DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
One Montvale Avenue Stoneham, MA 02180 (781) 596-7700 Fax:(781) 596-7896 Industry Information: www.fda.gov/oc/industry	05/04/2010 - 06/15/2010* FEI NUMBER 1273014

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

TO: Paul T. Sullivan, Chief Executive Officer

FIRM NAME	STREET ADDRESS
American Red Cross Blood Services	209 Farmington Ave
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Farmington, CT 06032-1955	American 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 WE OBSERVED:

OBSERVATION 1

Written standard operating procedures including all steps to be followed in the collection of blood and blood components for further manufacturing purposes are not always followed.

Specifically, American Red Cross Job Aid 15.4.ja068, titled, "Collection Site Evaluation Criteria" and American Red Cross Document Number 15.3.079, titled "Evaluation and setting Up the Collection Site" do not give specific environmental conditions or parameters for the set up of mobile sites in regards to temperature. Your firm continued to operate blood drives with deficiencies as noted in the following operation reports:

Temperature:

A.) On 2/27/2010 and 3/13/2010, blood drives were held at the Tully Health Center - Stamford. The operation record from the drive on 2/27/2010 states that, "Very cold in room 59° @ opening - then 61°. Shawana Rivero, Director of Collections notified. Volunteers state they are very uncomfortable with temperature. Colder in history area." The operation record from the drive on 3/13/2010 states, "Very cold in room 62° - maintenance called***Farmington notified - when temperature dropped to 60°. At 10:45, heat turned on by maintenance."

B.) Philip R. Smith Elementary School -South Windsor, date 2/8/2010, Comments "59° in room at opening - heat not working, closed around 3:15 to move to warmer area in building."

Ventilation:

C.) Masonicare at Newtown, date 4/9/2009, Operational Analysis "3 staff complained of not feeling well due to fumes***filled out Employee Injury Reports. Also donor felt unwell in Histories."

D.) Raymond T. Goldbach VFW Post, date 5/6/2009, Operational Analysis "Site was very smokey, due to smoking in bar. Even with door to bar closed, several staff were affected by smoke."

E.) VFW Post 5157, date 2/22/2010, Comments "Site had smokers in bar next door - smelly. (1) staff had to leave due to

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smoke issues - fans in place to circulate air."

Noise:

F.) On 3/21/2009 and 3/22/2009, blood drives were held at the Connecticut Expo Center. The Operation Record from the blood drive on 3/21/2009 states "Noise level was extreme due to several vendors and radio stations playing loud music at the same time, Latino festival." The operation record from the drive on 3/22/2009 states, "very loud music playing, unable to hear blood pressures at times - very difficult working conditions."

Privacy:

G.)Yale Grad School Arts & Sciences, date 3/2/2009, Operational Analysis "Site is very tight - confidentiality is hard to maintain - registration and reading in hallway."

Lighting:

H.) On 2/2/2009, 2/3/2009, and 2/5/2009, blood drives were held at the Yale Payne Whitney Gymnasium. The operation record from the drive on 2/2/2009 states, "site has inadequate lighting making phlebotomy difficult - extra lights needed." The operation record from the drive on 2/3/2009 state "Very poor lighting at this site making it difficult to see anything, and the operation record for the drive on 2/5/2009 states, "Terrible lighting."

OBSERVATION 2

Written records are not always made of investigations into unexplained discrepancies.

Specifically, there is no quality review of mobile site suitability for continued use.

I.)On 2/2/2009, 2/3/2009, and 2/5/2009, blood drives were held at the Yale Payne Whitney Gymnasium. The operation record from the drive on 2/2/2009 states, "site has inadequate lighting making phlebotomy difficult - extra lights needed." The operation record from 2/3/2009 states "Very poor lighting at this site making it difficult to see anything, and the operation record for the drive on 2/5/2009 states, "Terrible lighting."

2.) On 2/27/2010 and 3/13/2010, blood drives were held at the Tully Health Center - Stamford. The operation record from the drive on 2/27/2010 states, "Very cold in room 59° @ opening - then 61°. Shawana Rivero notified. Volunteers state they are very uncomfortable with temperature. Colder in history area." The operation record from the drive on 3/13/2010 states, "Very cold in room 62° - maintenance called***Farmington notified - when temperature dropped to 60°. At 10:45, heat turned on by maintenance."

3.) On 3/21/2009 and 3/22/2009, blood drives were held at the Connecticut Expo Center. The Operation Record from the

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blood drives on 3/21/2009 states "Noise level was extreme due to several vendors and radio stations playing loud music at the same time, Latino festival." The operation record from the drive on 3/22/2009 states, "very loud music playing, unable to hear blood pressures at times - very difficult working conditions."

OBSERVATION 3

The personnel responsible for the collection of blood or blood components are not adequate in number to assure competent performance of their assigned functions, and to ensure that the final product has the safety, purity, potency, identity and effectiveness it purports or is represented to possess.

Specifically, mobile blood drives are not adequately staffed per staffing matrix/staff version.

According to your staffing matrix, line staff, charge staffs, and mobile unit assistance (MUA) are required to be present at mobile blood drives. In addition to the above mentioned staffs, team supervisor is required if the blood drive has over 26 donors. ARC Connecticut and New England Region Blood Services Operational Records Addendum reviewed during this inspection reveal blood drives are not staffed adequately.

For Example:

a) West Haven Elks - Hall drive that took place on 4/16/2009 stated that the goal of the drive was 41 productive donors and the total hours of operation for the drive were 5 hours and 15 minutes. According to your firm's staffing matrix, this drive should have been staffed with five phlebotomists. Our audit of operation report for this drive showed there were only three phlebotomists present.

b.) Asnuntuck Community College drive that took place on 2/25/2010 stated that the drive had 58 scheduled donors and the total hours of operation for the drive were 5 hours. According to your firm's staffing matrix, this drive should have been staffed with one team Supervisor. There was no Team Supervisor present at this drive.

c.) Tighitco drive that took place on 2/15/2010 stated that the drive had 40 scheduled donors and the total hours of operation for the drive were 4 and 1/2 hours. According to your firm's staffing matrix, this drive should have been staffed with one Team Supervisor. There was no Team Supervisor present at this drive.

d.) Red Robin drive that took place on 2/15/2010 stated that the drive had 44 scheduled donors and the total hours of operation for the drive was 5 hours. According to your firm's staffing matrix, this drive should have been staffed with 5 phlebotomists, 1 MUA, and 1 Charge. According to the above noted operations record addendum, there were 4 phlebotomists and no charge person present at the blood drive.

e.) Ridgefield Parks & Recreation Center drive that took place on 12/22/2009 stated that the drive had 85 scheduled donors and the total hours of operation for the drive was 6 hours or more. According to the above noted operation record addendum,

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there was no charge person present at this drive.

f.). ARC Blood Services, CT Charter Oak drive that took place on 7/1/2009 stated that the drive had 62 scheduled donors and the total hours of operation for the drive was 6 hours or more. According to the above noted operation record addendum, there was no charge person present at this drive.

OBSERVATION 4

Laboratory records do not include the initials or signature of a second person showing that the original records have been reviewed for accuracy, completeness, and compliance with established standards.

Specifically, mobile blood drives operation records are not consistently being reviewed either by supervisor or charge person for accuracy and completeness.

For example:

a.) American Red Cross Operation Report Addendum for Drive ID#84188, Site #2984, and Drive Date 7/13/2009 had no Charge signature.
b.) American Red Cross Operation Report Addendum for Drive ID#86008, Site #6041, Drive Date 1/7/2010 had no Supervisor signature.
c.) American Red Cross Operation Report Addendum for Drive ID#86158, Site #6511, Drive Date 1/21/2010 had no Supervisor signature.
d.) American Red Cross Operation Report Addendum for Drive ID#84923, Site #5224, Drive Date 1/23/2010 had no Supervisor signature.
e.) American Red Cross Operation Report Addendum for Drive ID#85863, Site #6010, Drive Date 12/22/2009 had no Supervisor signature.
f.) American Red Cross Operation Report Addendum for Drive ID#83798, Site #3424, Drive Date 7/1/2009 had no Charge signature. Same person signature for Supervisor and Charge operation.
g.) American Red Cross Operation Report Addendum for Drive ID#86711, Site2136, Drive Date 5/28/2010 had no Charge signature. Same person signature for Supervisor and Charge operation.

OBSERVATION 5

Deviation from the procedural requirements of a decree of injunction.

Specifically, your firm filed inaccurate Exception Detail Reports and Letters of Notification of Suspension of Activity to the

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USFDA.

A.) On 5/10/2010, your firm submitted a Notification of Significant Corrective Action or Suspension of Activities, Doc 10.4ltr001 v-1.2 to the USFDA. This letter noted that there was a "Notification of Complete Suspension of Activities or Processes." Attached to this letter was Exception Detail Report E-0802346. E-0802346 stated that collection activities at the High Plains Community Center Blood Drive were suspended at 1:30 p.m. due to extreme temperature conditions.

1.) According to donor blood donation record from the High Plains Community Center Blood Drive, 16 donors were processed for whole blood collection units between 1:30-2:59pm. The whole blood unit # collected between 1:30-2:59 pm are as follows: 33FL33014, 33FL33015, 33FL33016, 33FL33017, 33FL33018, 33FL33019, 33FL33020, 33FL33021, 33FL33022, 33FL33023, 33FL33024, 33FL33025, 33FL33026, 33FL33027, 33FL33028, and 33FL33029 with a start time at 2:59pm.

B.) On 5/21/2010, your firm submitted a Notification of Significant Corrective Action or Suspension of Activities, Doc 10.4ltr001 v-1.2 to the USFDA. This letter noted that there was a "Notification of Complete Suspension of Activities or Processes." Attached to this letter was Exception Detail Report E-0809528. E-0809528 stated that collection activities were terminated at 1200 hours at the Bristol Eastern High School Blood Drive due hot temperatures and no air conditioning.

1.) According to donor's blood donation records from Bristol Eastern High School Blood Drive, the last phlebotomy for whole blood collections (unit#33GX 08775) was started at 12:32. This phlebotomy lasted 11 minutes.

C. On 5/19/2010, your firm opened Exception Detail Report (E-0807880). E-0807880 stated that your firm received a customer concern from (b) (6) regarding equipment issues and staff performance at the High Plains Community Center Blood Drive that was held on 5/ 8/2010.

1.) During our inspection, we collected a form, titled "American Red Cross Biomedical Services Form: Customer Concern Form, Doc 10.4.Zfrm001 W2004 v-1.0 and an email sent by (b) (6) Sponsor's Spokesperson to (b) (6), an Account Executive, of ARC Blood Services, Farmington, CT. This customer concern form and e-mail dated 5/10/2010, showed discovery date should have been documented as 5/10/2010, instead of 5/17/2010 as documented in your Exception Detail Report (E-0807880).

* DATES OF INSPECTION:
05/04/2010(Tue), 05/05/2010(Wed), 05/06/2010(Thu), 05/12/2010(Wed), 05/21/2010(Fri), 05/27/2010(Thu), 05/28/2010(Fri), 06/15/2010(Tue)

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