



DEPARTMENT OF HEALTH & HUMAN SERVICES

Certified/Return Receipt Requested

6/28/99 ERB m2747m

June 21, 1999

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

Frank Creeden, CEO &
Hospital Administrator
Providence Medical Center
8929 Parallel Parkway
Kansas City, KS 66112

KAN #99-021

Dear Mr. Schriock:

Recently an inspection was made of your blood bank facility located at the above address.. This inspection was conducted on May 3 to 10, 1999, by a Food and Drug Administration Investigator from this office who documented deviations from Title 21, Code of Federal Regulations, Parts 600-680. These deviations cause the blood products prepared at this location to be adulterated within the meaning of Section 501(a)(2)(B) of the Federal Food, Drug, and Cosmetic Act (Act). The deviations found include, but are not limited to, the following:

- Failure to follow certain Standard Operating Procedures (SOP's) [21 CFR 606.100(b)]. For example:
 - SOP "Transfusion Reaction Workup" states in part, "All possible transfusion reactions must be investigated... The workup should proceed, whether or not the physician deems it necessary." Approximately 34 transfusion reactions occurred since April 1998, however, 4 were not processed in accordance with the SOP.
 - SOP "Document Control" requires the indefinite retention of all completed transfusion service records, yet centrifuge quality control records are only being retained as current.
- Failure to have a second person review of all significant manufacturing records prior to the release of blood products. [21 CFR 606.100(c)]. For example:
 - The Transfusion Service Quality Control-Equipment form for February through April 1999 has not been reviewed.
 - The Daily Temperature and Blood Inspection Record pertaining to all temperature monitored equipment, has not been reviewed for December 1998.

Page 2
June 21, 1999
Providence Medical Center

- On May 23, 1998 the Daily Use Reagent Quality Control Record was performed and reviewed by the same employee.
- Failure to conduct adequate investigations of temperature chart recorder failures [21 CFR 606.60]. For example:
 - Smooth lines on recorder charts observed on 2-17 to 22-99 and 6-1 to 4-98, which may have been a re-setting of the chart without lifting the pen, but this was not documented.
 - No temperature recording occurred from 5-12 to 18-98; no documentation of product status performed.

This letter is not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to ensure adherence to each requirement of the Act and regulations.

You should know that these serious violations of the law may result in FDA taking regulatory action without further notice to you. These actions include, but are not limited to, seizure and/or obtaining a court injunction against further manufacturing of your blood products.

It is necessary for you to take action on this matter now. Please let this office know in writing within fifteen (15) working days from the date you received this letter what steps you are taking to correct the problem. We also ask that you explain how you plan to prevent this from happening again. If you need more time, let us know why and when you expect to complete your correction.

Your reply should be sent to Clarence R. Pendleton, Compliance Officer, at the above address.

Sincerely,



W. Michael Rogers
District Director
Kansas City District

cc: James Schriock, Regional Laboratory Director
Providence Medical Center
8929 Parallel Parkway
Kansas City, KS 66112