DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT OFFICE ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
6751 Steger Drive Cincinnati, OH 45237 (513) 679-2700	4/14-25/08
	FEI NUMBER 1073003

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED

TO: Dr. Yenshen Hseuh, CEO

FIRM NAME	STREET ADDRESS
American Red Cross Blood Services	502 E. Chestnut Street
CITY, STATE AND ZIP CODE	**TYPE OF ESTABLISHMENT INSPECTED**
Louisville, KY 40202	American Red Cross Regional Office

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 OBJECTION 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.

DURING AN INSPECTION OF YOUR FIRM (I) (WE) OBSERVED:

Observation 1

The firm failed to promptly, thoroughly and adequately investigate, correct and take steps to prevent the recurrence of each problem. For example:

a. On February 23, 2007, the firm logged a problem (b) (4) for a trend relating to incomplete or incorrect donor records (Apheresis Donor Continuous Record (b) (4)). The firm conducted a (b) (4) investigation and developed a formal Corrective Action Plan. The Effectiveness Check had failed. The firm's (b) (4) entitled (b) (4) (b) (4) states to evaluate why the effectiveness criteria was not met and develop a new corrective action if necessary. The firm did not conduct a follow-up to the failed Effectiveness Check and did not re-evaluate the Corrective Action. As of 4/17/08 there has been no additional follow-up action.

b. On January 24, 2008, the firm logged a problem (b) (4) for a trend relating to incomplete/incorrect/not reviewed Apheresis Alarm Log (b) (4). The firm was to conduct a (b) (4) investigation; however, as of April 17, 2008 the investigation has not been completed.

c. On December 31, 2007, the firm logged a (b) (4) problem (b) (4) relating to an employee documenting an illogical donor temperature. An investigation was done and it was determined that this was the second instance for this employee; therefore, the employee was verbally counseled. It was found that problem (b) (4) was the employee's third instance (b) (4). According to the corrective action, the employee should have received written counseling.

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Observation 2

The firm failed to notify consignee and/or FDA's Baltimore District Office within 48 hours after learning that a unit of unsuitable blood or blood component has been distributed. For example:

a. Twenty-six RBC units that were stored in the freezer for approximately 5-10 minutes. The units were placed on hold for the incorrect storage temperature. After a review of the daily quarantine reports, the supervisor discovered that the hold for unit (b) (6) had been removed and the products (code 04741 and 04761) were labeled and distributed. On March 20, 2007, the firm logged a (b) (4) problem (b) (4) for the 2 products (b) (6) that were released from electronic hold and distributed before the decision of the cMRB. There was no 48 hour notification to FDA's Baltimore District Office.

b. The firm logged a problem (b) (4) in response to fresh frozen plasma components from either whole blood or apheresis collection that failed to meet the required manufacturing timeframe, 8 hours in freezing environment for whole blood and 6 hours for apheresis. This problem was discovered on 12/8/05 and on December 15, 2005 the region was instructed to gain control of products. On January 18, 2006 the cMRB determined that fresh frozen plasma created greater than 8 hours was to be recalled. The River Valley Region had three products involved. The 48 hour notice was sent to FDA's Baltimore District Office on January 26, 2006.

Observation 3

The firm's (b) (4) entitled (b) (4) states that they must develop a formal Corrective Action Plan within 30 days of discovery for (b) (4) (b) (4) problems and within 45 days of discovery for (b) (4) problems. The firm did not meet these time frames for the following problems:

a. On March 6, 2007, the firm logged a (b) (4) problem (b) (4) for RBC's stored at incorrect temperature. This problem was discovered on March 5, 2007; however, the Corrective Action Plan was initially approved by QA on July 2, 2007.

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b. On June 22, 2007, the firm logged a (b) (4) problem (b) (4) for illogical donor temperature. This problem was discovered on June 18, 2007; however, the Corrective Action Plan was approved by QA on July 27, 2007. The Corrective Action Plan was then re-opened due to lack of documentation. The final QA approval was November 11, 2007.

c. On June 21, 2007, the firm logged a (b) (4) problem (b) (4) for a trend relating to incorrect/incomplete transporter and receiving checklist. This problem was discovered on June 21, 2007. An extension for more time to conduct the investigation was requested; however, the request was denied. The Corrective Action Plan was approved by QA on September 18, 2007.

Observation 4

Failure to notify FDA's Baltimore District Office and/or CBER within 45 days after learning that a unit of unsuitable blood or blood component was distributed. For example:

a. Fresh frozen plasma components from either whole blood or apheresis collection failed to meet the required manufacturing timeframe, 8 hours in freezing environment for whole blood and 6 hours for apheresis. This problem (b) (4) was discovered on 12/8/05; however, it was reported to FDA's Baltimore District Office on 3/23/06. The firm submitted the Biological Product Deviation on 3/23/06.

b. Twenty-six RBC units were stored in the freezer for approximately 5-10 minutes. The units were placed on hold for the incorrect storage temperature. After a review of the daily quarantine reports, the supervisor discovered that the hold for unit (b) (6) had been removed and the products (code 04741 and 04761) were labeled and distributed. On March 20, 2007, the firm discovered and logged a problem (b) (4) for the 2 products (b) (6) that were released from electronic hold and distributed before the decision of the cMRB. The Biological Product Deviation Report was submitted to CBER on 6/5/07 and the 45 day notification was sent to FDA's Baltimore District Office on June 5, 2007.

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Observation 5

Written standard operating procedures were not followed. For example:

The firm's Directive entitled (b) (4) [redacted] states that the firm has 5 business days to log in a problem. On September 12, 2006, a donor was inappropriately screened against the Donor Deferral Register. The donor's last name was spelled incorrectly and the social security number was unknown. The problem was discovered on January 26, 2007 and logged in on February 28, 2007 (b) (4) [redacted].

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