HFI-35

DEPARTMENT OF HEALTH & HUMAN SERVICES

M888N

Public Health Service
Food and Drug Administration

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

May 7, 1997

Ref: 97-DAL-WL-22

WARNING LETTER

VIA FACSIMILE
AND FEDERAL EXPRESS

Ms. Evelyn V. Houghton, Responsible Head
American Plasma, Inc.
719 Sawdust Road, Suite 205
Spring, Texas 77380

Dear Ms. Houghton:

During an inspection of American Plasma, Inc. plasma center located at 1223 West 43rd Street, Houston, Texas, U.S. License #1134-006, on March 3 through 18, 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 submit a significant change in manufacturing methods to FDA's Center for Biologics Evaluation and Research (CBER) in that the center's physician substitute was selecting, scheduling, and evaluating the clinical responses to donors immunized with tetanus toxoid without prior CBER approval [21 CFR 601.12(a) and 21 CFR 640.66].

2. Failure to record the donor number of a donor subject to a plasma overdraw in the equipment use record [21 CFR 606.160(a)(1)].

3. Failure to maintain the automated plasmapheresis equipment in a manner consistent with the manufacturer's instructions or the center's standard operating procedures [21 CFR 606.60(a)].

4. Failure to explain temperature deviations found on the freezer recorder chart [21 CFR 606.160(b)(3)(iii)].

5. Failure to follow standard operating procedures in that there is no documentation of review by a second responsible individual of quality control and plasma processing records [21 CFR 606.100(b)].

We acknowledge that on March 14, 1997, by facsimile, you notified all American Plasma Inc. centers to suspend the physician substitute's duties associated with the selection, scheduling and evaluation of clinical responses to the tetanus toxoid immunization.

Additionally, we acknowledge you have contacted the Center for Biologics Research and Evaluation for a variance from 21 CFR 640.66 in order to utilize a physician substitute for the immunization program.

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 establishments are 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.

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 yours,

Joseph R. Baca
District Director

JRB:RRR