



M270711

June 3, 1999

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Mr. Charles Auger
Director, Quality Assurance
SeraCare Acquisitions, Inc.
575 E. Main Street
Owatonna, MN 55060

WARNING LETTER

Dear Mr. Auger:

During the May 11-18, 1999 inspection of the SeraCare Acquisitions, Inc. Plasma Center located at 1 Maiden Lane, Raleigh, NC, FDA investigators documented violations of Sections 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 report error or accident in the manufacture of blood and/or blood products which might affect the safety, purity, and/or potency to CBER [600.14(a)] such as:
 - a. The training folder of former Biomedical Technician [REDACTED] revealed that on September 8, 1998, she was reprimanded for recording hematocrit and donor history questions without actually performing those duties. No Error/Accident or Incident form was completed, nor was there an investigation to determine the time period in which this occurred, the number of affected units, or the disposition of the units.
 - b. FDA was not notified of an error that occurred on June 29, 1998. The look-back that was subsequently conducted on March 9, 1999, did not identify two units that were obtained from a high-risk donor and distributed.
2. Failure to assure that personnel have the training and experience necessary for the competent performance of their assigned functions [21 CFR 606.20(b)] in that:
 - a. Training records, from May, 1998 to May, 1999, revealed that the Center Director acted as the "Designated Training Personnel" prior to being certified proficient in the areas she was teaching.

- a. Training records, from May, 1998 to May, 1999, revealed that the Center Director acted as the "Designated Training Personnel" prior to being certified proficient in the areas she was teaching.
 - b. The Center Director's Biomedical Technician I exam (dated 10/26/98) showed that there were areas with incorrect answers and pages with no answers recorded, however, training records showed that a score of 100% correct was recorded.
 - c. At least three of twenty-six Biomedical Technician's training folders did not show that any training was given while employed at the firm.
3. Failure to have physician or physician substitute present and on the premises during plasma collections [21 CFR 640.62]. (There is no current contract with an emergency care facility, and the physician's office is located approximately 110 miles from the plasma center.)
 4. Failure to have a staff person on the donor floor for a period of time on May 13, 1999, during the collection of four donors.
 - a. On May 13, 1999, an FDA investigator observed four donors in various stages of plasma collection with no phlebotomist on the floor. An apheresis machine alarm was sounding.
 5. Failure to maintain complete and accurate records [21 CFR 606.160(a)], in that:
 - a. Three plasma units were quarantined in frozen storage without any documentation as to the reason for them being unsuitable for distribution.
 - b. The donor receptionist failed to record the result for an abnormal Hemostat control on the first attempt resulting in an incorrect entry in the Hemostat Control Log.
 6. Failure of management to assure that training was administered to each employee responsible for preventing the recurrence of an error/accident investigated on November 25, 1998, in that:
 - a. Four employees who had responsibilities in the reception area (where the error occurred) were not retrained. The error involved the staff's practice of assigning incorrect expiration dates to the Refractor Controls.
 7. Failure of the physician substitute to adequately determine donor suitability during donor screening, in that:
 - a. Five units of plasma were collected from a donor who had a tongue piercing in October, 1998, even though the donor did not provide documentation showing that the piercing procedure was performed with sterile techniques.

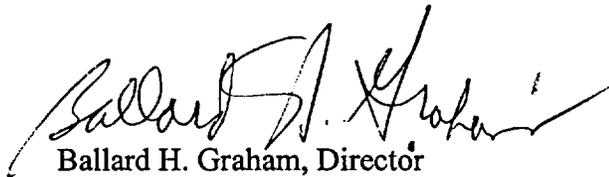
The above violations are not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to assure that this facility is in compliance with all requirements of the federal regulations.

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

Please notify this office in writing, within 15 working days of receipt of this letter, of the 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 directed to Barbara A. Wood, Compliance Officer, at the above address.

Sincerely yours,

A handwritten signature in black ink, appearing to read "Ballard H. Graham". The signature is fluid and cursive, with a long horizontal stroke at the end.

Ballard H. Graham, Director
Atlanta District