



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Central Region *M3565N*

Telephone (973) 526-6009

Food and Drug Administration
Waterview Corporate Center
10 Waterview Blvd., 3rd Floor
Parsippany, NJ 07054

March 16, 2000

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Mr. Patrick Wardell
Chief Executive Officer
St. Joseph's Hospital and Medical Center
703 Main Street
Paterson, New Jersey 07503

File No.: 00-NWJ-24

Dear Mr. Wardell:

During an inspection of St. Joseph's Hospital and Medical Center Blood Bank, located at 703 Main Street, Paterson, New Jersey, from February 7-10, 14, 17, 2000, an Investigator from this office documented violations of Section 501 (a) (2) (B) of the Federal Food, Drug and Cosmetic Act (the Act) and Title 21, Code of Federal Regulations (CFR), Parts 600-680, as they relate to collecting, processing, testing and distribution of blood and blood components. These deviations were cited on a FDA 483 List of Inspectional Observations issued to Dr. Linda Rankin, Director of Laboratories and responsible management at the close of the inspection.

The significant observations are as follows:

1. Inadequate controls and/or procedures in that units were improperly dispensed from the blood bank and an incorrect patient specimen was processed. For example:
 - Red Blood Cell unit # [REDACTED] was issued with the transfusion slip for unit # [REDACTED] on June 11, 1999. This unit was subsequently transfused and the transfusion information was documented on this incorrect transfusion record.
 - Red Blood Cell unit # [REDACTED] was issued with the transfusion slip of another unit on July 9, 1999. In addition, the blood bank failed to document when the error was discovered and the unit number indicated on the transfusion slip.

- Platelet unit # [REDACTED] was documented as being transfused on May 5, 1999, although the unit was physically located in the blood bank on May 9, 1999. Lab staff concluded that platelet unit # [REDACTED] was actually transfused.
 - Blood specimen for patient [REDACTED] was received by the blood bank and typed on October 4, 1999. The ordering slip accompanying the specimen was for patient [REDACTED]. The results for specimen [REDACTED] were entered by the technologist as [REDACTED].
2. Inadequate record keeping practices for the documentation of errors and accidents occurring in the blood bank. For example, investigations into the above mentioned incidents are not documented, there is no indication that any corrective action was taken to prevent these types of errors, nor is there evidence that the Blood Bank Manager or Medical Director had reviewed these errors .
 3. Failure to follow written procedures. For example:
 - *Error Correction* procedure was not followed in that the Error/Variance reports are not always completed when an error is identified. For example, the aforementioned incidents cited in item 1.
 - *Emergency Release* procedure was not followed, in that emergency release forms were found to be incomplete. The compatibility status of the units released are not documented on the form after the crossmatch is complete. In addition, the date/time released and the person inspecting and releasing the unit is not routinely documented on the form.
 4. Lack of, or inadequate Standard Operating Procedures for the following processes:
 - Lack of an approved procedure for the investigation of errors, implementing corrective actions and the documentation required.
 - Lack of written procedures for the receipt, documentation, evaluation, investigation and follow-up of post donation information reports.
 - Inadequate *Selection of Blood Donors* SOP in that it does not reflect the current questions asked on the donor medical history form.
 - Inadequate *Daily Quality Control* SOP in that it does not include procedures for comparing the reagents in each rack with the lot number of the reagents that have been quality tested.
 - Inadequate testing and processing procedures, in that they do not include procedures for sending specimens to the current EIA testing laboratory nor do they include procedures for NAT testing.
 - Inadequate *Labeling of Donor Blood and Components* SOP in that it does not reflect the current labeling practices of the blood bank.

5. There is no assurance that Standard Operating Procedures are reviewed periodically and appropriately updated by blood bank management.
6. Inadequate computer security in that employees have access to functions they are not qualified to perform. For example, Technical Assistants (TA) have access to the Blood Order Processing function, Blood Label Check function and Blood Product Testing function, although they are not qualified to perform the tasks in these functions. Additionally, Technologists have access to functions that are only to be performed by Senior Technologists or Supervisors. For example, on February 24, 1999, results for an antibody screen were entered into the computer under a Technical Assistant's code, although the TA is not qualified to perform this test.

The above deviations are not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to assure that your establishment is in compliance with all requirements of federal regulations, with regard to blood collection, processing, testing and distribution. You should take prompt action to correct these deviations. Failure to correct these deviations may result in regulatory action without further notice. Such action includes seizure and/or injunction.

We have received your written response to the FDA 483 issued on February 17, 2000. Your response appears appropriate to address these issues, however corrective actions, including retraining of staff, will need to be verified during the next inspection of your facility. It should be noted that although no transfusion reactions resulted from the incorrect release of units cited in Item 1, these errors and the failure to conduct a thorough investigation of these events and implement corrective and preventive actions, demonstrates serious deficiencies in your Quality Assurance (QA) System. Your further response should include specific steps you plan to implement to improve QA oversight.

Please notify this office in writing within 15 working days of receipt of this letter, of any additional steps you have taken to correct the noted violations, including supporting documentation. Your further response should be sent to the Food & Drug Administration, New Jersey District Office, 10 Waterview Blvd., 3rd Floor, Parsippany, New Jersey 07054, Attn: Mercedes B. Mota, Compliance Officer.

Sincerely,



Douglas I. Ellsworth
Director
New Jersey District, FDA