CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

203284Orig1s000

PROPRIETARY NAME REVIEW(S)

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

Proprietary Name Review--Final

Date:	November 29, 2012
Reviewer:	Carlos M Mena-Grillasca, RPh Division of Medication Error Prevention and Analysis
Team Leader:	Lubna Merchant, MS, PharmD Division of Medication Error Prevention and Analysis
Drug Name(s):	Ravicti (Glycerol Phenylbutyrate) Liquid
Strength:	1.1 g/mL
Application Type/Number:	NDA 203284
Applicant/Sponsor:	Hyperion Therapeutics
OSE RCM #:	2012-1109

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

CONTENTS

1 INTRODUCTION

This re-assessment of the proposed proprietary name, Ravicti is written in response to the anticipated approval of this NDA within 90 days from the date of this review. DMEPA found the proposed name, Ravicti, acceptable in OSE Reviews 2012-476 dated May 3, 2012.

2 METHODS AND DISCUSSION

For re-assessments of proposed proprietary names, DMEPA searches a standard set of databases and information sources (see section 4) to identify names with orthographic and phonetic similarity to the proposed name that have been approved since the previous OSE proprietary name review. For this review we used the same search criteria described in OSE Review 2012-476. We note that none of the proposed product characteristics were altered. However, we evaluated the previously identified names of concern considering any lessons learned from recent post-marketing experience, which may have altered our previous conclusion regarding the acceptability of the proposed proprietary name. The searches of the databases yielded one new name (Revatio), thought to look or sound similar to Ravicti and represent a potential source of drug name confusion. Failure mode and effects analysis was applied to determine if the proposed proprietary name could potentially be confused with Ravicti and lead to medication errors. This analysis determined that the name similarity between Ravicti and Revatio was unlikely to result in medication error for the reasons presented in Appendix A.

Additionally, DMEPA searched the USAN stem list to determine if the name contains any USAN stems as of the last USAN updates. The Safety Evaluator did not identify any United States Adopted Names (USAN) stems in the proposed proprietary name, as of November 20, 2012. The Office of Prescription Drug Promotion OPDP re-eviewed the proposed name on October 25, 2012 and had no concerns regarding the proposed name from a promotional perspective.

3 CONCLUSIONS

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

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

If you have further questions or need clarifications, please contact Franklin Stephenson, OSE project manager, at 301-796-3872.

4 REFERENCES

1. OSE Reviews

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

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

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

USAN Stems List contains all the recognized USAN stems.

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

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

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

No.	**Proposed name:** Ravicti **Dosage Form:** Liquid **Strength:** 1.1 g/mL **Usual Dose:** 5 to 12.4 g/m^2/day (4.5 -11.2 mL/ m^2/day) by mouth divided into three equal doses with meals	**Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion** **Causes (could be multiple)**	**Prevention of Failure Mode** **In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names**
1.	**Revatio** (Sildenafil) Tablets, 20 mg For oral suspension, 10 mg/mL Injection 10 mg/12.5 mL single-use vial Dosage: ***Oral administration:*** 20 mg three times daily (4-6 hours apart) ***Intravenous administration:*** 10 mg intravenously three times daily	Orthographic: Both names have 7 letters and a similar shape when scripted. Both names have an upstroke letter 't' in a similar position. Both names share the letter 'R', 'v', 'ti' in the same or similar positions. Route of administration: Both products can be administered by the oral route of administration. Frequency of administration: Both products are administered three times daily	Strength: Ravicti is a single strength product (1.1 g/mL) vs. Revatio is available in multiple strengths (20 mg, 10 mg/mL, 10 mg/12.5 mL), which would be required on a prescription. Dosage forms: Ravicti is available in one dosage form (oral liquid) vs. Revatio is available in multiple dosage forms (tablets, powder for oral suspension, injection), which would be required on a prescription. Setting of Use: Ravicti will be made available through a small network of specialty distributors, likely no more than three. In this distribution model, physicians submit prescriptions directly to the specialy pharmacies which in turn secure reimbursement from payers and ship the drug directly to eligible patients. This limited distribution as well as small patient population may help minimize drug confusion between Ravicti and Revatio.

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/s/

CARLOS M MENA-GRILLASCA
11/29/2012

LUBNA A MERCHANT
12/02/2012

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:	May 3, 2012
Reviewer:	Anne Crandall Tobenkin, PharmD Division of Medication Error Prevention and Analysis
Team Leader:	Lubna Merchant, PharmD, M.S. Division of Medication Error Prevention and Analysis
Division Director:	Carol Holquist, R.Ph. Division of Medication Error Prevention and Analysis
Drug Name(s):	Ravicti (Glycerol Phenylbutyrate) Liquid
Strength:	1.1 g/mL
Application Type/Number:	NDA 203284
Applicant/Sponsor:	Hyperion Therapeutics
OSE RCM #:	2012-476

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CONTENTS

1 INTRODUCTION

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

1.1 REGULATORY HISTORY

The proposed name, Ravicti, was found conditionally acceptable in OSE Review # 2011-1162, dated September 21, 2011 during the IND phase. The Application has subsequently converted to an NDA and as a result the name is being reviewed again along with the labels and labeling submitted at the time of the NDA name review. The product characteristics have not changed, although the presentation of the recommended doses have changed slightly, the final recommended dose is still within the range of the previous recommendations.

Table 1: Previous and current Ravicti doses

Doses reviewed in Ravicti OSE review # 2011-1162	Doses as proposed in the proprietary name review and submitted labeling
(b) (4)	(b) (4)

1.2 PRODUCT INFORMATION

The following product information is provided in the February 22, 2012 proprietary name submission.

- Active Ingredient: Glycerol Phenylbutyrate
- Indication of Use: Adjunctive therapy for chronic management of adult and pediatric (> 6 y.o.) with urea cycle disorders involving deficiencies of certain enzymes
- Route of Administration: Oral
- Dosage Form: Liquid
- Strength: 1.1 g/mL
- Dose and Frequency: 5 g/m^2/day to 12.4 g/m^2/day by mouth divided into three equal doses with meals

- How Supplied: 25 mL, 120 mL, 450 mL bottles
- Storage: Room temperature
- Container and Closure Systems: (b) (4) .

Per the submission, Ravicti will be made available through a small network of specialty pharmacy distributors, likely no more than three. In this distribution model, physicians submit prescriptions directly to specialty pharmacies which in turn secure reimbursement from payers and ship drug directly to eligible patients. This limited distribution as well as small patient population was considered during our analysis, although we noted that these patients are likely to experience frequent hospitalizations due to disease state related exacerbations.

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 Gastroenterology and Inborn Errors Products 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

The March 6, 2012 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

The proposed proprietary name, Ravicti, is comprised of a single word that does not contain any components (i.e. a modifier, route of administration, dosage form, etc.) that are misleading or can contribute to medication errors. Additionally, the applicant stated in the submission that the proposed name, Ravicti, was not derived from any one particular concept.

2.2.4 FDA Name Simulation Studies

Thirty three practitioners participated in DMEPA's prescription studies. The interpretations did not overlap with or appear or sound similar to any currently marketed products. The most common misinterpretations included confusing 'a' for 'o', 'n', 'f', and 'r' for 'v' and 'ee' and 'y' for the final 'i'. See Appendix C for the complete listing of interpretations from the verbal and written prescription studies.

2.2.5 Comments from Other Review Disciplines

In response to the OSE, March 8, 2012 e-mail, the Division of Gastroenterology and Inborn Error Products (DGIEP) did not forward any comments or concerns relating to the proposed name at the initial phase of the proprietary name review.

2.2.6 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, Ravicti. Table 2 lists the names with orthographic, phonetic, or spelling similarity to the proposed proprietary name, Ravicti, identified by the primary safety evaluator (SE), the Expert Panel Discussion (EPD), and other review disciplines. Because the recommended dose changed from the previous review (OSE review #2011-1162) , all names from the previous review were re-reviewed with the new product characteristics. One name from the previous review, Renvela, was thought to pose a risk of medication error due to the revised product characteristics and was included in Table 2. Table 2 also includes the names identified from the FDA Prescription Simulation and not identified by DMEPA, but require further evaluation.

Table 2: Collective List of Potentially Similar Names (DMEPA, EPD, Other Disciplines, and FDA Name Simulation Studies)

Names that are orthographically similar to Ravicti		
Janacti*** (EPD)	(b) (4)*** (EPD)	Kurvelo*** (EPD)
Brevital (EPD)	Evista (EPD)	ReVia (EPD)
Pavabid (EPD)	Parafon (EPD)	(b) (4) (EPD)
Navstel (EPD)	Savella (EPD)	Reversol (EPD)
Ruvite (EPD)	Kariva (EPD)	Rescula (SE)
Prandin (SE)	Pamelor (SE)	Panretin (SE)
Promacta (SE)	(b) (4)*** (SE)	(b) (4)*** (SE)
Roxicet (SE)	Renvela (OSE review # 2011-1162)	

Our analysis of the 23 names contained in Table 2 considered the information obtained in the previous sections along with their product characteristics. We determined all 23 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 Gastroenterology and Inborn Error Products (DGIEP) via e-mail on April 13, 2012. At that time we also requested additional information or concerns that could inform our review. Per e-mail correspondence from the DGIEP on April 17, 2012, they stated no additional concerns with the proposed proprietary name, Ravicti.

2 CONCLUSIONS

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

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

2.1 COMMENTS TO THE APPLICANT

We have completed our review of the proposed proprietary name, Ravicti, and have concluded that this name is acceptable. However, if any of the proposed product characteristics as stated in your February 22, 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.

3 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

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

proposed may provide a context for communication of the drug name and ultimately determine the use of the product in the *usual* clinical practice setting.

Typical product characteristics considered when identifying drug names that could potentially be confused with the proposed proprietary name include, but are not limited to; established name of the proposed product, proposed indication of use, dosage form, route of administration, strength, unit of measure, dosage units, recommended dose, typical quantity or volume, frequency of administration, product packaging, storage conditions, patient population, and prescriber population. 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**		
	Potential Causes of Drug Name Similarity	*Attributes Examined to Identify Similar Drug Names*	*Potential Effects*
Look-alike	Similar spelling	Identical prefix Identical infix Identical suffix Length of the name Overlapping product characteristics	• Names may appear similar in print or electronic media and lead to drug name confusion in printed or electronic communication • Names may look similar when scripted and lead to drug name confusion in written communication
	Orthographic similarity	Similar spelling Length of the name/Similar shape Upstrokes Down strokes Cross-strokes Dotted letters Ambiguity introduced by scripting letters Overlapping product characteristics	• Names may look similar when scripted, and lead to drug name confusion in written communication
Sound-alike	Phonetic similarity	Identical prefix Identical infix Identical suffix Number of syllables Stresses Placement of vowel sounds Placement of consonant sounds Overlapping product characteristics	• Names may sound similar when pronounced and lead to drug name confusion in verbal communication

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

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

1. Database and Information Sources

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

2. Expert Panel Discussion

DMEPA gathers gather CDER professional opinions on the safety of the proposed product and discussed the proposed proprietary name (Expert Panel Discussion). The Expert Panel is composed of Division of Medication Errors Prevention (DMEPA) staff and representatives from the 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 posses similarity that would cause confusion at any point in the medication use system, thus the name is eliminated from further review.

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

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

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

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

a. 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

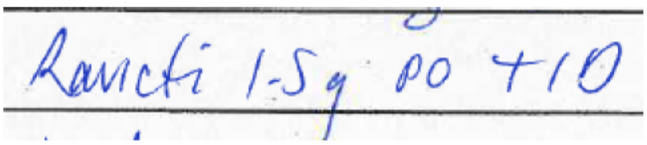
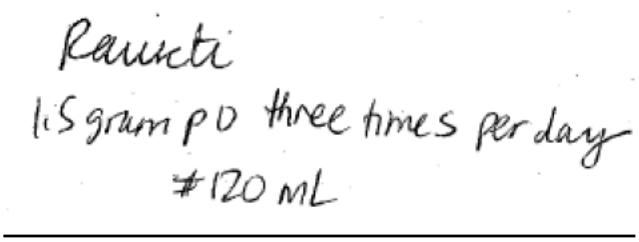
past but at great financial cost to the Sponsor and at the expense of the public welfare, not to mention the Agency's credibility as the authority responsible for approving the error-prone proprietary name. Moreover, even after Sponsors' have changed a product's proprietary name in the post-approval 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 Ravicti	Scripted May Appear as	Spoken May Be Interpreted as
R	'B', 'D', 'P', 'Pr', 'K'	'Wr', 'Br'
a	'el', 'ci', 'cl', 'd', 'o', 'u'	Any vowel
v	'r', 'u'	'f', 'ph', 'b'
i	'e'	Any vowel, 'ee', 'y'
c	'a', 'e', 'i', 'l', 'z'	's' or 'k'
t	'A', 'f', 'r', 'l', 'x'	'd 'or 'b'
i	'e'	Any vowel, 'ee', 'y'

Appendix C: Prescription Simulation Samples and Results

Figure 1. Prescription Simulation Study (Conducted on March 9, 2012)

Handwritten Requisition Medication Order	Verbal Prescription
Medication Order:  	Ravicti 1.5 grams by mouth three times per day
Outpatient Prescription:  	

FDA Prescription Simulation Responses (Aggregate 1 Rx Studies Report)

Inpatient	Voice	Outpatient
RAVICTI	RAVICTI	RAVICTI
RAVICTI	ROVITY	RAVICTI
RAVICTI	ROVICTEE	RANICTI
RAVICTI	RAVICTI	RAURTI
RAVICTI	RAVICTI	RARVICTI
RAVICTI	ROFIFTY?	RASICTI
RANCTI	ROGVICTI	RARICTI
RAVICTI	ROSICTY	RARICTI
RANCTI		RAVICTI
RAVICTI		RARUCTI
RAVICTI		RAVICTI
RAVICTI		
RAVICTI		
RAVICTI		

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 Ravicti	Failure preventions
Janacti***	Sitagliptin and Pioglitazone	Orthographic	The IND associated with this product (per the OSE record #2011-3288) was withdrawn from the Agency.
(b) (4)***	Aliskiren, Amlodipine, HCTZ	Orthographic	The Application was approved with the proposed name Amturnide (OSE review # 2010-2232)
Navstel	Calcium chloride, Dextrose, Magnesium chloride, Oxiglutatione, Potassium chloride, Sodium bicarbonate, Sodium chloride, Sodium phosphate	Orthographic	The name pair has sufficient orthographic differences that confusion is unlikely.
Pavabid	Papaverine	Orthographic	Approved outside of U.S. According to DARRTS, the application was (b) (4) .
(b) (4)		Orthographic	Listed in Orphan drug database, however no product characteristics associated with name, unable to find product in other commonly used drug databases and no IND or NDA associated with name.
(b) (4)		Orthographic	Proposed proprietary name, (b) (4)*** found unacceptable by OPDP and documented in OSE review (b) (4). Letter sent to Applicant.
(b) (4)***	Rixulitinib	Orthographic	Proposed proprietary name, (b) (4)*** found unacceptable in OSE review # (b) (4). New proprietary name, Jakafi*** found acceptable and is not orthographically similar to Ravicti.

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

Proposed name: Ravicti (Glycerol Phenylbutyrate) **Dosage Form: Liquid** **Strength: 1.1 g/mL** **Usual Dose: 5 g/m^2 to 12.4 g/m^2 per day in three divided doses (with meals)**	**Failure Mode:** **Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion**	**Prevention of Failure Mode:** **In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names**
Roxicet (Acetaminophen and Oxycodone) - 325 mg/5 mg/5 mL oral solution, 325 mg/5 mg oral tablet - One tablet or 5 mL by mouth four times daily, not to exceed 60 mL or 12 tablets per day	**Orthographic similarity** - Both names begin with a similar string, 'Rav' and 'Rox' - Both names are similar in length - Both names have a similar string at the end, 'ict' and 'icet' **Overlapping product characteristics** - Strength (both single strength, not required on prescription) - Dosage form (oral liquid/solution) - Dose (5 mL) - Frequency of administration (three times daily)	**Orthographic differences** - Ravicti has a letter following the final upstroke vs. Roxicet ends with an upstroke making the shape different - Letter string 'ict' in Ravicti appears orthographically different than the similarly situated letter string 'icet' in Roxicet
Renvela (Sevelamer) - 800 mg oral tablet, 0.8 g and 2.4 g powder for suspension - 800 to 2.4 g by mouth three times a day with meals	**Orthographic similarity** - Both names begin 'R' - Both names are similar in length - Both names have an upstroke toward the end of the name followed by one letter **Overlapping product characteristics** - Route of administration (oral) - Dose (2.4 g) - Frequency of administration (three times daily with meals)	**Orthographic differences** - Ravicti has a cross-stroke vs. Renvela does not have a cross-stroke **Product characteristic differences** - Dosage form (oral liquid vs. tablet or powder, must be designated on prescription)

Proposed name: Ravicti (Glycerol Phenylbutyrate) **Dosage Form: Liquid** **Strength: 1.1 g/mL** **Usual Dose: 5 g/m^2 to 12.4 g/m^2 per day in three divided doses (with meals)**	**Failure Mode:** **Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion**	**Prevention of Failure Mode:** **In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names**
Kurvelo*** (Levonorgestrel and Ethinyl Estradiol) - 0.15 mg/0.03 mg oral tablet - One tablet by mouth once daily or as directed	**Orthographic similarity** - 'K' and 'R' appear similar when scripted - Both names are similar in length - Both names have an upstroke at the end of the name **Product characteristic overlap** - Route of administration (oral)	**Orthographic differences** - Ravicti has a cross-stroke vs. Kurvelo does not have a cross-stroke giving the names different shapes **Product characteristic differences** - Frequency of administration (three times daily vs. once daily or as directed) - Dose (g or mL weight based regimen vs. one tablet)
Brevital (Methohexital) - 500 mg, 2.5 g for injection - For rectal, intravenous or intramuscular administration. Dosed at 1 mg/kg to 25 mg/kg once or continuous for anesthesia	**Orthographic similarity** - 'B' and 'R' appear similar when scripted - Both names have an upstroke towards the end of the name **Product characteristic overlap** - none	**Orthographic differences** - Ravicti has one upstroke toward the end of the name vs. Brevital has two upstrokes toward the end of the name giving the name a different shape **Product characteristic differences** - Route of administration (oral vs. intravenous, intramuscular or rectal) - Frequency of administration (three times a day vs. once or continuous for anesthesia)
Evista (Raloxifene) - 60 mg oral tablet - 60 mg or 1 tablet by mouth once daily	**Orthographic similarity** - Both names have similar letter strings, 'vict' and 'vist' - Both names are similar in length **Product characteristic overlap** - Route of administration (oral)	**Orthographic differences** - 'R' and 'E' do not resemble one another when scripted - Ravicti has a letter in between the upstroke and the 'v' vs. Evista has the 'v' following the upstroke giving the name a different shape when scripted **Product characteristic differences** - Dose (g or mL, weight based regimen vs. one tablet or 60 mg) - Frequency of administration (three times daily vs. once daily)

Proposed name: Ravicti (Glycerol Phenylbutyrate) **Dosage Form: Liquid** **Strength: 1.1 g/mL** **Usual Dose: 5 g/m^2 to 12.4 g/m^2 per day in three divided doses (with meals)**	**Failure Mode:** **Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion**	**Prevention of Failure Mode:** **In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names**
ReVia (Naltrexone) - 50 mg oral tablet - 50 mg or 1 tablet by mouth once daily	**Orthographic similarity** - Both names have similar beginning letter string, 'Ravi' vs. 'Revi' **Product characteristic overlap** - Route of administration (oral) - Dose (numerical similarity with 5 g or 5 mL and 50 mg)	**Orthographic differences** - Ravicti has seven letters vs. ReVia has five letters making it appear shorter when scripted - Ravicti has a cross-stroke at the end of the name vs. ReVia has no cross-stroke giving the name a different shape **Product characteristic differences** - Frequency of administration (three times daily vs. once daily)
Parafon [Forte DSC] (Chlorzoxazone) - 500 mg oral capsules - 500 mg to 750 mg by mouth three to four times daily	**Orthographic similarity** - 'R' and 'P' can appear similar when scripted - Both names are similar in length - Both names have upstrokes toward the end of the name **Product characteristic overlap** - Route of administration (oral) - Frequency of administration (three times daily)	**Orthographic differences** - Ravicti has one narrow letter after the upstroke at the end of the name vs. Parafon has two letters after the final upstroke giving the name a different shape **Product characteristic differences** - Dose (g or mL, weight based regimen vs. one capsule or 500 mg to 750 mg)
Savella (Milnacipran) - 12.5 mg, 25 mg, 50 mg, 100 mg oral tablet, also available in titration pack - Titrate up to maintenance dose of 50 mg or 100 mg by mouth twice daily	**Orthographic similarity** - Both names are similar in length - Both names have a similar letter string situated in the same place, 'avi' vs. 'ave' - Both names have an upstroke at the end of the name **Product characteristic overlap** - Route of administration (oral)	**Orthographic differences** - Ravicti has one upstroke at the end of the name vs. Savella has two upstrokes towards the end of the name - Ravicti has a cross-stroke in the name vs. Savella has no cross-stroke **Product characteristic differences** - Strength (single strength, 1.1 g/mL vs. 12.5 mg, 25 mg, 50 mg, 100 mg) - Dose (g or mL, weight based regimen vs. 12.5 mg, 25 mg, 50 mg, 100 mg or one tablet)

Proposed name: Ravicti (Glycerol Phenylbutyrate) **Dosage Form: Liquid** **Strength: 1.1 g/mL** **Usual Dose: 5 g/m^2 to 12.4 g/m^2 per day in three divided doses (with meals)**	**Failure Mode:** **Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion**	**Prevention of Failure Mode:** **In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names**
Reversol (Edrophonium) Reversol discontinued, generic equivalents available - 10 mg/mL injection - 0.2 mL injected subcutaneously or intramuscularly, first to determine reaction, followed by the remaining solution (up to 0.8 mL) in the syringe	**Orthographic similarity** - Both names begin with 'R' - Both names have an upstroke at or towards the end of the name - Both names are similar in length **Product characteristic overlap** - none	**Orthographic differences** - Ravicti has a letter following the upstroke vs. Reversol ends with the upstroke giving the name a different shape **Product characteristic differences** - Route of administration (oral vs. intravenous or intramuscular) - Frequency of administration (three times daily vs. once)
Ruvite (Cyanocobalamin) Ruvite discontinued, generic equivalents available - 1000 mcg/mL injection - 1 mL intramuscularly or subcutaneously	**Orthographic similarity** - Both names begin with 'R' - Both names have an upstroke toward the end of the name - Both names have one letter after the upstroke **Product characteristic overlap** - Dose (numerical similarity if dosed in mg)	**Orthographic differences** - none **Product characteristic differences** - Frequency of administration (three times daily vs. once daily or monthly) - Route of administration (oral vs. subcutaneous, intravenous, intramuscular)
Kariva (Desogestrel and Ethinyl Estradiol) - 0.15 mg/0.02 mg and 0.01 mg oral tablets - One tablet by mouth once daily or as directed	**Orthographic similarity** - 'R' and 'K' appear similar when scripted - Both names are similar in length **Product characteristic overlap** - Route of administration (oral) - Strength (both single strength)	**Orthographic differences** - Ravicti has an upstroke toward the end of the name vs. Kariva has no upstroke toward the end of the name giving the name a different shape **Product characteristic differences** - Dose (g or mL, weight based regimen vs. one tablet) - Frequency of administration (three times daily vs. once daily)

Proposed name: Ravicti (Glycerol Phenylbutyrate) **Dosage Form: Liquid** **Strength: 1.1 g/mL** **Usual Dose: 5 g/m^2 to 12.4 g/m^2 per day in three divided doses (with meals)**	**Failure Mode:** **Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion**	**Prevention of Failure Mode:** **In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names**
Rescula (Unoprostone) - 0.15% ophthalmic solution - One drop into the affected eye(s) twice daily	**Orthographic similarity** - Both names begin with 'R' - Both names have an upstroke toward the end of the name - Both names are similar in length **Product characteristic overlap** - Strength (both single strength)	**Orthographic differences** - Ravicti has a cross-stroke vs. Rescula does not have a cross-stroke giving the name a different shape **Product characteristic differences** - Dose (g or mL, weight based regimen vs. one drop)
Prandin (Repaglinide) - 0.5 mg, 1 mg, 2 mg oral tablet - 0.5 mg to 4 mg by mouth with meals, up to 16 mg a day	**Orthographic similarity** - 'P' and 'R' appear similar when scripted - Both names have an upstroke towards the end of the name - Both names are similar in length **Product characteristic overlap** - Frequency of administration (three times daily) - Route of administration (oral)	**Orthographic differences** - Ravicti has one narrow letter after the final upstroke vs. Prandin has two letters after the final upstroke making the name appear longer **Product characteristic differences** - Strength (1.1 g/mL, single strength, not required on prescription vs. 0.5 mg, 1 mg, 2 mg)
Pamelor (Nortriptyline) - 10 mg, 25 mg, 50 mg, 75 mg oral capsule - 10 mg/5 mL oral solution - 25 mg to 50 mg three to four times daily, not to exceed 150 mg in 24 hours	**Orthographic similarity** - 'R' and 'P' can appear similar when scripted - Both names have upstrokes towards the end of the name - Both names are similar in length **Product characteristic overlap** - Frequency of administration (three times daily) - Dosage form (oral solution) - Route of administration (oral)	**Orthographic differences** - Ravicti has a cross-stroke vs. Pamelor does not have a cross-stroke giving the name a different shape - Ravicti has one narrow letter after the final upstroke vs. Pamelor has two letters after the final upstroke making the name appear longer when scripted **Product characteristic differences** - Strength (1.1 g/mL, single strength, not required on prescription vs. 10 mg, 25 mg, 50 mg, 75 mg)

Proposed name: Ravicti (Glycerol Phenylbutyrate) **Dosage Form: Liquid** **Strength: 1.1 g/mL** **Usual Dose: 5 g/m^2 to 12.4 g/m^2 per day in three divided doses (with meals)**	**Failure Mode:** **Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion**	**Prevention of Failure Mode:** **In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names**
Panretin (Alitretinoin) - 0.1% topical gel - Apply to lesions two to four times daily	**Orthographic similarity** - 'R' and 'P' can appear similar when scripted - Both have a cross-stroke toward the end of the name **Product characteristic overlap** - Strength (single strength) - Frequency of administration (three times daily)	**Orthographic differences** - Ravicti has one letter after the final upstroke vs. Panretin has two letters after the final upstroke making the name appear longer **Product characteristic differences** - Dose (g or mL, weight based regimen vs. enough to cover lesions)
Promacta (Eltrombopag) - 12.5 mg, 25 mg, 50 mg, 75 mg oral tablets - One tablet by mouth once daily	**Orthographic similarities** - 'R' and 'Pr' appear similar when scripted - Both names have a 't' towards the end of the name - Both names have one letter following the final upstroke **Product characteristics** - Route of administration (oral)	**Orthographic differences** - none **Product characteristic differences** - Frequency of administration (three times daily with meals vs. once daily) - Dose (g or mL, weight based regimen vs. one tablet or 12.5 mg, 25 mg, 50 mg, 75 mg) - Strength (1.1. mg/mL, single strength, not required on prescription vs. 12.5 mg, 25 mg, 50 mg, 75 mg)

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/s/

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