NDA 203565/S-009

SUPPLEMENT APPROVAL

American Regent, Inc.
Attention: Elizabeth Ernst
Global Executive Director of Regulatory Affairs
5 Ramsey Road
Shirley, New York 11967

Dear Ms. Ernst:

Please refer to your supplemental new drug application (sNDA) dated and received August 16, 2019, 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 Prior Approval supplemental new drug application provides for revisions to the following sections of the approved labeling:

1. In section **1 Indications and Usage**, a minor editorial change to add the word "or"
2. Revised section **2 Dosage and Administration** to include new subsections **2.1 Recommended Dosage** and relevant language, **2.2 Preparation and Administration** and relevant language, **2.3 Repeat Treatment Monitoring Safety Assessment** and relevant language
3. In section **5 Warnings and Precautions** added a new subsection **5.2 Symptomatic Hypophosphatemia** with relevant language
4. In section **6 Adverse Reactions** added a new bullet titled **hypophosphatemia [Post-marketing Experience (6.2)]**
5. Revised language in section **6.2 Post-marketing Experience**

APPROVAL & LABELING

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

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 FDA.gov.[1] Content of labeling must be identical to the enclosed labeling (text for the Prescribing Information, 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 *SPL Standard for Content of Labeling Technical Qs and As*.[2]

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).

All promotional materials that include representations about your drug product must be promptly revised to be consistent with the labeling changes approved in this supplement, including any new safety information [21 CFR 314.70(a)(4)]. The revisions in your promotional materials should include prominent disclosure of the important new safety information that appears in the revised labeling. Within 7 days of receipt of this letter, submit your statement of intent to comply with 21 CFR 314.70(a)(4) to the address above, by fax to 301-847-8444, or electronically in eCTD format. For more information about submitting promotional materials in eCTD format, see the draft guidance for industry *Providing Regulatory Submissions in Electronic and Non-Electronic Format-Promotional Labeling and Advertising Materials for Human Prescription Drugs*.

REPORTING REQUIREMENTS

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

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[1] http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm
[2] We update guidances periodically. For the most recent version of a guidance, check the FDA Guidance Documents Database https://www.fda.gov/RegulatoryInformation/Guidances/default.htm.

If you have any questions, call Ms. June Germain, Safety Regulatory Project Manager, at 301-796-4024.

Sincerely,

{See appended electronic signature page}

Rosanna Setse, MD, PhD
Acting Deputy Director Safety
Division of Hematology Products
Office of Drug Evaluation I
Center for Drug Evaluation and Research

ENCLOSURES:
Content of Labeling
Prescribing Information
Patient Package Insert