

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:

022399Orig1s000

PROPRIETARY NAME REVIEW(S)

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

Date: March 28, 2011

Application Type/Number: NDA 022399

Through: Melina Griffis, R.Ph., Team Leader
Carol Holquist, R.Ph., Director
Division of Medication Error Prevention and Analysis (DMEPA)

From: Anne C. Tobenkin, Pharm.D.
Division of Medication Error Prevention and Analysis (DMEPA)

Subject: Proprietary Name Review

Drug Name(s): Horizant (Gabapentin Enacarbil) Extended-release Tablet
600 mg

Applicant/Sponsor: GlaxoSmithKline

OSE RCM #: 2011-355

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

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1 INTRODUCTION

This re-assessment of the proposed proprietary name is written in response to the anticipated approval of this NDA within 90 days from the date of this review. The Division of Medication Error Prevention and Analysis (DMEPA) found the proposed proprietary name, Horizant, acceptable in OSE Reviews #2009-1360, dated October 14, 2009 and #2010-2180, dated December 24, 2010.

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/or phonetic similarity to the proposed name that have been approved since the previous proprietary name review. We use the same search criteria previously used in the above stated reviews. Since none of the proposed product characteristics were altered we did not re-evaluate previous names of concern. The searches of the databases yielded four additional names (Viaject***, (b) (4)***, and Clozaril) thought to look similar to Horizant and represent a potential source of drug name confusion.

Three of the four names identified in the searches were eliminated for reasons described in Appendix A. Failure mode and effects analysis was applied to determine if the proposed proprietary name could potentially be confused with the remaining name and lead to medication errors. This analysis determined that the name similarity between Horizant and the remaining name was unlikely to result in medication error for the reasons presented in Appendix B.

Additionally, DMEPA searched the United States Adopted Names (USAN) stem list to determine if the name contains any USAN stems as of the last USAN update. DMEPA staff did not identify any United States Adopted Names (USAN) stems in the proposed proprietary name, Horizant, as of March 8, 2011.

3 CONCLUSIONS AND RECOMMENDATIONS

The re-evaluation of the proposed proprietary name, Horizant, did not identify any vulnerabilities that would result in medication errors with the additional names noted in this review. Thus, the Division of Medication Error Prevention and Analysis (DMEPA) has no objection to the proprietary name, Horizant, 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 Neurology Products should notify DMEPA because the proprietary name must be re-reviewed prior to the new approval date.

We are willing to meet with the Division for further discussion, if needed. If you have further questions or need clarifications, please contact Laurie Kelley, OSE Regulatory Project Manager, at 301-796-5068

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

4 REFERENCES

4.1 REVIEWS

1. OSE Review # 2009-1360, dated October 14, 2009. Proprietary Name Review; Zachary Oleszczuk, Pharm.D.
2. OSE Review # 2009-2180, dated December 24, 2009. Proprietary Name Review; Zachary Oleszczuk, Pharm.D.

4.2 DATABASES

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.
5. *CDER Proposed Names List*
Compiled list of proposed proprietary names submitted to the Division of Medication Error Prevention and Analysis (DMEPA) for review. The list is updated weekly and maintained by DMEPA.

Appendix A: Names of products not used in usual clinical practice for the reasons described.

Proprietary Name	Similarity to Horizant	Reason/Comments
Viaject*** (Recombinant human insulin)	Look-Alike	Proposed proprietary name for NDA 200476; found unacceptable in OSE review 2010-42 dated April 10, 2010 due to a USAN stem in the proposed name and likely confusion with three marketed products.
(b) (4)		

Appendix B: Risk of name confusion minimized by preventions listed.

Product name with potential for confusion	Similarity to proposed proprietary name	Strength and dosage form	Usual dose (if applicable)	Failure Mode of name confusion prevented by the combination of stated product characteristics as well as orthographic and/or phonetic differences as described.
Horizant (Gabapentin enacarbil)		600 mg oral tablet	One tablet by mouth in the evening	
Clozaril (Clozapine)	Look-Alike	25 mg, 100 mg oral tablet	25 mg by mouth once daily or 12.5 mg by mouth twice daily, daily dose increases of 25 mg to 50 mg per day up to maximum dose of 900 mg per day in divided doses	<p><i>Product differences</i></p> <ul style="list-style-type: none"> - Strength (600 mg, single strength not required on prescription vs. 25 mg, 100 mg) - Frequency (once daily in the evening vs. once daily for doses less than 100 mg, over 500 mg divided into three doses) - Monitoring/Distribution (none necessary vs. regular white blood cell counts and absolute neutrophil counts during treatment and only available through a distribution system that ensure monitoring of lab levels)

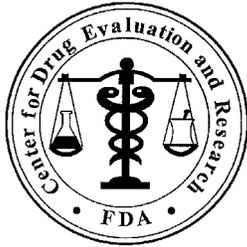
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**Department of Health and Human Services
Public Health Service
Food and Drug Administration
Center for Drug Evaluation and Research
Office of Surveillance and Epidemiology**

Date: December 24, 2009

To: Russell Katz, MD
Director, Division of Neurology Products (DNP)

Through: Kellie Taylor, PharmD, MPH, Team Leader
Denise P. Toyer, PharmD, Deputy Director
Division of Medication Error Prevention and Analysis (DMEPA)

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

Subject: Proprietary Name Review

Drug Name(s): Horizant (Gabapentin Enacarbil) Extended-release Tablets
600 mg

Application Type/Number: NDA 022399 (IND 071352)

Applicant: GlaxoSmithKline

OSE RCM #: 2009-2180

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1 INTRODUCTION

This re-assessment of the proprietary name is written in response to the anticipated approval of NDA 022399 within 90 days from the date of this review. The Division of Medication Error Prevention and Analysis (DMEPA) found the proposed proprietary name, Horizant, acceptable in OSE Review #2009-1360, dated October 14, 2009. The Division of Neurology Products did not have any concerns with the proposed name, Horizant, and the Division of Drug Marketing, Advertising and Communication (DDMAC) found the name acceptable from a promotional perspective on August 4, 2009.

2 METHODS AND RESULTS

For the reassessment of the proposed proprietary name, DMEPA staff search a standard set of databases and information sources (see section 4) to identify names with orthographic and/or phonetic similarity to the proposed name that have been approved since the previous proprietary name review. We used the same search criteria previously used in OSE Review #2009-1360, dated October 14, 2009, and since none of the proposed product characteristics were altered we did not re-evaluate previous names of concern. Additionally, DMEPA searches the United States Adopted Names (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.

The searches of the databases referenced in Section 4.2 did not yield any new names thought to look or sound similar to Horizant and represent a potential source of drug name confusion.

DMEPA staff did not identify any United States Adopted Names (USAN) stems in the proposed proprietary name, Horizant, as of December 20, 2009.

3 CONCLUSIONS AND RECOMMENDATIONS

The proprietary name risk assessment findings indicate that the proposed name, Horizant, is not vulnerable to name confusion that could lead to medication errors nor is the name considered promotional. Thus, the Division of Medication Error Prevention and Analysis (DMEPA) has no objection to the proprietary name, Horizant, 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 Neurology Products should notify DMEPA because the proprietary name must be re-reviewed prior to the new approval date.

4 REFERENCES

4.1 REVIEW

1. Oleszczuk, Z. OSE Review # 2009-1369, Proprietary Name Review of Horizant; October 14, 2009

4.2 DATABASES

1. *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.

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

USAN Stems List contains all the recognized USAN stems.

3. *CDER Proposed Names List*

Compiled list of proposed proprietary names submitted to the Division of Medication Error Prevention and Analysis (DMEPA) for review. The list is updated weekly and maintained by DMEPA.

Application Type/Number	Submission Type/Number	Submitter Name	Product Name
NDA-22399	ORIG-1	GLAXO GROUP LTD DBA GLAXOSMITHKLIN E	SOLZIRA

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
12/24/2009

DENISE P TOYER on behalf of KELLIE A TAYLOR
12/24/2009

DENISE P TOYER
12/24/2009



**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: October 14, 2009

To: Russell Katz, MD
Director, Division of Neurology Products

Through: Kellie Taylor, Pharm D, MPH, Team Leader
Division of Medication Error Prevention and Analysis
Denise Toyer, PharmD, Deputy Director
Carol Holquist, RPh, Director
Division of Medication Error Prevention and Analysis (DMEPA)

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

Subject: Proprietary Name Review

Drug Name(s): Horizant (Gabapentin Enacarbil) Extended-release Tablets

Application Type/Number: NDA 022399 (IND 071352)

Applicant/Applicant: GlaxoSmithKline

OSE RCM #: 2009-1360

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EXECUTIVE SUMMARY

Horizant is the proposed proprietary name for Gabapentin Enacarbil Extended-release 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, Horizant, acceptable 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 (DNP) should notify DMEPA because the proprietary name must be re-reviewed prior to the new approval date.

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 GlaxoSmithKline July 23, 2009, for an assessment of the proposed proprietary name, Horizant, regarding potential name confusion with other proprietary or established drug names in the usual practice settings. The Applicant submitted an external study conducted by [REDACTED] (b) (4), in support of their proposed proprietary name. GlaxoSmithKline also submitted container labels, carton and package insert labeling for review, which will be reviewed in a separate review (OSE Review #2009-114).

1.2 REGULATORY HISTORY

Horizant is the third proprietary name proposed under NDA 22-399. The first proprietary name Solzira*** was [REDACTED] (b) (4)

The Applicant then submitted an alternate name [REDACTED] (b) (4) which was [REDACTED] (b) (4)

1.3 PRODUCT INFORMATION

Horizant (Gabapentin Enacarbil) is being developed as a prodrug that is structurally similar to the neurotransmitter gamma-aminobutyric acid (GABA) indicated for the treatment of moderate to severe primary Restless Leg Syndrome (RLS). Horizant is available as a 600 mg orally extended-release tablet. The dose of Horizant is 600 mg orally once per day at 5 pm.

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, 2.2, and 2.3 identify specific information associated with the methodology for the proposed proprietary name, Horizant.

2.1 SEARCH CRITERIA

For this review, particular consideration was given to drug names beginning with the letter ‘H’ 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}

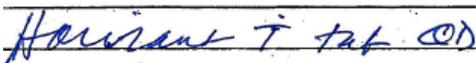
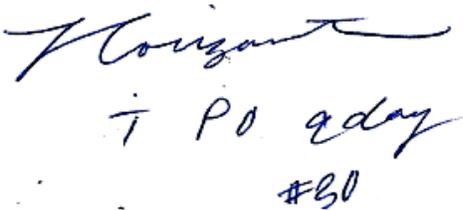
To identify drug names that may look similar to Horizant, the DMEPA staff also considers the orthographic appearance of the name on lined and unlined orders. Specific attributes taken into consideration include the length of the name (8 letters), upstrokes (two, capital letter ‘H’ and lower case letter ‘t’), downstrokes (one, lower case letter ‘z’), crosstrokes (one, lower case ‘t’), and dotted letters (one, lower case ‘i’). Additionally, several letters in Horizant 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 Horizant.

When searching to identify potential names that may sound similar to Horizant, the DMEPA staff searches for names with similar number of syllables (three), stresses (HOR-eh-zont, hor-EH-zont, and hor-eh-ZONT), and placement of vowel and consonant sounds. The Applicant’s intended pronunciation could not be taken into consideration, as it was not included in the Request for Proprietary Name Review. Additionally, the DMEPA staff considers that pronunciation of parts of the name can vary (See Appendix B). Furthermore, 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 medication order and verbal prescription was communicated during the FDA prescription studies.

Figure 1. Horizant Study (conducted on August 8, 2009)

HANDWRITTEN REQUISITION MEDICATION ORDER	VERBAL PRESCRIPTION
<p><u>Inpatient Medication Order:</u></p> 	<p>Horizant 1 tab po Qday Dispense: #30</p>
<p><u>Outpatient Medication Order:</u></p> 	

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)

2.3 EXTERNAL PROPRIETARY NAME RISK ASSESSMENT

For this product, the Applicant submitted an external evaluation of the proposed proprietary name. The Division of Medication Error Prevention and Analysis conducts an independent analysis and evaluation of the data provided, and responds to the overall findings of the assessment. When the external proprietary name risk assessment identifies potentially confusing names that were not captured in DMEPA's database searches or in the Expert Panel Discussion, these names are included in the Safety Evaluator's Risk Assessment and analyzed independently by the Safety Evaluator to determine if the potentially confusing name could lead to medication errors in usual practice settings.

After the Safety Evaluator has determined the overall risk associated with the proposed name, the Safety Evaluator compares the findings of their overall risk assessment with the findings of the proprietary name risk assessment submitted by the Applicant. The Safety Evaluator then determines whether the Division's risk assessment concurs or differs with the findings. When the proprietary name risk assessments differ, the Division of Medication Error Prevention and Analysis provides a detailed explanation of these differences.

3 RESULTS

3.1 DATABASE AND INFORMATION SOURCES

The searches yielded a total of twenty one names as having some similarity to the name Horizant.

Nineteen of the names were thought to look like Horizant. These include (b) (4), Aricept, Floranex, Florical, Florinef, Flurizan^{***}, Harmonex, Herceptin, Hetrazan, Horacort, Imagent, (b) (4)** , Moricizine, Nizoral, Norplant (b) (4), Thorazine, and Viviant^{***}. The remaining two names were thought to look and sound similar to Horizant; Horizon and Horsemint.

Additionally, DMEPA staff did not identify any United States Adopted Names (USAN) stems in the proposed proprietary name, as of August 12, 2009.

3.2 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 Horizant.

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

A total of twenty-one practitioners responded in the prescription analysis studies. Only one of the participants interpreted the name correctly as "Horizant," with correct interpretation occurring in the verbal prescription study. The remainder of the responses misinterpreted the drug name. The majority of misinterpretations occurred with the initial capital letter 'H' being misinterpreted as the combination 'Fl', capital letter 'N', or 'W'. In the verbal studies, the remaining responses were misspelled phonetic variations of the proposed name, Horizant. The majority of misinterpretations in the verbal study occurred with the initial letter 'a' being misinterpreted as 'i' or 'e'. See Appendix C for the complete listing of interpretations from the verbal and written prescription studies.

3.4 EXTERNAL STUDY

The proposed name risk assessment conducted by the (b) (4), identified and evaluated a total of six names thought to have some potential for confusion with the name Horizant: Atrovent, Beclovent, Caziant, Duravent, Serevent, and Survanta. None of the six names were previously identified in DMEPA staff searches. All six names were evaluated in Section 3.6 below.

Additionally, during our evaluation of the external name study DMEPA was unable to verify that one name, Duravent, had the product characteristics submitted by (b) (4) stated that (b) (4)

(b) (4) also stated that Duravent is (b) (4). Since (b) (4) did not provide a reference for where they obtained this information, DMEPA searched the databases listed in the Reference section of this review for this product.

Although we could not locate (b) (4) Duravent product. We did identify Duravent as the proprietary name for a product containing chlorpheniramine, methscopoloamine, and phenylephrine. This Duravent is available as a single strength oral chewable tablet containing 2 mg chlorpheniramine, 1.25 mg methscopoloamine, and 10 mg phenylephrine. The dose of this product is 1 to 2 tablets every 4 to 6 hours not to exceed 8 tablets in 24 hours. This product still appears to be marketed.

Since DMEPA was unable to verify the product characteristics submitted by (b) (4) for the product name 'Duravent' and DMEPA found a product name 'Duravent' with different product characteristics, DMEPA will evaluate the name Duravent as a proprietary name for two different products. Duravent [1] (b) (4) as described in the (b) (4) study, and Duravent [2] is used to designate the product containing chlorpheniramine, methscopoloamine, and phenylephrine. As such, a total of 28 names were analyzed to determine if the drug names could be confused with Horizant and if the drug name confusion would likely result in a medication error in the usual practice setting.

3.5 COMMENTS FROM THE DIVISION OF NEUROLOGY PRODUCTS (DNP)

In response to the OSE August 4, 2009 e-mail, DNP did not forward any comments and/or concerns on the proposed name at the initial phase of the name review.

On September 2, 2009, DMEPA notified the Division of Neurology Products via e-mail that we had no objections to the proposed proprietary name, Horizant. Per e-mail correspondence from the Division of Neurology Products on September 22, 2009, they indicated that they concur with our assessment of the proposed proprietary name, Horizant.

3.6 SAFETY EVALUATOR RISK ASSESSMENT

Independent searches by the primary Safety Evaluator did not identify any additional names which were thought to look similar to Horizant and represent a potential source of drug name confusion.

Thus, we evaluated a total of 28 names for their similarity to the proposed name.

4 DISCUSSION

Neither DDMAC nor the Division of Neurology Products had concerns with the proposed name Horizant. DMEPA did not identify other factors besides names with potential similarity to Horizant that would render the name unacceptable.

A total of 28 names were identified and evaluated by DMEPA. Three of the 28 names lacked convincing orthographic and/or phonetic similarity to the proposed proprietary name Horizant and were not evaluated further (see Appendix D).

Failure mode and effect analysis (FMEA) was then applied to determine if the proposed proprietary name could potentially be confused with the remaining 25 names and lead to medication errors. This analysis determined that the name similarity between Horizant was unlikely to result in medication errors with any of the 18 products for the reasons presented in Appendices E through K. This finding was consistent with and supported by an independent risk assessment of the proprietary name submitted by the Applicant.

5 CONCLUSIONS AND RECOMMENDATIONS

The Proprietary Name Risk Assessment findings indicate that the proposed name, Horizant, is not vulnerable to name confusion that could lead to medication errors. Thus the Division of Medication Error Prevention and Analysis (DMEPA) has no objection to the proprietary name, Horizant, for this product at this time. Additionally, DDMAC does not object to the proposed name, Horizant from a promotional perspective.

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.

5.1 COMMENTS TO THE DIVISION

We are willing to meet with the Division for further discussion, if needed. If you have further questions or need clarifications, please contact Laurie Kelley, OSE project manager, at 301-796-5068.

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 (DNP) should notify DMEPA because the proprietary name must be re-reviewed prior to the new approval date.

5.2 COMMENTS TO THE APPLICANT

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

If approval of the NDA is delayed beyond 90 days from the date of this review, the proprietary name must be re-reviewed prior to the new approval date.

If any of the proposed product characteristics are altered prior to approval of this NDA, the proprietary name should be resubmitted for review.

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.

4. *AMF Decision Support System [DSS]*

DSS is a government database used to track individual submissions and assignments in 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. *Electronic online version of the FDA Orange Book* (<http://www.fda.gov/cder/ob/default.htm>)

The FDA Orange Book provides a compilation of approved drug products with therapeutic equivalence evaluations.

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

USPTO provides information regarding patent and trademarks.

9. *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.

10. 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.

11. 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.

12. Stat!Ref (www.statref.com)

Stat!Ref contains full-text information from approximately 30 texts; it 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.

13. USAN Stems (<http://www.ama-assn.org/ama/pub/category/4782.html>)

USAN Stems List contains all the recognized USAN stems.

14. Red Book Pharmacy's Fundamental Reference

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

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

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

16. Medical Abbreviations Book

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

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

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 because similarly 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.

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.

Table 1. Criteria used to identify drug names that look- or sound-similar to a proposed proprietary name.

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

Lastly, 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/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 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 possess similarity that would cause confusion at any point in the medication use system, thus the name is eliminated from further review.

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

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

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

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.

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:

- a. 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)].
- 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.

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, Horizant	Scripted may appear as	Spoken may be interpreted as
Capital ‘H’	‘M’, ‘Fl’, ‘W’ or ‘N’	
Lower case ‘o’	‘a’, ‘e’, or ‘u’	‘A’, ‘E’ ‘I’, ‘ALL’, ‘U’, or ‘Y’
Lower case ‘r’	‘n’, ‘v’, or ‘x’	‘WR’
Lower case ‘i’	‘e’	A’, ‘E’, ‘ALL’, ‘U’, ‘O’, or ‘Y’
Lower case ‘z’	‘m’, ‘v’, or ‘r’	‘S’, ‘C, or ‘X’
Lower case ‘a’	‘c’, ‘ci’, ‘ce’, ‘el’, ‘s’, ‘x’ ‘e’, ‘o’, or ‘u’	‘E’, ‘I’, ‘ALL’, ‘U’, ‘O’, or ‘Y’
Lower case ‘n’	‘h’, ‘m’, ‘r’, ‘s’, or ‘x’	‘DN’, ‘GN’, ‘KN’, ‘MN’, or ‘PN’
Lower case ‘t’	‘f’, ‘r’, or ‘x’	‘D’ or ‘PT’

Appendix C: FDA Prescription Study Responses.

Inpatient Medication Order	Outpatient Medication Order	Voice Prescription
Hairant	Floriant	Horizant
Harican	Florizant	Horizent
Harirant	Florizant	Horizit
Harivan	Florizant	
Harivant	Florizant	
Haurant	Florizante	
Horirant	Florizart	
Horirant	Norizant	
Horivant	Worizant	

Appendix D: Proprietary names that lack convincing orthographic and/or phonetic similarities

Proprietary Name
Caziant
Aricept
Viviant ***

Appendix E: Proprietary names that are internationally registered

Proprietary Name	Similarity to Horizant	Active Ingredient	Country
Horacort	Look	budesonide	Poland
Horizon	Look and Sound	diazepam	Japan

Appendix F: Proposed proprietary names that were for products approved under a different proprietary name

Proprietary Name	Similarity to Horizant	Reason for Discard
(b) (4)	Look	(b) (4)
(b) (4) (etravirine)	Look	NDA #22-187 approved with the proprietary names Intelence

Appendix G: Proposed proprietary names that belong to an application for a product that has been withdrawn, the Agency refused to file, or drug products that are discontinued and no generic equivalent is available

Proprietary Name	Similarity to Horizant	Status and Date
(b) (4)	Look	(b) (4)
	Look	(b) (4)

Appendix H: Herbal products that are no longer manufactured

Proprietary Name	Active Ingredient	Similarity to Horizant
Harmonex	Standardized St. John's Wart flower extract (0.3% hypericin), and Standardized Siberian Ginseng root extract (0.8% eleutherosides)	Look

Appendix I: Products with no numerical overlap in strength and usual dose

Product name with potential for confusion	Similarity to Proposed Proprietary Name	Strength	Usual Dose (if applicable)
Horizant (gabapentin enacarbil) extended release tablets		Tablets: 600 mg extended release	600 mg orally once daily at 5 pm
Atrovent (ipratropium bromide)	Look and Sound	Inhalation aerosol: HFA: 17 mcg/actuation CFC: 18 mcg/actuation Inhalation solution: 0.02% Nasal Solution: 0.021 mg/spray and 0.042 mg/spray	Inhalation aerosol: Two inhalations four times a day. Patients may take additional inhalations as required; however, the total number of inhalations should not exceed 12 in 24 hours. Inhalation solution: 500 mcg (1 Unit-Dose vial) administered three to four times a day by oral nebulization. Nasal Solution: Two sprays per nostril two to four times daily.
Thorazine (chlorpromazine)	Look	Tablets: 10 mg, 25 mg, 50 mg, 100 mg, and 200 mg Extended-release Tablets: 30 mg, 75 mg, 150 mg, 200 mg, and 300 mg Oral Syrup: 10 mg/5 mL, 30 mg/mL, and 100 mg/mL Rectal Suppository: 25 mg and 100 mg Injection: 25 mg/mL	<p><u>Hospitalized Patients:</u></p> Acute Schizophrenic or Manic States: 500 mg orally a day is generally sufficient. Less Acutely Disturbed: 25 mg orally three times a day to 400 mg daily in three divided doses. <p><u>Outpatients:</u></p> 10 mg orally three to 25 mg orally six times daily depending on the indication.

Appendix J: Single strength products with multiple differentiating product characteristics

Product name with potential for confusion	Similarity to Proposed Proprietary Name	Strength	Usual Dose (if applicable)	Differentiating product characteristics
Horizant (gabapentin enacarbil) extended release tablets		Tablets: 600 mg extended release	Usual dose: 600 mg orally once daily at 5 pm.	
Beclovent (beclomethasone dipropionate)	Look and Sound	Inhalation aerosol: 42 mcg/actuation	1 or 2 nasal inhalations in each nostril twice a day	Dosage form (extended release tablets vs. inhalation/aerosol) Frequency (once daily vs. twice daily)
Serevent (salmeterol xinafoate)	Look and Sound	Metered dose powder for inhalation: 50 mcg per inhalation	1 inhalation twice daily	Dosage form (extended release tablets vs. metered dose powder for inhalation) Frequency (once daily vs. twice daily)
Survanta (beractant)	Look and Sound	Suspension for injection: 25 mg/mL	100 mg/kg/dose (birth weight) given every 6 hours up to 4 doses	Patient population (adults vs. premature infants in the first 48 hours of life) Dosage form (extended release tablets vs. suspension) Route of administration (oral vs. intrathecal) Frequency (once daily vs. 6 hours)
Norplant (levonorgestrel)	Look	Subdermal Capsules: 36 mg	Six capsules inserted in midportion of upper arm during first 7 days of onset of menses. Remove after 5 years	Dosage form (extended release tablets vs. subdermal capsules) Route of administration (oral vs. implant) Frequency (once daily vs. once every 5 years)

Product name with potential for confusion	Similarity to Proposed Proprietary Name	Strength	Usual Dose (if applicable)	Differentiating product characteristics
Horizant (gabapentin enacarbil) extended release tablets		Tablets: 600 mg extended release	Usual dose: 600 mg orally once daily at 5 pm.	
Herceptin (trastuzumab)	Look	Powder for injection: 440 mg/vial	<p>Adjuvant Treatment, Breast Cancer:</p> <p>4mg/kg as an intravenous infusion over 90 minutes then at 2 mg/kg as an intravenous infusion over 30 minutes weekly during chemotherapy for the first 12 weeks. One week following the last weekly dose of Herceptin, administer Herceptin at 6 mg/kg as an intravenous infusion over 30-60 minutes every three weeks for a total of 52 weeks of therapy</p> <p>As a single agent:</p> <p>Initial dose at 8 mg/kg as an intravenous infusion over 90 minutes. Subsequent doses at 6 mg/kg as an intravenous infusion over 30-minutes every three weeks.</p>	<p>Dosage form (extended release tablets vs. powder for injection)</p> <p>Route of administration (oral vs. intravenous infusion)</p> <p>Frequency (once daily vs. once weekly or once every three weeks)</p>

Appendix K: Products with overlap in strength, dose or are only available in one strength.

Failure Mode: Name confusion	Causes (could be multiple)	Rationale
Horizant (gabapentin enacarbil) extended release tablets	Tablets: 600 mg extended release	Usual dose: 600 mg orally once daily at 5 pm.

(b) (4)

Failure Mode: Name confusion	Causes (could be multiple)	Rationale
Horizant (gabapentin enacarbil) extended release tablets	Tablets: 600 mg extended release	Usual dose: 600 mg orally once daily at 5 pm.
<p>Duravent [2] (Chlorpheniramine, Methscopoloamine, and Phenylephrine)</p> <p><u>Dosage From:</u> Tablets</p> <p><u>Strength:</u> 2 mg Chlorpheniramine, 1.25 mg Methscopoloamine, and 10 mg Phenylephrine</p> <p><u>Usual Dose:</u> 1 to 2 tablets every 4 to 6 hours not to exceed 8 tablets in 24 hours</p>	<p>Phonetic similarity (both names contain the same number of syllables (3), and the ending of each name ('-rizant' vs. '-ravent') may sound similar when spoken)</p> <p>Orthographic similarity (both names contain the same number of letters (8), both contain the same number of upstrokes (2, capital 'H' and lower case 't' vs. capital 'D' and lower case 't') located in the same position (1st letter and 8th letters), both contain the same number of crosstrokes (1, lower case 't') located in the same position (8th letter), both contain the same 3rd letter ('r'), the second letter of each name ('o' vs. 'u') may appear similar when scripted, and the endings of both names ('ent' vs. 'ant') may appear similar when scripted)</p> <p>Both products are only available in one strength (600 mg vs. 2 mg Chlorpheniramine, 1.25 mg Methscopoloamine, and 10 mg Phenylephrine). Since both products are only available in one strength a prescriber would not have to include a strength when writing a prescription. Additionally, both products are available as tablets and share a route of administration (oral).</p>	<p>Phonetic and orthographic differences will help minimize the likelihood of medication error in the usual practice setting.</p> <p><i>Rationale:</i></p> <p>The risk for medication error is minimized by the phonetic differences in the names. Although, the endings of each name may sound similar when spoken, the beginning of each name ('Ho-' vs. 'Du') sounds different when spoken and will help to differentiate the products.</p> <p>The risk for medication error is also minimized by the orthographic differences in the names. The first letter of each name ('H' vs. 'D') appears different when scripted.</p> <p>Despite that both products are only available in one strength; the phonetic and orthographic differences minimizes the potential for confusion between Horizant and Duravent.</p>

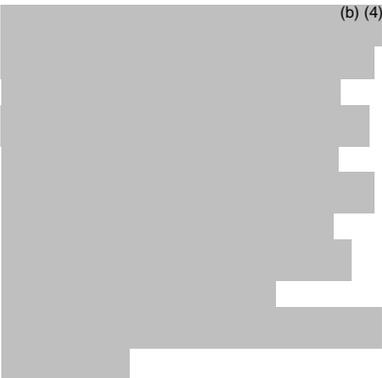
Failure Mode: Name confusion	Causes (could be multiple)	Rationale
Horizant (gabapentin enacarbil) extended release tablets	Tablets: 600 mg extended release	Usual dose: 600 mg orally once daily at 5 pm.
<p>Nizoral (ketoconazole)</p> <p><u>Dosage From:</u> Shampoo and Tablets</p> <p><u>Strength:</u> Shampoo: 2%</p> <p>Tablets: 200 mg</p> <p><u>Usual Dose:</u> Shampoo: Apply the shampoo to the damp skin of the affected area and a wide margin surrounding this area. Lather, leave in place for 5 minutes, and then rinse off with water. One application should be sufficient</p> <p>Tablets: 200 mg to 400 mg (one to two tablets) orally once daily</p>	<p>Orthographic similarity (both names contain a similar number of letters (8 vs. 7), both contain the same number of upstrokes (2, capital ‘H’ and lower case ‘t’ vs. capital ‘N’ and lower case ‘1’) located in similar positions (1st letter and 8th letters vs. 1st and 7th letters), both contain the same number of downstrokes (1, lower case ‘z’), both contain the same number of dotted letters (one, lower case ‘i’, both contain the same 6th letter (‘a’), and the 3rd (‘r’ vs. ‘z’) and 5th (‘z’ vs. ‘r’) letters of each name can appear similar when scripted)</p> <p>Both products are only available in one strength (600 mg vs. 200 mg). Since both products are only available in one strength a prescriber would not have to include a strength when writing a prescription. Additionally, both products are available as tablets, share a route of administration (oral), a frequency (once daily), and a dose (1 tablet).</p>	<p>Orthographic differences in each name will help minimize the likelihood of medication error in the usual practice setting.</p> <p><i>Rationale:</i></p> <p>The risk for medication error is minimized by the orthographic differences in the names. Although the names contain a similar number of letters (8 vs. 7), Horizant appears longer when scripted. Both names contain the same number of downstrokes (1 lower case ‘z’), however the downstroke appears in different positions (5th letter vs. 3rd letter). The names also contain a different number of crosstrokes (1, lower case ‘t’ vs. none).</p> <p>Additionally, if a strength or dose is included on the prescription the differences in strengths (600 mg vs. 200 mg) and dose (600 mg vs. 400 mg) will help to differentiate the two products.</p> <p>Although both products share some overlapping product characteristics, the orthographic differences in the name help to minimize the potential for confusion between Horizant and Nizoral.</p>

Failure Mode: Name confusion	Causes (could be multiple)	Rationale
Horizant (gabapentin enacarbil) extended release tablets	Tablets: 600 mg extended release	Usual dose: 600 mg orally once daily at 5 pm.
<p>Floranex (Lactobacillus Acidophilus)</p> <p><u>Dosage Form:</u> Chewable Tablet</p> <p><u>Strength:</u> 1 million units of Lactobacillus acidophilus and Lactobacillus bulgaricus</p> <p><u>Usual Dose:</u> one to two tablets orally once daily</p>	<p>Orthographic similarity (both names contain the same number of letters (8), both contain the same number of upstrokes (two, capital ‘H’ and lower case ‘t’ vs. capital ‘F’ and lower case ‘l’), both names contain a crosstroke (lower case ‘t’ vs. lower case ‘x’) located in the same position (8th letter), both contain the same 6th letter (‘a’), the 3rd (‘r’ vs. ‘z’) and 5th (‘z’ vs. ‘r’) letters of each name can appear similar when scripted, and the beginning of each name ‘Flor-’ vs. ‘Hor-’ may appear similar when scripted)</p> <p>Both products are only available in one strength (600 mg vs. 200 mg). Since both products are only available in one strength a prescriber would not have to include a strength when writing a prescription. Additionally, both products are available as tablets, share a route of administration (oral), a frequency (once daily), and a dose (1 tablet).</p>	<p>Orthographic differences in each name will help minimize the likelihood of medication error in the usual practice setting.</p> <p><i>Rationale:</i></p> <p>The risk for medication error is minimized by the orthographic differences in the names. Although both names contain the same number of upstrokes, (2, capital ‘H’ and lower case ‘t’ vs. capital ‘F’ and lower case ‘l’) the upstrokes appear in different positions (1st and 8th letter vs. 1st and 2nd letter).</p> <p>Additionally, if a strength is included on the prescription the difference in strengths (600 mg vs. 1 million units) will help to differentiate the two products.</p> <p>Although both products share overlapping product characteristics and the beginning of each name may appear similar when scripted, the orthographic differences in the ending of the name help to minimize the potential for confusion between Horizant and Floranex.</p>

Failure Mode: Name confusion	Causes (could be multiple)	Rationale
Horizant (gabapentin enacarbil) extended release tablets	Tablets: 600 mg extended release	Usual dose: 600 mg orally once daily at 5 pm.
<p>Florical (fluoride and calcium)</p> <p><u>Dosage Form:</u> Tablet</p> <p><u>Strength:</u> fluoride 3.7 mg and calcium 145 mg</p> <p><u>Usual Dose:</u> one tablet orally once daily</p>	<p>Orthographic similarity (both names contain the same number of letters (8), both names contain the same number of crosstrokes (lower case 't' vs. capital 'F'), both names contain the same number of dotted letters (one, lower case 'i'), both names contain an upstroke (lower case 't' vs. lower case 'l') in the eighth position, and the beginning of each name 'Flori-' vs. 'Hori-' may appear similar when scripted)</p> <p>Both products are only available in one strength (600 mg vs. fluoride 3.7 mg and calcium 145 mg). Since both products are only available in one strength a prescriber would not have to include a strength when writing a prescription. Additionally, both products are available as tablets, share a route of administration (oral), a frequency (once daily), and a dose (1 tablet).</p>	<p>Orthographic differences in each name will help minimize the likelihood of medication error in the usual practice setting.</p> <p><i>Rationale:</i></p> <p>The risk for medication error is minimized by the orthographic differences in the names. Although both names contain the same number of crosstrokes, the crosstrokes appear in different positions (8th letter vs. 1st letter). The ending of each name ('zant' vs. '-cal') also appears different when scripted.</p> <p>Additionally, if a strength is included on the prescription the difference in strengths (600 mg vs. 3.7 mg fluoride and 145 mg calcium) will help to differentiate the two products.</p> <p>Although both products share overlapping product characteristics and the beginning of each name may appear similar when scripted, the orthographic differences in the ending of the name help to minimize the potential for confusion between Horizant and Florical.</p>

Failure Mode: Name confusion	Causes (could be multiple)	Rationale
Horizant (gabapentin enacarbil) extended release tablets	Tablets: 600 mg extended release	Usual dose: 600 mg orally once daily at 5 pm.
<p>Florinef (Fludrocortisone Acetate)</p> <p><u>Dosage Form:</u> Tablet</p> <p><u>Strength:</u> 0.1 mg</p> <p><u>Usual Dose:</u> 0.1 mg orally once daily</p>	<p>Orthographic similarity (both names contain the same number of letters (8), both names contain the same number of crosstrokes (lower case ‘t’ vs. capital ‘F’), both names contain the same number of dotted letters (one, lower case ‘i’), both names contain an upstroke (lower case ‘t’ vs. lower case ‘f’) in the eighth position, both names contain the same number of downstrokes (1, lower case ‘z’ vs. lower case ‘f’) and the beginning of each name ‘Flori-’ vs. ‘Hori-’ may appear similar when scripted)</p> <p>Both products are only available in one strength (600 mg vs. 0.1 mg). Since both products are only available in one strength a prescriber would not have to include a strength when writing a prescription. Additionally, both products are available as tablets, share a route of administration (oral), a frequency (once daily), and a dose (1 tablet).</p>	<p>Orthographic differences in each name will help minimize the likelihood of medication error in the usual practice setting.</p> <p><i>Rationale:</i></p> <p>The risk for medication error is minimized by the orthographic differences in the names. Both names also contain a different number of crosstrokes (two, capital ‘H’ and lower case ‘t’ vs. one, capital ‘F’). The ending of each name (‘zant’ vs. ‘-nef’) also appears different when scripted.</p> <p>Additionally, if a strength or dose is included on the prescription the differences in strengths (600 mg vs. 0.1 mg) and dose (600 mg vs. 0.1 mg) will help to differentiate the two products.</p> <p>Although both products share overlapping product characteristics and the beginning of each name may appear similar when scripted, the orthographic differences in the ending of the name help to minimize the potential for confusion between Horizant and Florinef.</p>

Failure Mode: Name confusion	Causes (could be multiple)	Rationale
Horizant (gabapentin enacarbil) extended release tablets	Tablets: 600 mg extended release	Usual dose: 600 mg orally once daily at 5 pm.
<p>Horsemint (monarda punctata)</p> <p><u>Similarity to Horizant:</u> Look and Sound</p> <p><u>Dosage Form:</u> Tea bag for extraction</p> <p><u>Strength:</u> Unknown</p> <p><u>Usual Dose:</u> 4 cups daily between meals, for at least four weeks</p>	<p>Phonetic similarity (both names begin with the same three letters ('Hor-') and the ending of each name ('-ant' vs. '-int') may sound similar when spoken)</p> <p>Orthographic similarity (both names contain a similar number of letters (8 vs. 9), both contain the same number of upstrokes (2, capital 'H' and lower case 't') located in similar position (1st letter and 8th letter vs. 1st letter and 9th letter), both contain the same number of crosstrokes (1, lower case 't') located in similar positions (8th letter vs. 9th letter), both names contain the same number of dotted letters (1, lower case 'i'), both names contain the same 2nd and 3rd letter ('or'), and both names contain the letter 'n' in similar positions (7th letter vs. 8th letter))</p> <p>Both products are only available in one strength (600 mg vs. unknown). Since both products are only available in one strength a prescriber would not have to include a strength when writing a prescription. Additionally, both products share a route of administration (oral).</p>	<p>The availability of each product and the differences in frequencies will help minimize the likelihood of confusion that could lead to medication error for these two products. The proposed product, Horizant will be available as a prescription product. Horsemint is an herbal supplement that does not appear to be available commercially as a single ingredient product. After searching the databases referenced in Section 6, references 1 through 16, DMEPA was unable to locate a commercially available product that contains only horsemint.</p> <p>However, Horsemint did appear as an active ingredient of St. John's Good Mood that was used to obtain product characteristics for this review. Only Natural Medicines Comprehensive Database listed a dose of Horsemint as an active ingredient, however Natural Medicines Comprehensive Database failed to list a strength or dose of the of the product. Since Horsemint does not appear to be commercially available as a single active ingredient product, it is unlikely that a prescriber would prescribe Horsemint.</p> <p>Additionally, the one product listed that did contain Horsemint as an active ingredient has a different frequency. Horsemint is give four times daily while Horizant is give once daily. This difference in frequencies should also help to differentiate the two products.</p> <p>Since Horsemint is unlikely to be prescribed and the frequency of each product is different, the risk of confusion between the two products should be minimized</p>

Failure Mode: Name confusion	Causes (could be multiple)	Rationale
<p>Horizant (gabapentin enacarbil) extended release tablets</p>	<p>Tablets: 600 mg extended release</p>	<p>Usual dose: 600 mg orally once daily at 5 pm.</p>
<p>Flurizan^{***} (tarenflurbil)  (b) (4)  </p>	<p>Orthographic similarity (both names contain the same number of letters (8), both names both names contain the same number of crosstrokes (lower case ‘t’ vs. capital ‘F’), both name contain the same number of downstrokes (1, lower case ‘z’ located in similar positions (5th letter vs. 6th letter) both names contain the same number of dotted letters (one, lower case ‘i’) located in similar positions (4th letter vs. 5th letter), both names contain the same number of upstrokes (1, lower case ‘t’ vs. capital ‘F’), the letter ‘H’ may appear similar to the letter combination ‘Fl-’ when scripted, and both names contain the same five letter string ‘-rizan’ .</p> <p> (b) (4)</p>	<p>The orthographic difference in the name in addition to the differences in frequency of administration for each product will help minimize the likelihood of confusion that could lead to medication error for these two products.</p> <p>Each product contains the same number of upstrokes (2), however the upstrokes occur in different positions (1st and 8th letter vs. 1st and second letter). Additionally, even though the letter combination ‘Fl’ may appear similar to the letter ‘H’ when scripted, there has been no reported confusion of names that begin with ‘Fl’ and ‘H’. However, since medication errors are known to be under reported a negative finding can not guarantee that the errors are not occurring.</p> <p>Furthermore, the frequency of each product is different (once daily vs. twice daily).</p>

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