# CENTER FOR DRUG EVALUATION AND RESEARCH

***APPLICATION NUMBER:***

# 022345Orig1s000

# PROPRIETARY NAME REVIEW(S)

**Department of Health and Human Services**

**Public Health Service**

**Food and Drug Administration**

**Center for Drug Evaluation and Research**

**Office of Surveillance and Epidemiology**

| | |
|---|---|
| Date: | May 6, 2011 |
| Application Type/Number: | NDA 022345 |
| Through: | Zachary Oleszczuk, Pharm.D., Team Leader<br>Carol Holquist, R.Ph., Director<br>Division of Medication Error Prevention and Analysis |
| From: | Teresa McMillan, Pharm.D., Safety Evaluator<br>Division of Medication Error Prevention and Analysis |
| Subject: | Proprietary Name Review |
| Drug Name(s): | Potiga (Ezogabine) Tablets<br>50 mg, (b) (4) 200 mg, 300 mg, and 400 mg |
| Applicant: | Valeant Pharmaceuticals |
| OSE RCM #: | 2011-1299 |

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

## 1 INTRODUCTION

This re-assessment of the proposed proprietary name, Potiga, responds to the anticipated approval of NDA 022345 within 90 days from the date of this review. The Division of Medication Error Prevention and Analysis (DMEPA) found the proposed name, Potiga, acceptable in OSE Review #2008-2021, dated May 5, 2009, OSE Review #2009-2277, dated February 18, 2010, OSE Review #2010-1194, dated July 27, 2010, and OSE Review #2010-2279 dated on November 10, 2010 .

On April 28, 2011, DDMAC reviewed the proposed name and had no concerns regarding the proposed name from a promotional perspective and did not offer any additional comments relating to the proposed name.

## 2 METHODS

For the proposed proprietary name, Potiga, DMEPA safety evaluators search 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 completion of the previous OSE proprietary name reviews. The safety evaluator did not evaluate the names identified in the previous reviews because none of the product characteristics have been altered since the time of the last review. For this re-assessment, we used the same search criteria outlined in our previous OSE reviews.

Additionally, DMEPA searched the USAN stem list to determine if the name contains any USAN stems as of the last USAN updates. DMEPA bases the overall risk assessment on the findings of a Failure Mode and Effects Analysis (FMEA) of the proposed proprietary name, and focuses on the avoidance of medication errors.

## 3 RESULTS

The safety evaluator's search of the databases listed in Section 4 identified three additional names (n=3), (b) (4) and Zytiga which were thought to look and/or sound like Potiga. Our Failure Mode and Effect Analysis determined that the names identified would not cause confusion that would result in medication errors for the reasons listed in Appendix A. Additionally, DMEPA staff did not identify any United States Adopted Names (USAN) stems in the proposed proprietary name, as of April 28, 2011.

## 4 CONCLUSIONS AND RECOMMENDATIONS

The Proprietary Name Risk Assessment indentified that the proposed name, Potiga, is not vulnerable to name confusion that could lead to medication errors nor is it considered promotional. Thus, the Division of Medication Error Prevention and Analysis (DMEPA) has no objection to the proprietary name, Potiga, for this product.

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 Neurology Products should notify DMEPA because the proprietary name must be re-reviewed prior to the new approval date.

---

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

## 5 REFERENCES


***1.*** Turner, T; OSE review #2008-2010, Proprietary Name Review of Potiga; May 5, 2009.

***2.*** Turner, T; OSE review #2009-2277 Proprietary Name Review of Potiga; February 18, 2010.

***3.*** Oleszczuk, Z.; OSE review #2010-2279 Proprietary Name Review of Potiga (Ezogabine) [preaction]; NovemBer 10, 2010.

***4.*** Chan, I; OSE review #2010-440 Proprietary Name Review of (b) (4) [preaction]; June 3, 2010.

***5.*** Oleszczuk, Z.; OSE review #2010-1194 Proprietary Name Review of Potiga (Ezogabine) [preaction]; July 27, 2010.

***6.*** Oleszczuk, Z.; OSE review #2010-2279 Proprietary Name Review of Potiga (Ezogabine) [preaction]; November 10, 2010.

***7.*** Abdus-Samad, J.; OSE review #2011-1195 Proprietary Name Review of Zytiga; April 13, 2011.

***8.*** ***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.

***9.*** ***USAN Stems (http://www.ama-assn.org/ama/pub/category/4782.html)***

USAN Stems List contains all the recognized USAN stems.

***10.*** ***Division of Medication Error Prevention and Analysis proprietary name 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.

**Appendix A:** Name confusion is prevented by the combination of stated product characteristics and/ororthographic differences as described.

| Product Name with potential for confusion | Causes (Can be Multiple) | Rationale for Failure Mode Prevention |
|---|---|---|
| **Potiga (Ezogabine Tablets, USP)**<br><br>**50 mg, (b) (4) 200 mg, 300 mg, and 400 mg** | **N/A** | **Take 200 – 400 mg by mouth three times a day** |

(b) (4)

| | | |
|---|---|---|
| [redacted] (b) (4) | | |
| Zytiga<br>(abiraterone acetate) Tablets, 250 mg<br><br><u>Usual Dose</u><br>4 tablets (1000 mg) orally once daily 1 hour before or 2 hours after eating<br>Or<br>1,2,3 tablets (250 mg, 500 mg, or 750 mg) orally once daily 1 hour before or two hours after eating | <u>Orthographic</u><br>Both names contain 6 letters and both contain the same letter sting 'tiga' in the same position. | <u>Orthographic</u><br>The letter 'P' and the letter 'Z' are distinct. Potiga contains one downstroke and Zytiga contains two.<br><br><u>Usual Dose:</u><br>Three times daily vs. once daily<br><br><u>Strength:</u><br>50 mg, 100 mg, 200 mg, 300 mg, and 400 mg vs. 250 mg |

---

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

---

/s/

---

TERESA S MCMILLAN
05/06/2011

ZACHARY A OLESZCZUK
05/06/2011

CAROL A HOLQUIST
05/06/2011

**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: | November 9, 2010 |
| Through: | Denise P. Toyer, PharmD, Deputy Director<br>Division of Medication Error Prevention and Analysis (DMEPA) |
| From: | Zachary Oleszczuk, Pharm.D., Team Leader<br>Division of Medication Error Prevention and Analysis (DMEPA) |
| Subject: | Proprietary Name Review |
| Drug Name(s): | Potiga (Ezogabine) Tablets<br>50 mg, (b) (4), 200 mg, 300 mg, and 400 mg |
| Application Type/Number: | NDA 022345 |
| Applicant: | Valeant Pharmaceuticals North America |
| OSE RCM #: | 2010-2279 |

## 1 INTRODUCTION

This review responds to the anticipated approval of this NDA within 90 days from the date of this review. DMEPA found the proposed name, Potiga, acceptable in OSE Review #2008-2021, dated May 5, 2009, OSE Review #2009-2277, dated February 18, 2010, and OSE Review 2010-1194, dated July 27, 2010.

On June 3, 2010, DDMAC reviewed the proposed name and had no concerns regarding the proposed name from a promotional perspective and did not offer any additional comments relating to the proposed name. Furthermore, the review Division did not have any concerns with the proposed name, Potiga, during our previous reviews.

## 2 METHODS AND RESULTS

For the proposed proprietary name, DMEPA staff search 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. None of the product characteristics were altered since the time of the last review.

Additionally, DMEPA searches the USAN stem list to determine if the name contains any USAN stems as of the last USAN updates. DMEPA bases the overall risk assessment on the findings of a Failure Mode and Effects Analysis (FMEA) of the proposed proprietary name, and focuses on the avoidance of medication errors. We used the same search criteria used in our previous reviews for the proposed proprietary name, Potiga.

The searches of the databases did not yield any new names thought to look or sound similar to Potiga and represent a potential source of drug name confusion.

Additionally, DMEPA staff did not identify any United States Adopted Names (USAN) stems in the proposed proprietary name, as of November 3, 2010.

## 3 CONCLUSIONS AND RECOMMENDATIONS

The re-review of the proprietary name, Potiga, did not identify any additional names thought to look or sound similar to the proposed name since our last review. Thus, the Division of Medication Error Prevention and Analysis (DMEPA) has no objection to the proprietary name, Potiga, for this product at this time. Additionally,

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 Neurology Products should notify DMEPA because the proprietary name must be re-reviewed prior to the new approval date.

## 4 REFERENCES


***1.*** Turner, T; OSE review #2008-2010, Proprietary Name Review of Potiga; May 5, 2009.

***2.*** Turner, T; OSE review #2009-2277 Proprietary Name Review of Potiga; February 18, 2010.

***3.*** Oleszczuk, Z.; OSE review #2010-1194 Proprietary Name Review of Potiga (Ezogabine) [preaction]; July 27, 2010.

***4.*** **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.

***5.*** **USAN Stems (http://www.ama-assn.org/ama/pub/category/4782.html)**

USAN Stems List contains all the recognized USAN stems.

---

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

---

/s/

---

ZACHARY A OLESZCZUK
11/09/2010

DENISE P TOYER
11/10/2010

**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: | July 23, 2010 |
| To: | Russell Katz, MD, Director<br>Division of Neurology Products (DNP) |
| Through: | Denise P. Toyer, PharmD, Deputy Director<br>Carol Holquist., RPh, Director<br>Division of Medication Error Prevention and Analysis (DMEPA) |
| From: | Zachary Oleszczuk, Pharm.D., Team Leader<br>Division of Medication Error Prevention and Analysis (DMEPA) |
| Subject: | Proprietary Name Review |
| Drug Name(s): | Potiga (Ezogabine) Tablets<br>50 mg, (b) (4), 200 mg, 300 mg, and 400 mg |
| Application Type/Number: | NDA 022345 |
| Applicant: | Valeant Pharmaceuticals North America |
| OSE RCM #: | 2010-1194 |

# 1 INTRODUCTION

This review responds to the anticipated approval of this NDA within 90 days from the date of this review. DMEPA found the proposed name, Potiga, acceptable in OSE Review #2008-2021, dated May 5, 2009, as an IND. (b) (4) The Division of Neurology Products requested that the Sponsor petition the United States Adopted Naming Council (USAN)/ International Nonproprietary Name (INN) for a new established name. Additionally, we contacted the FDA USAN representative, David Lewis, on this issue.

Subsequently, DMEPA reviewed the proposed name, Potiga, under the NDA and found the name acceptable in OSE Review #2009-2277, dated February 18, 2010. Since, that review, the Applicant successfully petitioned USAN/INN and submitted the established name "Ezogabine" as a replacement to Retigabine on May 11, 2010.

On June 3, 2010, DDMAC reviewed the proposed name and had no concerns regarding the proposed name from a promotional perspective and did not offer any additional comments relating to the proposed name. Furthermore, the review Division did not have any concerns with the proposed name, Potiga, during our initial review.

# 2 METHODS AND RESULTS

## 2.1 PROPRIETARY NAME

For the proposed proprietary name, DMEPA staff search 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. None of the product characteristics other than the established name of the proposed product were altered since the time of the last review.

Additionally, DMEPA searches the USAN stem list to determine if the name contains any USAN stems as of the last USAN updates. DMEPA bases the overall risk assessment on the findings of a Failure Mode and Effects Analysis (FMEA) of the proposed proprietary name, and focuses on the avoidance of medication errors. We used the same search criteria used in OSE Review #2009-2277 dated February 18, 2010 for the proposed proprietary name, Potiga.

The searches of the databases did not yield any new names thought to look or sound similar to Potiga and represent a potential source of drug name confusion.

Additionally, DMEPA staff did not identify any United States Adopted Names (USAN) stems in the proposed proprietary name, as of July 15, 2010.

## 2.2 ESTABLISHED NAME

Because the established name of the proposed product was altered since our last review, we re-evaluate the previous names of concern. However, we did not find that the revision to the established name altered the findings of those names.

DMEPA does not have authority over established names thus, the established name does not undergo a separate complete name Risk Assessment by DMEPA. DMEPA evaluates the established name of the proposed product in the context of the proprietary name and the ability of the established name to function as a source of error for the proposed product. When DMEPA identifies such an error, we contact the appropriate Division in the Office of New Drugs (OND), as well as the Applicant to notify them of our findings as well as provide recommendations to minimize the risk of the errors we have identified. DMEPA did not identify any such risks for the established name "Ezogabine" for this product.

## 3 CONCLUSIONS AND RECOMMENDATIONS

The re-review of the proprietary name, Potiga, did not identify any additional names thought to look or sound similar to the proposed name since our last review. Thus, the Division of Medication Error Prevention and Analysis (DMEPA) has no objection to the proprietary name, Potiga, for this product at this time. Additionally, DMEPA did not identify any overt risks with the established name Ezogabine. Typically, DMEPA would not comment on a negative finding regarding the ability of the established name to function as a source of error since we do not have authority over these names. However, since this established name was changed because of a safety concern, DMEPA commented for the administrative record.

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 Neurology Products should notify DMEPA because the proprietary name must be re-reviewed prior to the new approval date.

## 4 REFERENCES


***1.*** Turner, T; OSE review #2008-2010, Proprietary Name Review of Potiga; May 5, 2009.

***2.*** Turner, T; OSE review #2009-2277 Proprietary Name Review of Potiga; February 18, 2010.

***3.*** **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.

***4.*** **USAN Stems** (**http://www.ama-assn.org/ama/pub/category/4782.html**)

USAN Stems List contains all the recognized USAN stems.

| Application Type/Number | Submission Type/Number | Submitter Name | Product Name |
|---|---|---|---|
| NDA-22345 | ORIG-1 | VALEANT PHARMACEUTICALS NORTH AMERICA | RETIGABINE |

---

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

---

/s/

---

ZACHARY A OLESZCZUK
07/28/2010

DENISE P TOYER
07/28/2010

DENISE P TOYER on behalf of CAROL A HOLQUIST
07/28/2010

**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: | February 18, 2010 |
| To: | Russell Katz, M.D., Director<br>Division of Neurology Products |
| Through: | Zachary Oleszczuk, Pharm.D., Acting Team Leader<br>Denise Toyer, Pharm.D., Deputy Director<br>Carol Holquist, RPh, Director<br>Division of Medication Error Prevention and Analysis |
| From: | Tara Turner, Pharm.D., Safety Evaluator<br>Division of Medication Error Prevention and Analysis |
| Subject: | Proprietary Name Review |
| Drug Name(s): | Potiga (Retigabine) Tablets<br>50 mg, (b) (4) 200 mg, 300 mg, and 400 mg |
| Application Type/Number: | NDA 022345 |
| Applicant: | Valeant Pharmaceuticals North America |
| OSE RCM #: | 2009-2277 |

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

# CONTENTS

## EXECUTIVE SUMMARY

Potiga is the proposed proprietary name for Retigabine Tablets. This proposed name was evaluated from a safety and promotional perspective based on the product characteristics provided by the Applicant. We sought input from pertinent disciplines involved with the review of this application and considered it accordingly. Our evaluation did not identify concerns that would render the name unacceptable based on the product characteristics and safety profile known at the time of this review. Thus, DMEPA finds the proposed proprietary name, Potiga, acceptable for this product. The proposed proprietary name must be re-reviewed 90 days before approval of the NDA.

Additionally, if any of the proposed product characteristics as stated in this review are altered, DMEPA rescinds this finding and the name must be resubmitted for review. The conclusions upon re-review are subject to change.

## 1 BACKGROUND

### 1.1 INTRODUCTION

This review is in response to a request from Valeant Pharmaceuticals North America, dated November 20, 2009 for re-assessment of the proposed proprietary name, Potiga, regarding potential name confusion with other proprietary or established drug names in the usual practice settings.

The Applicant also submitted draft container labels, carton and insert labeling, which will be evaluated in a separate forthcoming DMEPA review (OSE Review# 2009-2278). Additionally, the Applicant submitted a proposed Risk Evaluation and Mitigation Strategy (REMS). The REMS will be reviewed by OSE under separate cover.

### 1.2 REGULATORY HISTORY

The proposed proprietary name, Potiga, was previously submitted to IND 053950. The Division of Medication Error Prevention and Analysis (DMEPA) reviewed and had no objection to the proposed name in OSE Review# 2008-2021 dated May 5, 2009. NDA 022345 for Potiga was submitted on October 30, 2009. As such, the proposed name was submitted to the subject NDA for re-review.

In the original review of the proposed proprietary name, Potiga, DMEPA identified a concern with the proposed established name, Retigabine, regarding the potential for name confusion with Rotigotine (established name for Neupro) due to orthographic and phonetic similarities. The Division of Neurology Products agreed with our concern and requested that the Applicant petition the United States Adopted Names (USAN) Council for a new established name. According to their November 20, 2009 cover letter, the Applicant is pursuing 2 alternate established names, (b) (4) and Ezogabine (back-up). The USAN Council's process will not affect DMEPA's review of the proposed proprietary name.

### 1.3 PRODUCT INFORMATION

Potiga (retigabine) is a selective neuronal potassium channel opener. It is proposed as adjunctive treatment for patients 18 years of age and older with partial onset seizures with or without secondary generalization. The initial dose should be 100 mg orally 3 times daily (300 mg per day). The dose should be increased at weekly intervals by a maximum of 150 mg per day, given as 3 divided doses, up to a recommended maximum dose of 600 mg to 1200 mg per day based on individual patient response and tolerability. Potiga will be available as 50 mg, (b) (4), 200 mg, 300 mg, and 400 mg tablets. All strengths will be available in bottles of 90 tablets. Additionally, the product will be available in 2 titration packs: titration to 600 mg total daily dose and titration to 750 mg total daily dose. The information

regarding the titration packs is presented in the Applicant's request for proprietary name review. However, these packs are not listed in the draft insert labeling.

The product characteristics have not changed since the signature date of the proprietary name review (OSE Review #2008-2021).

## 2 METHODS AND MATERIALS

Appendix A describes the general methods and materials used by the Division of Medication Error Prevention and Analysis (DMEPA) when conducting a proprietary name risk assessment for all proprietary names. Sections 2.1 and 2.2 identify specific information associated with the methodology for the proposed proprietary name, Potiga.

### 2.1 SEARCH CRITERIA

For this review, particular consideration was given to drug names beginning with the letter 'P' when searching to identify potentially similar drug names, as 75% of the confused drug names reported by the USP-ISMP Medication Error Reporting Program involve pairs beginning with the same letter.[1,2]

To identify drug names that may look similar to Potiga, the DMEPA staff also considers the orthographic appearance of the name on lined and unlined orders. Specific attributes taken into consideration include the length of the name (six letters), upstrokes (two: capital letter 'P' and lower case 't'), downstrokes (one: lower case 'g'), cross-strokes (one: lower case 't') and dotted letters (one, lower case 'i'). Additionally, several letters in Potiga may be vulnerable to ambiguity when scripted (see Appendix B). As a result, the DMEPA staff also considers these alternate appearances when identifying drug names that may look similar to Potiga.

When searching to identify potential names that may sound similar to Potiga, the DMEPA staff searches for names with similar number of syllables (3), stresses (po-TI-ga or PO-ti-ga or po-ti-GA), and placement of vowel and consonant sounds. Additionally, the DMEPA staff considers that pronunciation of parts of the name can vary (see Appendix B). The Applicant's intended pronunciation of the proprietary name was not provided with the proposed name submission and, therefore, could not be taken into consideration. Moreover, names are often mispronounced and/or spoken with regional accents and dialects, so other potential pronunciations of the name are considered.

### 2.2 FDA PRESCRIPTION ANALYSIS STUDIES

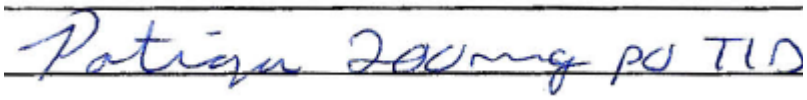
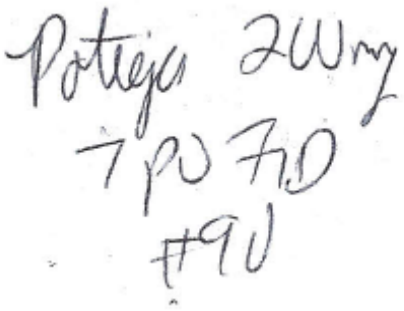
In order to evaluate the potential for misinterpretation of the proposed proprietary name in handwriting and verbal communication of the name, the following inpatient medication order, outpatient and verbal prescription was communicated during the FDA prescription studies.

---

[1] Institute for Safe Medication Practices. Confused Drug name List (1996-2006). Available at http://www.ismp.org/Tools/confuseddrugnames.pdf

[2] Kondrack, G and Dorr, B. Automatic Identification of Confusable Drug Names. Artificial Intelligence in Medicine (2005)

**Figure 1. Potiga Study (conducted on December 4, 2009)**

| HANDWRITTEN PRESCRIPITON AND MEDICATION ORDER | VERBAL PRESCRIPTION |
|---|---|
| Inpatient Medication Order:<br>  | "Potiga 200 mg<br>1 PO TID<br>#90" |
| Outpatient Prescription:<br>  | |

## 3 RESULTS

### 3.1 DATABASE AND INFORMATION SOURCES

The searches yielded a total of ten names as having some similarity to the proposed proprietary name, Potiga. Eight of the names were thought to look similar to Potiga (Potaba, Rotarix, Pilagan, Ritalin, Pentids, Prograf, Tygacil, and Pataday). One name (Boniva) was thought to sound similar to Potiga. The remaining name (Potiga) was thought to look and sound similar to Potiga.

Additionally, DMEPA staff did not identify any United States Adopted Names (USAN) stems in the proposed proprietary name as of December 2, 2009.

### 3.2 CDER EXPERT PANEL DISCUSSION

The Expert Panel reviewed the pool of names identified by DMEPA staff (See Section 3.1 above) and noted no additional names thought to have orthographic or phonetic similarity to Potiga.

DDMAC had no concerns regarding the proposed name from a promotional perspective, and did not offer any additional comments relating to the proposed name.

### 3.3 FDA PRESCRIPTION ANALYSIS STUDIES

For the study conducted on December 4, 2009, a total of sixteen practitioners responded but none of the responses overlapped with any existing or proposed drug names. Four of the participants interpreted the

drug name correctly as "Potiga", with correct interpretation occurring in the inpatient written study (n=1), the outpatient written study (n=2), and the verbal prescription study (n=1). The remainder of participants misinterpreted the drug name. The most common misinterpretations involved the letter 'o' being interpreted as 'a' (Patiga), the letter 'i' being interpreted as 'e' (Potega), or the letter 'i' being interpreted as 'ie' (Patiega, Potiega, Potiejer, Potiejo). One participant in the verbal study misinterpreted the drug name as Protega, which is similar in spelling to Protegra, a line of multivitamin products currently marketed in the U.S. This name has been included in our evaluation. See Appendix C for the complete listing of interpretations from the verbal and written prescription studies.

### 3.4 COMMENTS FROM THE DIVISION OF NEUROLOGY PRODUCTS (DNP)

#### *3.4.1 Initial Phase of Review*

In a response to the OSE December 7, 2009 e-mail, the Division of Neurology Products (DNP) stated "Our clinical team has no issues with the proposed proprietary name. The Team Leader has ok'ed your review."

#### *3.4.2 Midpoint of Review*

On February 2, 2010, DMEPA notified the Division of Neurology Products (DNP) via e-mail that we had no objections to the proposed proprietary name Potiga. Per e-mail correspondence from DNP on February 8, 2010, the Division stated that they are "OK with this decision".

### 3.5 SAFETY EVALUATOR RISK ASSESSMENT

Independent searches by the primary Safety Evaluator resulted in four additional names which were thought to look or sound similar to Potiga and represent a potential source of drug name confusion.

Three names were identified to have look-alike similarities (b) (4)***, Pexeva, and Pylera). The remaining name (Potega) was identified to have look-alike and sound-alike similarities.

Thus, we evaluated a total of 15 names: 10 identified in Database and Information Sources (Section 3.1), one identified in FDA Prescription Analysis Studies (Section 3.3) and four identified in this section by the primary Safety Evaluator.

## 4 DISCUSSION

### 4.1 PROMOTIONAL REVIEW

DDMAC did not find the name Potiga promotional. DMEPA and the Division of Neurology Products concurred with this assessment.

### 4.2 SAFETY REVIEW

DMEPA requested input from all stakeholders (e.g. clinical, chemistry, etc.). These stakeholders did not identify any factors that render the name unacceptable.

DMEPA identified and evaluated 15 names for their potential similarity to the proposed name, Potiga. No other aspect of the name was identified as a potential source for confusion. One of the 15 names identified, Potiga, is a trademark registered to Valeant Pharmaceuticals North America in the U.S. and many foreign countries and is the subject of this review. Thus, the name Potiga has been removed from further analysis. Two of the 15 names lacked convincing orthographic and/or phonetic similarity to Potiga and were not evaluated further (see Appendix D). Five of the 15 names were previously evaluated in OSE review# 2008-2021 (see Appendix E). Given that no product characteristics have been altered

since the signature date of that review, the original analyses are still valid and these names were not evaluated further.

Failure mode and effects analysis (FMEA) was then applied to determine if the proposed proprietary name could potentially be confused with the remaining seven names and lead to medication errors. This analysis determined that the name similarity between Potiga and the identified names was unlikely to result in medication errors with any of the seven products for the reasons presented in Appendices F through J.

# 5 CONCLUSIONS AND RECOMMENDATIONS

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

However, if any of the proposed product characteristics as stated in this review are altered prior to approval of the product, DMEPA rescinds this Risk Assessment finding and the name must be resubmitted for review. In the event that our Risk Assessment finding is rescinded, the evaluation of the name on resubmission is independent of the previous Risk Assessment, and as such, the conclusions on re-review of the name are subject to change. If the approval of this application is delayed beyond 90 days from the signature date of this review, the proposed name must be resubmitted for evaluation.

If you have further questions or need clarifications, please contact Laurie Kelley, Regulatory Project Manager, at 301-796-5068.

## 5.1 COMMENTS TO THE APPLICANT

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

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

## 6 REFERENCES


***1.*** Turner, Tara. OSE Review #2008-2021: Proprietary Name Review for Potiga. 5 May 2009.

***2. Micromedex Integrated Index (http://csi.micromedex.com)***

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

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

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. This is a database which was created for the Division of Medication Error Prevention and Analysis, FDA.

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

Drug Facts and Comparisons is a compendium organized by therapeutic course; contains monographs on prescription and OTC drugs, with charts comparing similar products.

***5. 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.

***6. 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.

***7. 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.

***8. Electronic online version of the FDA Orange Book (http://www.fda.gov/cder/ob/default.htm)***

Provides a compilation of approved drug products with therapeutic equivalence evaluations.

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

Provides information regarding patent and trademarks.

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

Contains full monographs for the most common drugs in clinical use, plus mini monographs covering investigational, less common, combination, nutraceutical and nutritional products. Provides a keyword search engine.

***11. 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.

***12. Natural Medicines Comprehensive Databases (www.naturaldatabase.com)***

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

***13. Stat!Ref (www.statref.com)***

Contains full-text information from approximately 30 texts. Includes tables and references. Among the database titles are: Handbook of Adverse Drug Interactions, Rudolphs Pediatrics, Basic Clinical Pharmacology and Dictionary of Medical Acronyms Abbreviations.

***14. USAN Stems (http://www.ama-assn.org/ama/pub/category/4782.html)***

List contains all the recognized USAN stems.

***15. Red Book Pharmacy's Fundamental Reference***

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

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

A web-based searchable version of the Drug Information Handbook.

***17. Medical Abbreviations Book***

Contains commonly used medical abbreviations and their definitions.

## APPENDICES

### Appendix A:

FDA's Proprietary Name Risk Assessment considers the potential for confusion between the proposed proprietary name and the proprietary and established names of drug products existing in the marketplace and those pending IND, NDA, BLA, and ANDA products currently under review by the Center. DMEPA defines a medication error as any preventable event that may cause or lead to inappropriate medication use or patient harm while the medication is in the control of the health care professional, patient, or consumer. [3]

For the proposed proprietary name, DMEPA staff search a standard set of databases and information sources to identify names with orthographic and phonetic similarity and hold a Center for Drug Evaluation and Research (CDER) Expert Panel discussion to gather professional opinions on the safety of the proposed proprietary name. DMEPA staff also conducts internal CDER prescription analysis studies. When provided, DMEPA considers external prescription analysis study results and incorporate into the overall risk assessment.

The Safety Evaluator assigned to the Proprietary Name Risk Assessment is responsible for considering the collective findings, and provides an overall risk assessment of the proposed proprietary name. DMEPA bases the overall risk assessment on the findings of a Failure Mode and Effects Analysis (FMEA) of the proprietary name, and focuses on the avoidance of medication errors.

FMEA is a systematic tool for evaluating a process and identifying where and how it might fail. [4] DMEPA uses FMEA to analyze whether the drug names identified with orthographic or phonetic similarity to the proposed proprietary name could cause confusion that subsequently leads to medication errors in the clinical setting. DMEPA uses the clinical expertise of its staff to anticipate the conditions of the clinical setting where the product is likely to be used based on the characteristics of the proposed product.

In addition, the product characteristics provide the context for the verbal and written communication of the drug names and can interact with the orthographic and phonetic attributes of the names to increase the risk of confusion when there is overlap or, in some instances, decrease the risk of confusion by helping to differentiate the products through dissimilarity. Accordingly, the DMEPA staff considers the product characteristics associated with the proposed drug throughout the risk assessment because the product characteristics of the proposed may provide a context for communication of the drug name and ultimately determine the use of the product in the *usual* clinical practice setting.

Typical product characteristics considered when identifying drug names that could potentially be confused with the proposed proprietary name include, but are not limited to; established name of the proposed product, proposed indication of use, dosage form, route of administration, strength, unit of measure, dosage units, recommended dose, typical quantity or volume, frequency of administration, product packaging, storage conditions, patient population, and prescriber population. Because drug name confusion can occur at any point in the medication use process, DMEPA staff considers the potential for confusion throughout the entire U.S. medication use process, including drug procurement, prescribing and ordering, dispensing, administration, and monitoring the impact of the medication.[5] DMEPA provides the product characteristics considered for this review in section one.

The Division of Medication Error Prevention and Analysis considers the spelling of the name, pronunciation of the name when spoken, and appearance of the name when scripted. DMEPA also compares the spelling of the proposed proprietary name with the proprietary and established name of existing and proposed drug products

---

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

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

[5] Institute of Medicine. Preventing Medication Errors. The National Academies Press: Washington DC. 2006.

because similarly in spelled names may have greater likelihood to sound similar to one another when spoken or look similar to one another when scripted. DMEPA staff also examines the orthographic appearance of the proposed name using a number of different handwriting samples. Handwritten communication of drug names has a long-standing association with drug name confusion. Handwriting can cause similarly and even dissimilarly spelled drug name pairs to appear very similar to one another. The similar appearance of drug names when scripted has led to medication errors. The DMEPA staff applies expertise gained from root-cause analysis of such medication errors to identify sources of ambiguity within the name that could be introduced when scripting (e.g.,"T" may look like "F," lower case 'a' looks like a lower case 'u,' etc). Additionally, other orthographic attributes that determine the overall appearance of the drug name when scripted (see Table 1 below for details). In addition, the DMEPA staff compares the pronunciation of the proposed proprietary name with the pronunciation of other drug names because verbal communication of medication names is common in clinical settings. If provided, DMEPA will consider the Applicant's intended pronunciation of the proprietary name. However, DMEPA also considers 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.

**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<br>Identical infix<br>Identical suffix<br>Length of the name<br>Overlapping product characteristics | • Names may appear similar in print or electronic media and lead to drug name confusion in printed or electronic communication<br>• Names may look similar when scripted and lead to drug name confusion in written communication |
| | Orthographic similarity | Similar spelling<br>Length of the name<br>Upstrokes<br>Down strokes<br>Cross-stokes<br>Dotted letters<br>Ambiguity introduced by scripting letters<br>Overlapping product characteristics | • Names may look similar when scripted, and lead to drug name confusion in written communication |
| Sound-alike | Phonetic similarity | Identical prefix<br>Identical infix<br>Identical suffix<br>Number of syllables<br>Stresses<br>Placement of vowel sounds<br>Placement of consonant sounds<br>Overlapping product characteristics | • Names may sound similar when pronounced and lead to drug name confusion in verbal communication |

Lastly, the DMEPA staff also considers the potential for the proposed proprietary name to inadvertently function as a source of error for reasons other than name confusion. Post-marketing experience has demonstrated that proprietary names (or components of the proprietary name) can be a source of error in a

variety of ways. Consequently, DMEPA considers and evaluates these broader safety implications of the name throughout this assessment and the medication error staff provides additional comments related to the safety of the proposed proprietary name or product based on professional experience with medication errors.

### 1. Database and Information Sources

DMEPA staff conducts searches of the internet, several standard published drug product reference texts, and FDA databases to identify existing and proposed drug names that may sound-alike or look-alike to the proposed proprietary name using the criteria outlined in Section 2.1. Section 6 provides a standard description of the databases used in the searches. To complement the process, the DMEPA staff use a computerized method of identifying phonetic and orthographic similarity between medication names. The program, Phonetic and Orthographic Computer Analysis (POCA), uses complex algorithms to select a list of names from a database that have some similarity (phonetic, orthographic, or both) to the trademark being evaluated. Lastly, the DMEPA staff review the USAN stem list to determine if any USAN stems are present within the proprietary name. The individual findings of multiple safety evaluators are pooled and presented to the CDER Expert Panel.

### 2. CDER Expert Panel Discussion

DMEPA conducts an Expert Panel Discussion to gather CDER professional opinions on the safety of the proposed product and the proposed proprietary name. The Expert Panel is composed of Division of Medication Errors Prevention (DMEPA) staff and representatives from the Division of Drug Marketing, Advertising, and Communications (DDMAC). The Expert Panel also discusses potential concerns regarding drug marketing and promotion related to the proposed names.

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

### 3. FDA Prescription Analysis Studies

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

In order to evaluate the potential for misinterpretation of the proposed proprietary name in handwriting and verbal communication of the name, inpatient medication orders and outpatient prescriptions are written, each consisting of a combination of marketed and unapproved drug products, including the proposed name. These orders are optically scanned and one prescription is delivered to a random sample of the 123 participating health professionals via e-mail. In addition, a verbal prescription is recorded on voice mail. The voice mail messages are then sent to a random sample of the participating health professionals for their interpretations and review. After receiving either the written or verbal prescription orders, the participants send their interpretations of the orders via e-mail to DMEPA.

### 4. Comments from the OND review Division or Generic drugs

DMEPA requests the Office of New Drugs (OND) or Office of Generic Drugs (OGD) Regulatory Division responsible for the application for their comments or concerns with the proposed proprietary name and any

clinical issues that may impact the DMEPA review during the initial phase of the name review. Additionally, when applicable, at the same time DMEPA requests concurrence/non-concurrence with DDMAC's decision on the name. The primary Safety Evaluator addresses any comments or concerns in the safety evaluator's assessment.

The OND or OGD Regulatory Division is contacted a second time following our analysis of the proposed proprietary name. At this point, DMEPA conveys their decision to accept or reject the name. The OND or OGD Regulatory Division is requested to concur/not concur with DMEPA's final decision.

## 5. Safety Evaluator Risk Assessment of the Proposed Proprietary Name

The primary Safety Evaluator applies his/her individual expertise gained from evaluating medication errors reported to FDA, conducts a Failure Mode and Effects Analysis, and provides an overall risk assessment of name confusion. Failure Mode and Effects Analysis (FMEA) is a systematic tool for evaluating a process and identifying where and how it might fail.[6] When applying FMEA to assess the risk of a proposed proprietary name, DMEPA seeks to evaluate the potential for a proposed proprietary name to be confused with another drug name because of name confusion and, thereby, cause errors to occur in the medication use system. FMEA capitalizes on the predictable and preventable nature of medication errors associated with drug name confusion. FMEA allows the Agency to identify the potential for medication errors due to orthographically or phonetically similar drug names prior to approval, where actions to overcome these issues are easier and more effective than remedies available in the post-approval phase.

In order to perform an FMEA of the proposed name, the primary Safety Evaluator must analyze the use of the product at all points in the medication use system. Because the proposed product is has not been marketed, the primary Safety Evaluator anticipates the use of the product in the usual practice settings by considering the clinical and product characteristics listed in Section one. The Safety Evaluator then analyzes the proposed proprietary name in the context of the usual practice setting and works to identify potential failure modes and the effects associated with the failure modes.

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

> ***"Is the proposed proprietary name convincingly similar to another drug name, which may cause practitioners to become confused at any point in the usual practice setting?"***

An affirmative answer indicates a failure mode and represents a potential for the proposed proprietary name to be confused with another proprietary or established drug name because of look- or sound-alike similarity. If the answer to the question is no, the Safety Evaluator is not 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

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

the name similarity could ultimately cause medication errors in the usual practice setting, the Safety Evaluator will then recommend the use of an alternate proprietary name.

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

1. DDMAC finds the proposed proprietary name misleading from a promotional perspective, and the Review Division concurs with DDMAC's findings. The Federal Food, Drug, and Cosmetic Act provides that labeling or advertising can misbrand a product if misleading representations are made or suggested by statement, word, design, device, or any combination thereof, whether through a PROPRIETARY name or otherwise [21 U.S.C 321(n); See also 21 U.S.C. 352(a) & (n)].
2. 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)].
3. 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.
4. The proposed proprietary name contains an USAN (United States Adopted Names) stem.
5. DMEPA identifies a potential source of medication error within the proposed proprietary name. For example, the proprietary name may be misleading or, inadvertently, introduce ambiguity and confusion that leads to errors. Such errors may not necessarily involve confusion between the proposed drug and another drug product.

If DMEPA objects to a proposed proprietary name on the basis that drug name confusion could lead to medication errors, the primary Safety Evaluator uses the FMEA process to identify strategies to reduce the risk of medication errors. DMEPA is likely to recommend that the Applicant select an alternative proprietary name and submit the alternate name to the Agency for DMEPA to review. However, in rare instances FMEA may identify plausible strategies that could reduce the risk of medication error of the currently proposed name. In that instance, DMEPA may be able to provide the Applicant 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. However, the safety concerns set forth in criteria a through e are supported either by FDA regulation or by external healthcare authorities, including the Institute of Medicine (IOM), World Health Organization (WHO), Joint Commission on Accreditation of Hospitals (JCOAH), and the Institute for Safe Medication Practices (ISMP). These organizations have examined medication errors resulting from look- or sound-alike drug names and called for regulatory authorities to address the issue prior to approval. Additionally, DMEPA contends that the threshold set for the Proprietary Name Risk Assessment is reasonable because proprietary drug name confusion is a predictable and a preventable source of medication error that, in many instances, the Agency and/or Applicant 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. Applicants have undertaken higher-leverage strategies, such as drug name changes, in the past but at great financial cost to the Applicant 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 Applicants' have changed a product's proprietary name in the post-approval phase, it is difficult to eradicate the original proprietary name from practitioners' vocabulary, and as a result, the Agency has continued to receive reports of drug name confusion long after a name change in some instances. Therefore, DMEPA believes that post-approval efforts at reducing name confusion errors should be reserved for those cases in which the potential for name confusion could not be predicted prior to approval (see Section 4 for limitations of the process).

## Appendix B: Letters with possible orthographic or phonetic misinterpretation

| **Letters in Name, Potiga** | **Scripted may appear as** | **Spoken may be interpreted as** |
|---|---|---|
| Capital 'P' | Capital 'B', 'R', or 'I' | 'B' |
| Lower case 'p' | 'x' or 'q' | 'b' |
| Lower case 'o' | 'a', 'e', 'u', or number '0' | 'All' or any vowel |
| Lower case 't' | 'l', 'r', 'x', or 'b' | 'd', 'pt' |
| Lower case 'i' | 'e' or 'l' | Any vowel |
| Lower case 'g' | 'q' or 'j' | 'j' |
| Lower case 'a' | 'c', 'o', or 'u' | Any vowel |

## Appendix C: Potiga Prescription Study Responses

| **Inpatient Medication Order** | **Voice Prescription** | **Outpatient Prescription** |
|---|---|---|
| Patiga | Protega | Patiega |
| Patiga | Protiga | Potega |
| Potiga | Potega (or Poteega or Potiga) | Potiega |
| Potiza | | Potiejer |
| Potriga | | Potiejer |
| | | Potiejo |
| | | Potiga |
| | | Potiga |

**Appendix D:** **Names lacking convincing look-alike or sound-alike similarities with Potiga**

| Proprietary Name | Source |
|---|---|
| Ritalin | EPD |
| Tygacil | EPD |

**Appendix E:** **Names evaluated in the previous review of Potiga (IND 053950)**

| Proprietary Name | Similarity to Potiga |
|---|---|
| Potaba | Look |
| Prograf | Look |
| Pataday | Look |
| Boniva | Sound |
| Protegra | Look and Sound |

**Appendix F:** **Product that is not currently marketed in the U.S.**

| Proprietary Name | Similarity to Potiga | Description | Disposition |
|---|---|---|---|
| Pentids | Look | (penicillin g potassium)<br>Tablets:<br>200,000 units; 250,000 units; 400,000 units; 800,000 units<br>For oral solution:<br>200,000 units/5 mL; 400,000 units/5 mL; | Withdrawn from effective 11/25/1992 (per DARRTS)<br>*Brand name product discontinued; generics not available<br>ANDA 062155, 062149, 060392 |

**Appendix G: Proprietary name that has never been marketed in the U.S.**

| Proprietary Name | Similarity to Potiga | Description | Disposition |
|---|---|---|---|
| (b) (4) | | | |

**Appendix H: Proprietary name trademarked (per USPTO and SAEGIS), but not marketed**

| Proprietary Name | Similarity to Potiga | Description | Owner |
|---|---|---|---|
| Potega | Look and Sound | Pharmaceutical preparations for the treatment of epilepsy, seizures and neurological disorders; potassium preparations for pharmaceuticals | Valeant Pharmaceuticals North America (owner unknown in Japan)<br>U.S. Federal, Canada, Mexico, Australia, Japan, Community Trademarks |

## Appendix I: Products with no overlap in strength or dose

| **Potiga (retigabine)** | | **Tablets:** **50 mg,** (b) (4) **200 mg, 300 mg, 400 mg** | **Initial dose should be 100 mg orally 3 times daily. Doses should be increased at weekly intervals by a maximum of 150 mg per day, given as 3 divided doses. Optimal dose is 600 mg to 1200 mg/day given as 200 mg to 400 mg orally 3 times daily** |
|---|---|---|---|
| **Product name with potential for confusion** | **Similarity to Proposed Proprietary Name** | **Strength** | **Usual Dose (if applicable)** |
| Rotarix<br>(rotavirus vaccine) | Look | Lyophilized powder for oral suspension:<br>rotavirus human 89-12 strain (G1P[8] type); $\geq 10^6$ cell culture infective dose per 1 mL (after reconstitution) | The vaccination series consists of two 1 mL doses administered orally. The first dose should be administered to infants beginning at 6 weeks of age. There should be an interval of at least 4 weeks between the first and second dose. The 2-dose series should be completed by 24 weeks of age |
| Pylera<br>(bismuth subcitrate potassium; metronidazole; tetracycline hydrochloride) | Look | Capsules:<br>Bismuth subcitrate potassium, 140 mg<br>Metronidazole, 125 mg<br>Tetracycline hydrochloride, 125 mg | Each dose of Pylera includes 3 capsules. Each dose of all 3 capsules should be taken 4 times a day, after meals and at bedtime for 10 days. One omeprazole 20 mg capsule should be taken twice a day with Pylera after the morning and evening meal for 10 days. |
| Pilagan<br>(pilocarpine nitrate) | Look | Ophthalmic solution: 1%, 2%, 4%<br>*Discontinued in 1998 (per Micromedex); generic pilocarpine products available | Instill 1 to 2 drops in the affected eye(s) up to 4 times per day |

**Appendix J: Product with numerically similar dose and strength, but different frequency**

| **Failure Mode: Name confusion** | **Causes (could be multiple)** | **Effects** |
|---|---|---|
| **Potiga (retigabine)** | **Tablets:** **50 mg, (b) (4) 200 mg, 300 mg, 400 mg** | **Initial dose should be 100 mg orally 3 times daily. Doses should be increased at weekly intervals by a maximum of 150 mg per day, given as 3 divided doses. Optimal dose is 600 mg to 1200 mg/day given as 200 mg to 400 mg orally 3 times daily** |
| Pexeva<br>(paroxetine mesylate)<br>Tablets:<br>10 mg, 20 mg, 30 mg, and 40 mg<br>Dose: 20 mg to 60 mg orally once daily | Orthographic similarity<br>Numerically similar strength<br>(10 mg, 20 mg, 30 mg, and 40 mg vs. 100 mg, 200 mg, 300 mg, and 400 mg)<br>Numerically similar dose | The orthographic differences in the names help to minimize the risk of medication errors in the usual practice setting. Although the beginning letters of the names may look similar when scripted ('Pexe' vs. 'Poti'), the downstroke in Potiga (lower case 'g') helps to provide differentiation.<br>The risk of medication errors is further reduced by the different frequencies of administration. The recommended dose of Pexeva ranges from 10 mg to 60 mg once daily. By contrast, the recommended initial dose of Potiga is 100 mg orally 3 times daily. The optimal dose is 200 mg to 400 mg orally 3 times daily. |

| Application Type/Number | Submission Type/Number | Submitter Name | Product Name |
|---|---|---|---|
| NDA-22345 | ORIG-1 | VALEANT PHARMACEUTICALS NORTH AMERICA | RETIGABINE |

---

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

---

/s/

---

TARA P TURNER
02/18/2010

ZACHARY A OLESZCZUK
02/18/2010

DENISE P TOYER on behalf of CAROL A HOLQUIST
02/18/2010