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.

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