DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
4040 North Central Expressway, Suite 300 Dallas, TX 75204 (214) 253-5200 Fax: (214) 253-5314 Industry Information: www.fda.gov/oc/industry	07/26/2010 - 08/09/2010* FEI NUMBER 1673040

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

TO: Ruth R. Cordell, Regional Quality Director

FIRM NAME	STREET ADDRESS
American National Red Cross SW Region - HT	10151 E 11th St
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Tulsa, OK 74128-3005	Red Cross

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

Recall records for distributed product are not complete.

Specifically, 25 B positive units being imported on import session 62843 into the Southwest Region component lab on 1/28/10 were left out of controlled storage for more than 30 minutes and subsequently recalled by the Donor and Client Support Center (DCSC), Charlotte, NC beginning on 2/12/10. When the case file for this problem (case file 2010021221150o5m, E-0784767, and BPDR 2609) was requested for review on 7/27/10 by FDA Investigator Hickok, there were no product dispositions for five Whole Blood Numbers (WBNs) involved in the recall and no second notification had been sent to the consignee. No second notifications were sent for WBNs 001Q 35750, 001LP04986, 001LP04983, 001LH00108, and 001GL53602. Per SOP 11.3.011 Version 1.5, if product dispositions are not received from a consignee within 30 days, a final notification letter must be sent to the consignee. For this recall, the final notification letter should have been sent on or before 04/03/2010, but was not sent until 07/28/2010.

Two additinal WBNs had a final disposition shown on the Component Status Change Record as "Q" for quarantine. Per SOP 11.4.frm9, Version 1.1 and Job Aid # 11.4.ja15 Version 1.0 Valid Disposition Codes, quarantine is not considered a valid final disposition. WBNs 001Q35742 and 001H31375 were changed from a final disposition status of quarantine to a disposition of destroyed after updated information on theWBNs status was received from the consignee on 7/28/10.

*** DATES OF INSPECTION:**
07/26/2010(Mon), 07/27/2010(Tue), 07/28/2010(Wed), 07/29/2010(Thu), 07/30/2010(Fri), 08/02/2010(Mon), 08/03/2010(Tue), 08/04/2010(Wed), 08/05/2010(Thu), 08/09/2010(Mon)

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	Janice M. Hickok, Investigator, Investigator Janice M. Hickok	08/09/2010