



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

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

Telephone: 407-475-4700  
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VIA FEDERAL EXPRESS

WARNING LETTER

FLA-99-84

August 12, 1999

John H. Flynn, President  
South Florida Blood Bank, Inc.  
933 45<sup>th</sup> Street North  
West Palm Beach, Florida 33407

Dear Mr. Flynn:

During an inspection of your licensed blood bank from July 12 through July 22, 1999, 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 complete and accurate donor deferral records are not being maintained. A deferred donor that tested repeatedly reactive HBsAg on February 12, 1998 (Unit #2251435) was improperly re-entered for donation on August 12, 1998 without a neutralization test being performed. This donor should have remained in deferral. However, the reactive test result in your computer system for Unit #2251435 was manually changed to a negative test result for re-entry purposes and this unsuitable donor was accepted for donation on three subsequent occasions (Units #7896092, #7974043, and #7993801). Unsuitable blood components prepared from those units were issued by your blood bank for transfusion purposes.

The investigator documented that positive viral marker test results for HBsAg and HCV, originally entered in your computer system resulting in donor deferrals, are routinely being manually changed to negative test results in what appears to be a work around the system to allow for the re-entry of qualified donors. Your written procedures fail to contain specific instructions for changing these electronic test results. We believe this practice contributed to the above incident and fails to ensure the integrity of the electronic testing data in your computer system.

Your established written procedure for donor deferral fails to include instructions for placing autologous donors that test repeatedly reactive for various viral markers into your deferral system to prevent subsequent allogeneic donations. For example, our investigator documented five autologous donors with repeatedly reactive HCV tests and one autologous donor with a repeatedly reactive HBc test that were not placed in deferral.

The inspection also revealed that no written procedures are established for physical quarantine and storage of untested and unsuitable blood components. During the inspection, a platelet component prepared from Unit #7985929, which tested repeatedly reactive for HIV 1-2, was not maintained in physical quarantine, could not be located, and there was no documentation available to show the final disposition of this component. There was also no documentation available to show the final disposition of another platelet component prepared from Unit #7974043 (collected from the above-mentioned HBsAg unsuitable donor) which expired at the consignee and was returned to your blood bank.

In addition, no written procedures are established for registering donors electronically and providing donors with AIDS educational information, or for explaining potential risks and complications of plateletpheresis to donors. On July 13, 1999 our investigator observed a first time plateletpheresis donor (Unit #7996566) who was not asked to read the informed consent nor were the possible risks explained to the donor prior to being asked to sign the consent and undergoing the plateletpheresis procedure.

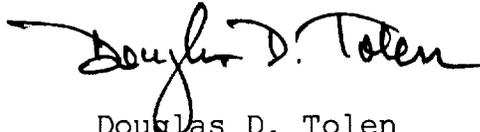
The inspection further revealed inadequate computer security to assure data integrity and failure to correct a deviation cited during our previous inspection. Our investigator observed an employee hired in January 1999 gaining access to your computer system using the same generic password provided to all new employees during training, and documented continued failure to recalibrate the blood collection scales on mobile units used in multiple blood drives on the same day.

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 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 period 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,

A handwritten signature in black ink that reads "Douglas D. Tolen". The signature is written in a cursive style with a large, looping initial "D".

Douglas D. Tolen  
Director, Florida District