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19900 MacArthur Blvd., Ste 300
Irvine, California 92612-2445
Telephone (949) 798-7600

WARNING LETTER

CERTIFIED MAIL - RETURN RECEIPT REQUESTED

Ralph M. Galustian
President and Chief Executive Officer
Alpha Therapeutic Corporation
5555 Valley Boulevard
Los Angeles, California 90032

W/L 46-00

Dear Mr. Galustian:

During an inspection of Alpha Therapeutics Plasma located at 8491 Sierra Avenue, Fontana, CA, conducted February 23rd through the 25th and 28th, 2000, FDA investigators documented violations of Section 501(a)(2)(B) of the Federal Food, Drug and Cosmetic Act (the Act) and Title 21, Code of Federal Regulations (CFR), Part 600 - 680 as follows:

1. Failure to establish and maintain adequate procedures for establishing donor suitability [21 CFR §606.100(a) and 640.63(c)] in that you are not providing donors with adequate information regarding high-risk behaviors nor are donor interviewers adequately assessing the donors understanding of the information.
2. Failure to maintain accurate donor deferral information [21 CFR §303.160(b)(1)(ii)] in that several donor cards in your manual donor tracking system were found out of alphabetical sequence.
3. Failure to calibrate on a regularly scheduled basis [21 CFR 606.60(a)] and at the minimum frequency required [21 CFR 606.60(b)] the [REDACTED] temperature probe used as part of the [REDACTED] system that is used to monitor the temperature of the freezer used to freeze and store donor plasma.
4. Failure to follow manufacturer's instructions for [REDACTED] Test Strips [21 CFR §606.65(e)] in that you are not testing the performance of reagent strips against known positive and negative specimen or controls whenever a new bottle is opened as outlined in the quality control section of the product insert.

The above is not intended to be an all-inclusive list of deviations which may exist at your facility. It is your responsibility to ensure that that your plasma center is in full compliance with the Act and regulations promulgated thereunder.

We request that you take prompt action to correct these deviations. Failure to make prompt corrections may result in regulatory action without further notice, such as license suspension and/or revocation, seizure and/or injunction.

In addition, we offer the following comments:

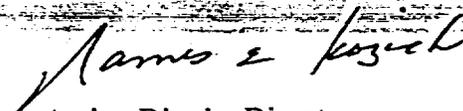
We acknowledge the receipt of your response to the FDA-483 Inspectional Observations. However, many inspectional observations listed on the current FDA-483 are similar to those for which your firm has been cited as a result of a previous inspection.

Please notify this office in writing, within fifteen (15) working days of your receipt of this letter, of the specific steps you have taken to correct the noted deviations and to prevent their recurrence. If corrective action cannot be completed within fifteen working days, please state the reason for the delay, and the time within which corrections will be completed.

Your reply should be directed to the Food and Drug Administration, Attention:

Thomas L. Sawyer
Director, Compliance Branch
Food and Drug Administration
19900 MacArthur Blvd., Suite 300
Irvine, CA 92612

Sincerely,


Acting District Director