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 (410) 779-5454	February 5, 2008 - July 3, 2008 FEI NUMBER 1122335

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED

TO: Christine M. Driscoll, Executive Director

FIRM NAME	STREET ADDRESS
American Red Cross Biomedical Services Headquarters	2025 E. Street, N.W.
CITY, STATE AND ZIP CODE	TYPE OF ESTABLISHMENT INSPECTED
Washington, DC 20006	ARC Blood Bank Headquarters

DURING AN INSPECTION OF YOUR FIRM I OBSERVED:

1. The American Red Cross Biomedical Services failed to promptly investigate, correct, and prevent the pervasive failure to control non-conforming and potentially non-conforming blood products. A review of records from twenty-four ARC Blood Service Regions for the period December 2006 through April 2008, revealed that ARC logged into SmartCAPA approximately 116 exception reports involving the distribution of blood products that ARC identified as non-conforming or potentially non-conforming, but had failed to prevent from being distributed. These problems resulted in retrieval of 218 non-conforming blood products. (This is not an all-inclusive number because ARC also logged problems into DTS during this period.)

For example:

- ARC logged into (b) (4) approximately 29 exception reports involving donor suitability, such as health history or Blood Donation Record deviations that were detected by ARC but the associated blood products were not controlled to prevent their distribution pending a determination regarding their suitability for transfusion. These problems resulted in retrieval of approximately 43 of those blood products. The exception reports are: (b) (4) (b) (4) (b) (4)

- ARC logged into (b) (4) approximately six exception reports involving ABO/Rh discrepancies and one HLA discrepancy that were detected by ARC but the associated blood products were not controlled to prevent their distribution pending a determination regarding their suitability for transfusion. These problems resulted in retrieval of approximately five blood products. The exception reports are: (b) (4) (b) (4)

- ARC logged into (b) (4) approximately two exception reports involving whole blood number discrepancies that were detected by ARC but the associated blood products were not controlled to prevent their distribution pending a determination regarding their suitability for transfusion. These problems resulted in retrieval of approximately nine blood products. The exception reports are: (b) (4)

- ARC logged into (b) (4) approximately three exception reports involving potential air contamination during the blood collection process that were detected by ARC but the associated blood products were not controlled to prevent their distribution pending a determination regarding their suitability for transfusion. These problems resulted in retrieval of approximately 12 blood products. The exception reports are: (b) (4)

- ARC logged into (b) (4) approximately six exception reports involving incomplete or unreviewed Apheresis Procedure Records that were detected by ARC but the associated blood products were not controlled to prevent their distribution pending a determination regarding their suitability for transfusion. These problems resulted in retrieval of approximately nine blood products. The exception reports are: (b) (4) (b) (4)

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	EMPLOYEE(S) NAME AND TITLE (Print or Type)	DATE ISSUED
	Barbara A. Gullick	Barbara A. Gullick, CSO	July 3, 2008

e-mailed to CDRH 7/3/08 bm

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• ARC logged into (b) (4) approximately seven exception reports involving failure to complete all required product testing or failure to review validation records. These deviations were detected by ARC but the associated blood products were not controlled to prevent their distribution pending a determination regarding their suitability for transfusion. These problems resulted in retrieval of approximately 22 blood products. The exception reports are: (b) (4)
(b) (4)

ARC was previously cited by FDA for similar violations on a Form FDA 483 Inspectional Observations (FDA 483) issued on December 21, 2005, at the New York Penn Region, an FDA 483 issued on August 4, 2004, at the Southern California Region, and FDA 483 issued in December 2002 at ARC's Biomedical Headquarters. ARC was also cited by FDA for this same violation in a letter issued pursuant to Paragraph VI.A. of the Consent Decree entered on May 12, 1993, in an Adverse Determination Letter (ADL) issued on March 28,2005, and in an ADL issued on November 21, 2006.

2. American Red Cross Biomedical Services failed to submit biological product deviations (BPDs) within 45 days as required in Paragraph X.D. of the April 15, 2003 Consent Decree of Permanent Injunction. The decree states in part that ARC must notify the FDA Baltimore District and report the identification of all known distributed units and the lot numbers, serial numbers, unit numbers, whole blood numbers, and expiration dates; the name and address of involved facilities, and a description of the event that caused the unsuitability to occur 45 days after initially learning that an unsuitable unit was distributed.

A review of American Red Cross Biomedical Services region exception reports, logged from December 2007 through April 2008, revealed that ARC did not submit approximately 10 biological product deviation reports (BPDRs) to FDA within 45 days after initially learning that approximately 27 non-conforming blood products, as identified by ARC, were distributed.

For Example:

• ARC logged into (b) (4) approximately three exception reports involving donor suitability Blood Donation Record deviations that were ultimately detected by ARC after failing to gain control of the product prior to performing the 200% review. The following exception reports are:

(b) (4) was discovered on 4/19/2007 and reported to FDA on 6/12/2007.
(b) (4) was discovered on 7/22/2007 and reported to FDA on 11/9/2007.
(b) (4) was discovered on 5/1/2007 and reported to FDA on 11/19/2007.

These problems resulted in the retrieval of approximately 5 blood products.

• ARC logged into (b) (4) approximately one exception report involving the distribution of non-conforming blood products with unacceptable temperatures. Exception (b) (4) was discovered 9/19/2007 and was submitted to FDA as a BPDR on 3/11/2008.

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This problem resulted in the retrieval of approximately 14 blood products.

3. The American Red Cross Biomedical Services failed to submit 48 hour consignee notifications as required in Paragraph X.E. of the April 17, 2003 Consent Decree of Permanent Injunction. The decree states in part that "Within 48 hours of initially learning that an unsuitable unit was distributed, ARC must notify consignees and the BLT-DO."

A review of American Red Cross Biomedical Services region exception reports, logged from December 2007 through April 2008, revealed that ARC did not submit approximately 20 consignee notifications to FDA within 48 hours of initially learning that approximately 61 non-conforming blood products, as identified by ARC, were distributed.

For Example:

- ARC logged into (b) (4) approximately five exception reports involving donor suitability Blood Donation Record deviations that were ultimately detected by ARC after failing to gain control of the product prior to performing the 200% review. The following exception reports are:

(b) (4) was discovered on 8/17/2007 and reported to FDA on 8/23/2007.
was discovered on 4/19/2007 and reported to FDA on 5/7/2007.
was discovered on 6/27/2006 and reported to FDA on 7/18/2007.
was discovered on 7/22/2007 and reported to FDA on 9/13/2007.
was discovered on 5/1/2007 and reported to FDA on 9/10/2007.

These problems resulted in the retrieval of approximately 9 blood products.

- ARC logged into (b) (4) approximately one exception report involving the distribution of non-conforming blood products with unacceptable temperatures. Exception (b) (4) was discovered 9/19/2007 and was reported to FDA in a 48 hour notification on 10/4/2007

This problem resulted in the retrieval of approximately 14 blood products.

- ARC logged into (b) (4) approximately two exception reports involving ABO/Rh discrepancies related to blood products and blood product labeling. Exception report (b) (4) was discovered on 5/23/2007 and the 48 hour notification was submitted to FDA on 6/22/2007. Exception report (b) (4) was discovered on 11/8/2007 and the 48 hour notification was submitted to FDA on 11/20/2007.

These problems resulted in the retrieval of approximately 3 blood products.

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