



Food and Drug Administration
Kansas City District
Southwest Region
11630 West 80th Street
Lenexa, Kansas 66214-3340

Telephone: (913) 752-2100

December 8, 2003

**CERTIFIED MAIL
RETURN RECEIPT REQUESTED**

WARNING LETTER

Ref. KAN 2004-02

Gregory B. Vinardi
President/CEO
Western Missouri Medical Center
403 Burkarth Road
Warrensburg, Missouri 64093

Dear Mr. Vinardi:

During an inspection of your unlicensed hospital blood bank, located at 403 Burkarth Road, Warrensburg, Missouri on September 4 to 17, 2003, our investigators documented deviations from Section 501(a)(2)(B) of the Federal Food, Drug, and Cosmetic Act (the Act) and the Current Good Manufacturing Practice (CGMP) Regulations for Blood and Blood Components under Title 21, Code of Federal Regulations (CFR), Parts 606 and 640. The deviations found include, but are not limited to, the following:

Failure to follow written standard operating procedures (SOP's) [21 CFR 606.100]. For example:

Fourteen of nineteen Transfusion Reaction Reports reviewed had various discrepancies and were not complete: Two reports showed hemoglobin present in the patient's urine and no further work-up/testing was performed. Ten reports showed incomplete and inconsistently documented test results in section 2 (Hemolysis) on the Transfusion Reaction Report. In two reports employees failed to identify with signature or date, work performed in the Specimen Collection box on the Transfusion Reaction Report.

Failure to concurrently maintain records during the collection of blood so that processing steps can be clearly traced [21 CFR 606.160(a)(1)]. For example:

Your SOP "THERAPEUTIC PHLEBOTOMY AND ASSESSMENT" states the documentation required and laboratory actions necessary to maintain records. Review of "THERAPEUTIC PHLEBOTOMY PATIENT LOG" showed incomplete records for three of fifteen patient forms.

Failure to assure that personnel have necessary experience in and a thorough understanding of the operations which they perform. Training is inadequate [21 CFR 606.20(b)]. For example:

Four of four employees interviewed are not following your SOP for investigation of transfusion reactions. This SOP is used as part of your on the job training. Employee training and interpretation regarding transfusion reaction work-up is inconsistent.

Failure to determine donor suitability on day of collection by means of a medical history [21 CFR 640.3(a)]. For example:

Review of Autologous donor records for 2002 showed patient's medical history taken upon initial donation but not on subsequent donations. Your SOP "AUTOLOGOUS TRANSFUSION" under "CRITERIA FOR DONATION" states a donor history will be evaluated on the day of donation.

In addition, although not included on the Form FDA 483 (List of Inspectional Observations) issued to you at the close of the inspection, we noted, and discussed with you, the firm's failure to address viral hepatitis qualifications as part of medical history [21 CFR 640.3(c)].

The above identified deviations are not intended to be an all inclusive list of deficiencies at your facility. It is your responsibility to assure that your establishment is in compliance with all requirements of the federal regulations.

You should take prompt measures to correct these deviations. Failure to promptly correct these deviations may result in regulatory action without further notice. Such action includes seizure and/or injunction.

We are in receipt of a response from your firm dated October 13, 2003 and signed by Kathy J. LeMay. Although it appears from your response that you are working toward correcting the deviations noted at your firm, you must adequately implement and maintain each corrective action to ensure its effectiveness. We will verify the adequacy of your corrective actions during our next FDA inspection.

Please notify this office in writing, within 15 working days of receipt of this letter, of any additional steps you have taken to correct the noted violations and to prevent their recurrence. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time within which the corrections will be completed.

Gregory B. Vinardi, President/CEO
Western Missouri Medical Center
December 8, 2003
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Your reply should be addressed to Joseph G. Kramer, Compliance Officer, at the above address.

Sincerely,



for Charles W. Sedgwick
District Director
Kansas City District