DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 20955/S-013
NDA 20955/S-015

SUPPLEMENT APPROVAL

Sanofi-aventis U.S. LLC
Attention: Debra Wiel
Manager, General Therapeutics
US Regulatory Affairs for Marketed Products
55 Corporate Drive, Room C-2203
Bridgewater, NJ 08807

Dear Ms. Wiel:

Please refer to your Supplemental New Drug Application (sNDA) dated June 30, 2010, received June 30, 2010, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Ferrlecit® (sodium ferric gluconate complex sucrose injection), 62.5 mg (12.5 mg/mL).

We acknowledge receipt of your amendments dated March 1, August 15 and August 24, 2011.

The March 1, 2011 submission constituted a complete response to our December 27, 2010 action letter.

This "Prior Approval" supplemental new drug application provides for revisions to the content and format of the Ferrlecit package insert, according to the Final Rule titled "Requirements on Content and Format of Labeling for Human Prescription Drug and Biologic Products" (published in the Federal Register dated January 24, 2006), and also includes new safety information.

We also refer to your sNDA, supplement S-015, dated and received February 25, 2011 and your amendment dated August 24, 2011. This "Changes Being Effected" supplemental new drug application provides for changes to the PI to include both vial and ampoule presentations.

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

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, Medication Guide), 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 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).

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 package 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 or by fax to 301-847-8444.

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, contact Trinh Scott, Regulatory Project Manager, at (301) 796-3311 or Trinh.Scott@fda.hhs.gov.

Sincerely,

{See appended electronic signature page}

Ann T. Farrell, M.D.
Division Director (Acting)
Division of Hematology Products
Office of Oncology Drug Products
Center for Drug Evaluation and Research
Food and Drug Administration

ENCLOSURE(S):
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/

ANN T FARRELL
08/25/2011