



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

d1500b

NEW YORK DISTRICT  
850 THIRD AVENUE  
BROOKLYN, NY 11232  
TEL. (718) 340-7000

**WARNING LETTER**

**CERTIFIED MAIL**  
**RETURN RECEIPT REQUESTED**

March 24, 1998

Debra Tascone  
Vice President of Administration  
North Shore University Hospital at Syosset  
221 Jericho Turnpike  
Syosset, NY 11791

Ref: 23-NYK-98

Dear Ms. Tascone:

During our inspection of the North Shore University Hospital at Syosset, blood bank, located at 221 Jericho Turnpike, Syosset, NY, conducted between March 2 and March 16, 1998, our investigators 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 through 680.

At the conclusion of the inspection, the investigators presented the enclosed Inspectional Observations (Form FDA-483) to Dr. Sidney S. Glasberg, Medical Director of the blood bank, and discussed their findings with him. The following violations were noted:

1. Failure to maintain donor deferral records from which unsuitable donors may be identified so that products from such individuals will not be distributed. For example: donor # 8060636 tested positive for HIV, donor #s 8050998 and 8050783 tested positive for HBsAG, and donor # 8064931 tested positive for Syphilis. These donors were not placed in a deferral system.
2. Failure to adequately assess the suitability of donors, in that, approximately ten percent of Donor Registration/Health History forms reviewed, were not complete and no justification was provided for acceptance of those donors. For example, High Risk Activity questions, and Medical History questions were not answered on these forms. These include, but are not limited to, donor #s : 8064655, 8064656, 8064924, 8064810, 8064811, and 8064917.
3. Failure to provide donors the opportunity to confidentially self-exclude at the time of donation, in accordance with the firm's "Donor Services General Policies".
4. Failure to perform calibration and/or maintenance on equipment used in the collection and processing of blood and blood components, as follows:

- a) The IVAC thermometers are not calibrated per the manufacturer's instructions.
  - b) The RPM and timers on the fixed speed centrifuges are not calibrated on a regularly scheduled basis as prescribed in the firm's standard operating procedures.
  - c) The Donormatic blood scale was not calibrated on a regularly scheduled basis.
5. Failure to maintain complete and adequate written standard operating procedures (SOPs) that reflect current operations, as follows:
- a) The HIV lookback procedure does not address the retrospective review of records of prior donations for donors who test positive for HIV.
  - b) There are no SOPs for handling post donation information reports.
  - c) There are no SOPs for the equipment quality control, calibration, and maintenance for the donor room Baumanometers and the Donormatic blood scale.
6. The container labeling for Red Blood Cells does not include the firm's registration number.

The above identified deviations are not intended to be an all inclusive list of deficiencies at your blood bank. It is your responsibility as the Vice President of Administration to assure that the blood bank 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 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: Fabio L. Mattiasich, Compliance Officer.

Sincerely,



Brenda J. Holman  
District Director

North Shore University Hospital at Syosset  
Page 3

cc: Jeanne Linden, M.D.  
Director, Blood and Tissue Resources  
New York State Department of Health