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CERTIFIED MAIL - RETURN RECEIPT REQUESTED

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WARNING LETTER

October 7, 1998

WL-1-9

Roger Seaver
President and CEO
Northridge Hospital Medical Center
18300 Roscoe Blvd.
Northridge, CA 91328

Dear Mr. Seaver:

During an inspection of your blood bank between September 2nd to September 9th, 1998, our investigator documented that your firm is in violation 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).

You should be aware that this inspection discovered a suspected transfusion related fatality which had not been reported to the Food and Drug Administration (FDA) counter to your own procedures. This situation has now been reported to the FDA; many of the aspects of this letter relate to our investigative findings of this incident. The violations found during our inspection are as follows:

1. Failure to follow Standard Operating Procedures (SOPs) [21 CFR 606.100(b)]. Examples include the following:

a) The blood bank's Protocol/Procedure, "Suspected Transfusion Reaction Investigation" was not followed relative to a patient that received a unit of Red Blood Cells on [REDACTED]. In this situation, you failed to follow your own SOP, in that:

- Your facility did not notify FDA as soon as possible (within twenty-four hours) of the occurrence of the fatality [21 CFR 606.170(b)].
- Your facility did not provide FDA with a written report of the incident within 7 days [21 CFR 606.170(b)].
- Your facility did not arrange for a post-transfusion, blood specimen from the patient.

- The blood bag involved, along with the filter and tubing attached, was not returned to the blood bank for evaluation.

In addition, your initial transfusion investigation was not performed in a timely manner in that the incident occurred on March 20, 1998, and it was not reported to the blood bank until March 25, 1998 and was not interpreted by a pathologist until April 21, 1998.

b) Relative to your blood bank's "Quality Assurance Program" and "Error Reporting Guidelines" there was no individual designated to:

- Annually reviewing SOP manuals for updates and changes;
- Review of monthly QC required by Blood Bank and donor room;
- Maintain an Error Variance Log;
- Perform annual evaluation of employee skills;
- Schedule and perform proficiency testing;
- Perform yearly self audits on all employees;
- Compile error reports that include description, corrective actions, and counseling summaries;
- Compile and report errors to the QA Committee on a quarterly basis;
- Look for problem trends in methodology, procedures, and personnel.

c) The Protocol/Procedure "Competency Testing" was not being followed. Examples include the following:

- Continuing education records are not kept for all employees;
- CAP surveys are not rotated among the staff;
- Annual evaluations are not conducted to evaluate skills;
- There is no ongoing review of computer errors and problems;
- There is no daily review of Blood Bank Logs and Audit reports to identify problems.

d) The Protocol/Procedure entitled "Procedure for blood and blood transport", part IV. Quality Control, Letter A, states that quality control of the transport container is to be performed semiannually. There was no documentation of any periodic testing of shipping containers showing they have the capacity to maintain proper temperatures during transit [21 CFR 606.160(b)(5)(iv)].

2. There was no written documentation for the calibration and standardization of blood bank equipment to include: blood bank centrifuges, thermometers, timing devices, and weight scales [21 CFR 606.60(a)&(b) and 21 CFR 606.160(b)(7)(iv)].

During our inspection it was observed that there had been no supervisor, since December 1997, assigned to accomplish the tasks listed under 1b and 1c. The regulations state that personnel responsible for the collection, processing, compatibility testing, storage and distribution of blood and blood components shall be adequate in number, educational background, training and experience to assure competent performance of their assigned functions, and to assure that the final product has the safety, purity, potency, identity and effectiveness it purports or is represented to possess [21 CFR 606.2(b)].

The above listed violations are not intended to be an all-inclusive list of deficiencies at your facility. You should be aware that management at the blood bank was issued an FDA Form 483 at the conclusion of the inspection on September 9, 1998 listing Inspectional Observations (copy enclosed). It is your responsibility to assure that your establishment is in compliance with all requirements of the federal regulations.

You should take prompt measures to correct these deviations. Failure to promptly correct these deviations may result in regulatory action without further notice. Such actions include injunction.

Please notify this office in writing, within fifteen (15) working days of the receipt of this letter, of the specific steps you have taken to correct the noted violations and to prevent their recurrence. If corrective action cannot be completed within the 15 working days, state the reason for the delay and the time within which the corrections will be completed.

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Your reply should be sent to: .

Robert W. Nicol
Compliance Officer
U.S. Food and Drug Administration
19900 MacArthur Blvd., Suite 300
Irvine, CA 92612-2445

Sincerely,



Elaine C. Messa
District Director

Enclosure Form FDA 483

cc: Louise E. Smith
Examiner
State of California
Department of Health Services
Lab Field Services
107 S. Broadway, Room 5016
Los Angeles, CA 90012