DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
300 River Place, Suite 5900 Detroit, MI 48207 (313) 393-8100 Fax: (313) 393-8139 Industry Information: www.fda.gov/oc/industry	04/05/2010 - 04/27/2010* FEI NUMBER 1873033

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

TO: Ms. Sharon L. Jaksa, CEO

FIRM NAME	STREET ADDRESS
American National Red Cross Great Lakes Region	1800 E Grand River Ave
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Lansing, MI 48912-2305	Blood Bank

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 OBSERVED:

OBSERVATION 1

Failure to perform a thorough investigation of a failure of a lot or unit to meet any of its specifications.

Specifically, 1) Investigation of exception report E-0632596 (I-0003622) failed to consider frozen red blood cells as potentially affected by the error resulting in a failure to recall frozen red blood cells (pcode 06200) unit #18FZ24606 as required by written procedure #11.2.002, Directive: Management of Suspect Products. Exception report #E-0632596 was initiated for an employee who was found not performing an arm scrub for 30 seconds and was not waiting or aware of the need to wait 30 seconds prior to performing the phlebotomy during whole blood collections. The cMRB decision was to recall all in dated transfusable components from 09/17/2001 to 08/10/2009. The cMRB decision failed to include frozen red blood cells (pcode 06200) in the evaluation. The firm had manufactured two frozen red blood cell units affected by this exception report with one unit (unit #18FZ24606) being shipped to a customer on 1/29/02.

OBSERVATION 2

A thorough investigation of each reported adverse reaction was not made.

Specifically, Medical Director reviews of Donor Reaction and Injury Records (DRIR) are not conducted within a reasonable amount of time as required by written procedure Doc # 15.3.055 titled, Work Instruction: Performing Final Case and Donor Suitability Assessment. Review of November 2009 DRIR's found 3 of 47 records had not been reviewed by the Medical Director as of this inspection, 1 DRIR was reviewed about three months after the date of the incident and 1 was reviewed 2 months after the date of the incident:

Case id # C200911141848o7a was for a donor reaction involving dizzy/lightheadedness and a prolonged recovery on 11/12/09. This record has not had Medical Director Review or Final Quality Review as of

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	Kelley L Clark, Investigator Kelley Clark	04/27/2010

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4/22/10.

Case id # C200911201635o4m was for a donor reaction involving a 4 ½" bruise reported by donor call back on 11/20/09. This record has not had Medical Director Review or Final Quality Review as of 4/22/10.

Case id # C200911051557o6z was for a donor reaction involving dizzy/lightheadedness and a bruise/swelling a little larger than a golf ball reported by donor call back on 11/5/09. The donor subsequently called in and stated she experienced additional lightheadedness and was transported by EMS to [redacted] on [redacted] This record has not had Medical Director Review or Final Quality Review as of 4/22/10.

Case id # 018-D-C200911280840o3n was for a donor reaction involving large hematoma on 11/27/09. This record had Medical Director Review and Final Quality Review on 2/19/10.

Case id # C200911271902o7a was for a donor reaction involving dizzy/lightheadedness and seizure/convulsion on 11/25/09. This record had Medical Director Review on 1/26/10 and Final Quality Review as of 2/19/10.

*** DATES OF INSPECTION:**
04/05/2010(Mon), 04/06/2010(Tue), 04/07/2010(Wed), 04/08/2010(Thu), 04/09/2010(Fri), 04/20/2010(Tue), 04/21/2010(Wed), 04/22/2010(Thu), 04/27/2010(Tue)

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	Kelley L Clark, Investigator	04/27/2010