



DEPARTMENT OF HEALTH & HUMAN SERVICES
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION

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PHILADELPHIA DISTRICT

900 U.S. Customhouse
2nd and Chestnut Streets
Philadelphia, PA 19106

Telephone: 215-597-4390

WARNING LETTER

February 26, 1999

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Larry Crowell, Administrator/CEO
Valley Medical Facilities, Inc.
Sewickley Campus Blood Bank
720 Blackburn Road
Sewickley, Pennsylvania 15143

Dear Mr. Crowell:

During an inspection of your facility, Valley Medical Facilities, Inc., Sewickley Campus Blood Bank, located at 720 Blackburn Road, Sewickley, Pennsylvania, which ended January 22, 1999, 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 adequately review all records pertinent to a unit of blood before its release or distribution [21 CFR § 606.100(c)], for example:

Unit C23711 was issued from Blood Bank with two different patient names on the Transfusion Record. This record accompanied the unit of blood to the hospital floor.

2. Failure to perform a thorough investigation, including conclusions and follow-up, of unexplained discrepancies in pertinent blood bank records [21 CFR § 606.100(c)] for the following:
 - a. issuance from Blood Bank of a unit of blood with two different patient names on the Transfusion Record as described above in item (1);
 - b. issuing a unit of blood for transfusion on the basis of an expired crossmatch (Transfusion Record 1160432);
 - c. interpreting antibody screen results for (6) donors, C22090 through C22095, as negative without the use of check cells to confirm that the screening test was valid;
 - d. a strongly reactive antibody screening result for donor C23068 was attributed to the wrong donor.

3. Failure to maintain and/or follow written standard operating procedures (SOP's) that include the steps to be followed in the collection, processing, storage, and distribution of blood and blood products [21 CFR § 606.100], for example:

Reports are not being generated for the purpose of trend analysis of errors and accidents as required by Standard Operating Procedure titled, LABORATORY QUALITY ASSURANCE REPORT.

4. Failure to assure competent performance of blood bank personnel at their assigned functions [21 CFR § 606.20], in that a blood bank phlebotomist's performance record from March of 1997 through January 1999 shows documentation of (22) technical/ procedural errors, for example:
 - a. the use of the same bleed number for two different donors;
 - b. two different units of blood collected on the same day assigned to the same donor's social security number;
 - c. mistakenly designating autologous donors as allogeneic donors on multiple occasions;
 - d. overdrawing a therapeutic phlebotomy by 100 ml;
 - e. incomplete donor history forms on multiple occasions;
 - f. failure to provide donor AIDS education materials;
 - g. failure to provide privacy for the CUE procedure;
 - h. blood sample tube mislabeling;
 - i. preparing FFP from whole blood more than 6 hours after collection.

Additionally, please note that regulations require that blood bank records be legible and indelible [21 CFR § 606.160(a)], and that, records are to be retained for no less than 5 years [21 CFR § 606.160(d)]. The above inspection revealed that raw data documentation of donor viral marker test results shows significant fading deterioration after only (6) months.

The above violations are not intended to be an all-inclusive list of deficiencies at your facility. As top management it is your responsibility to assure that your establishment is in compliance with all requirements of Federal Regulations as well as all other requirements of the FD&C Act.

We are concerned that this and previous inspections of your blood bank have revealed ongoing violations of Current Good Manufacturing Practice For Blood And Blood Components [21 CFR § 606] related to inadequate blood product record review, and, personnel failing to follow Blood Bank Standard Operating Procedures (previous FDA-483's are attached).

Page 3 - Larry Crowell

You should take prompt action to correct these deviations. Failure to promptly correct these deviations may result in regulatory action 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 all specific actions that have been implemented to correct the noted violations. This should include verification of the training of personnel, and, an explanation with verification of implementation of each step taken to prevent recurrence of similar violations. If corrective action cannot be completed within (15) working days, state the reason for delay and the time within which the corrections will be completed.

Your reply should be sent to the Food and Drug Administration, Philadelphia District Office, Room 900, U. S. Customhouse, 2nd and Chestnut Streets, Philadelphia, PA 19106, to the attention of William J. Forman, Compliance Officer.

Sincerely,



Thomas D. Gardine
District Director
Philadelphia District

Attachments:

FDA-483, Inspectional Observations, dated, 1/22/99, 3/17/97, & 12/12/95.

cc: Azizeh H. Djafari, M.D., Medical Director
Valley Medical Facilities, Inc.
Sewickley Campus Blood Bank
720 Blackburn Road
Sewickley, Pennsylvania 15143

PDH Bureau of Laboratories
Blood Bank Division
Pickering Way and Welsh Pool Road
Lionville, PA 19341