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Food and Drug Administration  
Denver District Office  
Building 20 - Denver Federal Center  
P. O. Box 25087  
Denver, Colorado 80225  
TELEPHONE: 303-236-3000

August 10, 1998

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

C. Ray Honaker  
CEO/Hospital Administrator  
St. Thomas More Hospital  
1338 Phay Avenue  
Canon City, Colorado 81212

Ref. # - DEN-98-16

**WARNING LETTER**

Dear Mr. Honaker:

During an inspection of your blood bank facility in St. Thomas More Hospital conducted from May 29 through June 5, 1998, Consumer Safety Officer Deborah S. Hammond documented the following violations of Section 501(a)(2)(B) of the Federal Food, Drug, and Cosmetic Act (the Act) and Title 21, Code of Federal Regulations (21 CFR), Parts 600-680:

1. Failure to maintain records of blood processing, including results and interpretation of all tests and retests [21 CFR 606.160(b)(2)]. For example, a record of duplicate HIV 1&2 testing of unit # [redacted] was not found.
2. Failure to maintain a record from which unsuitable donors may be identified so that products from such individuals will not be distributed [21 CFR 606.160(e)]. For example, the donor of unit # [redacted] tested repeat reactive for HCV, but was not added to the Permanent Deferral Log.
3. Failure to follow standard operating procedures or maintain records related to obtaining a written request from a physician and written consent from the patient for autologous donations [21 CFR 606.100(b) and 606.160(b)]. For example, the SOP for Autologous Transfusions, Rev. 4-98, requires a written request from the patient's physician and written consent from the patient for predeposit phlebotomy; however, a review of [redacted] [redacted] autologous donor records found [redacted] which were missing physician orders and [redacted] missing donor consent forms.

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4. Failure of standard operating procedures for autologous donations to reflect current acceptable practices [21 CFR 606.100(b)(7)]. For example, the procedure for Autologous Transfusions, Rev. 4-98, does not order the required laboratory tests on the first unit of blood collected from each donor in a 30-day period when no part of the blood is used for any purpose other than autologous transfusion.
5. Failure to maintain signed requests for therapeutic bleedings from the attending physician [21 CFR 606.160(b)(1)(iv)]. For example, ~~12~~ out of ~~12~~ therapeutic records reviewed were missing physician orders.
6. Failure to prominently label therapeutic units, which are unsuitable for transfusion, with "NOT FOR TRANSFUSION" and state the reason the unit is considered unsuitable [21 CFR 606.121(f)].
7. Failure to maintain records of the disposition of therapeutic units [21 CFR 606.160(b)(3)(I)]. For example, no disposition records for therapeutic units were observed.
8. Failure of standard operating procedures for therapeutic phlebotomy to reflect current acceptable practices [21 CFR 606.100(b)]. For example, the SOP for "Therapeutic Phlebotomy" allows a phone order for a therapeutic bleeding.
9. Failure to review pertinent records before the release or distribution of the finished blood units [21 CFR 606.100(c)]. For example, quality control records, temperature recording charts, the Fresh Frozen Plasma (FFP) Log, and the Blood Bank Donor Log are not always part of a second person review.

Your firm should also assure that all autologous units collected at your facility are labeled in accordance to standard operating procedures that reflect the requirements in 21 CFR 606.121(I). For your reference, enclosed are guidance documents on autologous blood collection and processing procedures dated March 15, 1989 and February 12, 1990.

This letter, as well as the Inspectional Observations, Form FDA-483, which was presented to and discussed with you at the close of the inspection is not intended to be an all inclusive list of deficiencies at your facility. Rather, they both represent unacceptable practices documented during our most recent inspection of your facility. It is your responsibility to insure that all requirements of the Act, and regulations promulgated thereunder, are being met.

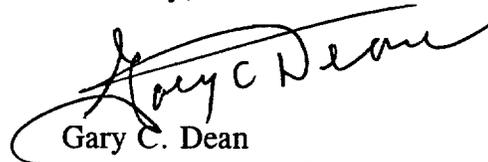
We acknowledge receipt of Laboratory Manager Charlotte K. Brown's response dated June 8, 1998, to the Form FDA-483 issued at the close of the inspection. Promised corrective actions will be verified during our next scheduled inspection. Failure to promptly correct these deviations may result in regulatory action being initiated without further notice. These include license suspension, license revocation, seizure, and injunction.

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Any additional response, if deemed necessary on your part, should be sent to the Food and Drug Administration, Denver District Office, Attention: Russell W. Gripp, Compliance Officer, at the above address

Sincerely,



Gary C. Dean  
Director, Denver District

cc: Charlotte K. Brown, MT(ASCP)  
Director, Laboratory Services  
St. Thomas More Hospital  
1338 Phay Avenue  
Canon City, Colorado 81212

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State Department of Public Health  
Division of Consumer Protection  
Attention: Tom Messenger, Director  
4300 Cherry Creek Drive South  
Denver, Colorado 80222-1530