HFI-35

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

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

Telephone: 407-475-4700
FAX: 407-475-4769

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

WARNING LETTER

FLA-99-57

April 30, 1999

Donald D. Doddridge
Chief Operating Officer
Florida Blood Services, Inc.
P.O. Box 2125
Tampa, Florida 33601

Dear Mr. Doddridge:

During an inspection of your licensed blood bank and control laboratory located at 3602 Spectrum Boulevard, Tampa, Florida, from January 25 through March 12, 1999, our investigators, Joan S. Norton and Paul L. Figarole, 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 incomplete, inaccurate, and/or nonexistent records for all blood components produced. No documentation was available to show the final disposition of plasma separated from whole blood unit #3375264 which tested repeatedly reactive HIV 1-2 on October 12, 1998, for plasma separated from fourteen (14) other units of whole blood processed between February 1998 and January 1999, or for platelets processed from six (6) units of whole blood on January 10, 1999. These blood components were not found in inventory and no documentation was available to show they were destroyed or that the platelets were used for quality control testing.

The inspection also revealed that [redacted] error messages on your computer system are not routinely reviewed, processed, and investigated to determine final disposition. The instructions for computer system training do not include a clear written explanation of what error messages are and what the user is supposed to do when an error message is encountered. No written procedures are established for the review, processing, and final disposition of error messages. In addition, your written procedures for computer validation do not include clear explanations of what to do when risk analysis weights fall between 0 to 9, how QA will perform validation review before and after testing, what the I/S Systems Manager is to review and how to perform the review, or when and how to document live system checks after testing on the training system.

We acknowledge receipt of your March 9, 1999 letter 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 concerning the computer system observations appear adequate. However, your response fails to adequately address the final dispositions of the twenty-one unaccounted for blood components specified above, including the unsuitable plasma component separated from blood unit #337264 which tested repeatedly reactive HIV 1-2. This response provides no assurance that a thorough investigation has been made to determine the disposition of these and possibly other unaccounted for blood components produced by your blood bank and does not alleviate our concerns.

During the inspection, you stated that these components could not have been shipped without being labeled. However, the units were not in inventory and there was no documentation of destruction. Members of your staff theorized that these blood components may have never been produced or that personnel may have wanded empty bags which 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 operating officer, 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,

Edward R. Atkins for

Douglas D. Tolen
Director, Florida District