



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

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

October 23, 1997

Ref: 98-DAL-WL- 6

WARNING LETTER

FEDERAL EXPRESS

Ms. Patsy A. Richardson
Executive Director and
Responsible Head
Texoma Regional Blood Center
3911 N. Texoma Parkway
Sherman, Texas 75090

Dear Ms. Richardson:

During an inspection of Texoma Regional Blood Center on September 30 through October 7, 1997, our investigator 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 (21 CFR), Parts 600-680 as follows:

Failure to maintain records concurrently with the performance of each significant step in processing, specifically relevant times of component processing. At least 86 components from March 1996 to June 1997 were manufactured from whole blood outside of the 8-hour time frame established in your standard operating procedure. Computer record times were altered for these units, thereby not reflecting the complete history of the work performed. [21 CFR 606.160]

Failure to have a written standard operating procedure outlining the input of data into the computer for component preparation. [21 CFR 606.100]

Failure to properly maintain adequate and complete donor records and quality control records. Quality control records did not reflect platelet testing for several months in 1997 when platelets were prepared. [21 CFR 606.160 and 640.25]

Failure to always conduct appropriate follow-up, investigation and maintain adequate records on adverse donor reactions, e.g., K45856, K46028 and J43974. [21 CFR 606.160]

Failure to assure that a designated, qualified person is present to direct matters

Page 2 - Ms. Patsy Richardson, Executive Director
October 23, 1997

relating to compliance and quality control. [21 CFR 606.10]

Failure to assure that employees have the necessary training to perform component preparation and quality control procedures. [21 CFR 606.20]

The investigator presented a list of observations (FDA-483) to you and your staff at the close of the inspection and a copy is being attached to this letter for your reference. 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. Please provide a written response to each observation listed on the FDA-483.

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 fifteen (15) working days of receipt of this letter, of the specific steps that 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 correction will be completed. Please address your response to Gwen Gilbreath, Compliance Officer.

Sincerely,


Sylvia G. Yett
for Joseph R. Baca
District Director

cc: Dr. Edgar McKee
Medical Director
Texoma Regional Blood Center
1111 Gallagher Rd.
Sherman, Texas 75090

Mr. Cleveland Roy
Chairman, Board of Trustees
Texoma Regional Blood Center
P.O. Box 1176
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