

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:
22-505

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: September 24, 2010

Application Type/Number: NDA 022505

Through: Zachary Oleszczuk, PharmD, Team Leader
Denise Toyer, PharmD, Deputy Director
Division of Medication Error Prevention and Analysis (DMEPA)

From: Cathy A. Miller, MPH, BSN, Safety Evaluator
Division of Medication Error Prevention and Analysis

Subject: Proprietary Name Review

Drug Name(s): Egrifta (Tesamorelin Acetate) for Injection
1 mg per vial

Applicant/Sponsor: Theratechnologies, Inc.

OSE RCM #: 2010-2006

1 INTRODUCTION

This re-assessment of the proprietary name is written in response to the anticipated approval of NDA 022505 within 90 days from the date of this review. The Division of Medication Error Prevention and Analysis (DMEPA) found the proposed proprietary name, Egrifta, acceptable in OSE Reviews #2009-1162 dated August 13, 2009 and OSE Review #2009-1338, dated May 6, 2010. The Division of Metabolism and Endocrinology Products did not have any concerns with the proposed name, Egrifta, and the Division of Drug Marketing, Advertising and Communications (DDMAC) found the name acceptable from a promotional perspective on July 2, 2009, December 30, 2009 and February 4, 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 OSE proprietary name review. We used the same search criteria previously used in OSE Reviews #2009-1162 and #2009-1558. 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 Analysis¹ (FMEA) of the proposed proprietary name, and focuses on the avoidance of medication errors.

The searches of the databases in Section 4 yield seven additional names thought to look like Egrifta. These names are: (b) (4), Xgeva***, (b) (4), and (b) (4).

Two of the seven names were eliminated for reasons described in Appendix A.

Failure mode and effects analysis (FMEA) was applied to determine if the proposed proprietary name could potentially be confused with the remaining five names and lead to medication errors. This analysis determined that the name similarity between Egrifta and five identified names was unlikely to result in medication error for the reasons presented in Appendix B.

DMEPA staff did not identify any United States Adopted Names (USAN) stems in the proposed proprietary name, Egrifta, as of September 16, 2010.

3 CONCLUSIONS AND RECOMMENDATIONS

The Proprietary Name Risk Assessment findings indicate that the proposed name, Egrifta, 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 has no objection to the proprietary name, Egrifta, 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 Metabolism and Endocrinology Products should notify DMEPA because the proprietary name must be re-reviewed prior to the new approval date.

¹ Institute for Healthcare Improvement (IHI). Failure Mode and Effects Analysis. Boston. IHI:2004.

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

4 REFERENCES

1. OSE review # 2009-1162 dated August 13, 2009; Proprietary Name Review of Egrifta; Miller, Cathy.
2. OSE review #2009-1558 dated May 6, 2010; Final Proprietary Name Review of Egrifta; Miller, Cathy.

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

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

3. ***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.

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 Name 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.

APPENDICES

Appendix A: Names Not Considered Further For Reasons Listed

Proprietary Name	Similarity to Visamerin	Reason/Comments
(b) (4)	Look-Alike	(b) (4)
	Look-Alike	

Appendix B: Potentially confusing names with orthographic and multiple differentiating product characteristics that decrease risk of medication errors.

Proposed name: Egrifta (Tesamorelin Acetate) for Injection	Strength: 1 mg/mL after reconstitution	Usual dose: 2 mg once daily subcutaneously
Failure Mode: Name confusion	Causes:	Prevention of Failure Mode:

(b) (4)

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Appendix B: Potentially confusing names with orthographic and multiple differentiating product characteristics that decrease risk of medication errors.

Proposed name: Egrifta (Tesamorelin Acetate) for Injection	Strength: 1 mg/mL after reconstitution	Usual dose: 2 mg once daily subcutaneously
Failure Mode: Name confusion	Causes:	Prevention of Failure Mode:

(b) (4)

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Appendix B: Potentially confusing names with orthographic and multiple differentiating product characteristics that decrease risk of medication errors.

Proposed name: Egrifta (Tesamorelin Acetate) for Injection	Strength: 1 mg/mL after reconstitution	Usual dose: 2 mg once daily subcutaneously
Failure Mode: Name confusion	Causes:	Prevention of Failure Mode:

(b) (4)



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Appendix B: Potentially confusing names with orthographic and multiple differentiating product characteristics that decrease risk of medication errors.

Proposed name: Egrifta (Tesamorelin Acetate) for Injection	Strength: 1 mg/mL after reconstitution	Usual dose: 2 mg once daily subcutaneously
Failure Mode: Name confusion	Causes:	Prevention of Failure Mode:
<p>Xgeva *** (Denosumab) Injection Strength: 120 mg/1.7 mL Dose: 120 mg every four weeks via subcutaneous injection ***Proposed proprietary name for BLA 125320 currently under review</p>	<p>Orthographic similarities: Both names contain the downstroke letter ‘g’ in the second letter position and contain the letter ‘a’ in the last letter position of the names.</p> <p>Overlapping product characteristics: Injection dosage forms Subcutaneous route of administration Single strength availability</p>	<p>Orthographic differences in the names in conjunction with variations in the dose preparation, and the dose presentation would minimize the potential for confusion.</p> <p>Orthographic differences: The first capital letter ‘X’ appears different than ‘E’ when scripted and the two upstroke/cross-stroke letters ‘ft’ in Egrifta are not present in Xgeva and provide orthographic distinction when scripted.</p> <p>Differentiating product characteristics: Egrifta is a powder for injection requiring that two 1 mg vials be reconstituted to achieve a dose of 2 mg. Instructions for use include detailed reference to how the product should be reconstituted and injected. Xgeva is a solution for injection available in a single use vial. Because both products are injections, the dose would likely be included on prescription orders (2 mg versus 120 mg). These differentiating product characteristics would likely prompt practitioners to verify the intended order if name confusion occurred.</p>

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Appendix B: Potentially confusing names with orthographic and multiple differentiating product characteristics that decrease risk of medication errors.

Proposed name: Egrifta (Tesamorelin Acetate) for Injection	Strength: 1 mg/mL after reconstitution	Usual dose: 2 mg once daily subcutaneously
Failure Mode: Name confusion	Causes:	Prevention of Failure Mode:

(b) (4)

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/s/

CATHY A MILLER
09/24/2010

ZACHARY A OLESZCZUK
09/24/2010

DENISE P TOYER
09/24/2010



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

Date: May 6, 2010

To: Mary Parks, M.D., Director
Division of Metabolism and Endocrinology Products

Through: Zachary Oleszczuk, PharmD, Acting Team Leader
Denise Toyer, PharmD, Deputy Director
Division of Medication Error Prevention and Analysis (DMEPA)

From: Cathy A. Miller, BSN, MPH, Safety Evaluator
Division of Medication Error Prevention and Analysis (DMEPA)

Subject: Proprietary Name Review

Drug Name(s): Egrifta (Tesamorelin Acetate) for Injection
1 mg per vial

Application Type/Number: NDA 022505

Applicant: Theratechnologies, Inc.

OSE RCM #: 2009-1558

1 INTRODUCTION

This re-assessment of the proprietary name is written in response to the anticipated approval of NDA 022505 within 90 days from the date of this review. The Division of Medication Error Prevention and Analysis (DMEPA) found the proposed proprietary name, Egrifta, acceptable in OSE Review #2009-1162 dated August 13, 2009. The Division of Metabolism and Endocrinology Products did not have any concerns with the proposed name, Egrifta, and the Division of Drug Marketing, Advertising and Communications (DDMAC) found the name acceptable from a promotional perspective on July 2, 2009, December 30, 2009 and February 4, 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 OSE proprietary name review. We used the same search criteria previously used in OSE Review# 2009-1162 dated August 13, 2009 for the proposed proprietary name, Egrifta. 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 Analysis¹ (FMEA) of the proposed proprietary name, and focuses on the avoidance of medication errors.

The searches of the databases in Section 4 did not yield any new names thought to look or sound similar to, Egrifta, and represent a potential source of name confusion.

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

3 CONCLUSIONS AND RECOMMENDATIONS

The Proprietary Name Risk Assessment findings indicate that the proposed name, Egrifta, 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 has no objection to the proprietary name, Egrifta, 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 Metabolism and Endocrinology Products should notify DMEPA because the proprietary name must be re-reviewed prior to the new approval date.

¹ Institute for Healthcare Improvement (IHI). Failure Mode and Effects Analysis. Boston. IHI:2004.

4 REFERENCES

1. OSE review # 2009-1162 dated August 13, 2009; Proprietary Name Review of Egrifta; Miller, Cathy.

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

Drugs@FDA contains most of the drug products approved since 1939. The majority of labels, approval letters, reviews, and other information are available for drug products approved from 1998 to the present.

Drugs@FDA contains official information about FDA approved [brand name](#), [generic drugs](#), [therapeutic biological products](#), [prescription](#) and [over-the-counter](#) human drugs and [discontinued drugs](#) and “[Chemical Type 6](#)” approvals.

3. *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.

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 Name 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-22505	ORIG-1	THERATECHNOLOGIES INC	Egrifta

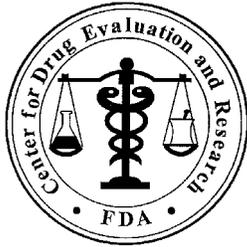
This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

CATHY A MILLER
05/06/2010

ZACHARY A OLESZCZUK
05/06/2010

DENISE P TOYER
05/06/2010



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

Date: August 13, 2009

To: Mark Parks, MD, Director
Division of Metabolism and Endocrinology Products

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

From: Cathy A. Miller, BSN, MPH, Safety Evaluator
Division of Medication Error Prevention and Analysis (DMEPA)

Subject: Proprietary Name Review

Drug Name(s): Egrifta (Tesamorelin Acetate) for Injection
1.1 mg per vial

Application Type/Number: NDA 22-505

Sponsor: Theratechnologies, Inc.

OSE RCM #: 2009-1162

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EXECUTIVE SUMMARY

This review is written in response to a request from Theratechnologies, Inc. dated April 27, 2009 to evaluate the proposed proprietary name, Egrifta. Egrifta is the proposed proprietary name for Tesamorelin Acetate for injection. 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, Egrifta, conditionally acceptable for this product. The proposed name must be reevaluated 90 days before approval of the NDA, even if the proposed product characteristics as stated in this review are not altered.

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 written in response to a request from Theratechnologies, Inc. dated June 17, 2009, for an assessment of the proposed proprietary name, Egrifta, regarding potential name confusion with other proprietary or established drug names in the usual practice settings. Along with their submission, the Applicant also submitted an independent proprietary name study performed by (b) (4) for this review. The Applicant also included container labels and carton labeling for review with this submission which will be evaluated in a separate forthcoming OSE review.

1.2 PRODUCT INFORMATION

Egrifta (Tesamorelin Acetate) for injection is being developed for the indication of induction and reduction of excess abdominal fat in HIV-infected patients with Lipodystrophy. Egrifta is a synthetic human Growth Hormone-Releasing Factor analogue that comprises the 44-amino acid sequence of human Growth Hormone-Releasing Factor (hGRF) with a binding affinity to hGRF receptors comparable to that of natural hGRF and an increased stability and half-life in humans.

The recommended dose of Egrifta is 2 mg injected subcutaneously once daily, preferably in the morning. Egrifta is supplied in a vial containing 1.1 mg of Tesamorelin Acetate and 55 mg of Mannitol as a lyophilized powder (1 mg/mL). The diluent (Sterile Water for Injection, USP) is provided in a separate vial for reconstitution. To mix Egrifta for administration, 2.2 mL of Sterile Water is first injected into Egrifta vial #1, mixed and drawn up into a syringe, and then injected into Egrifta vial #2. After mixing, 2 mL should be withdrawn for a final concentration of 2 mg/2 mL. If not used immediately, Egrifta should be discarded and should not be frozen or refrigerated after reconstitution. Egrifta should be administered subcutaneously and the recommended injection site is the abdomen, with injection sites rotated to different areas of the abdomen. Egrifta should not be injected into scar tissue, bruises or the navel.

Egrifta is supplied as a kit with two boxes of material. Box #1 (called the Medication Box) contains 60 Egrifta vials. Box #2 (called Injection Kit Box) contains (30) 10 mL vials of Sterile

Water for Injection, USP, (30) syringes with needles already attached, (30) 1 1/2” 18-gauge reconstitution needles (b) (4) and (30) injection needles 1/2” 27-gauge. Non-reconstituted vials of Egrifta should be refrigerated at 2°C to 8°C (36°F to 46°F).

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, Egrifta.

2.1 SEARCH CRITERIA

For this review, particular consideration was given to drug names beginning with the letter ‘E’ when searching to identify potentially similar drug names, as 75% of the confused drug names reported by the ISMP Medication Error Reporting Program involve pairs beginning with the same letter.^{1,2}

To identify drug names that may look similar to Egrifta, 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 (seven letters), upstrokes (three, capital letter ‘E’, and lowercase letters ‘f’ and ‘t’), down strokes (two, lower case letters ‘g’ and ‘f’), cross strokes (two, lower case letter ‘t’ or lower case ‘f’ if printed), and dotted (none). DMEPA also considers the variation in the appearance of the name if the lower case letter ‘f’ is not scripted with a downstroke. Additionally, several letters in Egrifta 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 Egrifta.

When searching to identify potential names that may sound similar to Egrifta, the DMEPA staff search for names with similar number of syllables (Three), stresses (E-grif-ta, e-GRIF-ta and e-grif-TA), and placement of vowel and consonant sounds. Additionally, the DMEPA staff considers that pronunciation of parts of the name can vary such as ‘E’ may sound like ‘Ah’ or ‘Ee’, and ‘grifta’ can sound like ‘gripta’ and ‘ta’ can sound like ‘da’. (See Appendix B) The Sponsor’s intended pronunciation (eh-GRIF-tuh) was also taken into consideration, as it was included in the Proprietary Name Review Request. However, names are often mispronounced and/or spoken with regional accents and dialects, so the potential pronunciations of the name are considered.

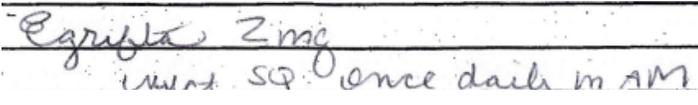
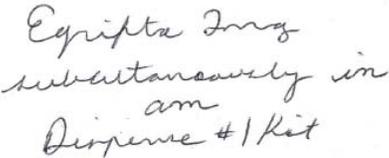
2.2 FDA PRESCRIPTION ANALYSIS STUDIES

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

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

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

Figure 1. Egrifta Rx Study (conducted on July 9, 2009)

HANDWRITTEN REQUISITION MEDICATION ORDER	VERBAL PRESCRIPTION
<p><u>Inpatient Medication Order:</u></p>  <p><i>Egrifta 2mg SQ once daily in AM</i></p>	<p>Egrifta</p> <p>Inject 2 milligrams subcutaneously each morning</p> <p>#1</p>
<p><u>Outpatient Prescription:</u></p>  <p><i>Egrifta 2mg subcutaneously in am Dispense #1 Kit</i></p>	

2.3 EXTERNAL PROPRIETARY NAME RISK ASSESSMENT

For this product, the Applicant submitted an external evaluation of the proposed proprietary name conducted by (b) (4) Inc. in June 2007. DMEPA 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 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, DMEPA provides a detailed explanation of these differences.

3 RESULTS

3.1 DATABASE AND INFORMATION SOURCES

The searches yielded a total of eight names as having some similarity to the name Egrifta.

All eight names identified were thought to look like Egrifta. These include: Agrylin, Egifilin, Eprolin, Epifenac, Epsilon, Eyeflur, (b) (4)*** and Prifitin.

Additionally, DMEPA staff did not identify any United States Adopted Names (USAN) stems in the proposed proprietary name, as of July 23, 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 Egrifta.

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

Twenty practitioners responded with none of the responses overlapping with an existing name. Nine participants interpreted the name correctly as “Egrifta,” with correct interpretation occurring only in the written studies. The majority of the misinterpretations in the written studies including ‘fta’ being misinterpreted as ‘pta’ (n=8). In the verbal studies, all responses were misspelled phonetic variations of the proposed name, Egrifta including ‘Agresta’ and ‘Aguesta’. See Appendix C for the complete listing of interpretations from the verbal and written prescription studies.

3.4 EXTERNAL STUDY

In the proposed name risk assessment submitted by the Applicant, (b) (4) identified and evaluated a total of 13 names thought to have some potential for confusion with the name Egrifta. Four of the names were thought to look like Egrifta: Anzemet, Estradiol, Omnicef and Quinapril. Six of the names were thought to sound like Egrifta: Aggrennox, Apligraf, Arixtra, Effexor, Requip and Rescriptor. Three names were thought to look and sound like Egrifta: Atrippla, Evista, and Prograf. Of the 13 names identified by the external study, DMEPA also identified Evista in the individual Safety Evaluator Risk Assessment (See Section 3.6). Thus, twelve names, Aggrennox, Anzemet, Apligraf, Arixtra, Atrippla, Effexor, Estradiol, Omnicef, Prograf, Quinapril, Requip, and Rescriptor will be added to the Safety Evaluator Risk Assessment.

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3.5 COMMENTS FROM THE DIVISION

In response to the OSE Date, June 21, 2009 e-mail, the Division of Metabolism and Endocrine Products (DMEP) did not forward any comments and/or concerns on the proposed name at the initial phase of the name review.

DMEPA notified the Division of Metabolism and Endocrine Products via e-mail that we had no objections to the proposed proprietary name, Egrifta, on August 7, 2009. Per e-mail correspondence from the Division of Metabolism and Endocrine Products on August 13, 2009, they indicated they had no concerns with the proposed proprietary name, Egrifta.

3.6 SAFETY EVALUATOR RISK ASSESSMENT

Independent searches by the primary Safety Evaluator resulted in the identification of 12 additional names which were thought to look or sound similar to Egrifta and represent a potential source of drug name confusion. Eleven names were thought to look like Egrifta including Apidra, Azopt, Byetta, Efudex, Epiduo, Epliga^{***}, Equetro, Etrafon, Exjade, Nplate and Reglan. One name, Evista, was thought to sound like Egrifta.

4 DISCUSSION

Neither DDMAC nor the review Division had concerns with the proposed name. DMEPA did not identify any issues other than sound and look-alike concerns that would render the name objectionable.

DMEPA identified and evaluated 32 names for their potential sound and look-alike similarity to the proposed name, Egrifta. Eight names lacked orthographic and/or phonetic similarity 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 24 names and lead to medication errors. This analysis determined that the name similarity between Egrifta was unlikely to result in medication errors with any of the 24 products for the reasons presented in Appendices E through J.

5 CONCLUSIONS AND RECOMMENDATIONS

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

However, if any of the proposed product characteristics as stated in this review are altered, 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. The proposed name must be resubmitted for

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

evaluation with the submission of the NDA. For questions or clarifications, please contact Mildred Wright, OSE Project Manager, at 301-796-1027.

6 COMMENTS TO THE APPLICANT

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

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

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

7 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 the overall risk assessment on the findings of a Failure Mode and Effects Analysis (FMEA) of the proprietary name, and focuses on the avoidance of medication errors.

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

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

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

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

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

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

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

because similarly 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 Sponsor’s intended pronunciation of the proprietary name. However, DMEPA also considers a variety of pronunciations that could occur in the English language because the Sponsor has little control over how the name will be spoken in clinical practice.

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

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

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

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

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)].

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

- 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 Sponsor 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 Sponsor with recommendations that reduce or eliminate the potential for error and, thereby, would render the proposed name acceptable.

In the event that DMEPA objects to the use of the proposed proprietary name, based upon the potential for confusion with another proposed (but not yet approved) proprietary name, DMEPA will provide a contingency objection based on the date of approval. Whichever product, the Agency approves first has the right to use the proprietary name, while DMEPA will recommend that the second product to reach approval seek an alternative name.

The threshold set for objection to the proposed proprietary name may seem low to the Sponsor. 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), the Joint Commission, and the Institute for Safe Medication Practices (ISMP). These organizations have examined medication errors resulting from look- or sound-alike drug names 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 Sponsor can identify and rectify prior to approval to avoid patient harm.

Furthermore, post-marketing experience has demonstrated that medication errors resulting from drug name confusion are notoriously difficult to rectify post-approval. Educational and other post-approval efforts are low-leverage strategies that have had limited effectiveness at alleviating medication errors involving drug name confusion. Sponsors have undertaken higher-leverage strategies, such as drug name changes, in the past but at great financial cost to the Sponsor and at the expense of the public welfare, not to mention the Agency's credibility as the authority responsible for approving the error-prone proprietary name. Moreover, even after Sponsors' have changed a product's proprietary name in the post-approval phase, it is difficult to eradicate the original proprietary name from practitioners' vocabulary, and as a result, the Agency has continued to receive reports of drug name confusion long after a name change in some instances. Therefore, DMEPA believes that post-approval efforts at reducing name confusion errors should be reserved for those cases in which the potential for name confusion could not be predicted prior to approval. . (See Section 4 for limitations of the process).

Appendix B: Letters with possible orthographic or phonetic misinterpretation

Letters in Name: Egrifta	Scripted may appear as	Spoken may be interpreted as
Capital 'E'	C, Ce, Cl, O, I or T	A, Ee, Ah, Uh
lower case letters 'grif'	---	grip
lower case 'g'	z, j, y, q, or f	j or k
lower case letters 'ta'	---	da
Lower case 'r'	n, a, u, or v	
lower case 'i'	e, l, r or u	any vowel
lower case 'f'	z, j, p or t	p
lower case 't'	l, i, b or f	d
lower case 'a'	o, e, r, c, ci, ce, u or x	any vowel

Appendix C: FDA Prescription Study Responses.

Inpatient Medication Order	Outpatient Prescription	Voice Prescription
Egrifta	Egrifta	Agresta
Egrifta	Egrifta	Aguesta
Egrifta	Egrifta	
Egrifta	Egrifta	
Egrifta	Egripta	
	Equipta	

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

Proprietary Name	Similarity to Egrifta
Aggrennox	Sound-Alike from (b) (4)
Anzemet	Look-Alike from (b) (4)
Estradiol	Look-Alike from (b) (4)
Omnicef	Look-Alike from (b) (4)
Prograf	Look- and Sound-Alike from (b) (4)
Quinapril	Look-Alike from (b) (4)
Requip	Sound-Alike from (b) (4)
Rescriptor	Sound-alike from (b) (4)

Appendix E: Proprietary names that are internationally registered

Proprietary Name	Similarity to Egrifta	Active Ingredient	Country
Egifilin	Look-Alike	Theophylline	Hungary
Eyeflur	Look-Alike	Flurbiprofen	Greece
Epifenac	Look-Alike	Diclofenac	Bahrain, Egypt, Iraq, Jordan, Kuwait, Lebanon, Libya, Oman, Qatar, Romania, Saudi Arabia, Sudan, United Arab Emirates and Yemen

Appendix F: Look-Alike Names of pending Applications with the Agency multiple differentiating product characteristics

Proprietary Name				Application Status
Egrifta (Tesamorelin Acetate)	1.1 mg per vial with reconstitution concentration of 1 mg/mL	2 mg once daily subcutaneously	Route of administration is subcutaneous Dosage form is lyophilized powder for injection Dose expressed as '2 mg' on prescription orders One Strength Available	
				(b) (4)
Epliga*** (Oxcarbazepine)				(b) (4)

^{7***} This is proprietary and confidential information that should not be released to the public. ***

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

Product name with potential for confusion	Similarity to Proposed Proprietary Name	Strength	Indication Usual Dose (if applicable)
Egrifta (Tesamorelin Acetate) Powder for Injection		1.1 mg per vial with reconstitution concentration of 1 mg/mL	To induce and maintain a reduction of excess abdominal fat in HIV-infected patients with lipodystrophy 2 mg once daily subcutaneously
Effexor (Venlafaxine Hydrochloride)	Sound-Alike by (b) (4)	25 mg, 37.5 mg, 50 mg, 75 mg, and 100 mg Tablets	Treatment of major depression 75 mg per day in two divided doses; dose may be increased to 225 mg per day in two to three divided doses
Exjade (Deferasirox)	Look-Alike	125 mg, 250 mg and 500 mg Tablets	Treatment of chronic iron overload due to blood transfusions 20 mg/kg daily; adjust dose in steps of 5 mcg/kg to 10 mcg/kg according to patient's response

Appendix H: Single strength overlap but differentiating product characteristics

Product name with potential for confusion	Strength	Usual Dose (if applicable)	Differentiating Product Characteristics
Egrifta (Tesamorelin Acetate) Powder for Injection	1.1 mg per vial with reconstitution concentration of 1 mg/mL	2 mg once daily subcutaneously	Route of administration is subcutaneous requiring preparation in syringe Dosage form is lyophilized powder for injection Dose expressed as '2 mg' on prescription orders
Apligraf (Living Skin Substitute) Disk	75 mm diameter disk	Apply to site weekly	Route of administration is topical Dosage form is skin graft/tissue Dose expressed as "apply" to area
Byetta (Exenatide)	250 mcg/mL	5 mcg to 10 mcg twice daily	Route of administration subcutaneous but includes device (pen) Dosage form is solution for injection Dose expressed '5 mcg' or 10 mcg' twice daily
Epiduo (Adapalene and Benzoyl Peroxide)	0.1 % Adapalene and 2.5 % Benzoyl Peroxide	Apply thin layer to face and/or trunk once daily	Route of administration is topical Dosage form is Topical Gel or Topical Solution Dose expressed as 'apply' to face/trunk

Evista (Raloxifene)	60 mg Tablet	One tablet daily	Route of administration is oral Dosage form is tablet Dose expressed as 'take one' or '60 mg' daily
Priftin (Rifapentine)	150 mg Tablet	Four tablets (600 mg) twice weekly for two months	Route of administration is oral Dosage form is tablet Dose likely to be expressed "150 mg – Take four tablets"

Appendix I: Numeric overlap in strength or dose but with differentiating product characteristics

Product name with potential for confusion	Strength	Usual Dose (if applicable)	Differentiating Product Characteristics
Egrifta (Tesamorelin Acetate) Powder for Injection	1.1 mg per vial with reconstitution concentration of 1 mg/mL	2 mg once daily subcutaneously	Route of administration is subcutaneous requiring preparation in syringe Dosage form is lyophilized powder for injection Dose expressed as '2 mg' on prescription orders One strength available Administration: Self-administration
Agrylin (Anagrelide Hydrochloride)	0.5 mg and 1 mg capsules	0.5 mg to 1 mg twice daily	Route of administration is oral Dosage form is capsule Dose expressed as '0.5 mg' or '1 mg' twice daily Two strengths available
Arixtra (Fondaparinux Sodium)	2.5 mg/0.5 mL, 5 mg/0.4 mL, 7.5 mg/0.6 mL and 10 mg/0.8 mL Solution for Injection	2.5 mg, 5 mg, 7.5 mg or 10 mg once daily	Dosage form is solution for injection Dose expressed as '2.5', '5', '7.5' or '10' mg Four strengths available
Azopt (Brinzolamide)	1 % Ophthalmic Solution	One drop to affected eye three times daily	Route of administration is topical ophthalmic Dosage form is Ophthalmic solution Dose expressed as 'instill one drop'
Efudex (Fluorouracil)	2 % and 5 % topical solution and cream	Apply twice daily to cover lesion	Route of administration is topical Dosage forms are topical solution and topical cream Dose expressed as 'apply to lesion'

			Two strengths available
Eprolin (Vitamin E)	200 units , 400 units and 1000 unit capsules	200 units to 1000 units once daily	Route of administration is oral Dosage form is capsule Three strengths available
Epsilan (Vitamin E)	200 units , 400 units and 1000 unit capsules	200 units to 1000 units once daily	Route of administration is oral Dosage form is capsule Three strengths available
Etrafon (Perphenazine and Amitriptyline)	2 mg/10 mg , 2 mg/25 mg and 4 mg/25 mg tablets	2 mg/10 mg to 4 mg/25 mg in two to four divided doses daily	Route of administration is oral Dosage form is tablet Three strengths available expressed in combination dose form
Equetro (Carbamazepine XR)	100 mg , 200 mg , and 300 mg	400 mg per day in divided doses; dose adjusted in 200 mg increments to maximum dose of 1600 mg per day	Route of administration is oral Dosage form is Extended-release capsule Dose expressed as '400 mg' or greater Three strengths available
NPlate (Romiplostim)	250 mcg/vial and 500 mcg/vial	1 mcg/kg initial dose; adjust dose in increments of 1 mcg/kg not to exceed 10 mcg/kg weekly	Route of administration is intravenous infusion Dose expressed in mcg/kg or mcg dose which would not have numeric overlap Two strengths available Administration: In clinical setting administered by health care professional
Reglan (Metoclopramide)	5 mg and 10 mg	10 mg to 15 mg four times daily	Route of administration is oral Dose expressed as '10 mg' or '15 mg' Two strengths available

Appendix J: Drug names with potential for confusion

<p>Proposed name: Egrifta</p>	<p>Strength 1.1 mg per vial with reconstitution concentration of 1 mg/mL</p>	<p>Indication: To induce and maintain a reduction of excess abdominal fat in HIV-infected patients with lipodystrophy Usual Dose: 2 mg once daily subcutaneously</p>
<p>Failure Mode: Name confusion</p>	<p>Causes</p>	<p>Prevention of Failure (name confusion) Leading to a Medication Error</p>
<p>Apidra (Insulin Glulisine) Injection 100 units/mL <u>Supplied as:</u> 10 mL vial 3 mL cartridge (OptiClik) 3 mL SolStar prefilled pen <u>Usual dose:</u> Subcutaneous Injection: Dose individualized based on blood glucose reading (usually between 0.5 to 1 unit/kg/day. Administer within fifteen minutes before a meal or within twenty minutes after starting meal Continuous Subcutaneous Infusion: Infusion rate based on individual blood glucose reading Intravenous Administration: Used in concentrations of 0.05 units/mL to 1 unit/mL with dose medically supervised for glycemic control based on individual blood glucose readings</p>	<p>Orthographic similarity: The capital letter ‘E’ can look like the capital letter ‘A’; the second letter ‘g’ can look like the second letter ‘p’; both names end with the letter ‘a’.</p>	<p>Orthographic differences in the names and differences in usual dose and dose presentation minimize the likelihood for confusion to result in a medication error. <i>Rationale:</i> Egrifta contains two upstroke/crossstrokes ‘f’ and ‘t’ at the end of the word that are not present in the same letter positions of Apidra, providing differentiating distinction in the shape/appearance of the name. Also, Egrifta contains an ‘f’ in the third from the last letter position that, if scripted as a downstroke, may provide added distinction. The dose presentation on prescription orders for the two names vary and provide distinction. <u>Outpatient prescription or Inpatient orders for subcutaneous injections would be written:</u> “Egrifta Use as Directed” Disp #1 Kit “Apidra” Use as directed Disp #1 vial or Disp #30 cartridges <u>Inpatient orders for Apidra subcutaneous injection and continuous intravenous infusion would be written:</u> Apidra “X units” subcutaneous. Although there is potential for numeric overlap in dose (2 mg versus 2 units) the usual dose for Apidra is much greater than 2 units (usually 0.5 unit to 1 unit per kg per day) and healthcare providers would likely question an Apidra order of 2 units SQ. Inpatient orders for Apidra are likely to be written to include “follow sliding scale” rather than specific “give 2 units”.</p>

		<p>Additionally, Apridra is administered several times daily ‘with meals’ and the units of measure is units versus milligrams (mg) for Egrifta.</p> <p>Apidra continuous infusion at ‘X’ units per hour; adjust according to blood glucose readings every ‘X’ hours. Although the units per hour infusion could overlap numerically with the Egrifta dose (2 units versus 2 mg) the route of administration (SQ versus IV) and the units of measure (mg versus units per hour) would be presented on orders, providing distinction that would minimize the potential for medication error.</p>
<p>Atripla (Efavirenz, Emtricitabine and Tenofovir Disproxil Fumarate) 600 mg/200 mg/300 mg tablet One tablet daily before bedtime</p>	<p>Orthographic similarities include: The capital letter ‘A’ can look like the capital letter ‘E’ and ‘pla’ can look like ‘fta’.</p> <p>Egrifta prescriptions may not always include the dose ‘2 mg’ but may be written instead as ‘Use as directed’.</p>	<p>Orthographic differences in the names and differences in usual dose and dose presentation minimize the likelihood for confusion to result in a medication error.</p> <p><i>Rationale:</i></p> <p>The upstroke/cross-stroke ‘t’ in Atripla varies from the downstroke ‘g’ in Egrifta.</p> <p>Although Egrifta may be written ‘use as directed’ without the dose included, prescription orders for Atripla would be written “Atripla Take one’ or ‘Take one tablet daily’. The words ‘take one’ and ‘take one tablet’ provide differentiation from ‘use as directed’ since Egrifta is an injection and ‘take’ or ‘take one’ does not apply to its use. Additionally, prescription orders written ‘use as directed’ may alert practitioners to look more carefully at both the name and the product information.</p>

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CATHY A MILLER
08/13/2009

KELLIE A TAYLOR
08/13/2009

DENISE P TOYER
08/14/2009

CAROL A HOLQUIST
08/14/2009