



DEPARTMENT OF HEALTH & HUMAN SERVICES

PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION

711
PHILADELPHIA DISTRICT

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

Telephone: 215-597-4390

WARNING LETTER

98-PHI-06

November 25, 1997

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Thomas H. Prickett, President/CEO
Suburban General Hospital
100 South Jackson Avenue
Pittsburgh, Pennsylvania 15202

GEN.	SPEC.
RELEASE	
F# _____	DATE <u>11/28/97</u>
Reviewed by: <u>William H. Houser</u>	

Dear Mr. Prickett:

During an inspection of Suburban General Hospital Blood Bank located at, 100 South Jackson Avenue, Pittsburgh, Pennsylvania, conducted from October 14-20, 1997, our investigator documented violations of Section 501(a)(2)(B) of the Federal Food, Drug, and Cosmetic Act (FD&C Act), and Title 21, Code of Federal Regulations (21 CFR), Parts 600-680 as follows:

- 1) Failure to maintain concurrent, detailed, legible, indelible, and/or accurate records [21 CFR § 606.160(a)]; in that,
 - a) There is neither a record of the production, nor, a final disposition for the plasma from Autologous unit #1266,
 - b) The BLOOD TRANSFUSION RECORD for Autologous units #1270 and #1271 documents the interpretation of results for antibody screens and autocontrols; however, the SGH DONOR WORKSHEET #1 shows no raw data for performance of these tests. Additionally, this worksheet neither identifies the performing laboratory technician nor the date and time of entries for other testing performed on these same units of blood,
 - c) There is no production record for the thawing of Fresh Frozen Plasma unit GK81605 which was transfused to a patient,
 - d) The SGH DONOR WORKSHEET #1 and the THAWED FRESH FROZEN PLASMA EXPIRATION DATE AND FINAL DISPOSITION RECORD show entries which are obliterated; for example, blood units #1264, GK69305, and KK20031.

2) Failure to maintain and/or follow adequate written standard operating procedures [21 CFR § 606.100(b); in that,

a) Blood Bank practice has not included implementation of Autologous Blood Transfusion Policy #14, titled Disposition of Blood and Components, which has an effective date of October 21, 1996,

Please note that our Form FDA-483, Inspectional Observations, issued to your firm October 21, 1996, cites a deviation, related to the disposition of Autologous Blood, which is similar to the violation described above in item #1a. Furthermore, Dr. Edberg's November 13, 1996, correspondence (attached), responding to the October 21, 1996, FDA-483 states, Policy #14 was established as part of "... specific steps we have taken to correct the noted violations and to prevent their recurrence.",

b) The required monthly high alarm check has been neither performed according to written procedure nor documented as being performed since the 1/97 installation of Blood Bank blood storage freezer,

c) Blood Bank QC-P.M.- SERVICE LOG is not always completed to document the performance of quality control and maintenance operations required by the procedure titled, BLOOD BANK IMMUNO HEMATOLOGY QUALITY CONTROL EQUIPMENT MAINTENANCE, for the following equipment:

Baxter Cellwasher	Minute Timer
Forma Sc Plasma Warmer	Jewett T100 Refrigerators
Microscope	Jewett F2007

d) Documentation of annual assessments for laboratory personnel which is required by SGH procedure titled, BLOOD BANK DEPARTMENT COMPETENCY TESTING, was not available for all Blood Bank employees.

3) Failure to observe, standardize, and/or calibrate equipment used in the collection, processing, compatibility testing, storage, and/or distribution of blood as prescribed in Standard Operating Procedures [21 CFR § 606.60]; in that,

Required monthly high/low alarm checks of blood storage refrigerators was performed only two times in the twelve months prior to 10/97.

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 the current inspection of your facility revealed similar quality control, equipment maintenance, and documentation violations as those listed on the FDA-483, Inspectional Observations (attached), issued to your firm, October 21, 1996. Additionally, not all corrective actions promised by your Director of Laboratories, Sanford H. Edberg, M.D., in his November 13, 1996, response to this October 1996 FDA-483, were implemented or being carried out according to procedure at the time of our current inspection.

We acknowledge the receipt of correspondence dated October 28, 1997, from Dr. Edberg, which proposes corrective actions to the items noted on the current Form FDA-483, issued October 20, 1997; however, in view of your past violative history we are asking that you 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.

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.

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, Attention: William J. Forman, Compliance Officer.

Sincerely,



Diana J. Kolaitis
District Director
Philadelphia District

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Attachments:

FDA-483, Inspectional Observations, dated, 10/21/96.

Correspondence from Sanford H. Edberg, M.D., SGH Medical
Director Blood Bank, dated, November 13, 1996.

FDA-483, Inspectional Observations, dated, 10/20/97.

cc:

Sanford H. Edberg, Director of Laboratories
Suburban General Hospital
100 South Jackson Avenue
Pittsburgh, Pennsylvania 15202

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