DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 203565/S-008

SUPPLEMENT APPROVAL

Luitpold Pharmaceuticals, Inc.
Attention: Raenel Gibson
Regulatory Affairs Director
6610 New Albany Road East
New Albany, OH 43054

Dear Ms. Gibson:

Please refer to your Supplemental New Drug Application (sNDA) dated May 10, 2018, received May 10, 2018, and your amendments, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for INJECTAFER® (ferric carboxymaltose injection), 750 mg Iron/15 mL.

This "Changes Being Effected" supplemental new drug application provides for the following changes:

1. The removal of the DRUG INTERACTIONS section from the Full Prescribing Information: Content to align with the Full Prescribing Information.
2. "Single-Use" has been changed to "Single-Dose" throughout the Prescribing Information.
3. A correction of the age range of patients enrolled to Trial 1VIT09030 in subsection 14.2 (Trial 2: Iron Deficiency Anemia in Patients with Non-Dialysis Dependent Chronic Kidney Disease) of the Prescribing Information.
4. The following correction of a grammatical error in subsection 12.3 (Pharmacodynamics) of the Prescribing Information: "…61% to 84% after.." to "…61% to 84% at…".
5. The following correction of a grammatical error in subsection 6.2 (Post-marketing Experience) of the Prescribing Information: "pruritis" to "pruritus".
6. Updated manufacturer information at end of the Patient Package Insert.

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 Prescribing Information and 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. If the content of labeling in SPL format initially submitted with this CBE-0 labeling supplement is identical to the attached approved labeling, an additional submission of content of labeling in SPL format is not required.

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 Microsoft Word format, that includes the changes approved in this supplemental application, as well as annual reportable changes. To facilitate review of your submission(s), 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).

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

ENCLOSURES:
Content of Labeling
Prescribing Information
Patient Package Insert

This is a representation of an electronic record that was signed electronically. Following this are manifestations of any and all electronic signatures for this electronic record.

/s/

ALBERT B DEISSEROTH
10/25/2018