DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
1431 Harbor Bay Parkway Alameda, CA 94502-7070 (510) 337-6700 Fax:(510) 337-6702 Industry Information: www.fda.gov/oc/industry	09/07/2010 - 09/13/2010
	FEI NUMBER 2972991

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

TO: Mr. Jay R. Winkenbach, CEO, Northern California Region

FIRM NAME	STREET ADDRESS
American National Red Cross (The)	2731 N 1st St
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
San Jose, CA 95134-2051	ARC - Community 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 maintain storage and distribution records.

Specifically, a summary listing of Biological Product Deviation Reports (BPDRs), covering the period of 1 July 2009 - 15 August 2010, had eighteen (18) BPDRs. Exception Detail Report, No. E - 0720636, logged 12/30/2009, involved thirty-one (31), imported Red Blood Cell units, Leukoreduced. A discrepancy, involving the temperature upon initial receipt of the units, was discovered after the units had been distributed. All 31 units had been distributed to the same consignee.

The Material Review Board (MRB) determination was to recall all 31 units. On 24 August 2009, the Donor & Client Support Center in Charlotte, NC assumed responsibility of the Consignee Notification functions for The American National Red Cross, Northern California Region.

A request was made by FDA, 09/08/2010, to review the documentation for Consignee Notification and all supporting documentation of product disposition. It was discovered that the supporting documentation of final disposition from the consignee could not be located. The Consignee was contacted for an additional copy, which was provided on 09/09/2010. It was then discovered that eight (8) of the 31 final dispositions on the Component Status Change Record (CSCR) Form had not been correctly filled out. The CSCR had initially indicated that all 31 units had been destroyed. However, 8 of the units had actually been transfused. Review by the Process Verifier, documented 03/04/2010, failed to identify these discrepancies. Corrective actions were initiated.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	LaVerne Puckett, Investigator	09/13/2010