CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

203565Orig1s000

PROPRIETARY NAME REVIEW(S)

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

Proprietary Name Review

Date:	June 26, 2013
Reviewer:	Kevin Wright, PharmD Division of Medication Error Prevention and Analysis
Team Leader:	Yelena Maslov, PharmD Division of Medication Error Prevention and Analysis
Division Director:	Carol Holquist, RPh Division of Medication Error Prevention and Analysis
Drug Name and Strength:	Injectafer (Ferric Carboxymaltose) Injection 750 mg per 15 mL (50 mg per mL)
Application Type/Number:	NDA 203565
Applicant/Sponsor:	Luitpold Pharmaceuticals, Inc.
OSE RCM #:	2013-849

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

CONTENTS

1 INTRODUCTION

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

1.1 REGULATORY HISTORY

The proposed proprietary name, Injectafer, was found conditionally acceptable in OSE Review# 2011-4477 dated February 22, 2012.

1.2 PRODUCT INFORMATION

The following product information is provided in the April 2, 2013 proprietary name submission.

- Active Ingredient: Ferric Carboxymaltose
- Indication of Use: indicated in the treatment of iron deficiency anemia in patients who are intolerant to oral iron and patients with chronic kidney disease
- Intended pronunciation: in-jekt-a-fer
- Route of Administration: Intravenous
- Dosage Form: Injection
- Strength: 750 mg Iron per 15 mL (50 mg per mL)
- Dose and Frequency: The recommended dosage is 15 mg/kg up to a maximum single dose of 750 mg of iron on two occasions separated by at least 7 days up to a cumulative dose of 1500 mg of iron. Injectafer treatment may be repeated if iron deficiency reoccurs.
- How Supplied: Single use vials
- Storage: store at 20° C to 25° C
- Container and Closure Systems: 15 mL vial

2. RESULTS

The following sections provide the information obtained and considered in the overall evaluation of the proposed proprietary name.

2.1 PROMOTIONAL ASSESSMENT

The Office of Prescription Drug Promotion OPDP determined the proposed name is acceptable from a promotional perspective. DMEPA and the Division of Hematology Products (DHP) concurred with the findings of OPDP's promotional assessment of the proposed name.

2.2 SAFETY ASSESSMENT

The following aspects were considered in the safety evaluation of the name.

2.2.1 United States Adopted Names (USAN) SEARCH

The June 11, 2013 search of the United States Adopted Name (USAN) stems did not identify that a USAN stem is present in the proposed proprietary name.

2.2.2 Components of the Proposed Proprietary Name

The Applicant indicated in their submission that the proposed name, Injectafer, is derived from the word "inject" and the suffix "fer", a part of the word "ferrous" or "ferric" referring to iron with the latter "a" in between. This proprietary name is comprised of a single word that does not contain any additional components (i.e. a modifier, route of administration, dosage form, etc.).

2.2.3 FDA Name Simulation Studies

Sixty-eight practitioners participated in DMEPA's prescription studies. The interpretations did not overlap with any currently marketed products nor did they appear or sound similar to any currently marketed products or products pending approval. In the written studies, 43 of 48 participants correctly interpreted the prescription. Common misinterpretations in the written study were the substitution of 'o', for 'a' and 'fen' and 'able' for 'fer'. In the voice study 5 of 20 participants correctly interpreted the prescription. Common misinterpretations in the voice study include: 'i' and 'o' for 'a'. We have considered these variations in our look-alike and sound-alike searches and analysis (see Appendix B). Appendix C contains the complete listing of interpretations from the verbal and written prescription studies.

2.2.4 Comments from Other Review Disciplines at Initial Review

In response to the OSE, May 3, 2013 e-mail, the Division of Hematology Products (DHP) did not forward any comments or concerns relating to the proposed name at the initial phase of the proprietary name review.

2.2.5 Failure Mode and Effects Analysis of Similar Names

Appendix B lists possible orthographic and phonetic misinterpretations of the letters and letter strings comprising the proposed proprietary name, Injectafer. Table 1 lists 33 names identified by the primary reviewer, the Expert Panel Discussion (EPD), (b) (4) and other review disciplines to have potential orthographic, phonetic, or spelling similarity to the proposed proprietary name, Injectafer.

DMEPA previously identified, evaluated, and determined 17 of the 33 names contained in Table 1 did not pose a risk for name confusion, Abacavir, Azactam, Caverject, Enegerix-B, (b) (4)***, Infanrix, Infectro, Infergen, Inlyta, Innertabs, Instafent, Pyrilafen Tannate, Spectazole, Angiofluor, Enjuvia, Injectapap, Venofer, (OSE Review 2011-4477 dated February 22, 2012). Since the product characteristics remain unchanged, and I agree with the conclusions reached in the previous review, this determination remains unchanged. The remaining 16 names were evaluated for their similarity to Injectafer and determined not to be a risk for confusion as described in Appendices D and E.

Table 1: Collective List of Potentially Similar Names (DMEPA, EPD, Other Disciplines, and External Name Study)					
Look Similar					
Abacavir	External Study	Amphadase TF	EPD	Angeliq	EPD
Azactam	External Study	Caverject	Both	Engerix-B	EPD
Engystol n	EPD	Ergocalciferol	EPD	Ergostat	EPD
Ergotrate	EPD	(b) (4)***	EPD	(b) (4)***	EPD
Infanrix	External Study	Infantaire	EPD	Infectrol	External Study
Infergen	EPD	Inlyta	EPD	Innertabs	External Study
Instafent	EPD	Integra	EPD	Interferon	EPD
Lagotine	EPD	Linjeta***	EPD	Onglyza	EPD
Pyrilafen Tannate	EPD	Spectazole	EPD		
Sound Similar					
Ivacaftor	EPD				
Look and Sound Similar					
Angiofluor	EPD	Enjuvia	EPD	Jectofer	EPD
Injectafer	EPD	Injectapap (2)	EPD	Venofer	Both

2.2.6 Communication of DMEPA's Analysis at Midpoint of Review

DMEPA communicated our findings to the Division of Hematology Products (DHP) via e-mail on June 17, 2013. At that time we also requested additional information or concerns that could inform our review. Per e-mail correspondence from the Division of Hematology Products (DHP) on June 25, 2013, they stated no additional concerns with the proposed proprietary name, Injectafer.

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3 CONCLUSIONS

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

If you have further questions or need clarifications, please contact Sue Kang, OSE project manager, at 301-796-4216.

3.1 COMMENTS TO THE APPLICANT

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

The proposed proprietary name must be re-reviewed 90 days prior to approval of the NDA. The results are subject to change. If any of the proposed product characteristics as stated in your April 2, 2013 submission are altered, the name must be resubmitted for review.

4 REFERENCES

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

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

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

   POCA is a database which was created for the Division of Medication Error Prevention and Analysis, FDA. As part of the name similarity assessment, proposed names are evaluated via a phonetic/orthographic algorithm. The proposed proprietary name is converted into its phonemic representation before it runs through the phonetic algorithm. Likewise, an orthographic algorithm exists which operates in a similar fashion.

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

   Drug Facts and Comparisons is a compendium organized by therapeutic course; it contains monographs on prescription and OTC drugs, with charts comparing similar products. This database also lists the orphan drugs.

4. ***FDA Document Archiving, Reporting & Regulatory Tracking System [DARRTS]***

   DARRTS is a government database used to organize Applicant and Sponsor submissions as well as to store and organize assignments, reviews, and communications from the review divisions.

5. ***Division of Medication Errors Prevention and Analysis proprietary name consultation requests***

   This is a list of proposed and pending names that is generated by the Division of Medication Error Prevention and Analysis from the Access database/tracking system.

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

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

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

   USPTO provides information regarding patent and trademarks.

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

   Clinical Pharmacology contains full monographs for the most common drugs in clinical use, plus mini monographs covering investigational, less common,

combination, nutraceutical and nutritional products. It also provides a keyword search engine.

9. ***Data provided by Thomson & Thomson's SAEGIS ™ Online Service, available at (www.thomson-thomson.com)***

   The Pharma In-Use Search database contains over 400,000 unique pharmaceutical trademarks and trade names that are used in about 50 countries worldwide. The data is provided under license by IMS HEALTH.

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

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

11. ***Access Medicine (www.accessmedicine.com)***

    Access Medicine® from McGraw-Hill contains full-text information from approximately 60 titles; it includes tables and references. Among the titles are: Harrison's Principles of Internal Medicine, Basic & Clinical Pharmacology, and Goodman and Gilman's The Pharmacologic Basis of Therapeutics.

12. ***USAN Stems (http://www.ama-assn.org/ama/pub/about-ama/our-people/coalitions-consortiums/united-states-adopted-names-council/naming-guidelines/approved-stems.shtml)***

    USAN Stems List contains all the recognized USAN stems.

13. ***Red Book (www.thomsonhc.com/home/dispatch)***

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

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

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

15. ***Medical Abbreviations (www.medilexicon.com)***

    Medical Abbreviations dictionary contains commonly used medical abbreviations and their definitions.

16. ***CVS/Pharmacy (www.CVS.com)***

    This database contains commonly used over the counter products not usually identified in other databases.

17. ***Walgreens (www.walgreens.com)***

    This database contains commonly used over the counter products not usually identified in other databases.

18. ***Rx List (www.rxlist.com)***

    RxList is an online medical resource dedicated to offering detailed and current pharmaceutical information on brand and generic drugs.

19. ***Dogpile (www.dogpile.com)***

    Dogpile is a Metasearch engine that searches multiple search engines including Google, Yahoo! and Bing, and returns the most relevant results to the search.

20. ***Natural Standard (http://www.naturalstandard.com)***

    Natural Standard is a resource that aggregates and synthesizes data on complementary and alternative medicine.

APPENDICES

Appendix A

FDA's Proprietary Name Risk Assessment considers the promotional and safety aspects of a proposed proprietary name. The promotional review of the proposed name is conducted by OPDP. OPDP evaluates proposed proprietary names to determine if they are overly fanciful, so as to misleadingly imply unique effectiveness or composition, as well as to assess whether they contribute to overstatement of product efficacy, minimization of risk, broadening of product indications, or making of unsubstantiated superiority claims. OPDP provides their opinion to DMEPA for consideration in the overall acceptability of the proposed proprietary name.

The safety assessment is conducted by DMEPA. DMEPA staff search a standard set of databases and information sources to identify names that are similar in pronunciation, spelling, and orthographically similar when scripted to the proposed proprietary name. Additionally, we consider inclusion of USAN stems or other characteristics that when incorporated into a proprietary name may cause or contribute to medication errors (i.e., dosing interval, dosage form/route of administration, medical or product name abbreviations, names that include or suggest the composition of the drug product, etc.). DMEPA defines a medication error as any preventable event that may cause or lead to inappropriate medication use or patient harm while the medication is in the control of the health care professional, patient, or consumer. [1]

Following the preliminary screening of the proposed proprietary name, DMEPA gathers to discuss their professional opinions on the safety of the proposed proprietary name. This meeting is commonly referred to the Center for Drug Evaluation and Research (CDER) Expert Panel discussion. DMEPA also considers other aspects of the name that may be misleading from a safety perspective. DMEPA staff conducts a prescription simulation studies using FDA health care professionals. When provided, DMEPA considers external proprietary name studies conducted by or for the Applicant/Sponsor and incorporates the findings of these studies into the overall risk assessment.

The DMEPA primary reviewer assigned to evaluate the proposed proprietary name is responsible for considering the collective findings, and provides an overall risk assessment of the proposed proprietary name. DMEPA bases the overall risk assessment on the findings of a Failure Mode and Effects Analysis (FMEA) of the proprietary name and misleading nature of the proposed proprietary name with a focus on the avoidance of medication errors.

DMEPA uses the clinical expertise of its staff to anticipate the conditions of the clinical setting where the product is likely to be used based on the characteristics of the proposed product. DMEPA considers the product characteristics associated with the proposed product throughout the risk assessment because the product characteristics of the

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

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

Typical product characteristics considered when identifying drug names that could potentially be confused with the proposed proprietary name include, but are not limited to; established name of the proposed product, proposed indication of use, dosage form, route of administration, strength, unit of measure, dosage units, recommended dose, typical quantity or volume, frequency of administration, product packaging, storage conditions, patient population, and prescriber population. DMEPA considers how these product characteristics may or may not be present in communicating a product name throughout the medication use system. Because drug name confusion can occur at any point in the medication use process, DMEPA considers the potential for confusion throughout the entire U.S. medication use process, including drug procurement, prescribing and ordering, dispensing, administration, and monitoring the impact of the medication.[2]

The DMEPA considers the spelling of the name, pronunciation of the name when spoken, and appearance of the name when scripted. DMEPA compares the proposed proprietary name with the proprietary and established name of existing and proposed drug products and names currently under review at the FDA. DMEPA compares the pronunciation of the proposed proprietary name with the pronunciation of other drug names because verbal communication of medication names is common in clinical settings. DMEPA examines the phonetic similarity using patterns of speech. If provided, DMEPA will consider the Sponsor's intended pronunciation of the proprietary name. However, DMEPA also considers a variety of pronunciations that could occur in the English language because the Sponsor has little control over how the name will be spoken in clinical practice. The orthographic appearance of the proposed name is evaluated using a number of different handwriting samples. DMEPA applies expertise gained from root-cause analysis of postmarketing medication errors to identify sources of ambiguity within the name that could be introduced when scripting (e.g.,"T" may look like "F," lower case 'a' looks like a lower case 'u,' etc). Additionally, other orthographic attributes that determine the overall appearance of the drug name when scripted (see Table 1 below for details).

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

Table 1. Criteria Used to Identify Drug Names that Look- or Sound-Similar to a Proposed Proprietary Name.

Type of Similarity	**Considerations when Searching the Databases**		
	Potential Causes of Drug Name Similarity	*Attributes Examined to Identify Similar Drug Names*	*Potential Effects*
Look-alike	Similar spelling	Identical prefix Identical infix Identical suffix Length of the name Overlapping product characteristics	• Names may appear similar in print or electronic media and lead to drug name confusion in printed or electronic communication • Names may look similar when scripted and lead to drug name confusion in written communication
	Orthographic similarity	Similar spelling Length of the name/Similar shape Upstrokes Down strokes Cross-strokes Dotted letters Ambiguity introduced by scripting letters Overlapping product characteristics	• Names may look similar when scripted, and lead to drug name confusion in written communication
Sound-alike	Phonetic similarity	Identical prefix Identical infix Identical suffix Number of syllables Stresses Placement of vowel sounds Placement of consonant sounds Overlapping product characteristics	• Names may sound similar when pronounced and lead to drug name confusion in verbal communication

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

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

1. Database and Information Sources

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

2. Expert Panel Discussion

DMEPA gathers gather CDER professional opinions on the safety of the proposed product and discussed the proposed proprietary name (Expert Panel Discussion). The Expert Panel is composed of Division of Medication Errors Prevention (DMEPA) staff and representatives from the Office of Prescription Drug Promotion (OPDP). We also consider input from other review disciplines (OND, ONDQA/OBP). The Expert Panel also discusses potential concerns regarding drug marketing and promotion related to the proposed names.

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

3. FDA Prescription Simulation Studies

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

In order to evaluate the potential for misinterpretation of the proposed proprietary name in handwriting and verbal communication of the name, inpatient medication orders and/or outpatient prescriptions are written, each consisting of a combination of marketed and unapproved drug products, including the proposed name. These orders are optically

scanned and one prescription is delivered to a random sample of participating health professionals via e-mail. In addition, a verbal prescription is recorded on voice mail. The voice mail messages are then sent to a random sample of the participating health professionals for their interpretations and review. After receiving either the written or verbal prescription orders, the participants record their interpretations of the orders which are recorded electronically.

4. Comments from Other Review Disciplines

DMEPA requests the Office of New Drugs (OND) and/or Office of Generic Drugs (OGD), ONDQA or OBP for their comments or concerns with the proposed proprietary name, ask for any clinical issues that may impact the DMEPA review during the initial phase of the name review. Additionally, when applicable, at the same time DMEPA requests concurrence/non-concurrence with OPDP's decision on the name. The primary Safety Evaluator addresses any comments or concerns in the safety evaluator's assessment.

The OND/OGD Regulatory Division is contacted a second time following our analysis of the proposed proprietary name. At this point, DMEPA conveys their decision to accept or reject the name. The OND or OGD Regulatory Division is requested to provide any further information that might inform DMEPA's final decision on the proposed name.

Additionally, other review disciplines opinions such as ONDQA or OBP may be considered depending on the proposed proprietary name.

5. Safety Evaluator Risk Assessment of the Proposed Proprietary Name

The primary Safety Evaluator applies his/her individual expertise gained from evaluating medication errors reported to FDA, considers all aspects of the name that may be misleading or confusing, conducts a Failure Mode and Effects Analysis, and provides an overall decision on acceptability dependent on their risk assessment of name confusion. Failure Mode and Effects Analysis (FMEA) is a systematic tool for evaluating a process and identifying where and how it might fail.[3] When applying FMEA to assess the risk of a proposed proprietary name, DMEPA seeks to evaluate the potential for a proposed proprietary name to be confused with another drug name because of name confusion and, thereby, cause errors to occur in the medication use system. FMEA capitalizes on the predictable and preventable nature of medication errors associated with drug name confusion. FMEA allows the Agency to identify the potential for medication errors due to orthographically or phonetically similar drug names prior to approval, where actions to overcome these issues are easier and more effective than remedies available in the post-approval phase.

In order to perform an FMEA of the proposed name, the primary Safety Evaluator must analyze the use of the product at all points in the medication use system. Because the proposed product is has not been marketed, the primary Safety Evaluator anticipates the use of the product in the usual practice settings by considering the clinical and product

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

characteristics listed in Section 1.2 of this review. The Safety Evaluator then analyzes the proposed proprietary name in the context of the usual practice setting and works to identify potential failure modes and the effects associated with the failure modes.

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

> ***"Is the proposed proprietary name convincingly similar to another drug name, which may cause practitioners to become confused at any point in the usual practice setting? And are there any components of the name that may function as a source of error beyond sound/look-alike?"***

An affirmative answer indicates a failure mode and represents a potential for the proposed proprietary name to be confused with another proprietary or established drug name because of look- or sound-alike similarity or because of some other component of the name. If the answer to the question is no, the Safety Evaluator is not convinced that the names posses similarity that would cause confusion at any point in the medication use system, thus the name is eliminated from further review.

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

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

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

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

a. OPDP finds the proposed proprietary name misleading from a promotional perspective, and the Review Division concurs with OPDP's findings. The Federal Food, Drug, and Cosmetic Act provides that labeling or advertising can misbrand a product if misleading representations are made or suggested by statement, word, design, device, or any combination thereof, whether through a PROPRIETARY name or otherwise [21 U.S.C 321(n); See also 21 U.S.C. 352(a) & (n)].

b. DMEPA identifies that the proposed proprietary name is misleading because of similarity in spelling or pronunciation to another proprietary or established name of a different drug or ingredient [CFR 201.10.(C)(5)].

c. FMEA identifies the potential for confusion between the proposed proprietary name and other proprietary or established drug name(s), and demonstrates that medication errors are likely to result from the drug name confusion under the conditions of usual clinical practice.

d. The proposed proprietary name contains an USAN (United States Adopted Names) stem.

e. DMEPA identifies a potential source of medication error within the proposed proprietary name. For example, the proprietary name may be misleading or, inadvertently, introduce ambiguity and confusion that leads to errors. Such errors may not necessarily involve confusion between the proposed drug and another drug product but involve a naming characteristic that when incorporated into a proprietary name, may be confusing, misleading, cause or contribute to medication errors.

If DMEPA objects to a proposed proprietary name on the basis that drug name confusion could lead to medication errors, the primary Safety Evaluator uses the FMEA process to identify strategies to reduce the risk of medication errors. DMEPA generally recommends that the Sponsor select an alternative proprietary name and submit the alternate name to the Agency for review. However, in rare instances FMEA may identify plausible strategies that could reduce the risk of medication error of the currently proposed name. In that instance, DMEPA may be able to provide the Sponsor with recommendations that reduce or eliminate the potential for error and, thereby, would render the proposed name acceptable.

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

The threshold set for objection to the proposed proprietary name may seem low to the Applicant/Sponsor. However, the safety concerns set forth in criteria a through e above are supported either by FDA regulation or by external healthcare authorities, including the Institute of Medicine (IOM), World Health Organization (WHO), the Joint Commission, and the Institute for Safe Medication Practices (ISMP). These organizations have examined medication errors resulting from look- or sound-alike drug names, confusing, or misleading names and called for regulatory authorities to address the issue prior to approval. Additionally, DMEPA contends that the threshold set for the Proprietary Name Risk Assessment is reasonable because proprietary drug name confusion is a predictable and preventable source of medication error that, in many instances, the Agency and/or Sponsor can identify and rectify prior to approval to avoid patient harm.

Furthermore, post-marketing experience has demonstrated that medication errors resulting from drug name confusion are notoriously difficult to rectify post-approval. Educational and other post-approval efforts are low-leverage strategies that have had limited effectiveness at alleviating medication errors involving drug name confusion. Sponsors have undertaken higher-leverage strategies, such as drug name changes, in the

past but at great financial cost to the Sponsor and at the expense of the public welfare, not to mention the Agency's credibility as the authority responsible for approving the error-prone proprietary name. Moreover, even after Sponsors' have changed a product's proprietary name in the post-approval phase, it is difficult to eradicate the original proprietary name from practitioners' vocabulary, and as a result, the Agency has continued to receive reports of drug name confusion long after a name change in some instances. Therefore, DMEPA believes that post-approval efforts at reducing name confusion errors should be reserved for those cases in which the potential for name confusion could not be predicted prior to approval.

Appendix B: Letters and Letter Strings with Possible Orthographic or Phonetic Misinterpretation

Letters in Injectafer,	Scripted May Appear as	Spoken May Be Interpreted as
Capital letter 'I'	A, L, J, T, U	
Lower case 'i'	e, l	y
Lower case 'n'	m, u, x, r, h, s	dn, gn, kn, mn, pn
Lower case 'j'	g, p, q, y	
Lower case 'e'	a, i, l, o, u,p	Any Vowel
Lower case 'c'	a, e, i, l	z, k, s if followed by an e or i
Lower case 't'	f, i, l, x	d, f, p, pt, v
Lower case 'a'	el, ci, cl, d, o, u	Any Vowel
Lower case 'f'	B, t,	
Lower case 'e'	a, i, l, o, u,p	Any Vowel
Lower case 'r'	e, n, s, v	

Letter strings		
In	Ur,	
Inj Ct	Ui, ny D	

Appendix C: Prescription Simulation Samples and Results

Figure 1. Injectafer Study (Conducted on April 22, 2013)

Handwritten Requisition Medication Order	Verbal Prescription
Medication Order: Injectafer 500mg IV today Outpatient Prescription: Patient _____ Date 4/18/13 Address _____ ℞ Injectafer #1 Bring to clinic MEDWATCH 1-800-FDA-1088 Refill(s):_____ Dr. OSE DEA No._____ Address _____ Telephone _____	Injectafer Bring to clinic #1

FDA Prescription Simulation Responses (Aggregate 1 Rx Studies Report)

190 People Received Study
68 People Responded

Study Name: Injectafer

Total	26	20	22	68
INTERPRETATION	**OUTPATIENT**	**VOICE**	**INPATIENT**	**TOTAL**
IJECTAFER	0	0	1	1
INJECTABLE	1	0	0	1
INJECTAFEN	1	0	0	1
INJECTAFER	24	5	19	48
INJECTAFTER	0	0	1	1
INJECTAFUR	0	1	0	1
INJECTERFOR	0	1	0	1
INJECTIFER	0	5	0	5
INJECTIFIR	0	1	0	1
INJECTIFOR	0	1	0	1
INJECTIFUR	0	1	0	1
INJECTOFER	0	3	1	4
INJECTOFER (BRING TO CLINIC)	0	1	0	1
INJECTOFOR	0	1	0	1

Appendix D: Proprietary names not likely to be confused or not used in usual practice settings for the reasons described.

No.	Proprietary Name	Active Ingredient	Similarity to Injectafer	Failure preventions
1.	Amphadase TF	Hyaluronidase	Look	The pair have sufficient orthographic and/or phonetic differences
2.	Angeliq	Drospirenone and Estradiol	Look	The pair have sufficient orthographic and/or phonetic differences
3.	Engystol N		Look	The pair have sufficient orthographic and/or phonetic differences
4.	Ergocalciferol		Look	The pair have sufficient orthographic and/or phonetic differences
5.	Ergostat	Ergotamine Tartrate	Look	The pair have sufficient orthographic and/or phonetic differences
6.	Ergotrate	Ergonovine Maleate	Look	The pair have sufficient orthographic and/or phonetic differences
7.	Infantaire	Acetaminophen	Look	The pair have sufficient orthographic and/or phonetic differences
8.	Injectafer	Ferric Carboxymaltose	Look and Sound	The subject of this review
9.	Integra	Multivitamin w/Iron	Look	The pair have sufficient orthographic and/or phonetic differences
10.	Interferon		Look	The pair have sufficient orthographic and/or phonetic differences
11.	Jectofer		Look and Sound	The entire application was withdrawn by the Applicant
12.				(b) (4)

13.	Onglyza	Saxagliptin	Look	The pair have sufficient orthographic and/or phonetic differences

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

No.	**Proposed name:** Injectafer (Ferric Carboxymaltose) **Dosage Form:** Solution for Injection **Strength:** 750 mg per 15 mL **Usual Dose:** 15 mg/kg (max: 750 mg as a single dose) OR (b) (4) mg as intravenous push	**Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion** **Causes (could be multiple)**	**Prevention of Failure Mode** **In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names**
1.	(b) (4)		

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

No.	**Proposed name:** Injectafer (Ferric Carboxymaltose) **Dosage Form:** Solution for Injection **Strength:** 750 mg per 15 mL **Usual Dose:** 15 mg/kg (max: 750 mg as a single dose) OR (b) (4) mg as intravenous push	**Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion** **Causes (could be multiple)**	**Prevention of Failure Mode** **In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names**
2.	Ivacaftor Generic for Kayldeco Dosage form: Capsule Strength: 150 mg Usual dose: Take 1 capsule orally twice daily	Phonetic Similarity to Injectafer -When spoken the last syllables of Injectafer and Ivacaftor may sound similar, 'fer' versus 'tor'. Dosage form -Both products are available as a single dosage form, the dosage form maybe omitted when prescribed. Strength -Both products are available as a single strength products, the strength maybe omitted when prescribed.	Phonetic Differences -When spoken Injectafer is comprised of 4 syllables (in-jekt-a-fer) compared to Ivacaftor which is comprised of 3 syllables (iva-caf-tor). -The 1st and 2nd syllables in Injectafer, sound different from Ivacaftor, 'in' versus 'iva' and 'jekt' versus 'caf'. Differing Product Characteristics -Dose (15 mg/kg or 750 mg intravenously versus 150 mg twice daily or 1 capsule twice daily) with no overlap in dose.

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

No.	**Proposed name:** Injectafer (Ferric Carboxymaltose) **Dosage Form:** Solution for Injection **Strength:** 750 mg per 15 mL **Usual Dose:** 15 mg/kg (max: 750 mg as a single dose) OR (b) (4) mg as intravenous push	**Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion** **Causes (could be multiple)**	**Prevention of Failure Mode** **In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names**
3.	Linjeta*** (Human Insulin, Monomeric Recombinant) Dosage form: Solution for injection Strength: 100 Units/mL Usual dose: 0.5-1 Unit/kg/day administered in 3 divided doses before meals Calculated dose: 10 Units subcutaneous three times a day OR 30 Units subcutaneous three times a day	Orthographic Similarity to Injectafer - The names share the letter string '-inje-'. Dosage form -Both products are available as a single dosage form, the dosage form maybe omitted when prescribed. Strength -Both products are available as a single strength products, the strength maybe omitted when prescribed.	Orthographic Differences - The 'c' at the 5th position of Injectafer looks different from 't' in Linjeta. -When scripted Injectafer appears longer than Linjeta, 10 letters versus 7 letters. Differing Product Characteristics -Dose (15 mg/kg or 750 mg intravenously versus 150 mg twice daily or 1 capsule twice daily) with no overlap in dose. -Frequency of administration (once daily administration versus three times daily)

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/s/

KEVIN WRIGHT
06/26/2013

YELENA L MASLOV
06/26/2013

CAROL A HOLQUIST
06/26/2013

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

Proprietary Name Review--Final

Date:	June 18, 2012
Reviewer:	Sarah K. Vee, PharmD, Safety Evaluator Division of Medication Prevention and Analysis
Team Leader	Yelena Maslov, PharmD, Acting Team Leader Division of Medication Prevention and Analysis
Drug Name and Strengths:	Injectafer (Ferric Carboxymaltose) Injection, [redacted] (b) (4) 750 mg/15 mL
Application Type/Number:	NDA 203565
Applicant/sponsor:	Luitpold Pharmaceuticals, Inc.
OSE RCM #:	2012-1135

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

CONTENTS

1 INTRODUCTION

This re-assessment of the proposed proprietary name, Injectafer is written in response to the anticipated approval of this NDA 203565 within 90 days from the date of this review. DMEPA found the proposed name, Injectafer, acceptable in OSE Review 2011-4477, dated February 22, 2012.

2 METHODS AND DISCUSSION

For re-assessments of proposed proprietary names, DMEPA searches a standard set of databases and information sources (see section 4) to identify names with orthographic and phonetic similarity to the proposed name that have been approved since the previous OSE proprietary name review. For this review we used the same search criteria described in OSE Review 2011-4477. We note that none of the proposed product characteristics were altered. However, we evaluated the previously identified names of concern considering lessons learned from recent post-marketing experience related to proprietary name confusion, which has not altered our previous conclusion regarding the acceptability of the proposed proprietary name, Injectafer.

The searches of the databases yielded one new name (Injectapap), thought to look and sound similar to Injectafer and represent a potential source of drug name confusion. Failure mode and effects analysis was applied to determine if the proposed proprietary name could potentially be confused with Injectapap and lead to medication errors. This analysis determined that the name similarity between Injectafer and the identified name was unlikely to result in medication error for the reasons presented in Appendix A.

Additionally, DMEPA searched the USAN stem list to determine if the name contains any USAN stems as of the last USAN updates. The Safety Evaluator did not identify any United States Adopted Names (USAN) stems in the proposed proprietary name, as of June 14, 2012. The Office of Prescription Drug Promotion (OPDP) re-reviewed the proposed name on May 17, 2012 and had no concerns regarding the proposed name from a promotional perspective.

3 CONCLUSIONS

The re-evaluation of the proposed proprietary name, Injectafer, did not identify any vulnerabilities that would result in medication errors with any additional names noted in this review. Thus, DMEPA has no objection to the proprietary name, Injectafer, 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 Hematology Products should notify DMEPA because the proprietary name must be re-reviewed prior to the new approval date.

If you have further questions or need clarifications, please contact Sue Kang, OSE project manager, at 301-796-4216.

3.1 COMMENTS TO THE APPLICANT

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

4 REFERENCES

1. **OSE Review 2011-4477 Injectafer (Ferric Carboxymaltose) Injection 50 mg/mL, Kimberly DeFronzo, RPh, MS, MBA, February 22, 2012.**

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

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

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

   USAN Stems List contains all the recognized USAN stems.

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

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

Appendix A: Proprietary names not likely to be confused or not used in usual practice settings for the reasons described.

Proprietary Name	Active Ingredient	Similarity to Injectafer	Failure Preventions
Injectapap	acetaminophen	Orthographic and Phonetic	Withdrawn FR effective 7/7/87

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/s/

SARAH K VEE
06/22/2012

YELENA L MASLOV
06/22/2012

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

Proprietary Name Review

Date:	February 22, 2012
Reviewer:	Kimberly DeFronzo, RPh, MS, MBA Division of Medication Error Prevention and Analysis
Team Leader:	Todd Bridges, RPh Division of Medication Error Prevention and Analysis
Division Director:	Carol Holquist, RPh Division of Medication Error Prevention and Analysis
Drug Name and Strength:	Injectafer (Ferric Carboxymaltose) Injection 50 mg/mL
Application Type/Number:	NDA 203565
Applicant:	Luitpold Pharmaceuticals, Inc.
OSE RCM #:	2011-4477

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CONTENTS

1 INTRODUCTION

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

1.1 REGULATORY HISTORY

The proposed proprietary name, Injectafer, was found acceptable by DMEPA in OSE Review #06-0025, dated February 2, 2007, and again in OSE Review #2007-1997, dated January 14, 2008 under NDA 22054. On March 11, 2008, the NDA 022054 received a "Non Approval" letter due to a mortality safety signal detected in the original clinical studies submission. Furthermore, the higher adverse event rate of this product as compared to oral iron products resulted in an unacceptable risk-benefit ratio. This NDA 022054 has not been withdrawn and is being cross-referenced for non-clinical data.

On October 3, 2011, Luitpold submitted new NDA 203565 seeking a broader indication with additional clinical data to support the safety and efficacy at a lower. In the previous NDA 022054, the proposed dose included a maximum cumulative dose of 2500 mg. However, in the current NDA 203565, the Applicant proposed a lower maximum cumulative dose of 1500 mg (with a maximum single dose of 750 mg) to address the toxicity issue.

On December 5, 2011, the Applicant submitted a proprietary name request under NDA 203565 for the proprietary name, Injectafer, which is the topic of this review.

1.2 PRODUCT INFORMATION

The following product information is provided in the December 5, 2011, proprietary name submission.

- Active ingredient: Ferric Carboxymaltose
- Indication of Use: For the treatment of iron deficiency anemia
- Route of administration: Intravenously
- Dosage form: Injection
- Dose and Frequency: Intravenous iron should not be used in lieu of an appropriate clinical evaluation for iron deficiency anemia. Consider the appropriateness of oral iron before prescribing intravenous iron. The recommended dosage is 15 mg/kg up to a maximum single dose of 750 mg of iron on two occasions separated by at least 7 days up to a cumulative dose of 1500 mg of iron. Injectafer treatment may be repeated if iron deficiency reoccurs. Injectafer must be administered intravenously, either as an undiluted slow intravenous push injection or by drip infusion. When administered via slow intravenous push injection, up to 750 mg of iron is delivered at the rate of approximately 100 mg per minute. When administered via intravenous infusion, 750 mg of iron is diluted in 250 ml of sterile 0.9% sodium chloride injection, USP and administered over 15 minutes. For stability reasons, dilutions to concentrations less than 2 mg iron/mL are not permissible.

- How Supplied: in [redacted] 15 mL single use vials containing no preservatives.

  [redacted]

  - Each 15 mL vial contains 750 mg of iron at 50 mg/mL in individually boxed or in packages of 2 [redacted]

- Storage: at 20-25°C (68-77° F); excursions permitted to 15-30° C (59-86° F). [See the USP controlled room temperature]. Do not freeze.
- Container and Closure Systems: The container/closure system of Injectafer does not contain [redacted]. The container closure system for each fill size is as follow:.

  Please note: [redacted].

[redacted]

Component	[redacted] 750 mg elemental iron
Container	15 mL vial with [redacted]
Rubber closure	
Seal	

[redacted]

Additionally, the insert labeling suggests the following:

- This product, when added to IV infusion bags (b) (4) containing 0.9% Sodium Chloride Injection, USP, at concentrations ranging from 2 mg to 4 mg of iron per mL, has been found to be physically and chemically stable for 72 hours when stored at room temperature.

2 RESULTS

The following sections provide the information obtained and considered in the evaluation of the proposed proprietary name.

2.1 PROMOTIONAL ASSESSMENT

The Office of Prescription Drug Promotion determined the proposed name is acceptable from a promotional perspective. DMEPA and the Division of Hematology Products (DHP) concurred with the findings of OPDP's promotional assessment of the proposed name.

2.2 SAFETY ASSESSMENT

The following aspects of the name were considered in the overall evaluation.

2.2.1 United States Adopted Names (USAN) SEARCH

On December 15, 2011, the United States Adopted Name (USAN) stem search identified that a USAN stem is not present in the proposed proprietary name.

2.2.2 Components of the Proposed Proprietary Name

The Applicant notes in their submission that the proprietary name is a combination of the word "inject" and the suffix "fer", a part of the word "ferrous" or "ferric" referring to iron, with the letter "a" in between. Since the proposed product is an injectable solution intended for intravenous administration, the prefix is not deemed misleading or contributing to medication error.

The Applicant further notes in the submission that the proposed name includes the suffix "fer" to suggest that this is an iron product since the modifier "fer" is widely used on iron products as a prefix or suffix to suggest the presence of iron (e.g.,Venofer®, Ferrlecit®, and Feraheme®, among numerous other iron products, both for parenteral and oral administration). DMEPA concurs with the Applicant's assessment and has no objection to the use of the suffix "fer" in the proprietary name for this iron supplement.

2.2.3 FDA Name Simulation Studies

Thirty-eight practitioners participated in DMEPA's prescription studies. The most common misinterpretation in the written studies was the lowercase letter 'a' for the lowercase letter 'i' and 'o' as well as lowercase letter 'f' for lowercase letter 'j'. The most common misinterpretation in the verbal study was the sound from letter 'e' in 'fer' for the letters 'o' as 'for', 'u' as 'fur', and 'i' as 'fir'. See Appendix C for the complete listing of interpretations from the verbal and written prescription studies.

2.2.4 Comments from Other Review Disciplines

In response to the OSE's December 15, 2011 e-mail, DHP did not forward any comments or issues relating to the proposed name at the initial phase of the proprietary name review.

2.2.6 Failure Mode and Effects Analysis of Similar Names

Appendix B lists possible orthographic and phonetic misinterpretations of the letters appearing in the proposed proprietary name, Injectafer.

Table 1 lists the names with orthographic, phonetic, or spelling similarity to the proposed proprietary name, Injectafer, identified by the primary reviewer, the Expert Panel Discussion (EPD), other review disciplines, the FDA Prescription Simulation studies and the external name study by (b) (4) conducted on November 11, 2005 (which was evaluated in review OSE RCM #06-0025). Additionally, all names from the two previous name reviews (OSE RCM #06-0025 and #2007-1997) are also included in Table 1 for evaluation due to changes in the product characteristics from the previous submission. The changes included:

1) Indication:
    a. Previous: For the treatment of iron deficiency anemia in patients with heavy uterine bleeding, who are postpartum, have inflammatory bowel disease or are on hemodialysis.
    b. Current: For the treatment of iron deficiency anemia.
2) Recommended dose:
    a. Previous: The recommended dose is calculated based on the patient's weight and their current hemoglobin levels with an average cumulative dose range of 200 mg to 2500mg.
    b. Current: The recommended dosage is 15 mg/kg up to a maximum single dose of 750 mg of iron on two occasions separated by at least 7 days, up to a cumulative dose of 1500 mg of iron.
3) Administration:
    a. Previous: May be administered either undiluted by ***rapid*** intravenous push injection or by intravenous infusion after dilution in 250 mL of normal saline.
    b. Current: May be administered either undiluted by ***slow*** intravenous push injection or by intravenous infusion over 15 minutes after dilution in 250 mL of normal saline.
4) How Supplied:
    a. Previous: Supplied in (b) (4) single dose vials
    b. Current: Supplied in (b) (4) 15 mL single dose vials

Table 1: Collective List of Potentially Similar Names (DMEPA, EPD, Other Disciplines, FDA Name Simulation Studies, and External Name Study if applicable)

Look Similar		Look Similar		Look and Sound Similar	
Name	***Source***	***Name***	***Source***	***Name***	***Source***
Infergen	FDA, External	Inlyta	FDA	Enjuvia	FDA
Spectazole	FDA	(b) (4) ***	FDA	Angiofluor	FDA
(b) (4) ***	FDA	Injectapap	FDA	Injectafer	FDA
Pyrilafen Tannate	FDA	Engerix-B	FDA		
Caverject	External	Infectrol	External		
Infanrix	External	Innertabs	External		
Abacavir	External	Azactam	External		
Venofer	External				

Our analysis of the 18 names contained in above Table 1 considered the information obtained in the previous sections along with their product characteristics. We determined these 18 names will not pose a risk for confusion as described in Appendix D and E.

2.2.7 Communication of DMEPA's Final Decision to Other Disciplines

DMEPA communicated our findings to the DHP via e-mail on February 15, 2012. At that time we also requested additional information or concerns that could inform our review. Per e-mail correspondence from DHP on February 22, 2012, they stated no issues with the proposed proprietary name, Injectafer.

3 CONCLUSIONS

The proposed proprietary name is acceptable from both a promotional and safety perspective. If you have further questions or need clarifications, please contact Sue Kang, OSE Project Manager, at 301-796-4216.

3.1 COMMENTS TO THE APPLICANT

We have completed our review of the proposed proprietary name, Injectafer, and have concluded that this name is acceptable. This proprietary name must be re-evaluated 90 days prior to the approval of the application. The conclusions upon re-review are subject to change. However, if any of the proposed product characteristics as stated in your December 5, 2011 submission are altered, DMEPA rescinds this finding and the name must be resubmitted for review.

REFERENCES

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

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

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

   POCA is a database which was created for the Division of Medication Error Prevention and Analysis, FDA. As part of the name similarity assessment, proposed names are evaluated via a phonetic/orthographic algorithm. The proposed proprietary name is converted into its phonemic representation before it runs through the phonetic algorithm. Likewise, an orthographic algorithm exists which operates in a similar fashion.

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

   Drug Facts and Comparisons is a compendium organized by therapeutic course; it contains monographs on prescription and OTC drugs, with charts comparing similar products. This database also lists the orphan drugs.

4. ***FDA Document Archiving, Reporting & Regulatory Tracking System [DARRTS]***

   DARRTS is a government database used to organize Applicant and Sponsor submissions as well as to store and organize assignments, reviews, and communications from the review divisions.

5. ***Division of Medication Errors Prevention and Analysis proprietary name consultation requests***

   This is a list of proposed and pending names that is generated by the Division of Medication Error Prevention and Analysis from the Access database/tracking system.

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

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

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

   USPTO provides information regarding patent and trademarks.

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

   Clinical Pharmacology contains full monographs for the most common drugs in clinical use, plus mini monographs covering investigational, less common, combination, nutraceutical and nutritional products. It also provides a keyword search engine.

9. ***Data provided by Thomson & Thomson's SAEGIS ™ Online Service, available at (www.thomson-thomson.com)***

   The Pharma In-Use Search database contains over 400,000 unique pharmaceutical trademarks and trade names that are used in about 50 countries worldwide. The data is provided under license by IMS HEALTH.

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

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

11. ***Access Medicine (www.accessmedicine.com)***

    Access Medicine® from McGraw-Hill contains full-text information from approximately 60 titles; it includes tables and references. Among the titles are: Harrison's Principles of Internal Medicine, Basic & Clinical Pharmacology, and Goodman and Gilman's The Pharmacologic Basis of Therapeutics.

12. ***USAN Stems (http://www.ama-assn.org/ama/pub/about-ama/our-people/coalitions-consortiums/united-states-adopted-names-council/naming-guidelines/approved-stems.shtml)***

    USAN Stems List contains all the recognized USAN stems.

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

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

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

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

15. ***Medical Abbreviations Book***

    Medical Abbreviations Book contains commonly used medical abbreviations and their definitions.

16. ***CVS/Pharmacy (www.CVS.com)***

    This database contains commonly used over the counter products not usually identified in other databases.

17. Walgreens (www.walgreens.com)

This database contains commonly used over the counter products not usually identified in other databases.

18. Rx List (www.rxlist.com)

RxList is an online medical resource dedicated to offering detailed and current pharmaceutical information on brand and generic drugs.

19. Dogpile (www.dogpile.com)

Dogpile is a Metasearch engine that searches multiple search engines including Google, Yahoo! and Bing, and returns the most relevant results to the search.

20. OSE Reviews

Pedersen, Kimberly. OSE Review 2007-1997: Proprietary Name Review for Injectafer, received September 18, 2007.

Arnwine, Kristina C. OSE Review 06-0025: Proprietary Name Review for Ferinject, received January 23, 2006.

APPENDICES

Appendix A

FDA's Proprietary Name Risk Assessment considers the promotional and safety aspects of a proposed proprietary name. The promotional review of the proposed name is conducted by OPDP. OPDP evaluates proposed proprietary names to determine if they are overly fanciful, so as to misleadingly imply unique effectiveness or composition, as well as to assess whether they contribute to overstatement of product efficacy, minimization of risk, broadening of product indications, or making of unsubstantiated superiority claims. OPDP provides their opinion to DMEPA for consideration in the overall acceptability of the proposed proprietary name.

The safety assessment is conducted by DMEPA. DMEPA staff search a standard set of databases and information sources to identify names that are similar in pronunciation, spelling, and orthographically similar when scripted to the proposed proprietary name. Additionally, we consider inclusion of USAN stems or other characteristics that when incorporated into a proprietary name may cause or contribute to medication errors (i.e., dosing interval, dosage form/route of administration, medical or product name abbreviations, names that include or suggest the composition of the drug product, etc.). DMEPA defines a medication error as any preventable event that may cause or lead to inappropriate medication use or patient harm while the medication is in the control of the health care professional, patient, or consumer. [1]

Following the preliminary screening of the proposed proprietary name, DMEPA gathers to discuss their professional opinions on the safety of the proposed proprietary name. This meeting is commonly referred to the Center for Drug Evaluation and Research (CDER) Expert Panel discussion. DMEPA also considers other aspects of the name that may be misleading from a safety perspective. DMEPA staff conducts a prescription simulation studies using FDA health care professionals. When provided, DMEPA considers external proprietary name studies conducted by or for the Applicant/Sponsor and incorporates the findings of these studies into the overall risk assessment.

The DMEPA primary reviewer assigned to evaluate the proposed proprietary name is responsible for considering the collective findings, and provides an overall risk assessment of the proposed proprietary name. DMEPA bases the overall risk assessment on the findings of a Failure Mode and Effects Analysis (FMEA) of the proprietary name and misleading nature of the proposed proprietary name with a focus on the avoidance of medication errors.

DMEPA uses the clinical expertise of its staff to anticipate the conditions of the clinical setting where the product is likely to be used based on the characteristics of the proposed product. DMEPA considers the product characteristics associated with the proposed product throughout the risk assessment because the product characteristics of the proposed

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

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

Typical product characteristics considered when identifying drug names that could potentially be confused with the proposed proprietary name include, but are not limited to; established name of the proposed product, proposed indication of use, dosage form, route of administration, strength, unit of measure, dosage units, recommended dose, typical quantity or volume, frequency of administration, product packaging, storage conditions, patient population, and prescriber population. DMEPA considers how these product characteristics may or may not be present in communicating a product name throughout the medication use system. Because drug name confusion can occur at any point in the medication use process, DMEPA considers the potential for confusion throughout the entire U.S. medication use process, including drug procurement, prescribing and ordering, dispensing, administration, and monitoring the impact of the medication.[2] The product characteristics considered for this review appears in Appendix B1 of this review.

The DMEPA considers the spelling of the name, pronunciation of the name when spoken, and appearance of the name when scripted. DMEPA compares the proposed proprietary name with the proprietary and established name of existing and proposed drug products and names currently under review at the FDA. DMEPA compares the pronunciation of the proposed proprietary name with the pronunciation of other drug names because verbal communication of medication names is common in clinical settings. DMEPA examines the phonetic similarity using patterns of speech. If provided, DMEPA will consider the Sponsor's intended pronunciation of the proprietary name. However, DMEPA also considers a variety of pronunciations that could occur in the English language because the Sponsor has little control over how the name will be spoken in clinical practice. The orthographic appearance of the proposed name is evaluated using a number of different handwriting samples. DMEPA applies expertise gained from root-cause analysis of postmarketing medication errors to identify sources of ambiguity within the name that could be introduced when scripting (e.g.,"T" may look like "F," lower case 'a' looks like a lower case 'u,' etc). Additionally, other orthographic attributes that determine the overall appearance of the drug name when scripted (see Table 1 for details).

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

Table 1. Criteria Used to Identify Drug Names that Look- or Sound-Similar to a Proposed Proprietary Name.

Type of Similarity	**Considerations when Searching the Databases**		
	Potential Causes of Drug Name Similarity	*Attributes Examined to Identify Similar Drug Names*	*Potential Effects*
Look-alike	Similar spelling	Identical prefix Identical infix Identical suffix Length of the name Overlapping product characteristics	• Names may appear similar in print or electronic media and lead to drug name confusion in printed or electronic communication • Names may look similar when scripted and lead to drug name confusion in written communication
	Orthographic similarity	Similar spelling Length of the name/Similar shape Upstrokes Down strokes Cross-strokes Dotted letters Ambiguity introduced by scripting letters Overlapping product characteristics	• Names may look similar when scripted, and lead to drug name confusion in written communication
Sound-alike	Phonetic similarity	Identical prefix Identical infix Identical suffix Number of syllables Stresses Placement of vowel sounds Placement of consonant sounds Overlapping product characteristics	• Names may sound similar when pronounced and lead to drug name confusion in verbal communication

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

1. Database and Information Sources

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

2. Expert Panel Discussion

DMEPA gathers gather CDER professional opinions on the safety of the proposed product and discussed the proposed proprietary name (Expert Panel Discussion). The Expert Panel is composed of Division of Medication Errors Prevention (DMEPA) staff and representatives from the Division of Drug Marketing, Advertising, and Communications (OPDP). We also consider input from other review disciplines (OND, ONDQA/OBP). The Expert Panel also discusses potential concerns regarding drug marketing and promotion related to the proposed names.

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

3. FDA Prescription Simulation Studies

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

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

professionals for their interpretations and review. After receiving either the written or verbal prescription orders, the participants record their interpretations of the orders which are recorded electronically.

4. Comments from Other Review Disciplines

DMEPA requests the Office of New Drugs (OND) and/or Office of Generic Drugs (OGD), ONDQA or OBP for their comments or concerns with the proposed proprietary name, ask for any clinical issues that may impact the DMEPA review during the initial phase of the name review. Additionally, when applicable, at the same time DMEPA requests concurrence/non-concurrence with OPDP's decision on the name. The primary Safety Evaluator addresses any comments or concerns in the safety evaluator's assessment.

The OND/OGD Regulatory Division is contacted a second time following our analysis of the proposed proprietary name. At this point, DMEPA conveys their decision to accept or reject the name. The OND or OGD Regulatory Division is requested to provide any further information that might inform DMEPA's final decision on the proposed name.

Additionally, other review disciplines opinions such as ONDQA or OBP may be considered depending on the proposed proprietary name.

5. Safety Evaluator Risk Assessment of the Proposed Proprietary Name

The primary Safety Evaluator applies his/her individual expertise gained from evaluating medication errors reported to FDA, considers all aspects of the name that may be misleading or confusing, conducts a Failure Mode and Effects Analysis, and provides an overall decision on acceptability dependent on their risk assessment of name confusion. Failure Mode and Effects Analysis (FMEA) is a systematic tool for evaluating a process and identifying where and how it might fail.[3] When applying FMEA to assess the risk of a proposed proprietary name, DMEPA seeks to evaluate the potential for a proposed proprietary name to be confused with another drug name because of name confusion and, thereby, cause errors to occur in the medication use system. FMEA capitalizes on the predictable and preventable nature of medication errors associated with drug name confusion. FMEA allows the Agency to identify the potential for medication errors due to orthographically or phonetically similar drug names prior to approval, where actions to overcome these issues are easier and more effective than remedies available in the post-approval phase.

In order to perform an FMEA of the proposed name, the primary Safety Evaluator must analyze the use of the product at all points in the medication use system. Because the proposed product is has not been marketed, the primary Safety Evaluator anticipates the use of the product in the usual practice settings by considering the clinical and product characteristics listed in Appendix B1 of this review. The Safety Evaluator then analyzes the proposed proprietary name in the context of the usual practice setting and works to identify potential failure modes and the effects associated with the failure modes.

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

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

> ***"Is the proposed proprietary name convincingly similar to another drug name, which may cause practitioners to become confused at any point in the usual practice setting? And Are there any components of the name that may function as a source of error beyond sound/look-alike"***

An affirmative answer indicates a failure mode and represents a potential for the proposed proprietary name to be confused with another proprietary or established drug name because of look- or sound-alike similarity or because of some other component of the name. If the answer to the question is no, the Safety Evaluator is not convinced that the names posses similarity that would cause confusion at any point in the medication use system, thus the name is eliminated from further review.

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

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

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

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

a. OPDP finds the proposed proprietary name misleading from a promotional perspective, and the Review Division concurs with OPDP's findings. The Federal Food, Drug, and Cosmetic Act provides that labeling or advertising can misbrand a product if misleading representations are made or suggested by statement, word, design, device, or any combination thereof, whether through a PROPRIETARY name or otherwise [21 U.S.C 321(n); See also 21 U.S.C. 352(a) & (n)].

b. DMEPA identifies that the proposed proprietary name is misleading because of similarity in spelling or pronunciation to another proprietary or established name of a different drug or ingredient [CFR 201.10.(C)(5)].

c. FMEA identifies the potential for confusion between the proposed proprietary name and other proprietary or established drug name(s), and demonstrates that medication errors are likely to result from the drug name confusion under the conditions of usual clinical practice.

d. The proposed proprietary name contains an USAN (United States Adopted Names) stem.

e. DMEPA identifies a potential source of medication error within the proposed proprietary name. For example, the proprietary name may be misleading or, inadvertently, introduce ambiguity and confusion that leads to errors. Such errors may not necessarily involve confusion between the proposed drug and another drug product but involve a naming characteristic that when incorporated into a proprietary name, may be confusing, misleading, cause or contribute to medication errors.

If DMEPA objects to a proposed proprietary name on the basis that drug name confusion could lead to medication errors, the primary Safety Evaluator uses the FMEA process to identify strategies to reduce the risk of medication errors. DMEPA generally recommends that the Sponsor select an alternative proprietary name and submit the alternate name to the Agency for review. However, in rare instances FMEA may identify plausible strategies that could reduce the risk of medication error of the currently proposed name. In that instance, DMEPA may be able to provide the Sponsor with recommendations that reduce or eliminate the potential for error and, thereby, would render the proposed name acceptable.

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

The threshold set for objection to the proposed proprietary name may seem low to the Applicant/Sponsor. However, the safety concerns set forth in criteria a through e above are supported either by FDA regulation or by external healthcare authorities, including the Institute of Medicine (IOM), World Health Organization (WHO), the Joint Commission, and the Institute for Safe Medication Practices (ISMP). These organizations have examined medication errors resulting from look- or sound-alike drug names, confusing, or misleading names and called for regulatory authorities to address the issue prior to approval. Additionally, DMEPA contends that the threshold set for the Proprietary Name Risk Assessment is reasonable because proprietary drug name confusion is a predictable and preventable source of medication error that, in many instances, the Agency and/or Sponsor can identify and rectify prior to approval to avoid patient harm.

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

believes that post-approval efforts at reducing name confusion errors should be reserved for those cases in which the potential for name confusion could not be predicted prior to approval.

Appendix B: Letters with Possible Orthographic or Phonetic Misinterpretation

Letters in Name, Injectafer	Scripted May Appear as	Spoken May Be Interpreted as
Capital 'I'	L	---
Lower case 'n'	m, u, x, r, h, s	dn, gn, kn, mn, pn
lowercase 'j'	g, p, q, y	---
lowercase 'e'	a, i, l, o, u, p	Any vowel
lowercase 'c'	a, e, i, l	z, k, s if followed by an e or i
lowercase 't'	r, f, x, A	d
lowercase 'a'	el, ci, cl, d, o, u	Any vowel
lowercase 'f';	t, l	---
lowercase 'r';	s, n, e, ,v	---

Appendix C: Prescription Simulation Samples and Results

Figure 1. Injectafer Study (Conducted on December 16, 2011)

Handwritten Medication Order	Verbal Prescription
Medication Order: Injectafer 750 mg IV push at 100 mg/1 min Outpatient Prescription: Patient _____ Date 12/15/11 Address _____ ℞ Injectafer 750mg #1 vial Bring to clinic MEDWATCH 1-800-FDA-1088 Refill(s):_____ Dr. Ose DEA No._____ Address _____ Telephone _____	"Injectafer 750 mg Bring one vial to clinic" Disp #1"

Study Name: Injectafer

85 People Received Study

38 People Responded

Study Name: Injectafer

INPATIENT	VOICE	OUTPATIENT
INFECTAFER (1)	IJECTIFUR (1)	INJECTAFER (8)
INJECTAFER (16)	INJECTAFER (2)	INJECTAFIR (1)
	INJECTIFER (3)	INJECTIFER (1)
	INJECTIVIFER (1)	INJECTOFER (1)
	INJECTOFER (1)	
	INJECTOFIR (1)	
	INJECTORFOR (1)	

Appendix D: Proprietary names not likely to be confused or not used in usual practice settings for the reasons described.			
Proprietary Name	**Active Ingredient**	**Similarity to Injectafer**	**Failure preventions**
Injectafer	Ferric Carboxymaltose	Look	Trademarked by Luitpold Pharmaceuticals, Inc. which is the Applicant for this NDA.
Caverject	Alprostadil	Look	The pair have sufficient orthographic and/or phonetic differences
Venofer	Iron sucrose complex	Look	The pair have sufficient orthographic and/or phonetic differences
Abacavir	Abacavir	Look	The pair have sufficient orthographic and/or phonetic differences
Azactam	Aztreonam	Look	The pair have sufficient orthographic and/or phonetic differences
Spectazole	Econazole	Look	The pair have sufficient orthographic and/or phonetic differences
Enjuvia	Conjugated estrogen	Look	The pair have sufficient orthographic and/or phonetic differences
Inlyta	Axitinib	Look	The pair have sufficient orthographic and/or phonetic differences
Pyrilafen Tannate	Phenylephrine Hydrochloride, Pyrilamine Maleate	Look	The pair have sufficient orthographic and/or phonetic differences
Engerix-B	Hepatitis B vaccine	Look	The pair have sufficient orthographic and/or phonetic differences
Angiofluor	Fluorescein dye	Look	The pair have sufficient orthographic and/or phonetic differences
Injectapap	Acetaminophen Injection	Look	Product is discontinued and does not appear in commonly used references such as rxlist.com, Redbook, Clinical Pharmacology, Facts & Comparisons online, Drugs@FDA, and Micromedex. Additionally, there are no equivalent generic products available.

Appendix D: Proprietary names not likely to be confused or not used in usual practice settings for the reasons described.			
Proprietary Name	**Active Ingredient**	**Similarity to Injectafer**	**Failure preventions**
(b) (4)			

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

Appendix E: Risk of medication errors due to product confusion minimized by dissimilarity of the names and/ or use in clinical practice for the reasons described.		
Proposed name: **Injectafer (Ferric Carboxymaltose) Injection**	**Strength(s):** **50 mg/mL**	**Usual dose:** **15mg/kg up to max single dose 750mg on two occasions separated by at least 7 days up to cumulative dose 1500mg intravenously**
Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion	**Causes (could be multiple)**	**Prevention of Failure Mode**
Infergen (Interferon Alfacon-1) Injection 9 mcg (0.3 mL) and 15 mcg (0.5 mL) Usual Dose: 9 mcg three times per week at intervals of at least 48 hours subcutaneously for 24 weeks	**Orthographic similarity** - Both names begin with the letters 'In' followed by letter 'e' with letters 'c' and 'r' that look similar when scripted ('In-ec' vs. 'In-er') - Both names share similar ending letters 'er' vs. 'en' when scripted **Product characteristic similarity** - Same dosage form (injection) and route of administration (parenteral)	**Orthographic differences** -Infergen contains eight letters compared to ten letters giving name a shorter appearance -Upstroke of "t" in Injectafer gives name visual difference -Placement of upstrokes and downstroke is different **Product characteristic differences** -Different strengths, doses, frequency of administration, and storage condition (refrigeration for Infergen vs. room temperature for Injectafer)
Infectrol (Neomycin Sulfate, Dexamethasone, Polymyxin B Sulfate) Ophthalmic Ointment and Suspension Neomycin Sulfate - 3.5 mg/g Dexamethasone - 0.1%/g Polymyxin B Sulfate - 10,000 u/g Usual Dose: Suspension: Instill 1 to 2 drops into affected eye(s)	**Orthographic similarity** -Both names begin with the letters 'In-ect' -Both names are similar in length with 9 vs. 10 letters - Both names have upstroke letters **Product characteristic similarity** - Both products are single strength products which can be omitted on a prescription	**Orthographic differences** - Infectrol has an extra ending upstroke 'l' and lacks the downstroke 'j' to provide orthographic distinction from Injectafer **Product characteristic differences** - Different dose - Different frequency of administration - Different directions for use (ophthalmic product to instill in the eye vs. injectable product for intravenous use only)

Appendix E: Risk of medication errors due to product confusion minimized by dissimilarity of the names and/ or use in clinical practice for the reasons described.		
Proposed name: **Injectafer (Ferric Carboxymaltose) Injection**	**Strength(s):** **50 mg/mL**	**Usual dose:** **15mg/kg up to max single dose 750mg on two occasions separated by at least 7 days up to cumulative dose 1500mg intravenously**
Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion	**Causes (could be multiple)**	**Prevention of Failure Mode**
every 4 h for 7 to 10 days; dosage may be increased to 2 drops every hour in severe infections Ointment: 3-4 applications to affected eye(s) per day		
Innertabs (Senna) Tablets 320 mg Usual Dose: 2 to 4 tablets or 640 mg to 1280 mg a day as needed	**Orthographic similarity** -Both names begin with the letters 'In-e' followed by letters 'ta' in the same position within the names -Both names share similar ending letters ('r' and 's') that look similar when scripted -Both names are similar in length with 9 vs. 10 letters - Both name share same number of upstroke letters in same positions **Product characteristic similarity** - Both products are single strength products which can be omitted on a prescription	**Orthographic differences** - Innertabs lacks the downstroke letter 'j' present in Injectafer **Product characteristic differences** - Different dose (dose must be calculated for Injectafer) - Different directions for use (take tablets orally as needed vs. must give intravenously on two occasions separated by at least 7 days) - Different frequency of administration
Infanrix (Diphtheria, acellular pertussis, and tetanus toxoids vaccine) Injection Diphtheria Toxoid	**Orthographic similarity** -Both names begin with the same letters 'In' **Product characteristic similarity**	**Orthographic differences** -Infanrix is shorter in length with only 8 letters vs. 10 letters in Injectafer -Infanrix lacks the third upstroke and

Appendix E: Risk of medication errors due to product confusion minimized by dissimilarity of the names and/ or use in clinical practice for the reasons described.		
Proposed name: **Injectafer (Ferric Carboxymaltose) Injection**	**Strength(s):** **50 mg/mL**	**Usual dose:** **15mg/kg up to max single dose 750mg on two occasions separated by at least 7 days up to cumulative dose 1500mg intravenously**
Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion	**Causes (could be multiple)**	**Prevention of Failure Mode**
Adsorbed 25U/0.5mL, Pertussis Vaccine, Acellular (Adsorbed) 25mcg/0.5mL, Tetanus Toxoid, Adsorbed 10U/0.5mL Usual Dose: 0.5 mL intramuscular begin at 8 weeks old then at 4-8 week intervals to complete a total of 3 doses	- Both products are single strength products which can be omitted on a prescription -Same dosage form (injection)	downstroke present in Injectafer **Product characteristic differences** Different dose, directions for use (Infanrix must be given at specified schedule vs. Injectafer must be given on two occasions separated by at least 7 days), and storage condition (refrigeration for Infanrix vs. room temperature for Injectafer) Note: Infanrix is no longer marketed.

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