



DEPARTMENT OF HEALTH AND HUMAN SERVICE

SCD/HFI-23

Public Health Service
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Food and Drug Administration
Seattle District
Pacific Region
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December 18, 1998

VIA FEDERAL EXPRESS

In reply refer to Warning Letter SEA 99-04

Susan Anders
Authorized Official
SeraCare Acquisitions, Inc.
611 Las Vegas Boulevard North
Las Vegas, Nevada 89101

WARNING LETTER

Dear Ms. Anders:

During an inspection of the SeraCare Acquisitions, Inc. plasma center located at 745 West Court Street, Pasco, WA, on November 11 – 21, 1998, 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. Two current and one previous physician substitute independently performed physical exams and informed consent procedures, and the previous physician substitute also independently reviewed serum protein electrophoresis (SPE) and syphilis results (RPR) prior to completing their required training.
 - b. One physician substitute was certified as proficient in their duties after 3.5 weeks of training, instead of after five weeks per the approved physician substitute training program.
 - c. There was no documentation of the physician substitute training for three physician substitutes. Information in donor records revealed that these three physician substitutes performed physical examinations and informed consent procedures, and one also performed SPE/RPR reviews prior to five weeks of employment and therefore they could not have completed the five week physician substitute training program.
 - d. During a physical examination, the physician substitute did not defer an individual who had a prior positive test for hepatitis and the individual was allowed to donate. There is no documentation of re-training concerning this error.

- e. An individual who was incarcerated for more than three days in the past twelve months was not deferred by the physician substitute during the physical examination and was accepted for donation. There is no documentation of re-training concerning this error.
 - f. During a donor physical, observed during the inspection, the physician substitute did not ask about existing tattoos and body piercing nor complete the Tattoo/Body Piercing Documentation form as required.
2. Failure of center technicians to adequately determine donor suitability during donor screening, in that:
- a. An individual (new donor) was deferred for medications during their physical examination, and the exam was not completed. The individual was allowed to donate when they returned to the center 18 days after their initial visit, without a physical examination being performed. The physical examination was completed seven days after the initial donation and the donor was then accepted into the plasmapheresis program [21 CFR 640.63(b)(1)].
 - b. Five individuals were allowed to continue to donate without current SPE/RPR results because their SPE/RPR results were missing or were not reviewed within the specified time frames. Fifty-one units were collected from these donors without having SPE/RPR results in their files [21 CFR 640.63(c)(5)].
 - c. There were four donations in which individuals experienced a weight loss greater than ten pounds within a two-month period and the donors were not evaluated prior to donation [21 CFR 640.63(c)].
 - d. An individual deferred by the center physician for an abnormal blood pressure was allowed to donate on the same day they were deferred, without acceptance into the plasmapheresis program by the center physician [21 CFR 640.63(b)(3)].
3. Failure to maintain complete and accurate records, in that:
- a. Documentation is incomplete when freezer temperatures reach warmer than -20 degrees Celsius and when there are gaps in the recording on the temperature-recording graphs for the freezer [21 CFR 606.160(3)(iii)].
 - b. An incorrect donor number was entered into the Permanent Rejection Registry Card for an individual who was permanently deferred for unsuitable test results [21 CFR 606.160(e)].
 - c. The documentation of the destruction of unsuitable units is not recorded in the appropriate destruction logs, or the documentation is not recorded concurrently with the action in that, there are conflicting dates in the destruction records [21 CFR 606.160(a)(1)].

4. Failure to follow written standard operating procedures in accordance with [21 CFR 606.100(b)], in that:
 - a. SOP QA08, QA Tracking/Trending, was not followed in that a corrective action plan was not developed to address significant increases or continued non-improvement for deficiencies such as three donations in a seven-day period, deficient physical exams, and SPE errors. Also, there is no documentation of the corrective action taken for 14 overbleeds attributed to improper bottle placement recorded on the event logs on four  machines.
 - b. Five individuals who experienced donor reactions where they lost consciousness were not treated with saline according to the procedures for Vasodepressor Reactions, and there is no documentation they were seen by the center physician/physician substitute.
 - c. The documentation for Post Donation Information Reports is incomplete, in that the dates two donors were incarcerated and another donor received tattoos was not determined. Therefore, the product suitability could not be determined.
5. Source Plasma is not stored at the correct temperatures immediately after filling, in that on three occasions plasma was exposed to temperatures warmer than -20 degrees Celsius. There is no documentation the Source Plasma remained frozen solid throughout the periods of elevated temperature [21 CFR 640.69(b)].

The above-identified deviations are not intended to be an all-inclusive list of deficiencies at this facility. It is the responsibility of SeraCare Acquisitions, Inc., to assure that this facility is in compliance with all requirements of the federal regulations.

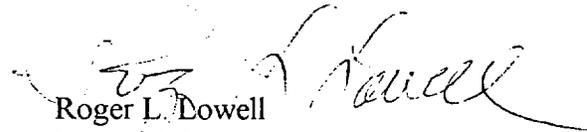
You should take prompt measures to correct these deviations. Failure to promptly correct these deviations may result in regulatory action without further notice. Such action includes seizure and/or injunction.

Seattle District has received a copy of your letter dated December 11, 1998, addressed to Judy Ciaraldi, CBER. The letter outlines tasks that you have completed as a result of the FORM FDA 483 issued at the close of the inspection. Both CBER and Seattle District are reviewing your letter. Our preliminary review indicates your response is not complete. You will be notified of our specific concerns after a review of your letter is finished.

Susan Anders, Authorized Official
SeraCare Acquisitions, Inc., Las Vegas, NV
Re: WL SEA 99-04
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Your reply should be directed to the Food and Drug Administration, Attention: Miriam Burbach, Acting Compliance Officer, at the above mailing address. Please provide a copy of your reply to Judy Ciaraldi, CBER.

Sincerely,


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District Director

cc: Claus Winther
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