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Food and Drug Administration
Seattle District
Pacific Region
22201 23rd Drive S.E.
Bothell, WA 98021-4421

April 7, 1999

Telephone: 425-486-8788
FAX: 425-483-4996

VIA FEDERAL EXPRESS

In reply refer to Warning Letter SEA 99-13

Claus L. Winther
Biologics Division President
SeraCare, Inc.
919 West Cucharras
Colorado Springs, Colorado 80905

WARNING LETTER

Dear Mr. Winther:

During an inspection of the SeraCare, Inc. plasma center located at 425 East Center Street, Pocatello, Idaho on January 28 through February 3, 1999, our investigator 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 physician substitutes have the training and experience necessary for the competent performance of their assigned functions [21 CFR 606.20(b)] in that:
 - a. The medical director's December 16, 1997, letter of recommendation and certification of competency for a physician substitute employed from December 10, 1997, through November 21, 1998, states that he supervised the physician substitute for five weeks and found the physician substitute to be competent in the required areas per the Physician Substitute Training Program. This timeline indicates the letter was signed by the medical director after one week of training and not five weeks as documented in the letter.
 - b. The Physician Substitute Training Program Checklist documents the training of this physician substitute was from December 10, 1997, through January 9, 1998, a four-week period.
 - c. There is no documentation of the Physician Substitute Training Program for another physician substitute, employed on/about December 12, 1997, for several days. On December 13, 1997, this physician substitute trainee independently performed a physical examination of an applicant donor. There is no documentation the medical director supervised the physical examination.

2. Failure to maintain and/or follow 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. Five donors experienced two red blood cell losses within an eight-week period and they were not deferred per procedure 30.12, RBC Losses. Four of the five donors had a red blood cell loss caused by a red blood cell spill into the collecting bottle. Procedure 30.12 does not define how a spill into the collecting bottle should be assessed in relation to calculating a red blood cell loss.
 - b. Procedures 30.2, Cleaning Maintenance and Repair, and 70.2, Equipment Log Repair, were not followed in that the Equipment Repair Log and [REDACTED] Events Tracking Log do not include a full description of the maintenance performed on the [REDACTED] machines, their performance prior to installation and following repairs.
3. Failure to maintain complete and accurate records, [21 CFR 606.160(a)(1)] in that:
 - a. The medical director does not date various record reviews, including the reviews of physical examinations and SPE results performed by the physician substitutes.
 - b. The [REDACTED] Events Tracking Log for the [REDACTED] machines do not contain a full description of problems, such as donor reactions, red blood cell losses into the plasma pooling bottle, error messages, and actions taken as required in procedure 70.9, [REDACTED] Events Tracking Log.
 - c. There was no documentation of the cleaning and maintenance of the [REDACTED] as required by procedure 70.10, [REDACTED] Maintenance & Cleaning Log, for the monthly maintenance of [REDACTED] machines in September 1998, and for the weekly maintenance on another machine during January 1999.
4. Failure to include a full explanation of donor adverse reactions in the donor records [21 CFR 640.72(d)] or include the results of the investigation and follow-up [21 CFR 606.160(b)(1)(iii)].
5. Failure to review total serum protein determination within 21 days after the sample is drawn to determine whether or not the donor may continue to donate [21 CFR 640.65(b)(2)(i)].

The above-identified deviations are not intended to be an all-inclusive list of deficiencies at this facility. It is the responsibility of SeraCare, Inc., to assure that this facility is in compliance with all requirements of the federal regulations. At the conclusion of the inspection Form FDA 483, Inspectional Observations, was issued to and discussed with Charles Auger, Director of Quality Assurance. A copy of this form is enclosed for your information.

Claus L. Winther
Biologics Division President
SeraCare, Inc., Colorado Springs, CO
Re: Warning Letter SEA 99-13
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We previously issued a warning letter to a SeraCare facility located in Pasco, WA in December 1998. Several of the root causes cited in both letters appear to be the same. It is the responsibility of SeraCare, Inc., to assure similar root causes occurring at more than one location be corrected at all associated facilities when they are first brought to your attention.

We received the letter dated February 15, 1999, from Charles Auger, Director of Quality Assurance. Corrective actions addressed in that letter may be referenced in your response to this letter as appropriate; however, your response did not provide sufficient detail to fully assess the adequacy of the corrective actions. Our comments are addressed in a separate letter also enclosed in this mailing.

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 the time within which the corrections will be completed.

Your reply should be directed to the Food and Drug Administration, Seattle District Office, Attention: Miriam Burbach, Acting Compliance Officer, at the above mailing address.

Sincerely,



Roger L. Lowell
District Director

Enclosure:
Form FDA 483

cc: Barry Plost, President & CEO
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Center Director
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Pocatello, Idaho 83201

Claus L. Winther
Biologics Division President
SeraCare, Inc., Colorado Springs, CO
Re: Warning Letter SEA 99-13
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Charles E. Auger
Director of Quality Assurance & Authorized Official
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Owatonna, Minnesota 55060