DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
US Customhouse, Rm 900 2nd & Chestnut St Philadelphia, PA 19106 (215) 597-4390 Fax: (215) 597-0875	08/29/2008 - 09/16/2008* FEI NUMBER 2573016

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
TO: James E. Starr, Chief Executive Officer

FIRM NAME	STREET ADDRESS
American Red Cross Greater Alleghenies Region	250 Jari Drive
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Johnstown, PA 15904	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

There is a failure to thoroughly review the failure of a batch or any of its components to meet any of its specifications whether or not the batch has been already distributed.

Between January 1, 2008 and August 31, 2008, the Greater Alleghenies Region (Region), failed to prevent the manufacture, distribution and subsequent transfusion, of three units of Packed Red Blood Cells (PRBC), which were manufactured from overweight units of Whole Blood. During the inspection, an internal query, performed by the Region on or about September 2, 2008, revealed:

A. Whole Blood Unit (b) (6) collected on August 25, 2008, was classified by the Region's collection staff as overweight. This unit was further manufactured, shipped on August 27, 2008 and later transfused.

B. Whole Blood Unit (b) (6) collected on January 28, 2008, was classified by the Region's collection staff as overweight. The unit was further manufactured, shipped on February 4, 2008 and later transfused.

C. Whole Blood Unit (b) (6) collected on January 24, 2008, was classified by the Region's collection staff as overweight. The unit was further manufactured, shipped on January 31, 2008 and later transfused.

OBSERVATION 2

Failure to perform a thorough investigation of an unexplained discrepancy.

The Region failed to initiate and/or perform a thorough investigation of the following unexplained discrepancies, as required in Paragraph IV.B.1 of the April 15, 2003, Consent Decree of Permanent Injunction (Decree):

A. From January 1, 2008 to August 31, 2008, the Region collected 78 units of Whole Blood which were classified as overweight. Three PRBC units, manufactured from three (i.e., (b) (6)) of the 78 overweight units, were subsequentially distributed and transfused. These three units were identified as problems on September 5, 2008 and logged them into the (b) (4) Automated Problem Management System (APMS) (Exception Detail Report (b) (4) on September 5, 2008. However, as of September 16, 2008, the Region has not initiated investigation of the remaining 75 overweight units nor has the Region logged these units into the APMS.

SEE REVERSE OF THIS PAGE	AMENDED	DATE ISSUED 09/17/2008

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
US Customhouse, Rm 900 2nd & Chestnut St Philadelphia, PA 19106 (215) 597-4390 Fax:(215) 597-0875	08/29/2008 - 09/16/2008* FEI NUMBER 2573016

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
TO: James E. Starr, Chief Executive Officer

FIRM NAME	STREET ADDRESS
American Red Cross Greater Alleghenies Region	250 Jari Drive
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Johnstown, PA 15904	Blood Bank

B. Red Blood Cells Pheresis Unit (b) (6) which was collected on April 24, 2008, by Employee (b) (6) exhibited a discrepancy. This discrepancy was detailed, by Employee (b) , on the supporting (b) (4) (b) (4) (Record) as "... the bag was full of air just like Saturday...". Red Blood Cells Pheresis Unit 27GJ73205 was manufactured and the two components were not distributed. The unit referenced on the Record is Red Blood Cells Pheresis Unit (b) (6) which was collected by Employee (b) on April 19, 2008. This unit was further manufactured and one of the components was distributed on April 25, 2008.

The discrepancy is specific to Red Blood Cells Pheresis Unit (b) (6) in that this problem was not identified and logged into the APMS, when the problem was initially discovered. The Region initiated a (b) (4) on April 24, 2008. On July 11, 2008, the Region identified this problem, initiated investigation and logged the problem into the APMS as Exception Detail Report (b) (4)

OBSERVATION 3

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

Specifically:

A. Initial Entry of Problems into the APMS:
Paragraph IV.B.1 of the Decree directs the establishment to develop and implement a Problem Management procedure to evaluate problems. Additionally, the internal procedure titled (b) (4) directs that problems must be documented within the APMS no more than 5 days after the discovery of the problem. The establishment does not always enter problems into the APMS within 5 days of discovery. For example:
1. Exception Number (b) (4) was discovered on September 6, 2007 and not entered into the APMS until September 17, 2007. This Region (b) (4) Problem Investigation was initiated in response to the FORM FDA 483 - INSPECTIONAL OBSERVATIONS (FDA 483) dated September 6, 2007.

2. On April 19, 2008, Red Blood Cells Pheresis Unit (b) (6) was collected, identified as unsuitable and detailed on a CIF. Investigation of this problem was initiated on July 11, 2008 (78 days post discovery) when the problem was logged into the APMS as Exception Number (b) (4) . Unit (b) (6) was manufactured and one of the two components was distributed on April 25, 2008.

3. 43 of 5707 year to date, Region (b) (4) Problem Investigations were not entered in the APMS within 5 days of discovery. For example:

Exception	Date Discovered	Date Entered	Days to Enter
(b) (4)	March 25, 2008	August 4, 2008	132
	April 4, 2008	August 4, 2008	112
	April 11, 2008	May 15, 2008	34

B. Corrective Action Plans (CAP):

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
US Customhouse, Rm 900 2nd & Chestnut St Philadelphia, PA 19106 (215) 597-4390 Fax:(215) 597-0875	08/29/2008 - 09/16/2008* FEI NUMBER 2573016

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

TO: James E. Starr, Chief Executive Officer

FIRM NAME	STREET ADDRESS
American Red Cross Greater Alleghenies Region	250 Jari Drive
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Johnstown, PA 15904	Blood Bank

The internal procedure titled (b) (4) directs that formal CAPs must be developed for (b) (4) problem investigations. The establishment does not always develop formal CAPs as directed. For example:

1. Exception Number (b) (4) dated May 21, 2008, details the entry of a two digit versus a three digit donor temperature into the Electronic Blood Donor Record. This (b) (4) problem investigation, is further documented as (b) (4) This Issue was closed on May 23, 2008, without the creation of a formal CAP.

2. Exception Number (b) (4) dated September 6, 2007, details the Region's investigation of the previous FDA 483. This (b) (4) problem investigation, is further documented as (b) (4) which is identified as a (b) (4) (b) (4) is pending resolution without the creation of a formal CAP.

C. Review of CAPs

1. The internal procedure titled (b) (4) identifies the classification of initially submitted CAPs, within the "Approval decision" field of the (b) (4) APMS as (b) (4) . However the internal procedure titled (b) (4)

2. The management and resubmission timeframes, of a proposed CAP, which is reviewed and classified as "rejected", is not thoroughly detailed within an internal procedure.

D. The internal document identified as (b) (4) Red Blood Cells Pheresis Unit (b) (6) , which was collected by Employee (b) on April 19, 2008, exhibited "too much air in the bag". This discrepancy was not recognized in accordance with the relevant internal procedure and resulted in the distribution of one manufactured component on April 25, 2008.

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
US Customhouse, Rm 900 2nd & Chestnut St Philadelphia, PA 19106 (215) 597-4390 Fax:(215) 597-0875	08/29/2008 - 09/16/2008* FEI NUMBER 2573016

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

TO: James E. Starr, Chief Executive Officer

FIRM NAME	STREET ADDRESS
American Red Cross Greater Alleghenies Region	250 Jari Drive
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Johnstown, PA 15904	Blood Bank

*** DATES OF INSPECTION:**
08/29/2008(Fri), 09/02/2008(Tue), 09/04/2008(Thu), 09/05/2008(Fri), 09/09/2008(Tue), 09/10/2008(Wed), 09/16/2008(Tue)

FDA EMPLOYEE'S NAME, TITLE, AND SIGNATURE:

Travis R Hunt, Investigator

SEE REVERSE OF THIS PAGE

AMENDED

DATE ISSUED
09/17/2008