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June 1, 1999

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

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

VIA FEDERAL EXPRESS

In reply refer to Warning Letter SEA 99-20

Barry Plost, President
SeraCare, Inc.
1925 Century Park E., Suite 1970
Los Angeles, California 90067-2701

WARNING LETTER

Dear Mr. Plost:

During an inspection of the SeraCare, Inc. plasma center located at 4017 Overland Road, Boise, Idaho on May 4 through 8, 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 adequately determine donor suitability in that:
 - a. During a donor physical observed during the inspection, the physician substitute performing the physical examination did not check the donor's legs for evidence of IV drug abuse [21 CFR 640.63(a)] as required in Standard Operating Procedure 20.35. The donor was accepted by the physician substitute for donation.
 - b. At least two donors were allowed to donate Source Plasma more than two times within a seven-day period [21 CFR 640.65(b)(5)].
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. SOP 30.16, *RBC Contaminated/Hemolyzed Plasma*, requires that the volume of any red cells spilled into the plasma collection container be estimated, and the loss be documented in the Events Log and donor record file. Thirteen instances of red cell spillage were recorded as "Ø RBC Loss" or were not estimated at all.

- b. SOP 70.9, [REDACTED] *Events Tracking Log*, requires that machine problems and actions taken in response be recorded in detail on the log. On six occasions, problems, including red cell spills, overdraws and blood in the anticoagulant bag, were not described in detail or were not described at all. There was no documentation of a failure investigation or follow up when these problems occurred.
3. Failure to maintain complete and accurate records [21 CFR 606.160(a)(1)] in that:
- a. The physical examination form for donor [REDACTED], dated March 25, 1999, has unanswered questions for surgery and blood transfusion.
 - b. "Unexplained needle marks" was not checked on the medical history form for unit DG0016291 collected on April 26, 1999.
 - c. The documentation of the bleed date for unit DT0003148 collected on October 20, 1998, was misdated as "21OCT98."

The above-identified deviations are not intended to be an all-inclusive list of deficiencies at this facility. It is your responsibility to assure that this facility is in compliance with all requirements of the federal regulations. The investigator issued Form FDA 483 to Anne Bryant, Center Manager, at the close of the inspection. A copy is enclosed for your review and action.

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.

The Seattle District issued warning letters to two other SeraCare facilities located in Pasco, Washington and Pocatello, Idaho in December 1998 and February 1999, respectively. Some of the root causes found in all three facilities appear to be the same. We stated in the February 1999; letter that it is the responsibility of SeraCare, Inc., to assure that similar root causes occurring at more than one location are corrected at all associated facilities when they are first brought to your attention.

We request a meeting with you at the FDA Seattle District Office on June 22, 1999 at 9:00 am, for you to present in writing and discuss with us the specific steps you have taken to correct the noted violations and to prevent their recurrence. Please bring with you other corporate officials that can assure appropriate corrective measures will be implemented to correct the noted deviations occurring in your facilities.

Barry Plost, President
SeraCare, Inc., Los Angeles, CA
Re: Warning Letter SEA 99-20
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If you respond to this letter prior to the June 22, 1999 meeting, your reply should be directed to the Food and Drug Administration, Seattle District Office, Attention: Miriam Burbach, Compliance Officer, at the above mailing address.

Sincerely,

for *Kenneth D. Quinn*
for Roger L. Lowell
District Director

Enclosure:

Form FDA 483 (Inspectional Observations)

cc: Claus L. Winther, President
Biologics Division
SeraCare, Inc.
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Colorado Springs, Colorado 80905

Anne Bryant, Center Director
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4017 Overland Road
Boise, Idaho 83705