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Food and Drug Administration  
Kansas City District  
Southwest Region  
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P.O. Box 15905  
Lenexa, Kansas 66285-5905

Telephone: (913) 752-2100

October 19, 2000

**CERTIFIED MAIL  
RETURN RECEIPT REQUESTED**

**WARNING LETTER**

Ref. KAN-2001-004

Ms. Phyllis A. Ericson, MS, MT (ASCP)  
Executive Director  
Community Blood Bank of the Lancaster County Medical Society  
Lincoln, Nebraska 68510-1496

Dear Ms. Ericson:

On August 28 – September 1, 2000, we conducted an inspection of your blood bank in Lincoln, Nebraska. The investigator documented deviations from the Current Good Manufacturing Practices (CGMP) in Title 21, Code of Federal Regulations, Part 606 [21 CFR 606]. These deviations cause the biologics products processed by your firm 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 but are not limited to the following:

1. A unit of blood drawn on 5/18/00 was not tested per manufacturer's instructions for Hepatitis B Surface Antigen (HBsAg). The unit's components were labeled and later shipped to consignees. [21 CFR 606.65(e)]
2. Failure to follow Standard Operating Procedures (SOPs) as evidence by the following:
  - a) A HBsAg test run on 5/19/00 was invalidated, due to an unexpected reactive result of a negative external control. Your firm's Standard Operating Procedure (SOP) was not followed for the resolution of the problem and an initially reactive unit was voided and tested again as the initial test of record. [21 CFR 606.20(b)]
  - b) Your firm's SOP states, Variance Reports are to be generated to inform the Laboratory Manager and the Quality Assurance Director of an unexpected negative external control. In the situation described above no report was generated. [21 CFR 606.160(b)(7)(iii)]
  - c) Your firm's SOPs do not depict the associated current method of operation, for example: a) the Amicus Plateletpheresis SOP does not describe the current method of deferring donors who have experienced red blood cell loss, b) the Duplicate Donor Identification System SOP does not describe what factors should

be considered in excluding potential duplicate donor cases or requiring further investigation. [21 CFR 606.100(b)]

3. Detection and resolution of duplicate donors is not always accomplished prior to release and shipment of associated blood products. [21 CFR 606.100(c)] For example:
  - a) Unit 3624937 Red Blood Cells, Leukocytes Reduced, was labeled on 6/22-23/00 and shipped on 6/26/00 and 6/30/00, respectively. The resolution of the duplicate donor associated with the unit occurred on 7/3/00.
  - b) Unit 9084673 Platelets, Red Blood Cells, and Leukocytes Reduced, was labeled on 8/28/00 and shipped on 8/29/00. The resolution of the duplicate donor associated with the unit occurred on 8/30/00.

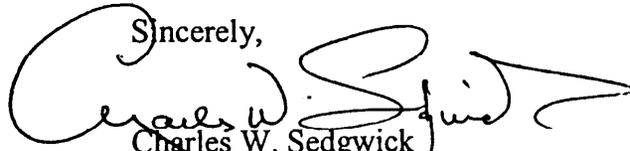
The above observations are not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to ensure that all blood and blood components processed, tested and distributed by your firm are in compliance with the Act and all requirements of the federal regulations.

We received a letter in response to the Form FDA 483 in our office on September 18, 2000. Your response appears appropriate to address these issues; however, corrective actions, including retraining of staff, will need to be verified during the next inspection. It should be noted that the observations made, especially in regard to invalid test runs, duplicate donors and failure to follow SOPS demonstrate serious deficiencies in your Quality Assurance system. Your further response should include specific steps you plan to implement to improve Quality Assurance oversight.

You should take prompt action to correct these violations and establish appropriate procedures that will prevent their recurrence. Failure to promptly correct these violations may result in regulatory action without further notice, such as seizure and/or injunction.

We request a response to this letter within fifteen (15) working days addressing any procedures implemented since your FDA 483 response. Include in your response any corrective actions you have taken or plan to take and have yet to complete. All the items stated in your response will be verified during our next inspection. If you have further questions or concerns, you should reply directly to Monica R. Maxwell, Compliance Officer, at the above address.

Sincerely,



Charles W. Sedgwick  
District Director  
Kansas City District