	<p>Orthographic: Both names share the letters ‘y’ and ‘t’ in the same positions (2nd and 6th positions respectively), beginning letters that appear similar when scripted (‘M’ vs. ‘N’), share the letter ‘i’ in similar positions of each name (8th vs. 7th position), share a similar letter string in a similar position of each name (‘-rbe-’ vs. ‘-sta-’) when scripted.</p> <p>Route of Administration: Oral</p> <p>Overlap in the Dosage Form: Tablets</p> <p>Partial Numerical Overlap in the Strength: 50 mg vs. 50 million units</p> <p>Partial Numerical Overlap in the Usual Dose: One tablet</p>	<p>Orthographic: The ending letter ‘q’ in Myrbetriq (vs. ‘n’ in Nysttin) provides a different shape for this name and can help differentiate Myrbetriq and Nystatin when scripted.</p>

<p>Proposed name: Myrbetriq (Mirabegron)</p> <p>Dosage Form(s): Extended-release Tablets</p> <p>Strength(s): 25 mg and 50 mg</p> <p>Usual Dose: 25 mg (or one tablet) orally once daily. Dose may be increased to 50 mg once daily. Severe renal or moderate hepatic impairment: 25 mg (or one tablet) orally 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> <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>Myphetane DX (Brompheniramine, Pseudoephedrine, and Dextromethorphan) Oral liquid 2 mg/30 mg/10 mg/5 mL</p> <p>(Discontinued, however, generic equivalents are available)</p> <p>Usual Dose: 5 mL (or one teaspoonful) orally every 4 to 6 hours.</p>	<p>Orthographic: Both names consist of 9 letters, begin with the letter string 'My-', share the letter string '-et-' in the same position of each name, and share similar letters in the same position of each name ('b' vs. 'h') when scripted.</p> <p>Route of Administration: Oral</p> <p>Partial Overlap in the Usual Dose: One (tablet vs. teaspoonful)</p>	<p>Orthographic: The ending letter 'q' in Myrbetriq and the letter 'p' in Myphetane DX provide different shapes for each name and can help differentiate Myrbetriq and Myphetane DX when scripted.</p> <p>Strength: 25 mg and 50 mg vs. single strength (2 mg/30 mg/10 mg/5 mL)</p>

<p>Proposed name: Myrbetriq (Mirabegron)</p> <p>Dosage Form(s): Extended-release Tablets</p> <p>Strength(s): 25 mg and 50 mg</p> <p>Usual Dose: 25 mg (or one tablet) orally once daily. Dose may be increased to 50 mg once daily. Severe renal or moderate hepatic impairment: 25 mg (or one tablet) orally 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> <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>Myobloc (RimabotulinumtoxinB) Injection, 5000 units/mL</p> <p>Usual Dose: Initial: 2500 to 5000 units intramuscularly divided among the affected muscles in patients previously treated with botulinum toxin; initial dose in previously untreated patients should be lower. Subsequent dosing should be optimized according to patient's response.</p>	<p>Orthographic: Both names begin with the letter string 'My-' and share the letter 'b' in the 4th position.</p>	<p>Orthographic: The ending letter 'q' in Myrbetriq and the letter 'e' between letters 'b' and 't' in this name (vs. no letters between letters 'b' and 'l' in Myobloc) provide a different shape for Myrbetriq and can help differentiate the two names when scripted.</p> <p>Strength: 25 mg and 50 mg vs. single strength (5000 units mL)</p>
<p>Mylanta (Calcium Carbonate and Magnesium Hydrochloride) Gelcaps, 550 mg/125 mg</p> <p>Usual Dose: 2 to 4 gelcaps between meals and at bedtime or as directed by a healthcare provider.</p>	<p>Orthographic: Both names begin with the letter string 'My-', share the letter 't' in the 6th position, and share a similar letter string in a similar position ('-be-' vs. '-la-').</p> <p>Route of Administration: Oral</p> <p>Dosage Form: Solid oral</p>	<p>Orthographic: The ending letter 'q' in Myrbetriq and the extra letter 'n' between the two upstrokes, 'l' and 't' in Mylanta provide different shapes for these two names and can help differentiate Myrbetriq and Mylanta when scripted.</p> <p>Strength: 25 mg and 50 mg vs. single strength (550 mg/125 mg)</p>

<p>Proposed name: Myrbetriq (Mirabegron)</p> <p>Dosage Form(s): Extended-release Tablets</p> <p>Strength(s): 25 mg and 50 mg</p> <p>Usual Dose: 25 mg (or one tablet) orally once daily.</p> <p>Dose may be increased to 50 mg once daily. Severe renal or moderate hepatic impairment:</p> <p>25 mg (or one tablet) orally 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> <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>Myfortic (Mycophenolate Sodium) Delayed-release Tablets 180 mg and 360 mg</p> <p>Usual Dose: 720 mg orally twice daily.</p>	<p>Orthographic/Phonetic: Both names begin with the letter string 'My-', share the letter 't' in the 6th position, share the letter 'i' in a similar position of each name (8th vs. 7th position), share a similar letter string in similar positions ('-be-' vs. '-fo-') when scripted. Phonetically, both names consist of 3 syllables with the first and last syllables sharing similar sounds when spoken ('Myr' vs. 'My' and 'riq' vs. 'tic')</p> <p>Route of Administration: Oral</p> <p>Dosage Form: Tablets</p>	<p>Orthographic: The ending letter 'q' in Myrbetriq (vs. 'c' in Myfortic) and the extra letter 'r' between letters 'f' and 't' in Myfortic provide different shapes for each name and can help differentiate Myrbetriq and Myfortic when scripted. Phonetically, the second syllable ('bet' vs. 'for') sounds different in each name and can help differentiate the two names when spoken.</p> <p>Strength: 25 mg and 50 mg vs. 180 mg or 360 mg</p>

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/s/

MANIZHEH SIAHPOUSHAN
06/08/2012

ZACHARY A OLESZCZUK
06/11/2012

CAROL A HOLQUIST
06/12/2012

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

Proprietary Name Review

Date: December 16, 2011

Reviewer(s): Teresa McMillan, PharmD, Safety Evaluator
Division of Medication Error Prevention & Analysis

Team Leader: Zachary Oleszczuk, PharmD, Team Leader
Division of Medication Error Prevention & Analysis

Division Director: Carol Holquist, RPh, Division Director
Division of Medication Error Prevention & Analysis

Drug Name(s) and Strength(s): (b) (4) (Mirabegron) Extended-release Tablets
25 mg and 50 mg

Application Type/Number: NDA 202611

Applicant/Sponsor: Astellas Pharma Global Development

OSE RCM #: 2011-3947

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TERESA S MCMILLAN
12/16/2011

ZACHARY A OLESZCZUK
12/19/2011

CAROL A HOLQUIST
12/19/2011



**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**

Date: July 15, 2011

Through: Todd Bridges, RPh, Team Leader
Kellie Taylor, PharmD, MPH, Associate Director
Carol Holquist, RPh, Director
Division of Medication Error Prevention and Analysis (DMEPA)

From: Colleen Brennan, RPh, Safety Evaluator
Division of Medication Error Prevention and Analysis (DMEPA)

Subject: Proprietary Name Reconsideration Request Review

Drug Name and Strengths: (b) (4) (Mirabegron) Tablets
25 mg and 50 mg

Application Type/ Number: IND 069416

Applicant/sponsor: Astellas Pharma Global Development Inc.

OSE RCM #: 2011-238

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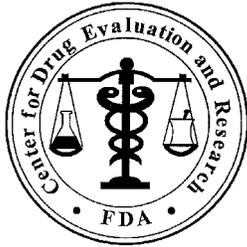
/s/

COLLEEN BRENNAN
07/18/2011

TODD D BRIDGES
07/18/2011

KELLIE A TAYLOR
07/18/2011

CAROL A HOLQUIST
07/19/2011



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

Date: August 10, 2010

Application Type/Number: IND 069416

Through: Todd Bridges, RPh, Team Leader
Denise Toyer, PharmD, Deputy Director
Carol Holquist, RPh, Director
Division of Medication Error Prevention and Analysis (DMEPA)

From: Deveonne Hamilton-Stokes, RN, BSN, Safety Evaluator
Division of Medication Error Prevention and Analysis (DMEPA)

Subject: Proprietary Name Review

Drug Name(s): (b) (4) (Mirabegron) Tablets
25 mg, 50 mg (b) (4)

Sponsor: Astellas Pharma

OSE RCM #: 2010-436

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Application Type/Number	Submission Type/Number	Submitter Name	Product Name
IND-69416	ORIG-1	ASTELLAS PHARMA GLOBAL DEVELOPMENT INC	YM178

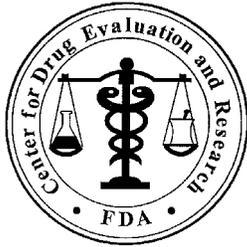
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DEVEONNE G HAMILTON-STOKES
08/10/2010

DENISE P TOYER
08/11/2010

CAROL A HOLQUIST
08/12/2010



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

Date: December 8, 2009

To: Scott Monroe, MD, Director
Division of Reproductive and Urology Drugs

Thru: Melina Griffis, RPh, Team Leader
Denise Toyer, PharmD, Deputy Director
Carol Holquist, RPh, Director
Division of Medication Error Prevention and Analysis (DMEPA)

From: Anne Crandall, PharmD, Safety Evaluator
Division of Medication Error Prevention and Analysis (DMEPA)

Subject: Proprietary Name Review

Drug Name(s): (b) (4) (Mirabegron) Tablets, 50 mg (b) (4)

Application Type/Number: IND # 069416

Sponsor: Astellas Pharma

OSE RCM #: 2009-1305

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

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Application Type/Number	Submission Type/Number	Submitter Name	Product Name
IND-69416	ORIG-1	ASTELLAS PHARMA GLOBAL DEVELOPMENT INC	YM178

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/s/

ANNE CRANDALL
12/08/2009

MELINA N GRIFFIS
12/09/2009

DENISE P TOYER
12/09/2009

CAROL A HOLQUIST
12/10/2009