



**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

Public Health Service

dir 86

HFI-35

**Food and Drug Administration**  
555 Winderley Place, Suite 200  
Maitland, Florida 32751

**CERTIFIED MAIL**  
**RETURN RECEIPT REQUESTED**

**WARNING LETTER**

FLA-98-52

June 10, 1998

German F. Leparc, M.D.  
Chief Executive Officer  
Florida Blood Services, Inc.  
P.O. Box 2125  
Tampa, Florida 33601-2125

Dear Dr. Leparc:

During an inspection of your licensed blood bank, located at 445 31st Street North, St. Petersburg, Florida, from April 27 through May 12, 1998, our investigator, Joan S. Norton, documented serious violations of 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 [Title 21, Code of Federal Regulations, Part 606 (21 CFR 606)].

The inspection revealed that your established written procedure for reporting FTA-ABS Indirect Fluorescent Antibody Test results is not in accordance with the test kit manufacturer's instructions for use in that your written procedure states that a repeat test reading of 1+ fluorescence is to be reported as "Non-Reactive", whereas the manufacturer's test kit instructions state that a repeat test reading of 1+ fluorescence is to be reported as "Reactive Minimal".

Your failure to follow the test kit manufacturer's instructions for reporting FTA-ABS confirmatory test results for syphilis resulted in the acceptance of donors who should have been deferred and the subsequent issuance of unsuitable blood components collected from those donors. This failure also resulted in your blood bank reporting non-reactive confirmatory test results for syphilis to other blood banks that you perform testing for under contract when the results should have been reported to them as reactive minimal.

The inspection also revealed that your established written procedure for the preparation of Cryoprecipitate AHF is not being followed. A combined total of thirty-five units of finished Cryoprecipitate AHF produced on December 1, 1997 and April 21, 1998, were not refrozen within one hour of the time the blood components were separated from the plasma as specified by your written procedure. In addition, documentation showed that a supervisor reviewed the production records for both days, but failed to prevent the issuance of these units which were subsequently recalled by your blood bank during the inspection.

We acknowledge receipt of your letter, dated May 19, 1998, submitted in response to the Inspectional Observations (Form FDA 483) issued at the close of the inspection, addressing the listed observations and stating corrective actions taken. The corrective actions stated in your response with regard to revisions of your written procedure for FTA-ABS test reporting, revisions of your written procedures and production logs for Cryoprecipitate production, and retraining of staff appear adequate. However, your response only addresses corrective action (deferral and recall of blood components) with regard to one donor (0052540) whose FTA-ABS confirmatory syphilis test results were reported incorrectly. This response does not alleviate our concerns regarding other donors that also had incorrect test results reported or the incorrect test reports sent to other blood banks that you perform testing for.

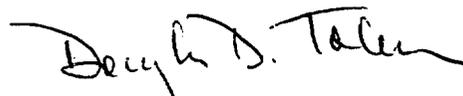
Including the two recalls above, our records show that your blood bank has initiated fourteen recalls of unsuitable blood components for various reasons over the last sixteen months. Resorting to recall time and again attempting to retrieve unsuitable blood components issued by your blood bank further demonstrates what may be additional inadequacies in written, training, and supervisory review procedures established by your blood bank.

The above identification of violations is not intended to be an all-inclusive list of deficiencies at your facility. As chief executive officer and medical director, it is your responsibility to ensure that all blood and blood components produced and issued by your blood bank are in compliance with the Act and the CGMP regulations. You should take prompt action to correct these violations. Failure to correct these violations may result in administrative and/or regulatory action without further notice. Such action includes, license suspension and/or revocation, seizure and/or injunction.

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 violations, including examples of any documentation showing that corrections have been achieved. If corrections cannot be completed within 15 working days, state the reason for the delay and the time frame within which corrections will be completed.

Your reply should be directed to Jimmy E. Walthall, Compliance Officer, U.S. Food and Drug Administration, 555 Winderley Place, Suite 200, Maitland, Florida 32751, telephone (407) 475-4731.

Sincerely,



Douglas D. Tolen  
Director, Florida District