



April 4, 2000

VIA FEDERAL EXPRESS

Russell Winther
President
SeraCare, Inc.
919 West Cucharras
Colorado Springs, CO 80905

WARNING LETTER
(00-ATL-34)

Dear Mr. Winther:

During an inspection of Avre, Inc., dba SeraCare Plasma Center located at 8805 White Bluff Road, Savannah, GA on February 8-11, 2000, 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 maintain and/or follow adequate written standard operating procedures (SOPs) to include all steps to be followed in the collection, processing, storage and distribution of blood and blood products[21 CFR 606.100(b)] in that:
 - (a) Firm failed to follow its lookback procedure by not sending the lookback/alert notification to the Manager of Quality Assurance within the required timeframe.
 - (b) The time limit from the collection of the plasma to its placement in the blast freezer is not documented in the firm's written procedures.
 - (c) Donor with an irregular pulse was not subsequently evaluated by the physician as per firm's procedures.
 - (d) Plasma units are not being processed one at a time as required by SOM, Section 3, VI Plasma Processing Procedure.

2. Failure to assure that personnel have the training and experience necessary for the competent performance of their assigned function [21 CFR 606.20(b)] in that:
 - (a) The Center Director signed off on the training certifications for two employees prior to receiving training in those specific areas.
 - (b) Donor Floor Supervisor and the QA Facilitator signed off on training documents prior to receiving certification as trainers.
 - (c) Physician Substitute certification was signed prior to receiving training in all aspects of the new standard operating procedures.
 - (d) No documentation that the Medical Director has participated in any training regarding the new [REDACTED] SOM.
 - (e) Failure to recognize unsuitable (hemolyzed) unit of plasma. This was a repeat observation from the previous inspection
3. Failure to maintain complete and accurate records [21CFR 606.160(a)] in that:
 - (a) Donor record for donor who was temporarily deferred due to incarceration did not indicate the period of incarceration.
 - (b) No acceptable return date was identified for two donors who were temporarily deferred on 1/21&22/00.
 - (c) Daily routine maintenance of the [REDACTED] freezer was not performed for 1/19-28/00, and weekly routine maintenance was not performed for weeks 1/19-22/00 and 1/25-29/00.

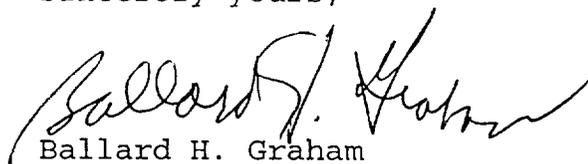
The above violations are not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to assure that this facility is in compliance with all requirements of the federal regulations.

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 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 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 time within which the corrections will be completed.

Your reply should be directed to Serene A. Kimel, Compliance Officer,
at the above address.

Sincerely yours,



Ballard H. Graham
Director, Atlanta District

cc: Ms. Patricia W. Chance, Center Director
Avre, Inc. dba SeraCare
8805 White Bluff Rd., Suite G
Savannah, GA 31406

Charles E. Auger
Director of Quality Assurance & Authorized Official
SeraCare, Inc.
515 E. Main Street
Owatonna, MN 55060