CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

022544Orig1s000

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	January 27, 2011
Application Type/Number:	NDA 022544
Through:	Kristina A. Toliver, PharmD, Team Leader Carol A. Holquist, RPh, Director Division of Medication Error Prevention and Analysis (DMEPA)
From:	Loretta Holmes, BSN, PharmD, Safety Evaluator Division of Medication Error Prevention and Analysis (DMEPA)
Subject:	Proprietary Name Review
Drug Name:	Gralise (Gabapentin) Tablets 300 mg and 600 mg
Applicant:	Abbott
OSE RCM #:	2010-2525

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

1 INTRODUCTION

This re-assessment of the proprietary name, Gralise, responds to the anticipated approval of NDA 022544 within 90 days from the date of this review. The Division of Medication Error Prevention and Analysis (DMEPA) found the proposed proprietary name, Gralise, acceptable in OSE Review 2010-846, dated July 13, 2010. The Division of Anesthesia and Analgesia Products did not have any concerns with the proposed name, Gralise, during our initial review. Additionally, the Division of Drug Marketing, Advertising and Communications (DDMAC) found the name acceptable from a promotional perspective on April 29, 2010 and December 7, 2010.

Since our previous proprietary name review of Gralise, it has been determined that this product does not meet the criteria for an extended-release dosage form designation. Thus, the established name for this product is "Gabapentin Tablets" and not "Gabapentin Extended-release Tablets". We anticipate this change in dosage form designation will increase the potential for medication errors to occur between Gralise and currently marketed immediate-release Gabapentin tablets and capsules when any of these products are prescribed using the established name. Gralise is not interchangeable with other Gabapentin products, thus, it is important to differentiate it from them. At this point, the labels and labeling will have to provide the means by which to differentiate Gralise from currently marketed Gabapentin products. We provide label and labeling recommendations to address this issue in OSE Review 2010-847.

2 METHODS

For the proposed proprietary name, DMEPA staff search a standard set of databases and information sources (see Section 5) to identify names with orthographic and/or phonetic similarity to the proposed name that have been approved since the completion of the previous OSE proprietary name review. We use the same search criteria outlined in OSE Review #2010-846, for the proposed proprietary name, Gralise. 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.

As stated in Section 1, it has been determined that this product does not meet the criteria for an extended-release dosage form designation. However, the frequency of administration (once daily) and other product characteristics have not changed since our previous name review. Our re-review of the look-alike and/or sound-alike names identified in our previous proprietary name review of Gralise has determined that the change in the established name has not changed our conclusions upon re-assessment of those names.

3 RESULTS

The safety evaluator searches of the databases listed in Section 5 identified two additional names, Salese and (b) (4) thought to look and/or sound similar to Gralise and represent a potential source of drug name confusion (see Appendix A). Additionally, DMEPA staff did not identify any United States Adopted Names (USAN) stems in the proposed proprietary name as of January 3, 2011.

4 CONCLUSIONS AND RECOMMENDATIONS

The Proprietary Name Risk Assessment indicates that the proposed name, Gralise, 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 proposed proprietary name, Gralise, 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 Anesthesia and Analgesia Products should notify DMEPA because the proprietary name must be re-reviewed prior to the new approval date.

5 REFERENCES

1. Park, J. OSE Review #2010-846: Proprietary Name Review for Gralise. July 13, 2010.

2. Mena-Grillasca, C. OSE Review #2010-847: Label and Labeling Review for Gralise. January 7, 2011.

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. ***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.

<u>Appendix A:</u> Risk of medication errors due to product confusion minimized by the reasons described

Proprietary Name: **Gralise (Gabapentin) Tablets**	**Strength:** **300 mg and 600 mg**	**Signa:** **1800 mg orally once daily with evening meal** **Titration doses: 300 mg, 600 mg, 900 mg, 1200 mg, 1500 mg, and 1800 mg**
Failure Mode: Name confusion	**Causes (could be multiple)**	**Rationale**
Salese (Eucalyptus oil, glycerin, sucralose, peppermint oil, wintergreen oil, xylitol, zinc) Oral Lozenges *Strength:* No strength *Dosage:* One lozenge as needed, up to 6 times per day	Orthographic similarity: The beginning letters ("G" vs. "S") may look similar when written. The sequential letters "al" and "se" are present in both names. The "i" in Gralise looks similar to the fourth position letter "e" in Salese. Phonetic similarity: Both names contain two syllables. The beginning syllables ("Gra" vs. "Sa") have a rhyming sound. The last syllables in the names ("lise" vs. "lese") sound identical. Both products are administered orally and can be administered once daily.	Medication errors unlikely to occur due to product characteristic differences between the names. *Rationale:* The letter "r" in Gralise makes the name appear slightly longer in length as compared to Salese. The hard "G" sound in Gralise vs. the softer sound of the letter "S" in Salese, may help to differentiate the beginning syllables from one another. Gralise is available in two strengths. Therefore, the strength would have to be specified on a prescription which would help to differentiate the names. Salese is an over-the-counter product available to patients through dentist's offices. Therefore, prescriptions would unlikely be written for Gralise.

(b) (4)

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/s/

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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:	July 13, 2010
To:	Bob Rappaport, MD, Director Division of Anesthesia and Analgesia Products
Through:	Carlos Mena-Grillasca, RPh, Team Leader Kellie Taylor, PharmD, MPH, Associate Director Denise Toyer, PharmD, Deputy Director Carol Holquist, RPh, Director Division of Medication Error Prevention and Analysis (DMEPA)
From:	Judy Park, PharmD, Safety Evaluator Division of Medication Error Prevention and Analysis (DMEPA)
Subject:	Proprietary Name Review
Drug Name(s):	Gralise (Gabapentin) Extended-release Tablets 300 mg and 600 mg
Application Type/Number:	NDA 022544
Applicant:	Abbott
OSE RCM #:	2010-846

CONTENTS

EXECUTIVE SUMMARY

This review summarizes DMEPA's evaluation of the proposed proprietary name, Gralise, for Gabapentin Extended-release Tablets. 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, Gralise, acceptable for this product.

If the approval of this NDA is delayed beyond 90 days from the signature date of this review, the proposed name must be resubmitted for evaluation.

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 responds to a request from Abbott on April 16, 2010, for an assessment of the proposed proprietary name, Gralise, regarding potential name confusion with other proprietary or established drug names in the usual practice settings. Additionally, the Applicant submitted an independent name analysis conducted by the (b) (4) for the name Gralise and the analysis was evaluated as part of this review.

The Applicant also submitted container labels which will be reviewed under separate cover (OSE RCM #2010-847).

1.2 PRODUCT INFORMATION

Gralise (Gabapentin Extended Release) Tablets is indicated for the management of postherpetic neuralgia. The usual dose is 1800 mg once daily with evening meal. The recommended titration schedule is as follows:

	Day 1	**Day 2**	**Days 3–6**	**Days 7–10**	**Days 11–14**	**Day 15**
Daily Dose	300 mg	600 mg	900 mg	1200 mg	1500 mg	1800 mg

Gralise will be available in 300 mg and 600 mg strengths in bottles of 90 tablets (b) (4)

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, Gralise.

2.1 SEARCH CRITERIA

For this review, particular consideration was given to drug names beginning with the letter 'G' 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]

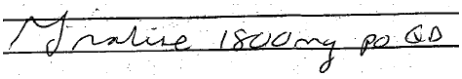
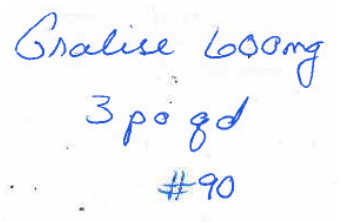
To identify drug names that may look similar to Gralise, the DMEPA staff also considers the orthographic appearance of the name on lined and unlined orders. Specific attributes taken into consideration include the length of the name (7 letters), upstrokes (two, capital letter 'G', lowercase letter 'l'), down strokes (possibly one if 'G' is scripted), cross strokes (none), and dotted letters (one, lower case 'i'). Additionally, several letters in Gralise 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 or sound similar to Gralise.

When searching to identify potential names that may sound similar to Gralise, the DMEPA staff search for names with similar number of syllables (2), stresses (GRA-lise, gra-LISE), and placement of vowel and consonant sounds. Additionally, the DMEPA staff considers that pronunciation of parts of the name can be misinterpreted (See Appendix B). The Applicant's intended pronunciation is *gra leez'*. However, 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 and outpatient medication orders and verbal prescription was communicated during the FDA prescription studies.

Figure 1. Gralise Prescription Study (conducted on April 29, 2010)

HANDWRITTEN MEDICATION ORDER	VERBAL PRESCRIPTION
Inpatient Medication Order: 	Gralise 600 mg #90 Take 3 PO Qday
Outpatient Medication Order: 	

[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 the usual practice settings.

After the Safety Evaluator has determined the overall risk associated with the proposed name, the Safety Evaluator compares the findings to their overall 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 DMEPA Safety Evaluator's database searches yielded a total of 15 names as having some similarity to the name, Gralise.

Twelve names were thought to look like Gralise by the DMEPA Safety Evaluators. These include: Crantex, Crolom, Dialose, (b) (4), Gladase, (b) (4), (b) (4), Orabase-B, Oralone, Orudis, Scabene, and Sustiva. The remaining three name, Cialis, Gralis, and (b) (4), were thought to look and sound like Gralise.

Additionally, DMEPA Safety Evaluators did not identify any United States Adopted Names (USAN) stems in the proposed proprietary name, as of June 7, 2010.

3.2 CDER EXPERT PANEL DISCUSSION

The Expert Panel reviewed the pool of names identified by DMEPA Safety Evaluators (see Section 3.1 above) and noted no additional names thought to have orthographic or phonetic similarity to Gralise. However, the Expert Panel noted that the immediate release gabapentin overlaps in strengths with the proposed product and off-label use of gabapentin with different dose may lead to medication errors.

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

3.3 FDA PRESCRIPTION ANALYSIS STUDIES

A total of 33 practitioners responded. Eighteen practitioners interpreted the name correctly as 'Gralise', with correct interpretations all occurring in the written studies. The most common misinterpretation occurred with the first letters in the inpatient written study. Practitioners misinterpreted the first letter, 'G' as 'F,' 'Mi' or 'T.' In the voice study, the majority of the practitioners misinterpreted the combination letters '-lise' as '-leef,' '-liess,' '-lease,' '-lis' (1 each) and '-leese,' (n = 4). None of the responses in any of the studies identified a currently marketed drug name.

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3.4 EXTERNAL NAME STUDY

The Applicant submitted a proprietary name risk assessment conducted by (b) (4) found the name acceptable. They identified and evaluated a total of 18 names thought to have some potential for confusion with the name Gralise. DMEPA did not identify any of the 18 names in their searches (Alesse, Aleve, Aralen, Clarinex, Galzin, Gantanol, Gardasil, Garlique, Glynase, Goserelin, Gramal, Granisetron, Granisol, Granulex, Gravol, Reliser, Seralis, and Talwin). These names will be evaluated in the Safety Evaluator Risk Assessment.

3.5 COMMENTS FROM THE DIVISION OF ANESTHESIA AND ANALGESIA PRODUCTS (DAAP)

3.5.1 Initial Phase of Review

In response to the OSE April 29, 2010 e-mail, DAAP had no objections to the proposed proprietary name, Gralise.

3.5.2 Mid-point of Review

On July 1, 2010, DMEPA notified DAAP via e-mail that we had no objections to the proposed proprietary name, Gralise. Per e-mail correspondence from DAAP on July 12, 2010, they indicated that they had no comments on the DMEPA assessment of the proposed proprietary name, Gralise.

3.6 SAFETY EVALUATOR RISK ASSESSMENT

Independent searches by the primary Safety Evaluator identified one additional name, Miralax, thought to look similar to Gralise and represent a potential source of drug name confusion.

Thus, 34 names were evaluated for their potential similarity to Gralise.

4 DISCUSSION

Gralise is the proposed proprietary name for gabapentin extended-release tablets. Gralise will be the first extended-release gabepentin product to be marketed if this NDA is approved. Thus our evaluation of the proposed product considered the potential for confusion between the immediate and extended-release products, and determined that potential for confusion exists (see Section 4.3).

Additionally, Gralise, was evaluated from promotional and safety perspective based on the product characteristics provided by the Applicant (see Section 4.1, 4.2).

4.1 PROMOTIONAL ASSESSMENT

DDMAC did not find the name Gralise promotional. DMEPA and DAAP concurred with this assessment.

4.2 SAFETY ASSESSMENT

4.2.1 Proprietary Name Risk Assessment

DMEPA identified a total of 34 names as having some potential similarity to the proposed name, Gralise. We did not identify other aspects of the proprietary name that could function as a source of error. Upon evaluation of the 34 names, 17 names were not evaluated further for the following reasons: 8 names lacked orthographic and/or phonetic similarity to Gralise (see Appendix D); 4 names were either withdrawn by the Sponsor or DMEPA previously objected to (see Appendix E); 4 names (Gramal, Gravol, Reliser, and Seralis) were names found in (b) (4) database but cannot be found in any of the commonly used medical references (see Appendix F); and 1 name was found to be a foreign product (See Appendix G).

Failure Mode and Effects Analysis was then applied to determine if the proposed name, Gralise, could potentially be confused with any of the remaining 17 names and lead to medication errors. This analysis determined that the name similarity between Gralise and all of the identified names was unlikely to result in medication errors for the reasons presented in Appendices H and J.

4.2.2 Established Name Risk Assessment

The introduction of Gralise by Abbott will provide the first extended-release formulation of gabapentin in the U.S. market. Although, the Applicant does not currently market an immediate-release formulation of gabapentin, gabapentin is currently marketed as an immediate release formulation in 100 mg, 300 mg and 400 mg capsules and 600 mg and 800 mg tablets. When Gralise is marketed, two gabapentin formulations, immediate-release and extended-release, will be available and will overlap in strengths (300 mg and 600 mg), dose (1800 mg), and route of administration (oral). Given these overlapping product characteristics, there is a risk of confusion between the two products when the products are prescribed by the established name, gabapentin, and the formulation descriptor (i.e. extended-release or ER) is omitted or overlooked. Post-marketing medication error reports demonstrate that such omissions and oversights are a source of error, particularly when products overlap in strength and dose.[3] Following the introduction of this extended-release product, errors could occur in several circumstances. The product could be ordered with an abbreviated name such as "Gabapentin 600 mg ER". When processing a prescription of "Gabapentin 600 mg ER tablets," a pharmacy staff member may overlook the ER descriptor and dispense the immediate-release formulation of gabapentin. Similarly, prescribers may inadvertently omit the dosage form when prescribing extended-release gabapentin tablets which would result in patients receiving the immediate-release formulation of gabapentin. Moreover, prescribers may specify "immediate-release" or "IR" when ordering or prescribing the immediate-release formulation of gabapentin, and these terms or abbreviation may be misinterpreted as "extended-release" or "ER" by pharmacy staff or nurses leading to the immediate-release product being dispensed in error.

In order to minimize such risk, the Applicant could have chosen product strengths that deviate from the immediate-release strengths and are not achievable by a combination of strengths. Thus, when the product is prescribed by the established name, the differences in strength offer an opportunity for an error to be detected and corrected before it reaches the patient, provided that the dose could not be achieved with the current formulation. However, since the Applicant has completed their clinical trials and submitted their new drug application, DMEPA acknowledges it is not feasible to change the product strength at this time. Thus, we considered other labeling and nomenclature measures that might help minimize confusion between the extended- and immediate-release products.

First, we considered whether the addition of a modifier (e.g. ER, XR, SR) to the proposed proprietary name, Gralise, would help to minimize confusion. These modifiers have been used for a number of marketed drugs to identify extended-release products. However, these modifiers are often reserved to distinguish two formulations with the same root name made by the same Applicant. However, since the Applicant does not currently market any immediate-release formulation of gabapentin and the immediate-release forms are marketed under different proprietary names (i.e. Neurontin), we do not believe the addition of a modifier to the proprietary name will help distinguish the two formulations. Moreover, the addition of a modifier to the proprietary name would not be expected to impact the risk of confusion when prescribers order the products using the established name only.

We also considered whether the addition of labeling statements would help to minimize errors with the immediate- and extended- release products. Although such statements are unlikely to impact the risk of practitioners omitting or overlooking the formulation descriptors, these statements might increase the detectability of the errors by highlighting the differences in dosage form and frequency of administration

[3] Lesar TS. Prescribing Errors Involving Medication Dosage Forms. *J Gen Intern Med.* 2002; 17(8): 579-587.

(three times daily versus once daily). Emphasizing this information on the carton labeling and container labels may allow pharmacists and nurses to detect confusion between the immediate- and extended-release products prior to dispensing or administration. DMEPA will provide specific label and labeling comments to minimize this risk in our forthcoming labeling review (RCM# 2010-847).

Nevertheless, because similar measures have been employed with other immediate- and extended-release products and some errors involving confusion have been reported, we anticipate some errors will occur involving confusion between Gralise and immediate-release formulations of gabapentin. Thus, monitoring for such errors is needed if Gralise is approved to determine if additional strategies are needed to further reduce the risk of confusion.

5 CONCLUSIONS AND RECOMMENDATIONS

The Proprietary Name Risk Assessment indicates that the proposed name, Gralise, is not vulnerable to look- and sound-alike confusion that could lead to medication errors nor is it considered promotional. However, since Gralise and the currently marketed gabapentin products overlap in dose (1800 mg), strengths (300 mg and 600 mg) and route of administration, we anticipate the potential for accidental or intentional substitution between the immediate release and the extended release formulations of gabapentin. DMEPA will provide label and labeling comments to minimize this risk in our forthcoming labeling review (RCM# 2010-847).

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 NDA 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 Abolade (Bola) Adeolu, OSE Project Manager, at 301-796-4264.

5.1 COMMENTS TO THE APPLICANT

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

If the approval of this NDA is delayed beyond 90 days from the signature date of this review or if **any** of the proposed product characteristics are altered prior to approval of the NDA, the proposed name must be resubmitted for evaluation.

6 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. [4]

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. [5] 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.[6] 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

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

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

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

Lastly, 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.[7] 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

[7] 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:

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, Gralise	**Scripted may appear as**	**Spoken may be interpreted as**
Capital 'G'	'A,' 'C,' 'D,' 'F,' 'M,' 'O,' 'S,' or 'T'	B, C or K
Lower case 'r'	'n,' 'e,' 'a,' 'i,' 'l,' or 'u'	r
Lower case 'a,' 'i' or 'e'	any vowel	any vowel
Lower case 'l'	'i,' 't,' 'e,' or 'b'	l

Appendix C: FDA Prescription Study Responses for Gralise.

Inpatient Medication Order	**Outpatient Medication Order**	**Voice Prescription**
Tralise	Gralise	Grilleef
Fralise	Gralise	Greliess
Tralise	Gralise	Brileese
Gralise	Gralise	Relis
Mralise	Gralise	Brilease
Gralise	Gralise	Grilleese
Miralise	Gralise	Grileese
Miralise	Gralise	Grileese
Fralise	Gralise	
Gralise	Gralise	
Gralise	Gralise	
Gralise		
Gralise		
Gralise		

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

Proprietary Name	Similarity to Gralise
Clarinex ((b) (4)	Sound and/or Look
Crantex	Look
Crolom	Look
Gantanol ((b) (4)	Sound and/or Look
Gardasil ((b) (4)	Sound and/or Look
Garlique ((b) (4)	Sound and/or Look
Goserelin ((b) (4)	Sound and/or Look
Granisetron ((b) (4)	Sound and/or Look

Appendix E: Proprietary names withdrawn by the Applicant, DMEPA objected to or approved under a different name

Proprietary Name	Similarity to Gralise	Status	Alternate proposed name
(b) (4)			

Appendix F: Names identified by (b) (4) but not found in any other commonly used medical references (e.g. Facts & Comparison, Clinical Pharmacology, Drugs@FDA)

Proprietary Name	Similarity to Gralise
Gramal	(b) (4) – Look and/or Sound
Gravol	(b) (4) – Look and/or Sound
Reliser	(b) (4) – Look and/or Sound
Seralis	(b) (4) – Look and/or Sound

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

Appendix G: Proprietary name of a foreign non-drug product

Proprietary Name	Similarity to Gralise	Countries
Gralis	(b) (4) – Look and/or Sound	France, Italy, Lithuania

Appendix H: Proprietary names with no overlap in strength or dose

Product name with potential for confusion	Similarity to Gralise	Dosage Form/ Strength	Usual Dose
Gralise (Gabapentin)	**NA**	**Extended-Release Tablet: 300 mg, 600 mg**	**1800 mg once daily orally with evening meal** **Titration doses: 300 mg, 600 mg, 900 mg, 1200 mg, 1500 mg, 1800 mg**
Alesse (Levonorgestrel/ Ethinyl Estradiol) **Discontinued; Generics available*	(b) (4) - Look and/or Sound	Tablet: 100 mcg/20 mcg	1 tablet once daily orally
Cialis (Tadalafil)	Look and Sound	Tablet: 2.5 mg, 5 mg, 10 mg, 20 mg	10 mg once prior to sexual activity or 2.5 mg once daily
Dialose (Docusate sodium) **Over the counter*	Look	Tablet: 100 mg	100 mg (1 tablet) once daily
Galzin (Zinc Acetate)	(b) (4) - Look and/or Sound	Capsule: 25 mg, 50 mg	50 mg (1 capsule) orally three times daily
Gladase (Papain/Urea)	Look	Topical ointment : Papain 830,000 USPu/1 g ; Urea 10%	Apply topically to wound; Change dressing once to twice daily
Granisol (Granisetron)	(b) (4) - Look and/or Sound	Oral solution : 2 mg/10 mL	2 mg (10 mL) orally once daily or 1 mg (5 mL) orally twice daily
Granulex (Trypsin/ Peru Balsam/ Castor Oil)	(b) (4) - Look and/or Sound	Topical spray: 0.12 mg; 87mg; 788 mg/g	1 application twice daily topically
Miralax (Polyethylene Glycol 3350) **Over the counter*	Look	Powder for solution: 17 g/scoopful	Dissolve 1 scoopful (17 g) in 4 to 8 ounces of water and drink once daily
Orabase-B (Benzocaine) **Over the counter*	Look	Dental paste: 20%	Apply to affected area in mouth up to four times daily
Oralone (Triamcinolone Acetonide)	Look	Dental paste: 0.1%	Apply to affected area in mouth once to three times daily

**Discontinued generic – RLD available*			
Orudis (Ketoprofen) **Discontinued; Generics available*	Look	Capsule: 25 mg, 50 mg, 75 mg	25 mg to 75 mg (1 capsule) three to four times daily
Scabene (Lindane) **Discontinued; Generics available*	Look	Topical lotion and shampoo: 1%	Apply topically once and wash off in 8 to 12 hours; Shampoo for 4 min and wash hair
Talwin (Pentazocine Lactate) Talwin NX (Naloxone /Pentazocine) Talwin 50 (Pentazocine Hydrochloride) **Discontinued; no generics available* Talwin Compound (Aspirin/Pentazocine) **Discontinued; no generics available*	(b) (4) - Look and/or Sound	Talwin: Injectable: 30 mg/mL Talwin NX: Tablet: 0.5 mg/ 50 mg Talwin 50: Tablet: 50 mg Talwin Compound: Tablet: 325 mg/12.5 mg	Talwin: 30 mg intravenously, intramuscularly or subcutaneously given once or every 2 to 4 hours Talwin NX: 1 tablet every 3 or 4 hours; increase to 2 tablets if necessary

Appendix I: Proprietary names with differentiating product characteristics

Product name with potential for confusion	Similarity to Gralise	Dosage Form/ Strength	Usual Dose	Differentiating product characteristics (Product vs. Gralise)
Gralise **(Gabapentin)**	**NA**	**Extended-Release Tablet:** **300 mg, 600 mg**	**1800 mg once daily orally with evening meal** **Titration doses:** **300 mg, 600 mg, 900 mg, 1200 mg, 1500 mg, 1800 mg**	**NA**
Aleve (Naproxen Sodium)	(b) (4) - Look and/or Sound	Tablet: 200 mg	200 mg every 8 to 12 hours as needed	**Frequency:** every 8 to 12 hours vs. once daily **Dose:**. 200 mg vs. 1800 mg **Availability:** OTC vs. Rx
Glynase (Glyburide, micronized)	(b) (4) - Look and/or Sound	Tablet: 1.5 mg, 3 mg, 6 mg	Individualized to patient; Ranges from 0.75 mg/day to 12 mg/day given single or divided dose	**Strength:** 1.5 mg, 3 mg, 6 mg vs. 300 mg, 600 mg **Dose:**. 0.75 mg/day to 12 mg/ day vs. 1800 mg

Appendix J: Proprietary names with overlapping product characteristics but differentiating orthographic and phonetic characteristics

Proposed name: **Gralise** **(Gabapentin)**	**Dosage Form/Strength:** **Extended-Release Tablet: 300 mg, 600 mg**	**Usual Dose:** **1800 mg once daily orally with evening meal** **Titration doses: 300 mg, 600 mg, 900 mg, 1200 mg, 1500 mg, 1800 mg**
Failure Mode: Name confusion	**Causes (could be multiple)**	
Sustiva (Efavirenz) Capsule: 50 mg, 200 mg Tablet: 600 mg Dose: 600 mg once daily taken on an empty stomach	The first letters 'S' and 'G' look similar when scripted; 'u' and 'ra' look similar when scripted; both contain an upstroke ('l' and 't'); ending letters ('a' and 'e') look similar Both have overlapping route of administration (oral), strength (600 mg), dose (600 mg), same dosage form (tablet) and frequency of administration (daily).	Orthographic and product differences in the names minimize the likelihood of medication error in the usual practice setting. *Rationale*: The orthographic differences minimize the likelihood of medication errors. The name pair overlaps in only one letter ('i') and the rest of the letters are different. Therefore, in order for the two drugs to be confused for one another, the healthcare practitioner would need to misinterpret 6 out of the 7 letters in the name. Additionally, the cross-stroke in the letter 't' in Sustiva provides distinct differentiation between the name pair. S U S T I V A G R A L I S E In addition to orthographic differences, there are some product characteristic differences to minimize the risk of confusion. Sustiva is to be taken on empty stomach since taking with food can increase the frequency of adverse events of Sustiva. On the contrary, Gralise is to be taken with a meal. Sustiva must also be taken with other anti-retroviral medications and not to be taken by itself. Therefore, Sustiva will likely be ordered and dispensed with other HIV medications alerting that Sustiva is for HIV indication. Furthermore, In conclusion, the differences in the letters in addition to the product differences minimize the risk of confusion between the name pair.

Aralen (Chloroquine Phosphate) Tablet: 500 mg (=300 mg base) Depends on indication of use; Doses include: 1) 500 mg (=300 mg) on exactly the same day of each week. 2) 1 g (=600 mg base) followed by an additional 500 mg (= 300 mg base) after 6 to 8 hours and a single dose of 500 mg (= 300 mg base) on each of 2 consecutive days. 3) 1 g (=600 mg base) daily for 2 days, followed by 500 mg (=300 mg base) daily for at least 2 to 3 weeks.	The beginning letters (scripted 'A' and non-script 'G') can look similar; overlapping letters ('ral'); both contain an upstroke ('l') in the same location in the name. Overlapping route of administration (oral), strength (300 mg), dosage form (tablet), and frequency of administration (daily).	Orthographic and product differences minimize the likelihood of medication error in the usual practice setting. *Rationale*: Although the two products may overlap if Aralen is calculated in base strength (300 mg) and dose (300 mg), it is unlikely that prescribers will prescribe in base strength since the product is marketed and available in 500 mg. Thus, the difference in strength and dose will provide differentiation between the two products. Additionally, DMEPA's search of the VONA database from 2000 through 2009 showed total prescriptions for Aralen 500 mg was only 1,000 prescriptions in 2009 and none in 2008[1]. *[1]SDI, Vector One®: National, Years 2000 2009, Extracted 7/2010.* Furthermore, the difference in ending letters ('en' vs. 'se') may provide differentiation between the name pair. A R A L E N G R A L I S E

Application Type/Number	Submission Type/Number	Submitter Name	Product Name
NDA-22544	ORIG-1	ABBOTT PRODUCTS INC	GABAPENTIN E-R TABLETS

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