DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT OFFICE ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
6000 Metro Drive, Suite 101 Baltimore, Maryland 21215 Phone: 410-779-5443	5/5/08 - 6/23/08
	FEI NUMBER 1173011

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED

TO: Gary J. Ouellette, Chief, Executive Officer, Greater Chesapeake and Potomac Region

FIRM NAME	STREET ADDRESS
American National Red Cross	4700 Mount Hope Drive
CITY, STATE AND ZIP CODE	TYPE OF ESTABLISHMENT INSPECTED
Baltimore, Maryland 21215	Blood Bank

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

1. The Greater Chesapeake and Potomac Region (hereafter, region) failed to identify, investigate, correct and trend all instances in which overweight units of whole blood have been collected. A query of this problem identified 197 instances in which overweight units were drawn between November 2006 and May 2008. The collection of overweight units of whole blood is a failure to follow step 3 of (b) (4), which states "Collect appropriate [redacted] (b) (4), requires that any deviation from standard operating procedures be logged, tracked and trend in the automated problem-management system.

However, in accordance with instructions from ARC Biomedical Headquarters (BHQ), approximately 100 of 197 instances of collection of overweight units that were listed in the query had not been logged, tracked and trended in the automated problem-management system because they were "self-identified and self-corrected" at the collection site. The region has no plans to implement a corrective action because, according to BHQ, overweight units of whole blood are not a 'problem' as defined in Paragraph 52 of the Consent Decree of Permanent Injunction, entered on April 15, 2003. For example:

a. Unit (b) (6) collected 5/18/2008
b. Unit [redacted] collected 3/22/2008
c. Unit [redacted] collected 1/24/2008
d. Unit [redacted] collected 11/26/2007
e. Unit [redacted] collected 8/7/2007

2. The collection of overweight units of whole blood was addressed during the April-June 2002 and September-January 2006 FDA inspections of this region. In the region's response to the September-January 2006 FDA 483 dated 3/30/06, the region stated that "the Education Coordinator redistributed a (b) (4) training document, which describes the critical steps required for using the (b) (4) scale, to all Whole Blood Collections staff" and that "the region completed the full implementation of the (b) (4) scales at all collection operations." This corrective action has not been effective as evidenced by the 197 overweight units collected during the period from November 2006 through May 2008. The region has yet to implement an effective corrective action to prevent the collection of overweight units of whole blood.

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3. This region is not performing required and thorough reviews of the manufacturing records before distributing blood components and, as a result, distributed non conforming blood products. Additionally, when the region discovers these violations, it fails to adequately investigate and correct the problems. Some examples include:

a. On 12/31/07, the region discovered that 10 leukoreduced red blood cells were irradiated and distributed on 11/22/07 without the required second party review of the irradiation batch record being performed prior to distribution. The region logged the problem into the APMS on 1/7/08, assigned it Exception Report (b) (4) and performed a (b) (4) investigation. The region did not do a root cause analysis as required in (b) (4) nor did the region develop a formal Corrective Action Plan (CAP) as required by (b) (4). Quality Assurance (QA) approved the closure of this exception report on 3/4/08 despite the fact the investigation did not determine why it took the supervisor nine days to uncover that this review had not been performed when the Irradiation Batch Record specifically states that "Review must be performed prior to the distribution of components." Additionally, QA did not address the failure to notify consignees of the distribution of an unsuitable blood component within 48 hours as required in Paragraph X.E of the April 15, 2003 Amended Consent Decree. The region did not notify consignees until 1/8/07, eight days after discovering the release of these unsuitable blood components.

b. On 5/14/07, the region discovered an ABO discrepancy involving two apheresis whole blood numbers associated with Platelet products (b) (6) that occurred on 5/13/07. The region performed a (b) (4) investigation (Exception Report (b) (4) initially on 5/17/07 and Material Review Board review (b) (4) initiated on 6/28/07. The initial investigation was inadequate because it failed to address whether the associated staff performed the verification steps required in (b) (4) and (b) (4). It was not until 11/29/07 when a follow up investigation was performed to address the verification steps. Additionally, the region did not develop a formal CAP as required by (b) (4) and therefore did not perform an effectiveness check based on the root cause of the problem investigation determined on 11/29/07. The final review and approval for closure was not performed by QA until 1/24/08.

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c. During a supervisory review of the (b) (4) (Quarantine) Report on 5/2/07, it was discovered that a (b) (4) Report was not generated for 11 whole blood numbers for whole blood collected on 3/28/07, nine whole blood numbers for whole blood collected on 4/10/07 and 37 whole blood numbers for whole blood collected on 4/11/07. The region assigned it Exception Report (b) (4) performed a (b) (4) investigation and developed a formal CAP. However, the investigation was inadequate because it did not address the reason for a late supervisory review when (b) (4) (b) (4) states that the supervisory review is to be performed "on a daily basis." The supervisory review on these reports occurred 21 to 35 days after the whole blood was collected and 114 blood components were distributed prior to the supervisor's review on 5/2/07. QA approved the closure of this investigation on 6/14/07.

d. On 10/1/07, the region discovered that the pre-labeling verification step required in (b) (4) (b) (4) (b) for 122 Platelets Pheresis Leukocytes Reduced products was not performed and, therefore, no one identified the failure to perform equipment quality control on three scales. The region performed a (b) (4) investigation (Exception Report (b) (4)) but did not perform a root cause analysis as required in (b) (4) (b) (4) The region only determined a probable cause which was "staff inattention to details" and did not develop a formal corrective action plan as required in (b) (4) (b) (4) Additionally, the region's investigation did not address the reason this failure was not found before the distribution of 12 products between on 9/30/07 and 10/1/07 when a supervisory review of the equipment and supply QC records is to be performed "before releasing the components to labeling." QA approved the closure of this investigation on 1/27/08.

4. The region has not implemented an effective corrective action to prevent whole blood number mix ups that are occurring at various stages in the manufacturing process and that are not being identified during the region's batch record reviews before distribution of affected blood products. For example,

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

a. The region identified a trend for whole blood number mix ups for BPD Code (b) (4) in November 2006 (Exception Report (b) (4). The region did not conduct an adequate investigation of the problem and it did not develop a formal CAP as required in (b) (4), (b) (4). The region's justification for not developing a formal corrective action plan was "...per (b) (4) for the time period 11012006 through 12222006, there have been no further occurrences of this type..." However, whole blood number mix ups continue to occur.

b. There have been approximately 15 whole blood number mix ups at various stages of the manufacturing process since the trend was identified in November 2006, including but not limited to the following:

i. The region was notified by a consignee on 12/18/07 that a Leukoreduced Red Blood Cell product tested as O Negative but was labeled O Positive. The region performed a level 3 investigation (Exception Report (b) (4) and determined that a technician had mixed up the whole blood numbers on two units. However, the region's investigation did not determine the reason this whole blood number mix up was not detected during the verification steps required in (b) (4) (b) (4)

ii. On 2/14/08, the region discovered a whole blood number mix up in the collection process. The region performed a (b) (4) investigation (Exception Report (b) (4) and determined that "all staff failed to observe that the incorrect label was applied to the collection set. This was missed in the donor room by the person who performed the VP [venipuncture] and discontinued the unit, the person who processed and packed the unit and the person who verified the units prior to transporting." The region did not develop a formal CAP as required by (b) (4) (b) (4) (b) (4) The only step taken was to notify staff of the error.

5. The region is not following (b) (4) (b) (4), in that the region does not determine the root cause for each problem that is investigated as a (b) (4) investigation including, but not limited to, Exception Report (b) (4) addressed in FDA 483 Item 3a above and Exception Report (b) (4) addressed in FDA 483 Item 3d above.

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6. The region is not following (b) (4) [redacted] (b) (4) [redacted] (b) (4) [redacted] (b) (4) [redacted] in that the region is not developing a formal CAP for all the level 3 investigations that were the focus of this inspection including, but not limited to, Exception Report (b) (4) [redacted] in FDA 483 Item 3a above, Exception Report (b) (4) [redacted] in FDA 483 Item 3b above, Exception Report (b) (4) [redacted] in FDA 483 Item 3d, Exception Report (b) (4) [redacted] in FDA 483 Item 4a above, and Exception Report (b) (4) [redacted] in FDA 483 Item 4.b.ii. above.

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