



Food and Drug Administration
Baltimore District Office
Central Region
6000 Metro Drive, Suite 101
Baltimore, MD 21215
Telephone: (410) 779-5454
FAX: (410) 779-5707

June 10, 2005

MODIFIED ADVERSE DETERMINATION LETTER

**BY FACSIMILE &
CERTIFIED MAIL
RETURN RECEIPT REQUESTED**

Mr. John F. McGuire
Executive Vice President
Biomedical Services
American National Red Cross
2025 E Street, N.W.
Washington, D.C. 20006

RE: United States v American National Red Cross, Civil Action No. 93-0949 (JGP)

Dear Mr. McGuire:

On May 16, 2005, the Food and Drug Administration (FDA) issued an Adverse Determination Letter (ADL) to the American Red Cross (ARC) assessing penalties pursuant to Paragraph X of the Amended Consent Decree of Permanent Injunction (Decree) entered on April 15, 2003. In accordance with Paragraph IX.A. of the Decree, ARC notified FDA by letter dated June 6, 2005, that it agrees with the May 16th ADL, except for assessment of penalties for recall B-1280-4.

FDA has reevaluated its records regarding recall B-1280-4 and determined that it should not have been included in the list of recalls that was attached to the May 16th ADL and that no penalties should have been assessed for that recall. In accordance with Paragraph IX.B. of the Decree, this letter modifies the May 16th ADL, as follows:

1. FDA reviewed its database and files to identify classified ARC-conducted recalls. FDA identified 135 events in which ARC reported to FDA that they retrieved unsuitable blood components that were distributed during the period, April 15, 2003 through April 15, 2004.
2. The 135 events involved 9,945 unsuitable blood components.
3. The total number of unsuitable blood components for which FDA is assessing a penalty under Paragraph X.A.2. of the Decree is 1,442.
4. FDA has revised the amount of the penalty to reflect removal of recall B-1280-4. The total penalty amount is \$3,405,000.

Mr. John F. McGuire
Page 2

5. Recall B-1280-4 has been removed from the list of recalls attached to the May 16th ADL. The revised list is attached to this letter.

Paragraph IX.B. of the Decree states, "If FDA affirms or modifies its determination, ARC shall, within 15 days of receipt thereof, either: (1) advise FDA in writing that it does not wish to appeal FDA's determination, pay the penalties assessed and accrued under paragraph IX.A. above, and submit a plan and, when applicable, interim plan describing how and within what time frames ARC proposes to come into compliance with the law and this Order, or (2) appeal FDA's determination to this Court."

FDA acknowledges receipt of ARC's interim compliance plan which was attached to its June 6th letter. That interim plan is under review by FDA.

Your response to this letter must be submitted to me at the Food and Drug Administration, Baltimore District Office, 6000 Metro Drive, Suite 101, Baltimore, Maryland 21215, with a copy to Jesse Goodman, M.D., M.P.H., Director, Center for Biologics Evaluation and Research, 1401 Rockville Pike, Rockville, Maryland 20852.

Sincerely yours,



Evelyn Bonnin
Acting Director, Baltimore District

ATTACHMENT

cc: Marsha Johnson Evans
President and Chief Executive Officer
American National Red Cross
2025 E Street, N.W.
Washington, D.C. 20006

C. William Cherry
Senior Vice President for Quality
and Regulatory Affairs
American National Red Cross
2025 E Street, N.W.
Washington, D.C. 20006

Mary Elcano
General Counsel
American National Red Cross
2025 E Street, N.W.
Washington, D.C. 20006

Mr. John F. McGuire

Page 3

Bonnie McElveen-Hunter
Chairman, Board of Governors
American National Red Cross
2025 E Street, N.W.
Washington, D.C. 20006

MODIFIED ATTACHMENT

**AMERICAN RED CROSS
CLASS II RECALLS FOR THE PERIOD 4/15/03 THROUGH 4/15/04**

The following regions have no recall information included in this report:

- Alabama Region
Birmingham, AL (Registration #1073001)
- Gulf Coast Region
Mobile, AL (Registration #1073005)
- Greater Ozarks-Arkansas Region
Little Rock, AR (Registration #2372998)
- Midwest Region
Omaha, NE (Registration #1973037)
- North Central Region
St. Paul, MN (Registration #2173038)
- Northeast Pennsylvania Region
Ashley, PA (Registration #2573018)
- Northern California
Oakland, CA (Registration #2971430)
- Puerto Rico Region
Rio Piedras, PR (Registration #2675945)
- South Carolina Region
Columbia, SC (Registration #1073009)
- Southern Region
Atlanta, GA (Registration #1073000)
- Tennessee Valley Region
Nashville, TN (Registration #1073006)

<u>Region/CFN</u>	<u>Recall Number</u>	<u>Number of Recalled Products/Product Type</u>	<u>Reason for Recall</u>	<u>Penalty Amount Per Blood Component</u>	<u>Total Penalty Amount</u>
Appalachian 1173010	B-0225-5 B-0226-5	43 – Platelets Pheresis 9 – Platelets Pheresis Irradiated	Failure to control suspect component(s) (inappropriate release-low platelet yield)	\$3,000	\$156,000
Arizona 2072997	B-0493-4	1 – Fresh Frozen Plasma	Failure to control suspect component(s) (inappropriate release after discovery of clots in red blood cells)	\$3,000	\$3,000
Badger- Hawkeye 2173028	B-1681-4	1 – Platelets Pheresis Leukocytes Reduced	Failure to control suspect component(s) (inappropriate release-quality control not completed)	\$3,000	\$3,000
Carolinas Region 1073007	B-0948-5	1 – Red Blood Cells	Failure to control suspect component(s) (failure to quarantine after receiving post donation information)	\$3,000	\$3,000
	B-0832-5	2 – Red Blood Cells Leukocytes Reduced	Donor suitability (travel in malarial risk area)	\$3,000	\$6,000
	B-0938-5	1 – Red Blood Cells Leukocytes Reduced	Donor suitability (failure to defer donor for lymphoma)	\$3,000	\$3,000
	B-0933-5	1 – Red Blood Cells Leukocytes Reduced	Donor suitability (travel in malarial risk area)	\$3,000	\$3,000
	B-0928-5	2 - Red Blood Cells Leukocytes Reduced	Donor suitability (travel in malarial risk area)	\$3,000	\$6,000
	B-0934-5	1 – Cryoprecipitated AHF	Donor suitability (failure to defer donor for CJD risk)	\$3,000	\$3,000
Central Ohio 1573013	B-1017-4 B-1018-4	1 – Red Blood Cells Leukocytes Reduced 1 – Recovered Plasma	Donor suitability (failure to follow SOPs—BDR high risk behavior answers changed by Health Historian)	\$3,000	\$6,000
	B-0256-4	1 – Red Blood Cells Leukocytes Reduced	Testing (recordkeeping error)	\$2,000	\$2,000
	B-0513-4	1 - Platelets Pheresis Leukocytes Reduced Irradiated	Collection (sterility compromised)	\$2,000	\$2,000
	B-0655-4 B-0656-4	1 – Platelets Leukocytes Reduced 1 – Fresh Frozen Plasma	Failure to control suspect component(s) (inappropriate release after discovery of clots in red blood cells)	\$3,000	\$6,000
	B-1066-4	4 - Red Blood Cells Pheresis Leukocytes Reduced	Component preparation (low volume)	No fine	No fine
	B-1013-4 B-1014-4 B-1015-4	1 – Red Blood Cells Leukocytes Reduced 1 – Platelets Leukocytes Reduced 1 – Recovered Plasma	Donor suitability (failure to defer donor for CJD risk)	\$3,000	\$9,000

<u>Recall FN</u>	<u>Recall Number</u>	<u>Number of Recalled Products/Product Type</u>	<u>Reason for Recall</u>	<u>Penalty Amount Per Blood Component</u>	<u>Total Penalty Amount</u>
	B-1379-4	1 - Platelets Pheresis Leukocytes Reduced Irradiated	Component preparation (low volume)	\$2,000	\$2,000
Central Plains 1973042	B-1132-4	1 - Platelets Pheresis Leukocytes Reduced	Re-release of unsuitable blood component	\$10,000	\$10,000
Connecticut 1273014	B-0072-4 B-0073-4	1 - Red Blood Cells Leukocytes Reduced 1 - Platelets Leukocytes Reduced	Donor suitability (travel in malarial risk area)	\$3,000	\$6,000
	B-0358-4 B-0359-4	1 - Red Blood Cells Leukocytes Reduced 1 - Fresh Frozen Plasma	Donor suitability (BDR questions unanswered)	No fine	No fine
	B-0546-4 B-0547-4	1 - Red Blood Cells Leukocytes Reduced 1 - Platelets Leukocytes Reduced	Donor suitability (BDR questions unanswered)	\$3,000	\$6,000
	B-0549-4 B-0550-4 B-0551-4	1 - Red Blood Cells Leukocytes Reduced 1 - Platelets Leukocytes Reduced 1 - Recovered Plasma	Donor suitability (BDR questions unanswered)	\$3,000	\$9,000
	B-0534-4 B-0535-4 B-0536-4	1 - Red Blood Cells Leukocytes Reduced 1 - Platelets Leukocytes Reduced 1 - Fresh Frozen Plasma	Donor suitability (BDR questions unanswered)	\$3,000	\$9,000
	B-0920-4 B-0921-4	1 - Red Blood Cells Leukocytes Reduced 1 - Platelets Leukocytes Reduced	Donor suitability (BDR questions unanswered)	\$3,000	\$6,000
	B-0923-4 B-0924-4	1 - Red Blood Cells Leukocytes Reduced 1 - Platelets Leukocytes Reduced	Donor suitability (BDR questions unanswered)	\$3,000	\$6,000
	B-0827-4	1 - Red Blood Cells Leukocytes Reduced	Donor suitability (BDR questions unanswered)	\$3,000	\$3,000
	B-1251-4	1 - Platelets Leukocytes Reduced	Donor suitability (BDR questions unanswered)	\$3,000	\$3,000
	B-1889-4 B-1890-4 B-1891-4	1 - Red Blood Cells Leukocytes Reduced 1 - Platelets Leukocytes Reduced 1 - Recovered Plasma	Donor suitability (failure to defer donor for CJD risk)	\$3,000	\$9,000
	B-1655-4	1 - Red Blood Cells Leukocytes Reduced	Donor suitability (travel in malarial risk area)	\$3,000	\$3,000
	B-1801-4 B-1802-4	1 - Red Blood Cells Leukocytes Reduced 1 - Platelets Leukocytes Reduced	Donor suitability (travel in malarial risk area)	\$3,000	\$6,000

<u>Recall FN</u>	<u>Recall Number</u>	<u>Number of Recalled Products/Product Type</u>	<u>Reason for Recall</u>	<u>Penalty Amount Per Blood Component</u>	<u>Total Penalty Amount</u>
	B-0556-5	1 - Red Blood Cells Leukocytes Reduced	Donor suitability (travel in malarial risk area)	\$3,000	\$3,000
Greater Lakes 1873033	B-0743-4	1 - Red Blood Cells Leukocytes Reduced	Donor suitability (BDR questions unanswered)	\$3,000	\$3,000
	B-0793-4	1 - Red Blood Cells Leukocytes Reduced	Donor suitability (BDR documentation missing for SARS)	\$3,000	\$3,000
	B-0966-4	2 - Fresh Frozen Plasma	Failure to control suspect product	\$3,000	\$15,000
	B-0967-4	2 - Cryoprecipitated AHF	(inappropriate release after discovery of clots in red blood cells)		
	B-0968-4	1 - Cryoprecipitated AHF Pooled			
	B-0406-4	1 - Red Blood Cells Leukocytes Reduced	Donor suitability (BDR questions unanswered)	\$3,000	\$6,000
	B-0407-4	1 - Fresh Frozen Plasma			
	B-1940-4	32 - Red Blood Cells Leukocytes Reduced	Collection (inadequate arm scrub)	\$2,000	\$96,000
	B-1941-4	1 - Cryoprecipitated AHF			
	B-1942-4	1 - Cryoprecipitated AHF Pooled			
	B-1943-4	5 - Platelets			
	B-1946-4	8 - Fresh Frozen Plasma			
	B-1944-4	1 - Plasma Cryoprecipitate Reduced			
	B-0477-4	1 - Red Blood Cells Leukocytes Reduced	Donor suitability (BDR questions unanswered)	\$3,000	\$6,000
	B-0478-4	1 - Recovered Plasma			
	B-0739-4	1 - Red Blood Cells Leukocytes Reduced	Component preparation (error in red cell recovery calculation)	No fine	No fine
	B-1342-4	2 - Red Blood Cells Pheresis	Component preparation (record keeping error)	\$2,000	\$4,000
	B-1519-4	1 - Plasma Cryoprecipitate Reduced	Failure to control suspect component(s) (inappropriate release after discovery of clots in red blood cells)	\$3,000	\$3,000
	B-1578-4	1 - Platelets Pheresis Leukocytes Reduced	Collection (failure to follow SOPs)	\$2,000	\$4,000
	B-1579-4	1 - Platelets Pheresis Leukocytes Reduced Irradiated			
	B-1118-4	1 - Platelets	Failure to control suspect component(s) (after supply defect discovered)	\$3,000	\$3,000
	B-1198-4	1 - Platelets Pheresis Leukocytes Reduced	Failure to control suspect component(s) (inappropriate release after discovery of low platelet yield)	\$2,000	\$2,000
	B-1352-4	1 - Platelets Pheresis	Component preparation (platelet yield and volume out-of-specifications)	\$1,000	\$1,000

<u>Re</u> <u>FN</u>	<u>Recall</u> <u>Number</u>	<u>Number of Recalled Products/Product</u> <u>Type</u>	<u>Reason for Recall</u>	<u>Penalty Amount</u> <u>Per Blood</u> <u>Component</u>	<u>Total Penalty</u> <u>Amount</u>
Greater Alleghenies 2573016	B-0595-4	1 - Red Blood Cells Leukocytes Reduced	Testing (unresolved test results)	No fine	No fine
	B-1055-4	6 - Platelets	Failure to control suspect component(s) (inappropriate release after discovery of low platelet yield)	\$3,000	\$18,000
	B-2018-4	2 - Red Blood Cells Leukocytes Reduced Irradiated	Component preparation (recordkeeping errors for irradiated components)	\$2,000	\$4,000
	B-2019-4	1 - Red Blood Cells Leukocytes Reduced	Donor suitability (an answer on BDR was "yes" with no supporting documentation)	\$3,000	\$3,000
	B-0219-5	1 - Red Blood Cells Leukocytes Reduced	Donor suitability (travel in malarial risk area)	\$3,000	\$3,000
		A total of 3,279 blood components were involved with this recall; approximately 382 of these blood components were collected between the date the Decree was entered on 4/15/2003 and the date the recall occurred on 7/22/2003.	Collection (inadequate arm scrub)	\$2,000 for each of 100 components	\$200,000
	B-0881-5 B-0882-5 B-0883-5 B-0884-5 B-0885-5 B-0886-5 B-0887-5 B-0888-5	Red Blood Cells Red Blood Cells Leukocytes Reduced Red Blood Cells Leukocytes Reduced Irradiated Platelets Platelets Irradiated Fresh Frozen Plasma Plasma Red Blood Cells for Further Manufacture of Non-Injectables			
Greater Chesapeake and Potomac 1173011	B-1603-4	8 - Platelets Pheresis Leukocytes Reduced	Component preparation (failure to determine white blood cell count)	\$2,000	\$16,000
	B-1583-4	3 - Red Blood Cells Leukocytes Reduced	Donor suitability (travel in malarial risk area)	\$3,000	\$9,000
	B-1584-4	3 - Red Blood Cells Leukocytes Reduced	Donor suitability (travel in malarial risk area)	\$3,000	\$9,000

<u>Recall FN</u>	<u>Recall Number</u>	<u>Number of Recalled Products/Product Type</u>	<u>Reason for Recall</u>	<u>Penalty Amount Per Blood Component</u>	<u>Total Penalty Amount</u>
	B-1596-4	6 - Platelets Pheresis Leukocytes Reduced	Collection (failure to follow manufacturer's instructions)	\$2,000	\$12,000
	B-1383-4	125 - Platelets Pheresis	Failure to control suspect component(s) (failure to perform QC testing)	\$3,000 for each of 100 blood components	\$300,000
	B-1586-4	1 - Red Blood Cells Leukocytes Reduced	Donor suitability (travel/residency in malarial risk area)	\$3,000	\$3,000
	B-0799-5	1 - Red Blood Cells Leukocytes Reduced	Donor suitability (travel in malarial risk area)	\$3,000	\$3,000
	B-0851-5	1 - Red Blood Cells Leukocytes Reduced	Donor suitability (failure to defer donor for taking Amiodarone)	\$3,000	\$9,000
	B-0852-5	1 - Platelets			
	B-0853-5	1 - Fresh Frozen Plasma			
	B-0300-4	3 - Red Blood Cells Leukocytes Reduced	Collection (sterility compromised)	\$2,000	\$6,000
Heart of America 1473043	B-1574-4	166 - Platelets Pheresis Leukocytes Reduced	Collection (failure to follow manufacturer's instructions)	\$2,000 for each of 100 blood components	\$200,000
	B-1575-4	34 - Platelets Pheresis Leukocytes Reduced			
	B-1576-4	Irradiated 47 - Fresh Frozen Plasma			
	B-1421-4	3 - Red Blood Cells Leukocytes Reduced	Donor suitability (travel in malarial risk area)	\$3,000	\$9,000
	B-1630-4	43 - Red Blood Cells Leukocytes Reduced	Donor suitability (use of obsolete SOP for CJD risk)	\$3,000	\$237,000
	B-1632-4	4 - Platelets Pheresis Leukocytes Reduced			
	B-1634-4	5 - Fresh Frozen Plasma			
	B-1635-4	4 - Frozen Plasma			
	B-1637-4	23 - Recovered Plasma			
	B-1622-4	2 - Platelets Pheresis	Labeling (wrong product code)	\$2,000	\$4,000
	B-1707-4	1 - Red Blood Cells Leukocytes Reduced	Donor suitability (failure to perform a complete search of donor information in the database)	\$3,000	\$6,000
	B-1708-4	1 - Fresh Frozen Plasma	Component preparation (failure to perform QC testing)	No fine	No fine
	B-1722-4	2 - Platelets Pheresis Leukocytes Reduced	Donor suitability (travel in malarial risk area)	\$3,000	\$6,000
	B-1839-4	2 - Red Blood Cells Leukocytes Reduced	Donor suitability (travel in malarial risk area)	\$3,000	\$6,000

<u>Reg. FN</u>	<u>Recall Number</u>	<u>Number of Recalled Products/Product Type</u>	<u>Reason for Recall</u>	<u>Penalty Amount Per Blood Component</u>	<u>Total Penalty Amount</u>
	B-1920-4	1 - Red Blood Cells Leukocytes Reduced	Donor suitability (failure to defer donor for cancer)	\$3,000	\$3,000
Indiana-Ohio 1873031	B-0053-5	2 - Red Blood Cells Leukocytes Reduced (Split unit)	Failure to control suspect component(s) (failure to quarantine components after receiving post donation information)	\$3,000	\$6,000
	B-0096-5	1 - Red Blood Cells Leukocytes Reduced	Component preparation (failure to collect QC sample)	\$2,000	\$2,000
	B-0854-4	3 - Red Blood Cells Leukocytes Reduced	Failure to control suspect component(s) (inappropriate release of components that were to be discarded)	\$3,000	\$9,000
	B-0142-5	2 - Platelets Pheresis	Component preparation (volume too great for one collection bag)	\$1,000	\$2,000
	B-1811-4 B-1812-4 B-1813-4 B-1814-4	155 - Red Blood Cells Leukocytes Reduced 1 - Red Blood Cells Leukocytes Reduced Irradiated 25 - Platelets Leukocytes Reduced 31 - Fresh Frozen Plasma	Collection (inadequate arm scrub)	\$2,000 for each of 100 blood components	\$200,000
	B-1518-4	1 - Red Blood Cells Leukocytes Reduced	Failure to control suspect component(s) (quarantine error with overweight unit)	\$3,000	\$3,000
Lewis and Clark 3072990	B-1843-4 B-1844-4 B-1845-4	6 - Cryoprecipitated AHF 4 - Fresh Frozen Plasma 1 - Plasma Cryoprecipitate Reduced	Failure to control suspect component(s) (inappropriate release after discovery of clots in Red Blood Cells)	\$3,000	\$33,000
Mid-Atlantic 1173024	B-1011-4	13 - Red Blood Cells Leukocytes Reduced 11 - Recovered Plasma	Collections (sterility compromised)	\$2,000	\$48,000
	B-1720-4	1 - Red Blood Cells Leukocytes Reduced	Donor suitability (failure to defer donor with melanoma)	\$3,000	\$3,000
Missouri- Illinois 1973035	B-1512-4 B-1513-4	1 - Red Blood Cells Leukocytes Reduced 1 - Recovered Plasma	Donor deferral (duplicate donor records)	\$2,000	\$4,000
	B-1524-4	1 - Platelets Pheresis Leukocytes Reduced	Failure to control suspect component(s) (inappropriate release due to low platelet yield)	\$3,000	\$3,000
New England 1270026	B-0091-5	1 - Red Blood Cells Leukocytes Reduced	Donor suitability (travel in malarial risk area)	\$3,000	\$3,000

<u>Re</u> <u>FN</u>	<u>Recall</u> <u>Number</u>	<u>Number of Recalled Products/Product</u> <u>Type</u>	<u>Reason for Recall</u>	<u>Penalty Amount</u> <u>Per Blood</u> <u>Component</u>	<u>Total Penalty</u> <u>Amount</u>
	B-0810-4 B-0811-4 B-0812-4	15 - Red Blood Cells Leukocytes Reduced 1 - Red Blood Cells Leukocytes Reduced Irradiated 1 - Fresh Frozen Plasma	Donor suitability (failure to ask and document BDR questions for SARS)	\$3,000	\$51,000
	B-0755-4	1 - Platelets Pheresis Leukocytes Reduced	Failure to control suspect component(s) (inappropriate release due to low platelet yield)	\$3,000	\$3,000
	B-0723-4	1 - Red Blood Cells Leukocytes Reduced	Donor suitability (travel in malarial risk area)	\$3,000	\$3,000
	B-0865-5 B-0866-5 B-0868-5 B-0869-5 B-0870-5 B-0871-5 B-0872-5 B-0873-5 B-0875-5 B-0876-5	A total of 16,393 blood components were involved in this recall; approximately 7,330 of those blood components were collected between the date of the entry of the Decree on 4/15/2003 and the date of the recall on 3/8/2004. Red Blood Cells Red Blood Cells Pheresis Red Blood Cells Leukocytes Reduced Red Blood Cells Leukocytes Reduced Irradiated Red Blood Cells Washed Red Blood Cells Leukocytes Reduced Washed Red Blood Cells Deglycerolized Leukocytes Reduced Red Blood Cells Frozen Platelets Pheresis Leukocytes Reduced Irradiated Platelets Pheresis Irradiated	Donor suitability (obsolete CJD information sheet used)	\$3,000 for each of 100 blood components	\$300,000
	B-1238-4 B-1239-4	1 - Fresh Frozen Plasma 3 - Plasma Frozen Within 24 hours	Failure to control suspect component(s) (inappropriate release after discovery of clots in red blood cells)	\$3,000	\$12,000
	B-1926-4	2 - Red Blood Cells Leukocytes Reduced	Donor suitability (travel in malarial risk area)	\$3,000	\$6,000
	B-1486-4 B-1487-4	2 - Red Blood Cells Leukocytes Reduced Irradiated 1 - Recovered Plasma	Donor suitability (failure to defer donor for hepatitis risk)	\$3,000	\$9,000

<u>Recall #</u>	<u>Recall Number</u>	<u>Number of Recalled Products/Product Type</u>	<u>Reason for Recall</u>	<u>Penalty Amount Per Blood Component</u>	<u>Total Penalty Amount</u>
	B-1723-4 B-1724-4	26 - Platelets Pheresis Leukocytes Reduced 14 - Fresh Frozen Plasma	Collection (failure to follow manufacturer's instructions)	\$2,000	\$80,000
	B-1475-4	1 - Platelets Pheresis Leukocytes Reduced	Component preparation (inappropriate volume)	\$2,000	\$2,000
	B-1473-4 B-1474-4	2 - Red Blood Cells 1 - Red Blood Cells Leukocytes Reduced	Donor suitability (travel in malarial risk area)	\$3,000	\$9,000
	B-1479-4 B-1480-4	1 - Red Blood Cells Leukocytes Reduced 1 - Recovered Plasma	Donor suitability (failure to defer donor for hepatitis risk)	\$3,000	\$6,000
	B-1803-4 B-1804-4	5 - Red Blood Cells Leukocytes Reduced 3 - Recovered Plasma	Donor suitability (BDR questions unanswered for CJD)	\$3,000	\$24,000
	B-1904-4	1 - Red Blood Cells Leukocytes Reduced	Donor suitability (failure to determine hepatitis risk)	\$3,000	\$3,000
	B-0616-4	1 - Recovered Plasma	Donor suitability (failure to defer donor for CJD risk)	\$3,000	\$3,000
	B-1832-4 B-1833-4	2 - Red Blood Cells Leukocytes Reduced 1 - Fresh Frozen Plasma	Donor suitability (use of obsolete SOP for CJD risk)	\$3,000	\$9,000
	B-1645-4	1 - Red Blood Cells Leukocytes Reduced	Donor suitability (travel in malarial risk area)	\$3,000	\$3,000
	B-1816-4	1 - Red Blood Cells Leukocytes Reduced	Donor suitability (residence in malarial risk area)	\$3,000	\$3,000
New York- Penn 2438445	B-0328-5	1 - Red Blood Cells Leukocytes Reduced	Donor suitability (BDR questions unanswered)	\$3,000	\$3,000
	B-0565-5 B-0566-5	7 - Platelets Pheresis Leukocytes Reduced 9 - Platelets Pheresis Leukocytes Reduced Irradiated	Collection (failure to follow manufacturer's instructions)	\$2,000	\$32,000
	B-0625-5	1 - Red Blood Cells Leukocytes Reduced	Donor suitability (travel in malarial risk area)	\$3,000	\$3,000
	B-1295-4 B-1296-4	1 - Platelets Pheresis Leukocytes Reduced 1 - Platelets Pheresis Leukocytes Reduced Irradiated	Component preparation (platelet yield and plasma volume not adequate)	\$1,000	\$2,000
	B-1762-4 B-1763-4	2 - Platelets Pheresis Leukocytes Reduced 3 - Platelets Pheresis Leukocytes Reduced Irradiated	Donor suitability (travel in malarial risk area)	\$3,000	\$15,000

<u>Re</u> <u>FN</u>	<u>Recall</u> <u>Number</u>	<u>Number of Recalled Products/Product</u> <u>Type</u>	<u>Reason for Recall</u>	<u>Penalty Amount</u> <u>Per Blood</u> <u>Component</u>	<u>All Penalty</u> <u>Amount</u>
	B-0428-4	1 - Red Blood Cells Leukocytes Reduced	Donor suitability (travel in malarial risk area)	\$3,000	\$3,000
	B-1838-4	1 - Red Blood Cells Leukocytes Reduced	Donor suitability (travel in malarial risk area)	\$3,000	\$3,000
Northem Ohio 1573019	B-0541-4	1 - Red Blood Cells Leukocytes Reduced	Donor suitability (travel/residence in malarial risk area)	\$3,000	\$3,000
	B-0271-4	1 - Platelets Pheresis Leukocytes Reduced	Component preparation (no documentation of white blood cell count for leukocytes reduced component)	\$2,000	\$2,000
	B-0295-5	1 - Red Blood Cells Leukocytes Reduced	Donor suitability (failure to defer donor for hepatitis risk)	\$3,000	\$9,000
	B-0298-5	1 - Platelets Leukocytes Reduced			
	B-0299-5	1 - Recovered Plasma			
	B-0439-5	1 - Red Blood Cells Leukocytes Reduced	Donor suitability (failure to defer donor for CJD risk)	\$3,000	\$6,000
	B-0440-5	1 - Recovered Plasma			
	B-0545-4	1 - Red Blood Cells Pheresis	Failure to control suspect component(s) (inappropriate release without required testing)	\$3,000	\$3,000
	B-0809-4	1 - Platelets Pheresis Leukocytes Reduced	Collection (sterility compromised)	\$2,000	\$2,000
	B-1476-4	349 - Platelets Pheresis Leukocytes Reduced; distributed between 3/19/2003 to 5/2/2003; 120 of these blood components were distributed between the entry of the Decree on 4/15/2003 and the date of the recall on 5/2/2003.	Failure to control suspect component(s) (inappropriate release without required testing)	\$2,000 for each of 100 blood components	\$200,000
	B-1381-4	1 - Red Blood Cells Leukocytes Reduced	Donor suitability (travel in malarial risk area)	\$3,000	\$3,000 ;
	B-1382-4	1 - Platelets Pheresis Leukocytes Reduced	Collection (sterility compromised)	\$2,000	\$2,000
	B-1443-4	1 - Platelets Pheresis Leukocytes Reduced	Failure to control suspect component(s) (failure to quarantine components after receiving post donation information)	\$3,000	\$3,000
	B-1610-4	1 - Platelets Pheresis Leukocytes Reduced	Failure to control suspect component(s) (failure to quarantine after receiving post donation information)	\$2,000	\$2,000
Pacific Northwest 3072996	B-0040-5	1 - Plasma Cryoprecipitate Reduced	Component preparation (recordkeeping errors related to freezing times)	No fine	No fine

<u>Recall FN</u>	<u>Recall Number</u>	<u>Number of Recalled Products/Product Type</u>	<u>Reason for Recall</u>	<u>Penalty Amount Per Blood Component</u>	<u>Total Penalty Amount</u>
	B-0182-5	2 - Red Blood Cells	Donor suitability (travel in a malarial risk area)	\$3,000	\$6,000
	B-0581-5	1 - Red Blood Cells Leukocytes Reduced	Donor suitability (travel in malarial risk area)	\$3,000	\$3,000
	B-0768-5	255 - Cryoprecipitated AHF Pooled	Component preparation (failure to perform QC testing)	\$2,000 for each of 100 blood components	\$200,000
	B-1864-4	1 - Red Blood Cells Leukocytes Reduced	Donor suitability (failure to follow donor screening SOPs for hematocrit determination)	\$2,000	\$2,000
Penn-Jersey 2573021	B-1154-4	5 - Red Blood Cells Pheresis Leukocytes Reduced	Failure to control suspect component(s) (inappropriate release of low volume component)	\$2,000	\$10,000
River Valley 1573003	B-1450-4	1 - Cryoprecipitated AHF	Failure to control suspect component(s) (inappropriate release after discovering clots in red blood cells)	\$3,000	\$3,000
	B-1531-4 B-1532-4 B-1533-4 B-1534-4 B-1535-4 B-1536-4 B-1537-4 B-1538-4	12 - Whole Blood 26 - Red Blood Cells 333 - Red Blood Cells Leukocytes Reduced 25 - Red Blood Cells Leukocytes Reduced Irradiated 70 - Platelets 9 - Platelets Irradiated 108 - Fresh Frozen Plasma 6 - Cryoprecipitated AHF	Collection (inadequate arm scrub)	\$2,000 for each of 100 blood components	\$200,000
	B-1593-4 B-1594-4 B-1595-4	39 - Platelets Pheresis 5 - Platelets Pheresis Leukocytes Reduced 1 - Fresh Frozen Plasma	Collection (collection kits not used within acceptable time period)	\$2,000	\$90,000
Southeastern Michigan 1873044	B-0311-5 B-0312-5	35 - Red Blood Cells Leukocytes Reduced 45 - Platelets Leukocytes Reduced	Collection (failure to follow manufacturer's instructions)	\$2,000 for each of 100 blood components	\$200,000
	B-0320-4	1 - Red Blood Cells Leukocytes Reduced	Donor suitability (travel in malarial risk area)	\$3,000	\$3,000
	B-0380-4	1 - Red Blood Cells Leukocytes Reduced	Component preparation (failure to follow SOPs-red blood cells prepared >8 hours after collection)	\$2,000	\$2,000
	B-0563-4	1 - Red Blood Cells Leukocytes Reduced	Donor suitability (travel in malarial risk area)	\$3,000	\$3,000

<u>Re</u>	<u>FN</u>	<u>Recall Number</u>	<u>Number of Recalled Products/Product Type</u>	<u>Reason for Recall</u>	<u>Penalty Amount Per Blood Component</u>	<u>Total Penalty Amount</u>
		B-0776-4	1 - Red Blood Cells Leukocytes Reduced	Donor suitability (travel in malarial risk area)	\$3,000	\$3,000
		B-0819-4 B-0820-4	1 - Red Blood Cells Leukocytes Reduced 1 - Platelets Leukocytes Reduced	Component preparation (overweight unit)	\$2,000	\$4,000
		B-1484-4	2 - Red Blood Cells Pheresis	Failure to control suspect component(s) (inappropriate release of low volume components)	\$2,000	\$4,000
		B-0774-4 B-0775-4	1 - Red Blood Cells Leukocytes Reduced 1 - Platelets	Donor suitability (residence in malarial risk area)	\$3,000	\$6,000
		B-0821-4	1 - Red Blood Cells Leukocytes Reduced	Donor suitability (travel in malarial risk area)	\$3,000	\$3,000
Southern California	2072994	B-0756-4	4 - Fresh Frozen Plasma	Failure to control suspect component(s) (inappropriate release due to clots)	\$3,000	\$12,000
Southwest	1673040	B-1912-4 B-1913-4 B-1914-4	1 - Red Blood Cells Leukocytes Reduced 1 - Red Blood Cells Leukocytes Reduced Irradiated 2 - Platelets Leukocytes Reduced	Donor suitability (residence in malarial risk area)	\$3,000	\$12,000
		B-1910-4	1 - Red Blood Cells Leukocytes Reduced	Donor suitability (travel in malarial risk area)	\$3,000	\$3,000
Western Lake Eric	1573020	B-1704-3	1 - Platelets Pheresis Leukocytes Reduced	Component preparation (low platelet yield)	No fine	No fine