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DEPARTMENT OF HEALTH AND HUMAN SERVICE

Public Health Service

Refer to: CFN 1173808

Food and Drug Administration
Baltimore District Office
900 Madison Avenue
Baltimore, MD 21201-2199
Telephone: (410) 962-3396
FAX: (410) 962-2219

M310312

October 29, 1999

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Thomas A. Fleury, M.D.
Director, Laboratory Services
Sibley Memorial Hospital
5255 Loughboro Road, Northwest
Washington, D.C. 20016

Dear Dr. Fleury:

During a Food and Drug Administration (FDA) inspection of your hospital blood bank located in Washington, D.C. on September 28 through October 4, 1999, our investigator 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 600-680, as follows:

1. Failure to document permanent and temporary patient deferrals per 21 CFR 606.160(b)(1)(ii), in that you failed to record in the blood bank deferral list the permanent deferral of Donor [REDACTED] for whom unit #S01869 tested HIV-1/2 initially reactive, repeat reactive, and Western Blot indeterminate. Also, Donor [REDACTED] was not temporarily deferred for whom unit #S00753 tested HIV p24 Antigen initially reactive, repeat reactive, and indeterminate by neutralization.
2. Failure to follow standard operating procedures per 21 CFR 606.100(b), as follows:
 - Your procedures require that donors meeting the deferral criteria described in Item 1 be deferred and that such deferral be documented in the donor deferral list. The deferrals were not documented.
 - Your procedures require that the physicians of autologous donors be notified in writing of reactive viral test marker results. Donors [REDACTED] and [REDACTED] tested initially and repeat reactive for HIV p24 Antigen and HBc, respectively; however, there was no documentation that their physicians were ever notified of these test results.
 - Your procedures require that donors be notified when tested and found positive for Anti-HIV-1/2 and FTA. Donors [REDACTED] and [REDACTED] tested initially and repeat reactive for FTA and Anti-HIV-1/2, respectively; however, there was no documentation that they were ever notified of these test results.

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3. Failure to establish scientifically sound and appropriate specifications, standards, and test procedures to assure that blood and blood components are safe, pure, potent, and effective per 21 CFR 606.140(a). For example, your procedure for reentry of donors allows for reentry of those found to be Anti-HIV-1/2 licensed Western Blot indeterminate. Additionally, the donor deferral procedures do not address donor deferrals when the Western Blot test results are indeterminate.
4. Failure to maintain equipment and to document the maintenance of equipment used in the processing of blood and blood components per 21 CFR 606.60(a). For example, the maintenance of Helmer platelet incubators and InstaCool plasma thawing equipment was not being performed in accordance with the equipment manufacturer's manual, nor was there any documentation to show that such maintenance was being performed.

The above violations 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 the federal regulations.

You should take prompt measures to correct these deviations. Failure to do so may result in regulatory action without further notice. Such action includes seizure and/or injunction.

You should 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, Northern Virginia Resident Post, 101 West Broad Street, Suite 400, Falls Church, Virginia 22046, to the attention of Gerald W. Miller, Compliance Officer. Mr. Miller can be reached at (703) 235-8440, extension 504.

Sincerely,



Carl E. Draper
Acting Director, Baltimore District