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February 22, 1999

Food and Drug Administration  
Seattle District  
Pacific Region  
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P.O. Box 3012  
Bothell, WA 98041-3012

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VIA FEDERAL EXPRESS

In reply refer to Warning Letter SEA 99-07

M. Sue Preston  
Authorized Official  
Alpha Therapeutic Corporation  
5555 Valley Boulevard  
Los Angeles, California 90032-3548

WARNING LETTER

Dear Ms. Preston:

During an inspection of the Alpha Therapeutic Corporation plasma center located at 7726 15<sup>th</sup> Avenue NW, Seattle, Washington on January 8 – 26, 1999, our investigators 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 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 in accordance with 21 CFR 606.100(b) in that:
  - a. There are no standard operating procedures instructing employees what procedures should be followed when Source Plasma is collected in the wrong plasma bottle. Source Plasma has been transferred from a plasma bottle with one integrally attached sample vial into a plasma bottle with two integrally attached sample vials, by cutting the line from the original plasma bottle, attaching it to the port of the second bottle and draining the plasma into it. The two attached sample vials were also filled at the same time. There is no documentation of the units involved, the date, or the personnel performing this transfer.
  - b. On November 24, 1998, a donor was not disconnected from the [REDACTED] after the second occurrence of the Safety System Fault Detection error alarm, as required by Training Manual VI-093, [REDACTED] Safety System Fault Detection Messages. Training Manual VI-093 provides instructions to manually infuse the donor's red blood cells if the alarm occurs a second time during the same donation and to remove the machine from service. The error alarm occurred a third time during the same donation, the donor was not disconnected, and the machine remained in service.
  - c. On five occasions since July 1998, the volume of red blood cell loss was not documented on the donor cards per Training Manual VI-089, [REDACTED] Red Plasma. There is no documentation to confirm that the donors did not require an eight-week deferral.

- d. The Training Manual VI-078, [REDACTED] Prepare for Plasma Collection was not followed, resulting in two donors being overbled because the wrong nomogram value was selected.
  - e. The Training Manual V-005 Donor Reactions procedure does not provide detailed methods for determining when a donor is suitable to continue donating after experiencing a hypotensive/vaso vagal reaction. A donor that had been disconnected following an infiltration lost consciousness, fell, and received a laceration which later required stitches. The donor's vital signs were taken after the incident. Even though the donor's temperature was 96.3° Fahrenheit, lower than the firm's minimum acceptable range of 97° Fahrenheit, the donation was continued when the donor returned to the donor floor. Management verbally acknowledged that continuing this donation was an unacceptable practice.
2. Failure to assure that personnel responsible for collecting and processing blood or blood components have the necessary training to ensure that the final product has the safety, purity, and potency it is represented to possess in accordance with 21 CFR 606.20(b) in that:
    - a. On more than one occasion since April 1998, a fully trained technician, employed for two years and certified in plasma, donor floor and donor screening operations, transferred Source Plasma collected in a plasma bottle with one integrally attached pilot sample vial, into a second bottle with two integrally attached pilot sample vials. This unauthorized practice resulted in the failure to assure all pilot samples were collected in a manner that did not contaminate the contents of the final container [21 CFR 640.69(d)(4)].
    - b. A second employee performed plasma-processing operations with no documentation of training or certification in the plasma processing area.
3. Failure to maintain complete and accurate records, [21 CFR 606.160(a)(1)] in that:
    - a. There was no documentation maintained of the unit numbers, dates, and employees involved, when the testing laboratory was sent only one sample instead of the required two samples for PCR/anti-HBs and viral marker testing when Source Plasma was collected in the wrong bottle.
    - b. Employees completing the Plasma Donor List and Shipping Record do not initial each processing operation they complete when they prepare the Source Plasma bottles and the pilot tubes for shipping. Confirmation of who prepared the individual bottles cannot be determined because the employee for each processing operation is not documented.

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

M. Sue Preston, Authorized Official  
Alpha Therapeutic Corporation, Los Angeles, CA  
Re: Warning Letter SEA 99-07  
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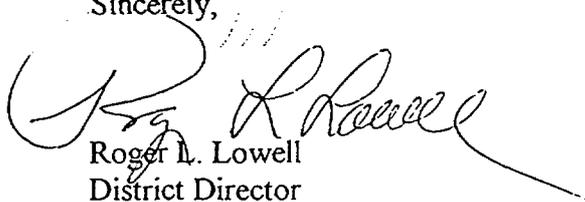
This is the second Warning Letter issued within seven months for deficiencies occurring at this location. Whereas the specific deficiencies listed in each letter are not the same, the root causes may be similar. The practice of transferring Source Plasma from the original collection bottle to a second bottle compounded the original error and resulted in multiple deficiencies. The FDA does not expect to see this type of practice occurring in a center such as yours purporting to have an adequate and fully trained staff under responsible management oversight.

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, their root causes, and how you will 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

cc: John Luther  
Center Director  
Alpha Therapeutic Corporation  
7726 15<sup>th</sup> Avenue NW  
Seattle, WA 98117

cc: Ralph Galustian  
CEO  
Alpha Therapeutic Corporation  
5555 Valley Boulevard  
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