



DEPARTMENT OF HEALTH & HUMAN SERVICES

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(purged)

11/7/99

Food and Drug Administration
Denver District Office
Building 20 - Denver Federal Center
P.O. Box 25087
Denver, Colorado 80225-0087
TELEPHONE: 303-236-3000

June 28, 1999

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Mr. Claus L. Winther, President
SeraCare, Inc.
Biologics Division
919 W. Cucherras
Colorado Springs, CO 80905

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Ref. # - DEN-99-10

Dear Mr. Winther:

During an inspection of the SeraCare plasma center located at 606 West North Temple, Salt Lake City, Utah, on April 29, 1999 through May 6, 1999, Investigator Kelly Moore documented violations of Section 501(a)(2)(B) of the Food, Drug, and Cosmetic Act and Title 21, Code of Federal Regulations (21 CFR), Parts 600-680, as follows:

1. The [redacted] procedure, SOP [redacted], required the documentation of errors using a [redacted] form [redacted]. The [redacted] procedure, SOP [redacted] required the trending of errors using a [redacted] form [redacted]. [redacted] information was used to improve processes, if a need was shown. A review of these records for July 1998 through February 1999 revealed an increase in screening and restick errors, but documentation of investigation and corrective action was not observed. Tracking Records for March 1999 were not found. Tracking Records for April 1999 were not reviewed by management.
2. Personnel were not always trained or experienced to ensure competent performance of their assigned functions. For example, a screening technician ([redacted]) was observed collecting a blood sample and collecting plasma from donors. A physician substitute ([redacted]) was working in the donor screening area and collecting plasma from donors. Documentation that these employees received training for the functions they were performing was not observed. Also, the physician substitute was approved on 12/2/98; however, the physician substitute signed off on [redacted] donor physical examines, Informed Consent for Plasmapheresis forms, Direct Questions On High Risk Behavior and Has Risk Activities sheets, and Facts About the HIV Tests sheets prior to 12/2/98.

3. Records were not always maintained concurrent with each step in the processing of plasma. For example: (1) the permanent deferral card for donor [redacted] indicated a deferral on 1/6/99, but the Unsuitable Product Checklist indicated 1/19/99; and (2) the Confirmation Logs for donors [redacted] and [redacted] indicated their unsuitable plasma units were disposed on 11/6/98, but the test results were not received until 11/7/98.
4. Units which test repeatedly reactive for antibody to human immunodeficiency virus (HIV), or otherwise, were determined to be unsuitable based on other testing such as for the Hepatitis C Virus (HCV), were not quarantined promptly, and when necessary, a "lookback" was not conducted promptly. For example, donor [redacted] tested reactive for HIV on 2/19/99, but the donor's units were not quarantined and a lookback conducted until 2/22/99; donors [redacted] and [redacted] tested reactive for HCV on 2/19/99, but the donors' units were not quarantined until 2/11/99; donors [redacted] and [redacted] tested reactive for HCV on 2/19/99, but the donors' units were not quarantined until 2/22/99; and donor [redacted] tested reactive for HCV on 1/19/99, but the donor's units were not quarantined until 1/19/99.
5. Records from which unsuitable donors may be identified so that products from such individuals will not be distributed do not provide adequate confidentiality of donor information. For example, donors deferred prior to 1990 were listed with their reason for permanent deferral in the permanent deferral rolodex that was available to plasma center employees.
6. Records from which unsuitable donors may be identified were not always accurate. For example, donor [redacted] tested reactive for HCV and HbsAg on 2/19/99, but the donor's first name was recorded incorrectly. The State Health Department was also provided with the donor's incorrect first name on a Confidential Morbidity Report Card.
7. Records of quarantine, notification, testing, and disposition for units, which were tested and found unsuitable, were not always found or were incomplete. For example:
 - a. the [redacted] procedure, SOP [redacted] required the initiation of an Unsuitable Product Checklist form #60.7D whenever a unit was reported viral marker reactive (Anti-HIV 1/2, HIV-1Ag, HbsAg, Anti-HCV); however, these forms were not found for donors [redacted] or [redacted] who tested positive for anti-HCV;
 - b. the [redacted] procedure, SOP [redacted] required a two person verification for certain activities; however, a review of [redacted] Unsuitable Product Checklist forms revealed [redacted] that were missing the second person check for required entries;
 - c. the [redacted] procedure, SOP [redacted] and the [redacted] procedure, SOP [redacted], required donor notification with a Donor Notification Letter, Form 60.7B, with the former procedure requiring notification within one working day of the center receiving reactive test results (HIV, HCV, HBsAg, ALT, Syphilis); however, a review of [redacted] Unsuitable Product Checklist forms revealed [redacted] missing an entry that the Donor Notification Letters were sent and that most were not notified within one working day, and;

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- d. the [redacted] procedure, SOP [redacted] required an Unsuitable Result/NDDR Report, form 60.7A, to be faxed to the testing laboratory within one working day; however, a review of [redacted] Unsuitable Product Checklist forms revealed [redacted] were missing an entry that the testing laboratory was notified and [redacted] revealed that the testing laboratory was notified after one working day.

The above violations are not intended to be an all-inclusive list of deficiencies at your facility. It was your responsibility as President of the Biologics Division of SeraCare to assure that your establishment was 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.

We are in receipt of your letter dated May 28, 1999 responding to the Notice of Observations, Form FDA 483, issued to your firm at the end of the inspection. Please notify this office in writing, if warranted, within 15 working days of receipt of this letter, of any further steps you have taken to correct the noted violations and to prevent their recurrence. You will receive an acknowledgement letter and any comments to your letter in the near future.

Any further reply should be sent to the attention of Compliance Officer Russell W. Gripp at the address at the top of this letter.

Sincerely,



Gary C. Dean
District Director

cc: Charles Auger
Director of Quality Assurance and Authorized Official
American Plasma Management
d.b.a., SeraCare, Inc.
515 E. Main Street
Owatonna, MN 55060

Mark Trimble
Center Director
American Plasma Management
d.b.a., SeraCare, Inc.
606 West North Temple
Salt Lake City, UT 84116

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