



DEPARTMENT OF HEALTH AND HUMAN SERVICES

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Food and Drug Administration  
Minneapolis District Office  
Central Region  
212 Third Avenue South  
Minneapolis, MN 55401  
Telephone: (612) 334-4100  
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December 23, 2003

**WARNING LETTER**

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

**Refer to MIN 04 - 11**

James M. Shaw  
Administrator  
Rusk County Memorial Hospital & Nursing Home  
900 College Avenue West  
Ladysmith, Wisconsin 54848

Dear Mr. Shaw:

During an inspection of your hospital transfusion service on August 7-8, 2003, our Investigator documented violations of the Current Good Manufacturing Practice (CGMP) regulations for blood and blood components under Title 21, Code of Federal Regulations, Parts 600-680 [21 CFR 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"). We note that you have already corresponded with the Centers for Medicare and Medicaid Services (CMS) in connection with the facts described below, and we review that correspondence below.

Deviations were noted as follows:

1. Records are not adequately maintained concurrently with the performance of each significant step in the compatibility testing, storage and distribution of each unit [21 CFR 606.160(a)(1), (b)]. For example:
  - a. A patient's blood specimen was properly tested during the screening process and correctly documented in the laboratory's log book as type O, Rh positive. However those blood type results were not entered concurrently onto the "Emergency Transfusion Request," "Transfusion Requisition" and "Crossmatch Transfusion Report" documents. Instead, the blood bank technician incorrectly documented a patient's blood type result on those documents as type A, Rh positive.

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- b. Red Blood Cells, units [redacted] and [redacted], were removed from the blood bank refrigerator and/or distributed. However, the blood bank technician responsible did not document this action on the "Unit Sign-Out Sheet," the distribution record used for this purpose.
2. Records pertinent to the unit are not reviewed before the release or distribution of the final product [21 CFR 606.100(c)]. There was no review of records for discrepancies before or after Red Blood Cells, units [redacted] and [redacted], were issued by the blood bank technician.
3. Written standard operating procedures (SOPs) in the compatibility testing, storage and distribution of blood and blood products for transfusion are not followed [21 CFR 606.100(b)]. Your SOP entitled "Emergency Crossmatch Procedure" was not followed in connection with Red Blood Cells, units [redacted] and [redacted]. For example, there were no blood return slips completed for these products, which a blood bank technician provided to the Emergency Transport team upon transferring a patient to another hospital.
4. Personnel responsible for the compatibility testing, storage and distribution of blood and blood components failed to have adequate educational background, training and experience, including professional training as necessary, or combination thereof, to assure competent performance of their assigned functions [21 CFR 606.20(b)]. There were no proficiency test results [21 CFR 606.160(b)(5)(v)] for the blood bank technician responsible for the actions described in paragraphs 1-3, above, and who was involved in a transfusion-related event.

The above deviations are not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to ensure that your establishment is in compliance with all requirements of federal regulations, with regard to compatibility testing, storage, and distribution. You should take prompt action to correct these deviations. Failure to correct these deviations may result in regulatory action without further notice, such as seizure and/or injunction.

We have reviewed your letter to CMS dated September 2, 2003, in response to the Form CMS-2567 that was issued at the conclusion of the inspection of your facility by CMS. As you are aware, several items noted on the Form CMS-2567 reference violations of the cGMP regulations for blood and blood components under 21 CFR Part 600-680. As a result of our review, we have the following comments:

- In your response, you provided excerpts from several SOPs including, but not limited to, compatibility testing, emergency transfusions and distribution.

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Please provide the SOPs in their entirety so that they may be more adequately and thoroughly evaluated.

- In your response, you indicated that you will revise many of your SOPs to address the issues noted during the inspection. However, your proposed corrective actions did not provide any information as to how the staff will be trained and/or apprised of the revisions or changes in the procedures and/or your operations.

Please notify this office in writing within 15 working days of receipt of this letter, of any additional steps you have taken to correct the noted violations, including supporting documentation. Your further response should be sent to Compliance Officer Jane E. Nelson at the address on the letterhead.

Sincerely,



W. Charles Becoat  
Director  
Minneapolis District

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