



DEPARTMENT OF HEALTH AND HUMAN SERVICE

Southwest Region

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Food and Drug Administration
Denver District Office
Bldg. 20-Denver Federal Center
P.O. Box 25087
6th Avenue & Kipling Street
Denver, Colorado 80225-0087
Telephone: 303-236-3000
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September 28, 2000

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Mr. David J. Baltzer
President
Rehoboth McKinley Christian Hospital
1901 Red Rock Drive
Gallup, New Mexico 87301

Ref. # DEN-00-43

Dear Mr. Baltzer:

On August 3 through August 14, 2000, Investigator Cynthia Jim of our office conducted an inspection of Rehoboth McKinley Christian Hospital. Our inspection documented deviations from the Current Good Manufacturing Practice Regulations, Title 21, Code of Federal Regulations (21 CFR), Parts 211 and 600 – 680. These deviations cause your blood products to be adulterated within the meaning of Section 501(a)(2)(B) of the Federal Food, Drug, and Cosmetic Act (the Act). Deviations noted include:

Failure to assure all test results are completed and reviewed prior to release of units or that donor history information is reviewed by an attending physician, as required by 21 CFR 606.100 (c). For example, our inspection revealed that your firm released units from quarantine and shipped them prior to obtaining the results of viral marker testing. Also, there is no evidence that an attending physician has reviewed donor history information prior to donation. In several instances, donors answering yes to questions related to medications or cardiovascular problems were allowed to donate without any indication that these were reviewed and approved by an attending physician.

Failure to assure that equipment used in the collection, processing, compatibility testing, storage and distribution of blood and blood components are standardized and calibrated to assure they perform in the manner for which they are designed, as required by 21 CFR 606.60. For example, our investigator observed that your personnel were not calibrating the (XXX) Blood Weight Monitor according to the manufacturer's operating manual.

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Failure to properly label units with the accurate volume of blood intended for transfusion, as required by 21 CFR 606.121. For example, your facility uses blood bags that are labeled to contain 500 milliliters. In several instances, our investigator determined that your facility collected less than 500 ml, however these units were not labeled as "Low Volume Units." Also, the amount of anticoagulant was not adjusted to correct for the amount of blood actually collected.

Failure to follow standard operating procedures regarding the collection of units from autologous donors, as required by 21 CFR 606.100. For example, our inspection revealed that units were collected from donors weighing less than 110 pounds. Your standard operating practices specifically states that patients weighing less than 110 pounds are not candidates for autologous donations.

Failure to properly train personnel responsible for the collection, processing, compatibility testing, storage or distribution of blood or blood components to assure that the final product has the safety, purity, potency, identity and effectiveness it purports or is represented to possess, as required by 21 CFR 606.20. For example, therapeutic phlebotomies were performed without first obtaining a hemogram, as required by your standard operating procedures. Also, a therapeutic phlebotomy was performed on a patient with a hemocrit of 54.8 although the physician's orders required the treatment be stopped when the HCT was 55 or less. Training records do not indicate that all employees have been trained in new procedures established in February 2000. There are also several instances where the use of whiteout and/or erasures were made to records in contradiction to your firm's procedures.

We acknowledge receipt of your September 14, 2000 response to the FDA form 483. The corrective actions outlined in your response to observation #2 regarding the calibration of the (X X X) Blood Weight Monitor do not appear to be consistent with the manufacturer's operating manual. Page 6 of the manufacturer's manual describes the steps needed to calibrate the device at weights different from 585 grams. Step 5.5 in this manual then directs the user to follow the initial steps in 4.3 – 4.4 for the new specified weight. Your procedure states, (X X X X X) (X X X X X X X X) We suggest that you contact the manufacturer to obtain further information to insure the correct operation of this instrument. Also, with regards to observation #4, you have corrected your procedures to allow for the collection of blood from donors weighing less than 110 pounds. Please be aware that low volume units must be labeled as such, as the ratio of anticoagulant to plasma makes these units suitable only for subsequent autologous transfusion as RBCs. For 500-milliliter bags, low volume is considered to be between 335 milliliters to 449 milliliters. If less than 335 milliliters are drawn, the amount of anticoagulant must be adjusted or the unit should be destroyed. Transfusing units with the incorrect ratio of anticoagulant to plasma may cause an adverse reaction to the patient.

The above identified deviations 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. Therefore, you should take prompt action to correct

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these violations. Failure to do so may result in regulatory action without further notice, including seizure and/or injunction.

You should notify this office in writing, within fifteen (15) working days of receipt of this letter, of any other additional steps you have taken to correct the noted violations and to prevent their recurrence. If corrective action cannot be completed within fifteen (15) working days, state the reason for the delay and the time within which the corrections will be completed.

Your response should be sent to Regina A. Barrell, Compliance Officer, Food and Drug Administration, Denver District, P. O. Box 25087, Denver, Colorado 80225-0087. If you have any further questions, please feel free to contact Ms. Barrell at (303) 236-3043.

Sincerely,



Thomas A. Allison
District Director

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