DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT OFFICE ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
1 Montvale Avenue Stoneham, MA 02180 781-596-7700	11/12-24/08
	FEI NUMBER 1273014

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED

TO: Paul T. Sullivan, CEO

FIRM NAME	STREET ADDRESS
American Red Cross Blood Services	209 Farmington Avenue
CITY, STATE AND ZIP CODE	TYPE OF ESTABLISHMENT INSPECTED
Farmington, CT 06032	Licensed Blood Establishment

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

Failure to adequately investigate, correct, and prevent recurring problem of distributing blood and blood components without ice to consignees.

Specifically,

a. The problem for (b) (4) was discovered on 3/20/08. The problem involved shipment of 16 red blood cells without ice to a consignee. This was a (b) (4) investigation. The consignee was instructed to destroy the units by Hospital Services Supervisor referred(JO). No hold was placed on the units. A corrective action,and a three months effectiveness check from June to August were developed and implemented. On 9/9/08 during QA review of (b) (4) resulted in problem (b) (4) to address why units were not placed on hold.

b. On 7/16/08 another incident regarding shipment of red cell without ice to consignee occurred; an exception (b) (4) was opened on 7/17/08. The problem involved distribution of 23 red blood cell without ice to consignee. This issue also resulted in consignee being instructed to destroy the units by (b) No hold was placed on the units. A corrective action was developed and implemented; and a 3 months effectiveness checks from September to November was implemented.

Observation 2

Written procedure was not followed regarding handling of "Management of Suspect Products".

Specifically,

On 3/20/08 and 7/17/08 (b) (4) and (b) (4) Hospital Services Supervisor(JO)instructed the consignees to destroy units, instead of referring the customer complaints to ARC, Dedham, MA for follow up, as it's written in ARCBS (b) (4) (b) (4) which stipulates on page 3 of 10 that " (b) (4) apply the appropriate hold or assertion (b) (4) In both cases, Hospital Service Supervisor (b) (6) was not following procedure.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	EMPLOYEE(S) NAME AND TITLE (Print or Type)	DATE ISSUED
		ANTHONY N. ONIANWA-Investigator Alice C. Silva, Investigator	12/24/08

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

Observation 3:

Failure to sign and date equipment validation/revalidation records.

Specifically,

(b) (4) Equipment ID's: (b) (4) not sign/date; and the work order closed dates were not documented on the equipment problem/deficiency reports. According to ARC CT Blood Service local operating procedure, (b) (4) titled (b) (4) (b) (4) requires that equipment validation be signed and dated, and work order closed date be documented.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	EMPLOYEE(S) NAME AND TITLE (Print or Type)	DATE ISSUED
		Alice C. Silva, Investigator Anthony N. Oranuba - Investigator	12/24/2008