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VIA FEDERAL EXPRESS

Food and Drug Administration
555 Winderley Pl., Ste. 200
Maitland, Fl 32751

WARNING LETTER

FLA-01-80

August 27, 2001

James R. Nathan, President -
Lee Memorial Health System -
8300 College Parkway, Suite 201
Ft. Myers, Florida 33919

Dear Mr. Nathan:

During an inspection of your unlicensed blood bank, located at the Lee Memorial Hospital, 2776 Cleveland Avenue, Ft. Myers, Florida, on June 11-20, 2001, 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 failure of your blood bank to adequately determine the suitability of persons to serve as whole blood donors. One donor (unit [REDACTED]) tested repeatedly reactive for HIV 1-2 in screening tests performed on March 21, 2001 and was never placed in deferral. Donor deferral records maintained electronically failed to contain the names of all donors who were determined unacceptable for donation based on donor suitability questions. At least ten donors answered yes to donor screening questions on a mobile unit that resulted in temporary and/or permanent deferral on manual registration records. However, these donors were not found in the electronic deferral records. In addition, nine of these donors were not found in the donor base as ever being registered. If any of these donors presented themselves for donation at your blood bank at a later date, they could be registered in your computer as first time donors with no past deferral history and accepted for donation.

The inspection also revealed inadequate training of personnel in the operations they perform and failure to maintain employee-training records. The blood center coordinator responsible for assuring that donor room personnel are trained and competent in their assigned duties has received no prior CGMP training and has no prior experience in donor center operations. This lack of personnel training has resulted in inadequate supervision of your blood bank operations as demonstrated by the inspectional findings.

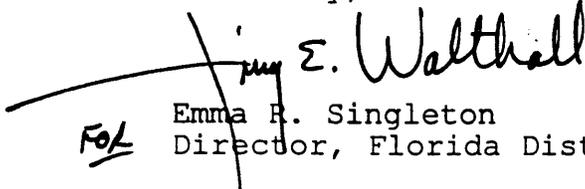
Other deviations documented by the investigator during the inspection included: failure to establish and implement a written quality assurance program; failure to establish written procedures for receiving and evaluating information on possible product deviations; failure to establish written procedures for review and evaluation of post donation information; and inadequate written procedures for performing RPR testing in accordance with the manufacturer's directions. The investigator also documented that three donors were asked to sign donor consents acknowledging they had read the AIDS education material and had given a true and accurate medical history prior to an interview or being given any information on AIDS. In addition, one phlebotomist did not follow the established written procedure for arm preparation prior to venipuncture.

The above violations are not intended to be an all-inclusive list of deficiencies at your blood bank facility. As president of the Lee Memorial Health System, 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 further regulatory action being taken by FDA without further notice. Such action includes seizure and/or injunction.

We request that you notify this office in writing, within fifteen (15) working days of receipt of this letter, of the specific steps you have taken to correct these violations and to prevent their recurrence. Your response should include examples of documentation showing that corrections have been achieved. If corrective action cannot be completed 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 Jimmy E. Walthall, Compliance Officer, U.S. Food and Drug Administration, 555 Winderley Place, Suite 200, Maitland, Florida 32751, telephone (407) 475-4731.

Sincerely,


FOL
Emma R. Singleton
Director, Florida District