DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 203565/S-005

SUPPLEMENT APPROVAL
FULFILLMENT OF POSTMARKETING REQUIREMENT

Luitpold Pharmaceuticals, Inc.
Attention: Marsha Simon
Director, Regulatory Affairs
800 Adams Avenue
Norristown, PA 19403

Dear Ms. Simon:

Please refer to your Supplemental New Drug Application (sNDA) dated July 28, 2017, received July 28, 2017, and your amendments, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for INJECTAFER (ferric carboxymaltose injection), 750 mg/15 mL.

This Prior Approval supplemental new drug application provides for updates to the United States Prescribing Information (USPI) to adhere to the Pregnancy and Lactation Labeling Final Rule, removal of section 7 DRUG INTERACTIONS, and other minor formatting changes. The Patient Information label was also updated to be consistent with the USPI. In addition, this action includes fulfillment of Post Marketing Requirement 2064-1 based upon the final clinical study report submitted for clinical study 1VITI3036 entitled, "*A Multi-center, Open-label, Single Arm Study to Characterize the Pharmacokinetics and Pharmacodynamics Profile of Intravenous Ferric Carboxymaltose in Pediatric Subjects 1-17 years old with Iron Deficiency Anemia (IDA).*"

APPROVAL & LABELING

We have completed our review of this supplemental application, as amended. It is approved, effective on the date of this letter, for use as recommended in the enclosed, agreed-upon labeling text.

CONTENT OF LABELING

As soon as possible, but no later than 14 days from the date of this letter, submit the content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format using the FDA automated drug registration and listing system (eLIST), as described at http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm. Content

of labeling must be identical to the enclosed labeling (text for the package insert, text for the patient package insert), with the addition of any labeling changes in pending "Changes Being Effected" (CBE) supplements, as well as annual reportable changes not included in the enclosed labeling.

Information on submitting SPL files using eList may be found in the guidance for industry titled "*SPL Standard for Content of Labeling Technical Qs and As*" at http://www.fda.gov/downloads/DrugsGuidanceComplianceRegulatoryInformation/Guidances/UCM072392.pdf.

The SPL will be accessible from publicly available labeling repositories.

Also within 14 days, amend all pending supplemental applications that include labeling changes for this NDA, including CBE supplements for which FDA has not yet issued an action letter, with the content of labeling [21 CFR 314.50(l)(1)(i)] in MS Word format, that includes the changes approved in this supplemental application, as well as annual reportable changes and annotate each change. To facilitate review of your submission, provide a highlighted or marked-up copy that shows all changes, as well as a clean Microsoft Word version. The marked-up copy should provide appropriate annotations, including supplement number(s) and annual report date(s).

REQUIRED PEDIATRIC ASSESSMENTS

Under the Pediatric Research Equity Act (PREA) (21 U.S.C. 355c), all applications for new active ingredients, new indications, new dosage forms, new dosing regimens, or new routes of administration are required to contain an assessment of the safety and effectiveness of the product for the claimed indication(s) in pediatric patients unless this requirement is waived, deferred, or inapplicable.

Because none of these criteria apply to your application, you are exempt from this requirement.

FULFILLMENT OF POSTMARKETING REQUIREMENT(S)/COMMITMENT(S)

We have received your submission dated July 28, 2017, containing the final report for the following postmarketing requirement listed in the July 25, 2013 approval letter.

PMR 2064-1 Identify an optimal dose of INJECTAFER (ferric carboxymaltose injection) for the pediatric patient population. Conduct one or more pharmacokinetic (PK) and pharmacodynamic (PD) trials in pediatric patients aged 1 to <17 years with iron deficiency anemia sufficient to justify and to characterize the dose to be tested in a confirmatory clinical trial of safety and efficacy. Identify the most relevant PD endpoints to measure.

Final Protocol Submission:	07/2014
Trial Completion:	07/2016
Final Report Submission:	07/2017

We have reviewed your submission and conclude that the above requirement was fulfilled.

We remind you that there is a postmarketing requirement listed in the July 25, 2013 approval letter that is still open.

REPORTING REQUIREMENTS

We remind you that you must comply with reporting requirements for an approved NDA (21 CFR 314.80 and 314.81).

If you have any questions, call Thomas Iype, Regulatory Project Manager, at (240) 402-6861.

Sincerely,

{See appended electronic signature page}

Albert Deisseroth, MD, PhD
Supervisory Associate Division Director
Division of Hematology Products
Office of Hematology and Oncology Products
Center for Drug Evaluation and Research

ENCLOSURE:
Content of Labeling

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

/s/

ALBERT B DEISSEROTH
01/26/2018