



June 15, 1998

Food and Drug Administration
Kansas City District Office
11630 West 80th Street
P.O. Box 15905
Lenexa, Kansas 66285-5905

Telephone: (913) 752-2100

WARNING LETTER

Mr. Joseph F. Abrutz, Jr., Administrator
Cameron Community Hospital
1015 West 4th Street
Cameron, Missouri 64429

Dear Mr. Abrutz:

During an inspection of your hospital's blood bank at the above location on May 4-11, 1998, and concluding on May 19, 1998, an investigator of our office documented violations 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 complete records of adverse transfusion reaction investigations [606.170(a)] in that:
 - a. Adverse reaction reports dated 7/17/97, 7/3/97 and 12/12/97 lack investigational conclusions and follow-up.
 - b. The report of suspected transfusion reaction, patient observation record, and laboratory analytical record constituting documentation of the 7/3/97 adverse reaction report pertaining to a post transfusion death, lack indication of review/evaluation by authority beyond personnel who recorded the original data.
2. Failure to maintain adequate Standard Operating Procedures (SOP) for reporting transfusion reactions [21 CFR 606.160(b)(6)] in that, SOP, "TRANSFUSION REACTION," (revision date, August 30, 1994), requires reporting of only hepatitis related and hemolytic transfusion reactions to the source facility for blood products used by your blood bank. No reference is made to forwarding copies of adverse reaction reports for all blood and blood products determined to be at fault to the manufacturer or collecting facility [21 CFR 606.170(a)].

3. Failure to assure required storage conditions of Platelets Concentrate [21 CFR 640.25(a)] in that:
 - a. Storage temperatures are not monitored and recorded.
 - b. There are no data confirming that the test tube rocker used for agitation of stored Platelets Concentrate is adequate for the intended purpose.

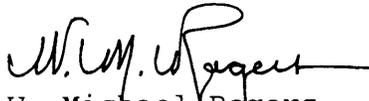
The above identified deviations are not intended to be an all inclusive list of deficiencies at your facility. At the conclusion of the inspection, Form FDA 483, Inspectional Observations was issued to , and discussed with you. It is your responsibility as Hospital Administrator to assure that your establishment is in compliance with all applicable requirements of federal regulations.

You should take prompt measures to correct these deviations. Failure to promptly correct these deviations may result in regulatory actions without further notice. Such action includes 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 actions 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 Noel G. Ferguson, Compliance Officer, at the above address.

Sincerely,



W. Michael Rogers
District Director
Kansas City District