



May 7, 2004

**WARNING LETTER NO. 2004-NOL-26**

**FEDERAL EXPRESS  
OVERNIGHT DELIVERY**

Mr. Robert C. Davidge, CEO  
Our Lady of the Lake Hospital, Inc.  
Blood Bank  
5000 Hennessey Boulevard  
Baton Rouge, Louisiana 70808

Dear Mr. Davidge:

During an inspection of your hospital blood bank, located at 5000 Hennessey Boulevard, Baton Rouge, Louisiana, on March 30 - April 2, 5 - 8, 2004, our investigator documented deviations from the Current Good Manufacturing Practice (CGMP) regulations for blood and blood components under Title 21, *Code of Federal Regulations* (CFR), Parts 600-680 (21 CFR 600 - 680). These deviations cause your blood products to be adulterated within the meaning of Section 501(a)(2)(B) of the Federal Food, Drug, and Cosmetic Act (the Act). You can find the Act and the other regulations through links in FDA's home page at <http://www.fda.gov>.

The deviations documented were as follows:

1. Your facility failed to perform a thorough investigation and make a record of the conclusions and follow-up of unexplained discrepancies [21 CFR 606.100(c)]. Specifically, for the period March 2003 to March 2004, your facility documented over 800 instances in which the secondary review of donor records detected undocumented or unexplained medical history questions or incomplete medical evaluations. Your facility does not have records to document that the blood /blood components from these donations were quarantined pending determination of donor suitability, any follow-up made to determine the suitability of the donor prior to the release of the units, the date of any follow-up, and the identification of the person(s) who made the follow-up and completed the donor record.
2. Records are not concurrently maintained with the performance of each significant step in the collection and processing of each unit of blood and blood components so that all steps can be clearly traced [21 CFR 606.160(a)(1)]. For Example:
  - a. On June 25, 2003, your facility accepted a Donor Record, pertaining to unit [ ] that was submitted to you by the donor via facsimile after the unit was collected on June 24, 2003. The components from this unit (leukoreduced RBCS and recovered plasma) were distributed on June 30, 2003.



The above deviations are not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to ensure that all blood products distributed by your facility are in compliance with the Act and the CGMP regulations. You should take prompt action to correct these deviations. Your failure to correct these deviations may result in regulatory action being taken by FDA without further notice. Possible actions include seizure and/or injunction.

We are aware that during the inspection, Mr. Kirk G. Wilson, President and COO, made a verbal commitment to correct violations observed at your firm. However, we request that you notify this office in writing, within fifteen (15) working days of receipt of this letter, of specific steps you have taken to correct these deviations, including examples of any documentation such as employee training records, written standard operating procedures, or other records demonstrating corrective action. If you cannot complete corrections within 15 working days, state the reason for the delay and the time period within which corrections will be completed.

Your reply should be directed to Mark W. Rivero, Compliance Officer, at the above address.

Sincerely,

  
Patricia K. Schafer  
Acting District Director  
New Orleans District

Enclosure: Form FDA 483

cc: [redacted], Medical Director  
Our Lady of the Lake Hospital, Inc. - Blood Bank  
5000 Hennessey Boulevard  
Baton Rouge, Louisiana 70808