DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville, MD 20857

ANDA 078215

GeneraMedix Inc.
Attention: Christopher Zuccarelli
Sr. Vice President, Technical Operations
150 Allen Road, Suite 110
Liberty Corner, NJ 07938

Dear Sir:

This is in reference to your abbreviated new drug application (ANDA) dated March 21, 2006, submitted pursuant to section 505(j) of the Federal Food, Drug, and Cosmetic Act (the Act), for Sodium Ferric Gluconate Complex in Sucrose Injection, 12.5 mg Iron/mL; packaged in 5 mL Single-dose Vials.

Reference is also made to your amendments dated June 19, September 10, and October 24, 2007; February 14, July 1, August 6, October 7, October 21, November 7, November 10, November 11, and December 16, 2008; April 22 (2 submissions), April 27, June 25, August 6, September 23, November 10, November 25, and December 9, 2009; March 24, May 24, June 21, and September 8, 2010; and March 30, 2011.

We have completed the review of this ANDA and have concluded that adequate information has been presented to demonstrate that the drug is safe and effective for use as recommended in the submitted labeling. Accordingly the ANDA is approved, effective on the date of this letter. The Division of Bioequivalence has determined your Sodium Ferric Gluconate Complex in Sucrose Injection, 12.5 mg Iron/mL, to be bioequivalent and, therefore, therapeutically equivalent to the reference listed drug, Ferrlecit Injection, 12.5 mg Iron/mL, of Sanofi Aventis US, LLC.

Under section 506A of the Act, certain changes in the conditions described in this ANDA require an approved supplemental application before the change may be made.

We note that if FDA requires a Risk Evaluation & Mitigation Strategy (REMS) for a listed drug, an ANDA citing that listed drug also will be required to have a REMS, See 505-1(i).

Postmarketing reporting requirements for this ANDA are set forth in 21 CFR 314.80-81 and 314.98. The Office of Generic Drugs should be advised of any change in the marketing status of this drug.

Promotional materials may be submitted to FDA for comment prior to publication or dissemination. Please note that these submissions are voluntary. If you desire comments on proposed launch promotional materials with respect to compliance with applicable regulatory requirements, we recommend you submit, in draft or mock-up form, two copies of both the promotional materials and package insert directly to:

Food and Drug Administration
Center for Drug Evaluation and Research
Division of Drug Marketing, Advertising, and Communications
5901-B Ammendale Road
Beltsville, MD 20705

We call your attention to 21 CFR 314.81(b)(3) which requires that all promotional materials be submitted to the Division of Drug Marketing, Advertising, and Communications with a completed Form FDA 2253 at the time of their initial use.

As soon as possible, but no later than 14 days from the date of this letter, please submit updated content of labeling [21 CFR 314.50(1)] in structured product labeling (SPL) format, as described at http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm, that is identical in content to the approved labeling (including the package insert, and any patient package insert and/or Medication Guide that may be 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/DrugsGuidanceComplianceRegulatoryInforation/Guidances/U_CM072392.pdf

The SPL will be accessible via publicly available labeling repositories.

Sincerely yours,

{See appended electronic signature page}

Keith Webber, Ph.D.
Deputy Director
Office of Pharmaceutical Science
Center for Drug Evaluation and Research

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

/s/

ROBERT L WEST

03/31/2011

Deputy Director, Office of Generic Drugs
for Keith Webber, Ph.D.