



60 8th Street, N.E.
Atlanta, Georgia 30309

November 15, 1996

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Mr. Gene A. Erickson
Chief Executive Officer
Carolina Georgia Blood Center
515 Grove Road
Greenville, South Carolina 29607

WARNING LETTER

Dear Mr. Erickson:

During an inspection of your blood bank, located at 515 Grove Road, Greenville, South Carolina 29607, on September 3-20, 1996, our investigators documented violations of Section 501(a)(2)(B) of the Federal Food, Drug, and Cosmetic Act and Title 21, Code of Federal Regulations (21 CFR), Parts 600-680 as follows:

1. Failure to assure that personnel have the necessary training and experience relating to their respective functions to assure competent performance of their assigned functions, and to ensure that the final product has the safety, purity, potency, identity and effectiveness it purports or is represented to possess [21 CFR 606.20(b)] in that:
 - (a) The Platelet QC failed for the month of August, 1996. Records indicated that a centrifuge was identified as the problem; however, records failed to show that the centrifuge was taken out of service for repairs.
 - (b) Laboratory employees failed to perform test according to manufacturer directions and specifications, e.g., failure to perform initially reactive HAG test in duplicate using the same test system.
 - (c) Laboratory employees failed to handle properly alarm reports/alarm messages received from the Data Management System. The daily "Alarm Report" is discarded prior to reviewing/resolving the unusual testing issues. The Alarm Report contained unresolved testing issues from January 27, 1996, through September 4, 1996. For an example, the Alarm Report contained 6 samples with viral tests (HAG) that were transferred and retransferred into DMS on 5/3/96 and/or 5/4/96 and again on 5/7/96.

- (d) Health Historians failed to adequately determine the suitability of persons to serve as the source of whole blood.
 - (e) Phlebotomist routinely recorded the volume drawn as 450 mls. prior to completion of the procedure.
2. Failure to maintain concurrent, detailed and/or accurate records [21 CFR 606.160(a)] in that the data that is in the deferral database revealed that conflicting data was listed on the computer generated deferral list, for example:
- (a) Donor TED is listed on the deferral list as hepatitis confirmed, but the donor inquiry shows components from the 8/18/87 and 8/15/90 donations were distributed for transfusion. There was no entry in the record to explain why some components from this donor were destroyed and others distributed.
 - (b) Review of test records failed to support the deferral category of HBSC. There is no entry in the record to explain this donor being listed as confirmed positive.
 - (c) Donor TED is currently permanently deferred for high risk behaviors.
3. Failure to maintain an adequate monitoring system regarding making entries into the computer and documenting the final disposition of blood components. Record/documentation review revealed that units of blood/blood components were located in the computer system without a final disposition.
4. Failure to maintain and/or follow adequate written standard operating procedures [21 CFR 606.100(b)] in that:
- (a) Review of the Anti-HCV Positive Donor Re-entry SOP dated July, 1995; does not reference or explain permanent deferral of the donor if a subsequent unit test repeat reactive after the donor has been re-entered.
 - (b) The Anti-HIV Lookback procedure does not require routine follow-up with the consignees if incomplete data is received.
 - (c) The training SOPs for Donor Services, Product Management and Technical Services are not specific in detailing the intervals for annual proficiency testing.
 - (d) There is no written SOP that requires Parallel Processing Center (PPC) test tapes to be reviewed and retained. The PPC test tapes of viral marker test runs are routinely discarded.

- (e) There is no procedure in place to log in power failures which result in testing equipment and computer system shutdowns in the laboratory.

We have reviewed your September 27, 1996 letter in response to the September 20, 1996 Form FDA 483 issued at the conclusion of the inspection. Corrective actions addressed in that letter may be referenced in your response to this letter, as appropriate; however, some of your responses do not appear to be adequate, and your responses may be verified on reinspection. We have the following comments regarding your response; the item numbers correspond to the item numbers on the Form FDA 483:

- 1a. Documentation presented during the inspection indicated the Platelet QC failed for the month of August, 1996. During the inspection, the QA Officer indicated that all equipment functioned properly. However, your response indicated that the QC was performed by different technicians, and one centrifuge was identified as the problem. This indicates inadequate procedures performed by the technicians and a need for retraining on the procedure of manufacturing platelets.
- 1b. Your response does not address the practice that some Laboratory Employees did not recognize the importance of initially reactive HAG test being repeated in duplicate from the same test system. This has been an industry/FDA requirement since before 1986. Also, the individual responsible for supervisory review failed to identify that the sample should not have been tested by two test systems.
- 1c. It is still not clear the reason the alarm reports were being generated if they were not going to be reviewed. Your response did not address how these reports will be used in the future.
- 1d. The example cited here was just one example of laboratory employees being inadequately trained; there are other examples that demonstrate a lack of training. Your response did not address these other areas.
- 1e. The documentation states the wrong ABO/Rh type. Your response did not provide an explanation as to how the wrong results were entered in the computer.
- 2a. Your response does not address your course of action for any unusual changes in testing procedures.
- 2b. The statement, "Staff has been advised that documentation must be more specific," does not provide any training given or any examples of what is needed.
- 2c. You did not provide any documentation that stated the DMS was down for any period of time.
- 3a. Your response failed to address whether this was a technical problem or if the wrong sample was pulled for retesting. It is very important that our investigators

are provided all needed documentation during the inspection.

- 9a. Your firm should make an attempt to resolve as many of the lost products as possible. Your response did not address your plans for those products that were identified during the inspection.
11. Your response indicated that the documentation was performed on the wrong forms. When was the proficiency testing actually done?
12. No documentation was provided of this in-service training.
13. The SOP #DS0007 appears adequate; however, your SOP was not followed in determining the eligibility of donor AMF.
14. The practice of recording the volume drawn as 450 ml. before the collection is completed is not Good Manufacturing Procedure. Data on any record should be the original data, not corrected data.
16. Your response did not address if a responsible individual was reviewing the Daily QC records. Also, no documentation of training given was provided.

The above violations are not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to assure that your facility is in compliance with all requirements of the federal regulations.

You should take prompt action to correct these deviations. Failure to promptly correct these deviations may result in regulatory action without further notice. Such action includes license suspension and/or revocation, seizure and/or injunction.

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

Your reply should be sent to the attention of Barbara A. Wood, Compliance Officer, at the above address.

Sincerely yours,

for Roger E. Kline
Ballard H. Graham, Director
Atlanta District

cc: E. Arthur Dreskin, M.D.
Responsible Head