



Food and Drug Administration
Detroit District
1560 East Jefferson Avenue
Detroit, MI 48207-3179
Telephone: 313-226-6260

CERTIFIED MAIL

RETURN RECEIPT REQUESTED

April 13, 2000

WARNING LETTER
2000-DT-18

David Grignon, M.D.
Interim Pathologist-in-Chief
for DMC University Laboratories
Harper Hospital
3990 John R
Detroit, Michigan 48201

Dear Dr. Grignon:

An inspection of your Blood Bank facility located at Harper Hospital, 3990 John R, Detroit, Michigan 48201, was conducted on January 25 – February 2, 2000 by the Food and Drug Administration. The inspection revealed significant deviations from the Current Good Manufacturing Practice Regulations for Blood and Blood Products, and Finished Pharmaceuticals, Title 21, Code of Federal Regulations, Part 606, 610, 640, and 211 (21 CFR 606, 610, 640, and 211). These deviations cause your products, Autologous Whole Blood, Washed Autologous Red Cells, and Frozen/ Deglycerized Autologous Red Cells to be in violation of the Food, Drug, and Cosmetic Act (FD&C Act), Section 501(a)(2)(B), as follows:

1. Failure to perform/maintain computer validation [21 CFR 211.68] in that:
 - a. there was no validation protocol to show how the system was tested and what were the expected outcomes;
 - b. there was no documentation to identify the operator performing each significant step, date completed, whether expected outcomes were met, and management review;
 - c. there was no documentation to show if problems were experienced during the process, and how they were solved;
 - d. there was no documentation to show if the validation was reviewed prior to software implementation.

2. Failure to follow standard operating procedures (SOPs) [21 CFR 606.100(b)] in that:
 - a. four RBC units were frozen although hematocrits were below the stated range of [REDACTED];
 - b. the lot number and expiration date of saline added for weight adjustment of RBCs was not recorded;
 - c. there is no documentation to show that three employees are proficient to perform donor phlebotomy.
3. Failure to follow SOPs for investigating adverse recipient reactions [21 CFR 606.100(b)(9)] in that the pathologist's interpretation of a febrile non-hemolytic transfusion reaction was not entered into the computer system's "BAD" file, nor was it recorded in the Problem/Antibody file.
4. Failure to assure that equipment performs in the manner in which it was intended [21 CFR 606.60] in that:
 - a. in March 1999, QC for both red cell washers produced unacceptable results, and service was called. During the interim period between the initial unacceptable result and repair of the equipment ([REDACTED] months) over [REDACTED] units were washed;
 - b. there is no documentation of temperatures and RPMs each day of use for refrigerated centrifuges;
5. Failure to review component processing records prior to unit/lot release [21 CFR 606.100(c)] in that there is no documentation to show review of Autologous RBC Freezing Record, RBC Deglycerolization Record, and Blood Cell Processor Washed Unit logs.
6. Failure to maintain component processing records [21 CFR 606.160(b)(2)(ii)] in that:
 - a. there is no documentation to show which red cell washer is used in the processing of a red cell unit;
 - b. there is no documentation to assure that units are frozen within [REDACTED] hour of the addition of glycerol;
 - c. there is no documentation to show units are weighed during the deglycerization process.
7. Failure to maintain quality control records [21 CFR 606.160(b)(5)] in that:
 - a. the preventative maintenance schedule for microhematocrit centrifuges and freezers is not always followed;
 - b. raw data for refrigerator and centrifuge testing is not always available for review;
 - c. there is no documentation of monthly QC for refrigerated centrifuges.

The above is not intended to be an all-inclusive list of deviations which may exist at your firm. It is your responsibility to ensure that your blood bank is in full compliance with the Act and regulations promulgated thereunder. You should take prompt action to correct these deviations and to establish procedures to prevent their recurrence. Failure to promptly correct these deviations may result in regulatory action against your firm without further notice. Such actions may include but are not limited to seizure, and/or injunction.

We acknowledge receipt of your letter dated March 6, 2000, which includes your response to the FDA-483 issued at the conclusion of the inspection. We offer the following comments:

1. Your response item #1, regarding validation of the blood bank computer software did not include a copy of the protocol for our review. The protocol and/or validation summary should include items such as how the system is tested, expected outcomes, whether outcomes were met, worst case scenarios, etc..
2. Your response item #2c, states that you have revised the RBC freezing procedure to extend the length of time between removing a unit from refrigeration and placing the glycerolized unit in the freezer to "not to exceed [redacted] hours". You also state that the process will be completed well within the [redacted] hour time limit. Review of "Autologous RBC Freezing Record" does not show a place on the record for recording of the time a unit is removed from refrigeration and/or a time that it is placed in the freezer. In addition, there is no indication that employees were trained on the revised procedure.
3. Your response item #5 indicates that you revised the QC procedure for the cell washers. The revised procedure was not included in documentation that accompanied your response. In addition, there is no indication that employees were trained on the revised procedure.
4. Your response item #7 does not indicate if employees were trained on the revised procedure for transfusion reactions.
5. Your response items 8 and 9 indicate that you have created competency documents for employees to demonstrate proficiency in blood bank procedures. Please be reminded that documentation of proficiency should be maintained in a training file or personnel file.
6. Your response item #10 indicates that you are developing a monthly checklist for scheduled QC and PM. Your response does not indicate when you anticipate completion/ implementation of the checklist. You also state that the supervisor of the Biomedical Department was provided a copy of the PM schedule, but there is no indication that this information was shared with his/her employees, and that the department is committed to strict adherence to the schedule.

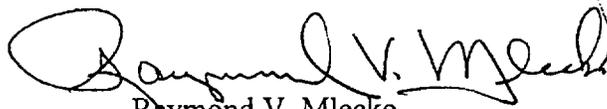
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7. Your response item #11 indicates that you have made changes to the procedure for using the [REDACTED] centrifuges, but the revised procedure was not included in documentation that accompanied your response. In addition, there is no indication that employees were trained in the revised procedure.

Please notify this office in writing, within fifteen (15) working days of your receipt of this letter, of the specific steps you have taken or will take to correct the noted deviations and to prevent their recurrence. If corrections can not be completed within 15 working days, please state the reason for the delay, and the time within which corrections will be completed.

Your response should be directed to this office at the address above, to the attention of Ms. Kathleen M. Lewis, Compliance Officer.

Sincerely yours,



Raymond V. Mlecko
District Director
Detroit District