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Food and Drug Administration
7200 Lake Ellenor Drive
Orlando, FL 32809

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

WARNING LETTER

FLA-97-71

July 18, 1997

German F. Leparc, M.D.
Responsible Head
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 3602 Spectrum Boulevard, Tampa, Florida, from June 2 through June 12, 1997, our investigator, Joan S. Norton, documented 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)].

Inspection revealed that your blood bank failed to consistently follow established written procedures and test kit manufacturer's instructions for viral marker testing. For example, duplicate repeat testing on blood unit #3144673 found to be initially reactive for HIV 1-2 was not performed. Three unsuitable blood components (red blood cells, platelets, and plasma) prepared from this blood unit were released for distribution based on a single negative repeat test. Also, reagents from two different test kit lots were used for HBsAg test batch #BH0066 causing the test to be invalid. Fifty-seven unsuitable blood components (red blood cells and platelets) were released for distribution based on this invalid test. In addition, thirteen units of platelets were released for distribution based on invalid Treponema Palladium test results from a batch run on November 5, 1996.

The release for distribution of the above unsuitable blood components based on invalid and/or incomplete test results shows that the procedures in place for supervisory review and quality control are inadequate to insure that all blood products produced and released for distribution by your blood bank meet the standards designed to insure the safety and purity of such products. In addition, your blood bank failed to promptly notify FDA of these reportable errors and/or accidents as required.

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The inspection also revealed that donor screening personnel failed to examine both arms of donors #3445291 and #3445293 for signs of narcotic addiction. However, donor suitability records for both donors documented that the arms of both donors were found to be satisfactory. We note that our investigator orally discussed this same deviation with donor screening personnel during a recent inspection of your collection site on Davis Island.

The above identification of violations is not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to ensure that all blood products produced and distributed by your blood bank are in compliance with the Act and the requirements of 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.

You should notify this office in writing, within 15 working days of receipt of this letter, of specific steps you have taken to correct these violations. 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, 7200 Lake Ellenor Drive, Suite 120, Orlando, Florida 32809, telephone (407) 648-6823, extension 263.

Sincerely,



Douglas D. Tolen
Director, Florida District