



DEPARTMENT OF HEALTH & HUMAN SERVICES

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New York District

Food & Drug Administration
850 Third Avenue
Brooklyn, NY 11232

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Rick J. Varone
President & Chief Executive Officer
Staten Island University Hospital
475 Seaview Avenue
Staten Island, NY 10305-3498

December 20, 1999

Ref: NYK-2000-18

Dear Mr. Varone:

During an inspection of the Staten Island University Hospital's blood bank located at the above address, on September 27 through October 12, 1999, our investigator documented violations of Section 501(a)(2)(B) of the Federal Food, Drug, and Cosmetic Act (the Act) and deviations from Current Good Manufacturing Practice for Blood and Blood Components, Title 21, Code of Federal Regulations (21 CFR), Parts 606 and 640, as follows:

1. Failure to maintain complete and adequate records from which unsuitable donors may be identified so that products from such individuals will not be distributed as required by 21 CFR 606.160(e). For example, units #8913894, #8913701, #6664000, and #6524647 that tested repeatedly reactive for HBcAb or core antibodies and unit #6663591 that tested repeatedly reactive for syphilis were not entered into the in-house donor deferral system as required by the blood bank's written standard operating procedure (SOP).

2. Failure to prepare the skin of the donor at the site of phlebotomy by a method that gives maximum assurance of a sterile container of blood as required by 21 CFR 640.4(f). For example, the investigator observed three blood collections where the phlebotomist touched the intended venipuncture site after the arm preparation procedure was completed.

3. Failure to follow written SOPs for plateletpheresis quality control testing as required by 21 CFR 606.100(b) and 640.25. For example, quality control procedures were not performed on each platelet unit as required by the blood bank's written SOP. Further, there was no record of corrective action taken when quality control test results failed to meet prescribed requirements such as platelet count.

4. Failure to store fresh frozen plasma in a manner that will show evidence of thawing as required by 21 CFR 640.34(g)(2). For example, plasma units were placed in the freezer without the presence of a crease or indentation as required by the blood bank's written SOP.

5. Failure to maintain complete and adequate records of proper temperature maintenance for reissued blood as required by 21 CFR 606.160(b)(3)(iv) and 640.2(e). For example, there was no documentation of the storage temperature of units returned from the operating room as required by the blood bank's written SOP.

6. Failure to maintain complete and adequate records of the quality control performance checks and calibrations of equipment as required by 21 CFR 606.160(b)(5). For example, there were incomplete records of the quarterly performance testing of automatic cell washers and quarterly calibration checks of the Coulter counter instrument as required by the blood bank's written SOPs.

7. Failure to maintain complete and adequate written SOPs that reflect current blood bank operations as required by 21 CFR 606.100(b) and 606.60. For example, with respect to the computer system in use, there were no SOPs available for security procedures for unauthorized access, review of the system and correction of errors, and control of changes in hardware and software.

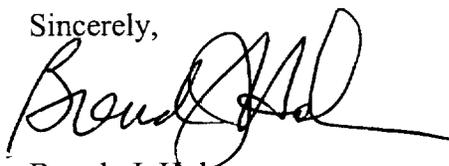
Neither the above-identified deviations nor the list of inspectional observations (a copy of the Form FDA 483 is enclosed) given to Dr. Charles Zaroulis, Medical Director at the conclusion of the inspection is intended to be an all-inclusive list of deficiencies at your blood bank. It is your responsibility to ensure that your blood bank is in compliance with all requirements of the Act and federal regulations.

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 the specific steps you have taken to correct the noted violations and to prevent their recurrence. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time within which the corrections will be completed.

Your reply should be sent to the Food and Drug Administration, 850 Third Avenue, Brooklyn, NY 11232, Attention: Bruce A. Goldwitz, Compliance Officer, Tel. (718) 340-7000 ext. 5507.

Sincerely,



Brenda J. Holman
District Director