



DEPARTMENT OF HEALTH & HUMAN SERVICES

560  
9/2/97  
Public Health Service  
Food and Drug Administration

Dallas District  
3310 Live Oak Street  
Dallas, Texas 75204-6191

August 28, 1997

Ref: 97-DAL-WL-40

**WARNING LETTER**

**VIA FEDERAL EXPRESS  
AND FACSIMILE**

Ms. Sue Preston, Responsible Head  
Alpha Therapeutic Corporation  
5555 Valley Blvd.  
Los Angeles, California 90032

Dear Ms. Preston:

During an inspection of your Alpha Plasma Center located at 5512 East Reno, Del City, Oklahoma, on July 28 through 30, 1997, and August 4 through 6, 1997, 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 obtain written consent for the automated plasmapheresis procedure after a qualified licensed physician had explained the hazards of the procedure to the prospective donor. A donor was plasmapheresed three times before the informed consent document was signed. [21 CFR 640.41].
2. Failure to prepare and maintain a written report of the investigation of an adverse reaction associated with bleed number [REDACTED] including conclusions and follow-up. [21 CFR 603.170].
4. Failure to maintain accurate records from which unsuitable donors may be identified so that products from such individuals will not be distributed. [21 CFR 606.160(e)].

5. Failure to follow written standard operating procedures, [21 CFR 606.100(b)], in that:
  - a. Medical review and other procedures were not followed allowing a donor to be plasmapheresed three times before written consent for automated plasmapheresis was obtained.
  - b. Alpha's Donor Incident Report, Form 2721, was not completed documenting the supportive care given to a donor who experienced a donor reaction.
  - c. A donor losing 327 milliliters of red blood cells was permitted to donate during the eight (8) week deferral period.
  - d. Reconciliation checks of the permanent reject cards against the latest additions to the Memphis Lab rejection list were not properly performed.

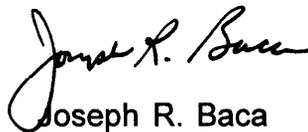
The above violations are not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility as Responsible Head to assure that your establishment is in compliance with all requirements of the federal regulations.

You should take prompt measures to correct these violations. 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 sent to the attention of Reynaldo R. Rodriguez, Jr., Compliance Officer, at the above letterhead address.

Sincerely,



Joseph R. Baca  
Dallas District Director

JRB:RRR

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cc: Mr. Troy L. Wheeler, Center Manager  
Alpha Plasma Center  
5512 E. Reno  
Del City, Oklahoma 73117