DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT OFFICE ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
P.O. Box 25087, Building 20 Denver Federal Center Denver, Colorado 80225-0087 303-236-3000	4/14/08-5/23/08
	FEI NUMBER 3001451955

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED

TO: Julia L. Wulf, Chief Executive Officer

FIRM NAME	STREET ADDRESS
The American National Red Cross	6616 South 900 East
CITY, STATE AND ZIP CODE Salt Lake City, Utah 84121	TYPE OF ESTABLISHMENT INSPECTED Regional Blood Bank

DURING AN INSPECTION OF YOUR FIRM I OBSERVED:

This document lists observations made by the FDA representative(s) during the inspection of your facility. They are inspectional observations, and do not represent a final Agency determination regarding your compliance. If you have an objection regarding an observation, or have implemented, or plan to implement, corrective action in response to an observation, you may discuss the observation or action with the FDA representative(s) during the inspection or submit this information to FDA at the address above. If you have any questions, please contact FDA at the phone number and address above.

1. The Monthly Summary Problem Reports from March of 2006 to the present documented an ongoing trend under BPD code (b) (4) (Records: Inappropriate review of one's work). American Red Cross Blood Services has not implemented an effective corrective action to prevent this deviation from occurring in their present operations.

Specifically,

a. in June of 2006 the firm implemented a corrective action in which the charge person would assign an individual to perform (b) (4) review. The individual performing the review would not perform any other tasks on the Blood Donation Record (BDR). The corrective action failed the effectiveness check in August of 2006.

b. in November of 2006 the firm implemented a corrective action in which the charge person would perform the (b) (4) review on all BDRs. The charge person would then assign another staff member to look over the Blood Donation Records (BDR) for the charge person's initials. The individual would then segregate the Blood Donation Records which contained the charge person's initials and another member of the staff (not involved in the (b) (4) review) would review those records. The corrective action failed the effectiveness check in January of 2007.

c. in January of 2007 the firm implemented three corrective actions: Corrective Action # 1- The collections manager in Idaho, Utah and Montana will review policy record (b) (4) with staff (b) (6), and (b) respectively; Corrective Action # 2-Collections managers in Idaho, Utah and Montana will instruct collections staff that corrective actions that are approved by the Quality Assurance Department for implemetation are not optional. All corrective action requirements must be adhered to strictly by all collections staff; and Corrective Action # 3- Collections charges/supervisors will have a staff member review all BDRs at the collection site to determine if the charge/supervisor is documented on the BDR. The staff member will then segregate the Blood Donation Records which have the charge/supervisor performing any function on that BDR by either applying flag stickers to the BDR, or placing them into

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separate piles. The charge will then distribute the BDR to another staff member who is not involved in the process to complete the (b) (4) review. The corrective actions failed the effectiveness checks in February of 2008.

In March of 2008 the firm opened a new trend exception report (b) (4) for the same BPD code (b) (4) (b) (4).

2. In December of 2006 the firm recognized a trend in BPD code (b) (4) (Collection Site Set-Up Daily Function Check Form Incorrect/Incomplete) errors. This trend was documented in Exception Report #(b) (4). The firm did not implement a timely corrective action for this trend, in that the corrective action was not approved by QA until June of 2007 and the corrective action (part 1 and 2) was not implemented until the Fall of 2007 (August and September of 2007).

3. Since February of 2006 American Red Cross Blood Services has documented an ongoing trend in problems under BPD code (b) (4) (travel to malaria endemic area/history of malaria). They failed to implement any preventative measures to reduce occurences of BPD code (b) (4).

4. Corrective Action Plans developed to prevent the recurrence of problems are not always submitted to the Quality Assurance Department within 30 days. Five out of the 89 (b) (4) problems reviewed were not submitted to QA within 30 days ((b) (4) and (b) (4)).

5. The Quality Assurance review is not being completed within 5 business days. Twenty-one out of the 120 Level 3 problems examined were not reviewed by the Quality Assurance Department within 5 business days (b) (4) (b) (4) (b) (4).

6. The Problem Management Directive requires problems to be documented into the automated problem-management system (APMS) within five business days from the date of discovery. Problems # (b) (4) (b) (4) were logged into the system more than 5 business days from the date of discovery.

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7. The firm's use of repetitive cycles of submissions and rejections of Corrective Action Plans and the use of time extensions without limits is suspending the 30 day time frame to provide timely corrective actions. The following incidents are examples of the above:

a. Exception Detail Report #(b) (4) was discovered on 12/26/06. The corrective action plan for this exception was due to the Quality Assurance Department (QA) on 1/25/07. The problem manager asked for and was granted an extension of the due date until 2/5/07. The problem manager asked for and was denied a second extension of the due date until 2/16/07. The corrective action plan for the exception was submitted to QA on 2/5/07. The corrective action plan was rejected by QA on 2/13/07. The problem manager revised the plan and submitted the corrective action plan to QA on 5/16/07. The corrective action plan was rejected by QA on 5/25/07. The problem manager revised the plan and submitted it back to QA on 5/25/07. The Quality Assurance Officer approved the corrective action plan for(b) (4) on 5/29/07.

b. Exception Detail Report #(b) (4) was discovered on 2/4/07. The corrective action plan for this exception was due to the Quality Assurance Department (QA) on 3/6/07. The corrective action plan for the exception was submitted to QA on 3/2/07. The corrective action plan was rejected by QA on 3/9/07. The problem manager revised the plan and submitted the corrective action plan to QA on 4/4/07. The corrective action plan was rejected by QA on 4/11/07. The problem manager revised the plan and submitted it back to QA on 4/14/07. The corrective action plan was rejected by QA on 4/20/07. The problem manager revised the plan and submitted it back to QA on 4/20/07. The Quality Assurance department approved the corrective action plan for(b) (4) on 4/27/07.

c. Exception Detail Report #(b) (4) was discovered on 8/21/07. The corrective action plan for this exception was due to the Quality Assurance Department (QA) on 9/20/07. The corrective action plan for the exception was submitted to QA on 9/19/07. The corrective action plan was rejected by QA on 9/26/07. The problem manager revised the plan and submitted the corrective action plan to QA on 12/11/07. The exception report was routed to QA two more times for corrections and on 12/18/07, the QA department approved the corrective action plan for(b) (4).

d. Problem Report # (b) (4) was discovered on 7/20/06. The corrective action plan for this problem was due to the Quality Assurance Department on 8/19/06. The corrective action plan for the problem was submitted to QA on 8/1/06. The corrective action plan was rejected by QA on 8/10/06. The problem manager revised the plan and submitted the corrective action plan to QA on 8/10/06. The corrective

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action plan was rejected by QA on 8/17/06. The problem manager revised the plan and submitted the corrective action plan to QA on 9/5/06. The corrective action plan was rejected by QA on 9/12/06. The problem manager revised the plan and submitted it back to QA on 9/19/06. The corrective action plan was rejected by QA on 9/26/06. The corrective action plan was again submitted to the QA department and was rejected by QA on 10/4/06. The problem manager revised the plan and submitted it back to QA on 10/6/06. The corrective action plan was approved by the Quality Assurance Officer on 10/6/06.

8. Immediate or timely action to mitigate risk and prevent reoccurence is not always taken.

a. Exception Detail Report # (b) (4) was discovered on 12/26/06, but the problem manager did not initiate an investigation into the problem until 7/17/07.

b. Exception Detail Report (b) (4) was discovered on 12/8/06, but the problem manager did not initiate an investigation into the problem until 1/10/07.

c. The problem manager submitted the corrective action for Exception Detail Report (b) (4) to the Quality Assurance Department for approval on 9/19/07. The corrective action plan was Rejected on 9/26/07. The problem manager did not work on revising the corrective action plan for (b) (4) until 11/30/07.

d. The problem manager submitted the corrective action for Exception Detail Report (b) (4) to the Quality Assurance Department for approval on 3/7/07. The corrective action plan was Rejected on 3/27/07. The problem manager did not work on revising the corrective action plan for (b) (4) until 7/9/07.

9. The firm did not follow (b) (4) in that on 4/2/07 a mobile blood drive at (b) (4) closed early due to a power outage, but the FDA was not notified of the suspension of activities until 4/10/07.

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10. American Red Cross Blood Services failed to submit Biological Product Deviation Reports to FDA within 45 days from the date of discovery.

Specifically, eighteen of the Biological Product Deviation filed between 3/1/06 and 4/23/08 were reported to FDA more than 50 days after they were discovered by the firm.

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