CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

203565Orig1s000

OTHER 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

Label, Labeling and Packaging Review

Date:	July 15, 2013
Reviewer:	Kevin Wright, PharmD Division of Medication Error and Prevention Analysis
Acting Team Leader:	James Schlick, RPh, MBA Division of Medication Error and Prevention Analysis
Associate Director:	Scott Dallas, RPh Division of Medication Error and Prevention 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 #:	2013-820

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

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1 INTRODUCTION

This review evaluates the proposed container label, carton and insert labeling for Injectafer (Ferric Carboxymaltose) NDA 203565 for areas of vulnerability that could lead to medication errors.

1.1 REGULATORY HISTORY

Injectafer (Ferric Carboxymaltose Injection) is currently under review by the Division of Hematology Products (DHP). The labels and labeling were previously reviewed in OSE RCM# 2011-4401 dated, June 7, 2012. The applicant received a complete response letter from the Agency dated, July 23, 2012. On January 30, 2013, the Applicant submitted the container labels and carton labeling for review as part of a class 2 resubmission.

1.2 PRODUCT INFORMATION

The following product information is provided in the January 30, 2013 submission.

- Active Ingredient: Ferric Carboxymaltose
- Indication of Use: who are intolerant to oral iron, have had unsatisfactory response to oral iron, or who have chronic kidney disease not on dialysis.
- Route of Administration: Intravenous
- Dosage Form: Solution for Injection
- Strength: 750 mg per 15 mL (50 mg per mL)
- Dose and Frequency: administer intravenously either as an undiluted slow intravenous push injection or by a drip infusion. The recommended dosage is 15 mg/kg body weight 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.
- How Supplied: 15 mL vials in packages of 1 (b) (4)
- Storage: store at 20°C to 25°C (68°F to 77°F); excursions permitted to 15°C to 30°C (59°F to 86°F)
- Container and Closure System: glass vial with (b) (4) cap

2 METHODS AND MATERIALS REVIEWED

2.1 LABELS AND LABELING

Using the principles of human factors and Failure Mode and Effects Analysis,[1] along with post marketing medication error data, the Division of Medication Error Prevention and Analysis (DMEPA) evaluated the following:

- Container Labels submitted January 30, 2013 (Appendix A)
- Carton Labeling submitted January 30, 2013 (Appendices B and C)
- Insert Labeling submitted January 30, 2013 (no image)

2.2 PREVIOUSLY COMPLETED REVIEWS

DMEPA had previously reviewed the container labels and carton labels for Injectafer in OSE Review# 2011-4401 and we looked at the reviews to ensure all our recommendations were implemented.

3 CONCLUSIONS AND RECOMMENDATIONS

The updated labels and labeling implemented the majority of the recommendations outlined in the letter to the Applicant dated July 11, 2012 and the complete response letter dated July 23, 2012. However, there are outstanding recommendations along with some newly identified issues.

A. Container Labels

1. We continue to recommend, the Applicant revise the proprietary name to appear in title case (e.g. Injectafer).
2. Ensure the established name is at least ½ the size of the proprietary name taking into account all pertinent factors, including typography, layout, contrast, and other printing features. Additionally, the established name should have a prominence commensurate with the prominence of the proprietary name in accordance with 21 CFR 201.10(g)(2).
3. Revise the package type term from "(b) (4)" to "Single Dose Vial".
4. Remove the bold font from the distributor's name and the statement "Rx Only" to place emphasis on more important information such as the statement "Single Dose Vial. Discard Unused Portion".
5. Increase the size of the strength per mL statement, "50 mg/mL".

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

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