



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service  
Food and Drug Administration

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19900 MacArthur Blvd., Ste 300  
Irvine, California 92612-2445  
Telephone (949) 798-7600

WARNING LETTER

February 28, 2001

CERTIFIED MAIL - RETURN RECEIPT REQUESTED

George W. Graham, President and CEO  
Torrance Memorial Medical Center  
3330 West Lomita Boulevard  
Torrance, CA 90505

WL 27-01

Dear Mr. Graham:

During an inspection of your unlicensed blood bank, transfusion and testing service located in Torrance, CA, conducted January 22 through 25, 2001; an FDA investigator documented violations of current Good Manufacturing Practices (cGMP, Title 21, Code of Federal Regulations (CFR), §§ 600 through 680) that cause all blood products collected, processed, compatibility tested or stored at your facility to be adulterated within the meaning of Section 501(a)(2)(B) of the Federal Food, Drug and Cosmetic Act (the Act). The violations from cGMP include:

1. Failure to maintain records that include permanent and temporary deferrals for health reasons [§606.160(b)(1)(ii)] in that donors testing repeatedly reactive were not deferred as appropriate by the [REDACTED] computer system, which maintains donor deferral information at your firm.
2. Failure to follow all steps in standard operating procedures (SOPs) designed to look at prior donations of a donor who has donated and subsequently tests repeatedly reactive for human immunodeficiency virus or is otherwise determined to be unsuitable [§606.100(b)(19)] in that donors testing repeatedly reactive were not deferred as required by your firm's SOP.
3. Failure to maintain and follow all steps in the collection, processing, compatibility testing, storage and distribution of blood and blood components including criteria used to determine donor suitability [§606.100(b)(1)(ii)] in that unacceptable answers to donor questionnaire questions were not clarified prior to collection and distribution of the unit.
4. Failure to maintain records concurrently with the performance of each significant step [§606.160(a)] in that incubation time periods are not directly recorded on the [REDACTED] but recorded on "scrap paper" which is later copied and discarded.

The above listed violations are not intended to be an all-inclusive list of deviations that may exist at your facility. It is your responsibility to ensure that that your blood establishment is in full compliance with

Letter to Mr. Graham

Page 2

the Act and regulations promulgated thereunder. You should take prompt action to correct these deviations. Failure to promptly correct these deviations may result in further regulatory action without further notice, which may include Order for Retention, Recall and/or Destruction, and/or Injunction.

We have received your response to the Form FDA-483, Inspectional Observations, dated February 19, 2000. During the inspection, Ms. Julia Tobin, Blood Bank Supervisor, suggested to our investigator that the reason a donor's record in the computer system did not reflect the correct deferral status was possibly due to a computer "glitch". The donor in question was repeatedly reactive for HIV 1/2, the nurses at the donor center would not have been able to determine that the donor was unacceptable and the donor would have been allowed to donate. There is no further review of donor acceptability records before product release for distribution at your establishment. Because of all the factors mentioned above, the District feels that the failure of your establishment to defer this donor created a potentially serious health hazard. You indicate in your response that the donor deferral software did not allow access to a file and the deferral information to be input because the file was already opened by a second individual and your software does not allow the file to be accessed by two accounts at the same time. In addition, you say that the operators received an appropriate error message indicating access to the file was denied.

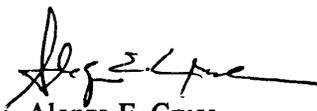
To prevent recurrence of the deferral failure, you state "when the supervisor review performed on all deferred donor the [redacted] file will be checked for the proper codes in [redacted]". You do not indicate you provided the operators inputting the data any information or instructions on how to respond when they encounter the access denied error message in the future to ensure that the data they are entering is accepted. Additionally, you did not provide any information as to the results of your investigation into the failure, to include a review of all donor records to assess the extent of the problem in order to uncover units that were donated after a donor should have been deferred. If you find any donors that should have been deferred, you need to determine the disposition of any units found and update the status of those donors as necessary. Please perform this review of all donor records, specifically looking for failures to appropriately defer donors, and provide us with the results of this review to include an accounting of any units donated after the donor should have been deferred.

Please notify this office in writing, within fifteen (15) working days of your receipt of this letter, of the specific steps you have taken to correct the noted deviations and to prevent their recurrence. If corrective action cannot be completed within fifteen working days, please state the reason for the delay, and the time within which corrections will be completed.

Your reply should be directed to the Food and Drug Administration, Attention:

Thomas L. Sawyer  
Director, Compliance Branch  
Food and Drug Administration  
19900 MacArthur Blvd., Suite 300  
Irvine, CA 92612

Sincerely,



Alonza E. Cruse  
District Director