



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Baltimore District Office
Central Region
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November 15, 2006

CONSENT DECREE CORRESPONDENCE

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Mr. John F. McGuire
Interim President and CEO
and 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:

The Food and Drug Administration (FDA) issued an Adverse Determination Letter (ADL) to the American Red Cross (ARC) on September 7, 2006, 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 September 27, 2006, that it agrees with the September 7, 2006 ADL, except for assessment of penalties imposed for certain events involving the distribution of unsuitable blood or blood components. ARC requested that FDA reconsider "the per unit amount of fines imposed for certain recall events...because these events are for the same issues, and occurred during the same time periods, as events for which FDA assessed lower fines in the May 16, 2005, ADL."¹ In addition, ARC suggested that certain events were improperly included because 1) the unsuitable blood component was distributed prior to entry of the Decree on April 15, 2003; and 2) the release of the unsuitable blood components occurred without any fault by ARC.

After reevaluating FDA records related to each of the events identified by ARC in its September 27, 2006 letter and considering the factors set forth in Paragraph X.A.2. of the Decree, FDA has determined as follows:

¹ The penalty provision described in Paragraph X of the Decree relates to ARC's distribution of unsuitable blood or blood components for which FDA determines that the release was preventable by ARC. Although the distribution of unsuitable blood components in this instance is related to voluntary recall actions conducted by ARC, the penalties are not imposed for recall events but for the number of unsuitable blood components distributed by ARC.

1. **Apheresis Prime Time Issue (Bates page 057447)**: FDA agrees that this event is similar to other events that were subject to a lower fine in the May 16, 2005 letter. Therefore, FDA agrees to reduce the total penalty amount for the distribution of unsuitable blood components related to recall numbers B-1531-5, B-1532-5 and B-1533-5 from \$400,000 to \$200,000 (\$2,000 for each of 100 blood components). This event occurred in the Penn-Jersey Region and relates to ARC's failure to update the written procedures for the Baxter Amicus Separator at the time the operator's manual was updated by the manufacturer. The event involved the distribution of 1,976 Platelets Pheresis Leukocytes Reduced blood components; 736 Platelets Pheresis Leukocytes Reduced Irradiated blood components; and 1,635 Fresh Frozen Plasma blood components.
2. **Penn-Jersey Region BPDR Number 2004-022-0725703 Related to Recall Numbers 1542-5 and B-1543-5 (Bates page 047449)**: FDA agrees to remove from the September 7, 2006 ADL the blood components associated with this deviation report. FDA has discovered that it incorrectly included this event in the ADL. Instead, BPDR number 2005-022-0839888 (associated with recall number B-1637-5) and the resulting \$5,000 penalty should have been included in the ADL. That event occurred in the Penn-Jersey Region and involved ARC's failure to quarantine components after receiving post donation information. As a result of that failure to control suspect blood components, one Fresh Frozen Plasma was distributed March 17, 2005, resulting in a \$5,000 penalty which is \$5,000 less than the original \$10,000 penalty.
3. **Malaria (Bates page 057448 and 057460)**: FDA does not agree to reduce the penalty amounts assessed for the distribution of unsuitable blood components related to donor screening for malarial risk areas, as listed on Bates page 057460 of ARC's September 27, 2006 letter (recall numbers B-2381-5, B-0078-6, B-0715-6, B-2382-5, B-2380-5, B-0887-6, B-0716-6, B-2384-5, B-1407-5, B-1426-5, B-0479-6, B-0480-6, B-1424-5, B-0519-6, B-0445-6, B-0277-6, B-1910-5, B-1045-5, B-0672-6, B-1176-6). FDA's decision is based on the second factor set forth in Paragraph X.A.2. because of the "ARC's trends with respect to the same or similar events involving the release of unsuitable products." FDA's evaluation of its records indicates ARC has continued to report a significant number of similar events. Therefore, the penalty amount will remain at \$4,000 per blood component.

Additionally, ARC noted that the distribution of an unsuitable Red Blood Cells Leukocytes Reduced blood component by the Southern California Region (associated with recall number B-0277-6) should not have been included in the September 7, 2006 ADL, because it was collected prior to entry of the amended Decree on April 15, 2003. FDA agrees to remove one Red Blood Cells Leukocytes Reduced blood component from the event related to recall number B-0277-6. The total penalty amount for this event will be changed from \$8,000 to \$4,000.

4. **Southern Region Biological Product Deviation Report (BPDR) Number 2004-003-0591717 Related to Recall Number B-0895-6 (Bates page 057448)**: FDA agrees to remove from the ADL the three Plasma, Frozen blood components associated with recall number B-0895-6 (Southern Region) because those blood components were distributed before ARC discovered clots in the associated Red Blood Cells. Removing these blood components will reduce the total penalty by \$15,000.
5. **Obsolete Creutzfeldt Jakob Disease (CJD) Donor Information Sheet (Bates page 057447-057448)**: FDA does not agree to reduce the penalty amounts assessed for the distribution of unsuitable blood components related to recall numbers B-1114/1115/1116/1118/1119/1120-5 and B-0311 through 0321-6. These events relate to the use of an obsolete CJD donor information sheet in the Indiana-Ohio

and the Greater Alleghenies Regions. FDA's decision is based on the first factor set forth in Paragraph X.A.2 of the Decree because of the "potential effect of the event on the public health, e.g., the number and seriousness of exposures." Although FDA assessed a lower penalty amount for similar events listed in the May 16, 2005 ADL, these additional events indicate that the use of the obsolete donor information sheet presented a greater potential effect on public health, given the number of additional exposures. Therefore, the total penalty amount will remain at \$400,000 for each event (\$4,000 for each of 100 blood components.)

6. Additional Modifications: FDA is also modifying the September 7, 2006 ADL as follows:

- A. FDA is removing the Fresh Frozen Plasma blood component distributed by the Southeastern Michigan Region and associated with BPDR number 2004-013-0514574 (recall number B-1456-5) because FDA discovered during its reevaluation that the distribution of this component represents a minor violation or no violation of the laws administered by the FDA, and should have been classified as a market withdrawal. Therefore, the total penalty amount for this event has been changed from \$12,000 to \$8,000.
- B. FDA is removing the event associated with recall number B-0819-5, which occurred in the Penn-Jersey Region, because FDA discovered during its reevaluation that ARC's actions related to this event represents a minor violation or no violation of the laws administered by the FDA, and should have been classified as a market withdrawal. Removing this event will reduce the total penalty by \$15,000.

Based on these decisions and in accordance with Paragraph IX.B. of the Decree, FDA is modifying the September 7, 2006 ADL by reference to this letter as follows:

1. FDA reviewed its database and files to identify events associated with ARC's distribution of unsuitable blood or blood components. FDA identified 163 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, 2005.
2. The 163 events involved 12,222 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 1072.
4. FDA has revised the \$4,224,000 amount of the penalty to reflect the changes noted above. The new total penalty amount is \$3,981,000.

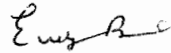
Paragraph IX.B. of the Decree states, "If FDA affirms or modifies its determination, ARC shall, within 15 days of receipt thereof, either: (1) advise FDA in writing that it does not wish to appeal FDA's determination, pay the penalties assessed and accrued under paragraph IX.A. above, and submit a plan 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."

This letter also acknowledges receipt of ARC's interim compliance plan which was included in its September 27, 2006 letter. The interim plan is under review by FDA.

Page 4 – Mr. John F. McGuire

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,



Evelyn Bonnin
Director, Baltimore District

Attachment

cc: 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
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Bonnie McElveen-Hunter
Chairman, Board of Governors
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MODIFIED ATTACHMENT

AMERICAN RED CROSS

CLASS II RECALLS FOR THE PERIOD 4/15/03 THROUGH 4/15/05 (EXCLUDING THOSE PREVIOUSLY ADDRESSED IN THE MAY 15, 2005 PARAGRAPH X ADVERSE DETERMINATION LETTER)

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

- Alabama Region, FDA Registration 1073001
- Central Plains, Wichita, KS, FDA Registration 1973042
- Gulf Coast, Mobile, AL, FDA Registration 1073005
- Midwest, Omaha, NE, FDA Registration 1973037
- Northern California, Oakland, CA, FDA Registration 2971430
- Puerto Rico, Rio Piedras, PR, FDA Registration 2675945
- Tennessee Valley, Nashville, TN, FDA Registration 1073006

<u>Region/CFN</u>	<u>Biological Product Deviation Number/ 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	2004-035-0621471 B-2423-5	1 - Red Blood Cells	Failure to control suspect blood component(s) (inappropriate release-enzyme immunoassay (EIA) positive hepatitis B core)	\$5,000	\$5,000
Arizona 2072997	2004-007-0416380 B-1480-5	1 -Red Blood Cells Leukocytes Reduced Irradiated	Component preparation (discrepant irradiation times documented)	\$3,000	\$3,000
	2004-007-0575401 B-0390-5	6 -Platelets Pheresis Leukocytes Reduced	Component preparation (no confirmation of leukocyte reduction)	\$4,000	\$24,000
	2004-007-0649384 B-1763-5	1 - Platelets Pheresis Leukocytes Reduced Irradiated	Donor eligibility (Blood Donation Record (BDR) question unanswered)	\$3,000	\$6,000
	B-1764-5	1 - Fresh Frozen Plasma Pheresis			
Badger- Hawkeye 2173028	2003-03-20217889 B-1676-4 B-1677-4 B-1678-4	1 - Red Blood Cells Leukocytes Reduced 1 - Platelets Leukocytes Reduced 1 - Fresh Frozen Plasma	Donor eligibility (failure to defer donor for increased risk of infection with hepatitis)	\$4,000	\$12,000

<u>Region/CFN</u>	<u>Biological Product Deviation Number/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>
Carolinas Region 1073007	2004-012-0715488 B-0999-5	1 - Red Blood Cells Leukocytes Reduced	Donor eligibility (travel in malarial risk area)	\$4,000	\$4,000
	2004-012-0505489 B-1019-5 B-1020-5	3 - Red Blood Cells Leukocytes Reduced 1 - Plasma Frozen	Donor eligibility (failure to follow standard operating procedures (SOPs) for donors unable to answer health questions on their own)	\$2,000	\$8,000
	2003-012-0122163 B-2381-5	1 - Platelets Pheresis Leukocytes Reduced	Donor eligibility (travel in malarial risk area)	\$4,000	\$4,000
	2003-012-0176772 B-1201-5	1 - Red Blood Cells Leukocytes Reduced	Testing (sample tube mislabeling mix-up)	\$5,000	\$5,000
	2003-012-0210391 B-0078-6	3 - Platelets Pheresis Leukocytes Reduced	Donor eligibility (travel to malarial risk area)	\$4,000	\$12,000
	2004-012-0343049 B-1953-5	1 - Red Blood Cells Leukocytes Reduced	Failure to control suspect blood component(s) (unit not placed on hold when deviation on BDR was found)	\$5,000	\$5,000
	2004-012-0370556 B-0715-6	1 - Red Blood Cells Leukocytes Reduced	Donor eligibility (travel in malarial risk area)	\$4,000	\$4,000
	2004-012-0378599 B-2382-5	1 - Red Blood Cells Leukocytes Reduced	Donor eligibility (travel in malarial risk area)	\$4,000	\$4,000
	2004-012-0379026 B-2380-5	1 - Red Blood Cells Leukocytes Reduced	Donor eligibility (travel in malarial risk area)	\$4,000	\$4,000
	2004-012-0398025 B-0931-6 B-0932-6	1 - Red Blood Cells Leukocytes Reduced 1 - Recovered Plasma	Failure to control suspect blood component(s) (inappropriate release of products from a deferred donor)	\$5,000	\$10,000
	2004-012-0456922 B-0888-6	1 - Red Blood Cells Leukocytes Reduced	Failure to control suspect blood component(s) (products were not discarded after discovery of an error on the BDR)	\$5,000	\$5,000

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	2004-012-04868895 B-0887-6	1 – Red Blood Cells Leukocytes Reduced	Donor eligibility (travel in a malarial risk area)	\$4,000	\$4,000
	2004-012-0544145 B-0716-6	2 – Red Blood Cells Pheresis Leukocytes Reduced	Donor eligibility (travel to malarial risk area)	\$4,000	\$8,000
	2004-012-0559097 B-0860-6	1 – Red Blood Cells Leukocytes Reduced	Failure to control suspect blood component(s) (intended for validation study)	\$5,000	\$5,000
	2004-012-0577082 B-0885-6 B-0886-6	1 – Red Blood Cells Leukocytes Reduced 1 – Fresh Frozen Plasma	Donor eligibility (BDR question related to Creutzfeldt Jakob Disease (CJD) was unanswered)	\$4,000	\$8,000
	2004-012-0589867 B-2384-5	1 – Red Blood Cells Leukocytes Reduced	Donor eligibility (travel in a malarial risk area)	\$4,000	\$4,000
	2004-012-0603330 B-0175-6	1 – Platelets Pheresis Leukocytes Reduced	Component preparation (platelet yield too high for storage in a single bag)	\$4,000	\$4,000
	2004-012-0631857 B-0738-6	1 – Platelets Pheresis Leukocytes Reduced	Collection (failure to follow manufacturer's instructions)	\$3,000	\$3,000
	2004-012-0719187 B-0994-5	1 – Platelets Pheresis Leukocytes Reduced	Failure to control suspect blood component(s) (inappropriate release after noting discrepant information on the apheresis procedure record)	\$5,000	\$5,000
	2005-012-0810629 B-2026-5	1 – Red Blood Cells Leukocytes Reduced	Donor eligibility (travel in malarial risk area)	\$4,000	\$4,000
	2005-012-0821156 B-1928-5	1 – Platelets Pheresis Leukocytes Reduced	Collection (failure to follow manufacturer's instructions)	\$3,000	\$3,000
	2005-012-0882462 B-0415-6	17 – Platelets Pheresis Leukocytes Reduced	Donor eligibility (travel in malarial risk area)	\$4,000	\$68,000
	2005-012-0931808 B-0452-6 B-0453-6	1 – Red Blood Cells Leukocytes Reduced 3 – Platelets Pheresis Leukocytes Reduced	Donor eligibility (travel in malarial risk area)	\$4,000	\$16,000

<u>Region/CFN</u>	<u>Biological Product Deviation Number/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>
	2004-012-0358460 B-0867-6 B-0868-6 B-0869-6 B-0870-6 B-0871-6 B-0872-6 B-0873-6	7 - Red Blood Cells Leukocytes Reduced 4 - Red Blood Cells Pheresis Leukocytes Reduced 6 - Platelets Pheresis Leukocytes Reduced 4 - Platelets Pheresis Leukocytes Reduced Irradiated 2 - Plasma Frozen Cryoprecipitated Reduced 2 - Cryoprecipitated AHF 4 - Recovered Plasma	Failure to control suspect blood component(s) (units not placed on hold when deviation on BDRs were found)	\$5,000	\$145,000
Central Ohio 1573013	2004-016-0431548 B-2005-4	1 - Platelets Pheresis Leukocytes Reduced Irradiated	Failure to control suspect blood component(s) (inappropriate release after discovery of low platelet yield)	\$5,000	\$5,000
	2004-016-0449876 B-2012-4	2 - Red Blood Cells Leukocytes Reduced	Donor eligibility (quality control (QC) for Hemostat could not be verified)	\$3,000	\$6,000
Connecticut 1273014	B-0116-5 B-0541-5	2 - Red Blood Cells Pheresis - Split Unit 1 - Red Blood Cells Pheresis	Component preparation (failure to perform quality control testing) Failure to control suspect blood component(s) (low volume Red Blood Cells)	\$3,000 \$5,000	\$6,000 \$5,000
	B-1237-5 B-1238-5 B-1239-5 B-1240-5	2 - Red Blood Cells Leukocytes Reduced 2 - Platelets Leukocytes Reduced 2 - Fresh Frozen Plasma 2 - Recovered Plasma	Donor eligibility (travel in a CJD risk area)	\$4,000	\$32,000
Great Lakes 1873033	2004-018-0386370 B-1672-4	1 - Platelets Pheresis Leukocytes Reduced	Failure to control suspect blood component(s) (product intended for validation study)	\$5,000	\$5,000
	2004-018-0474355 B-0067-5 B-0068-5	1 - Red Blood Cells Leukocytes Reduced 1 - Recovered Plasma	Failure to control suspect blood component(s) (sterility may have been compromised)	\$5,000	\$10,000
	2004-018-0503561 B-0072-5 B-0073-5	1 - Red Blood Cells Leukocytes Reduced 1 - Fresh Frozen Plasma	Donor eligibility (failure to follow up on medications taken by donor)	\$2,000	\$4,000
	2004-018-0631286 B-0549-5	1 - Red Blood Cells Leukocytes Reduced	Donor eligibility (hematocrit result was not documented)	\$3,000	\$3,000

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	2004-018-0687247 B-0595-5	1 – Red Blood Cells Leukocytes Reduced	Donor eligibility (hemoglobin was unsatisfactory and hematocrit not documented)	\$3,000	\$3,000
	2005-018-0751704 B-1112-5 B-1113-5	2 – Red Blood Cells Leukocytes Reduced 1 – Fresh Frozen Plasma	Donor eligibility (failure to follow SOPs for travel outside the U.S.)	\$4,000	\$12,000
	2005-018-1081407 B-0587-6	1 – Red Blood Cells Leukocytes Reduced	Donor eligibility (travel in malarial risk area)	\$4,000	\$4,000
	2005-018-1008818 B-0602-6	2 – Red Blood Cells Pheresis	Collection (sterility may have been compromised and failure to follow manufacturer's instructions)	\$5,000	\$10,000
Greater Alleghenies 2573016	B-0208-5	1 – Platelets Pheresis Leukocytes Reduced	Component preparation (failure to determine white blood cell count and failure to follow manufacturer's instructions)	\$4,000	\$4,000
	B-0209-5	2 – Platelets Pheresis Leukocytes Reduced	Donor eligibility (failure to defer donor for taking Feldene)	\$2,000	\$4,000
	B-0904-5	1 – Red Blood Cells Leukocytes Reduced	Donor eligibility (travel in malarial risk area)	\$4,000	\$4,000
	B-0924-5	1 – Red Blood Cells Pheresis Leukocytes Reduced	Failure to control suspect blood component(s) (unit not tagged for hematocrit testing after device malfunction)	\$5,000	\$5,000
	B-1337-5 B-1338-5	1 – Red Blood Cells Leukocytes Reduced 1 – Cryoprecipitated AHF	Donor eligibility (failure to defer donor for taking Avodart)	\$5,000	\$10,000
	B-1396-5	1 – Platelets Pheresis Leukocytes Reduced	Component preparation (platelet yield too high for single bag)	\$4,000	\$4,000
	B-1890-5 B-1891-5 B-1892-5	2 – Red Blood Cells Leukocytes Reduced 1 – Fresh Frozen Plasma 2 – Recovered Plasma	Donor eligibility (failure to defer donor for CJD risk)	\$4,000	\$20,000
	B-1944-5	1 – Red Blood Cells Leukocytes Reduced	Donor eligibility (failure to defer donor who reported taking medication on the Medication Deferral List)	\$5,000	\$5,000

<u>Region/CFN</u>	<u>Biological Product Deviation Number/ 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-0320-6 B-0313-6 B-0317-6 B-0311-6 B-0314-6 B-0315-6 B-0318-6 B-0312-6 B-0316-6 B-0319-6 B-0321-6	1 – Red Blood Cells CPDA-1 for Manufacturing Non-Injectables 2 – Red Blood Cells Pheresis Leukocytes Reduced 3 – Liquid Plasma 2,121 – Red Blood Cells Leukocytes Reduced 278 – Platelets Leukocytes Reduced 1 – Platelet Pheresis Leukocytes Reduced 176 – Cryoprecipitated AHF 36 – Red Blood Cells Leukocytes Reduced Irradiated 332 – Fresh Frozen Plasma 44 – Plasma Cryoprecipitated AHF 1755 – Recovered Plasma	Donor eligibility (use of obsolete CJD information form)	\$4,000 for each of 100 blood components	\$400,000
Greater Chesapeake and Potomac 1173011	2004-053-0420855 B-0480-5	1 – Red Blood Cells Leukocytes Reduced	Donor eligibility (BDR question pertaining to Avodart unanswered)	\$5,000	\$5,000
	2004-053-0571810 B-0763-5	1 - Red Blood Cells Leukocytes Reduced	Donor eligibility (failure to defer donor for taking Tazorac)	\$2,000	\$2,000
	2004-053-0560252 B-0765-5	3 – Platelets Pheresis Leukocytes Reduced	Donor eligibility (travel in malarial risk area)	\$4,000	\$12,000
	2004-053-0517279 B-0766-5	2 – Platelets Pheresis Leukocytes Reduced	Donor eligibility (travel in malarial risk area)	\$4,000	\$8,000
	2004-053-0580808 B-0841-5 B-0842-5	1 – Red Blood Cells Leukocytes Reduced 1 – Recovered Plasma	Donor eligibility (failure to defer donor for history of hepatitis)	\$4,000	\$8,000
	2004-053-0689598 B-1580-5 B-1581-5	1 – Red Blood Cells Leukocytes Reduced 1 – Fresh Frozen Plasma	Failure to control suspect blood component(s) (quarantine error with overweight unit)	\$5,000	\$10,000
Greater Ozarks- Arkansas 2372998	2004-055-0413840 B-2020-5 B-2021-5	1 – Red Blood Cells Leukocytes Reduced 1 – Fresh Frozen Plasma	Donor eligibility (failure to defer donor for hepatitis risk)	\$4,000	\$8,000

<u>Region/CFN</u>	<u>Biological Product Deviation Number/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>
	2003-055-0219886 B-2073-5	4 – Fresh Frozen Plasma	Failure to control suspect blood component(s) (inappropriate release after discovering clots in red blood cells)	\$5,000	\$20,000
	2003-055-0280152 B-2121-5	156 – Platelets Pheresis Leukocytes Reduced	Component preparation (failure to perform monthly QC for platelet pheresis products)	\$3,000 for each 100 blood components	\$300,000
	2003-055-0136101 B-2202-5	1 – Red Blood Cells Leukocytes Reduced	Failure to control suspect blood component(s) (inappropriate release after reactive West Nile pool was reported)	\$5,000	\$5,000
	2005-055-0953356 B-0689-6 B-0691-6 B-0692-6	5 – Red Blood Cells Leukocytes Reduced 1 – Fresh Frozen Plasma 3 – Recovered Plasma	Donor eligibility (failure to defer donor for hepatitis risk)	\$4,000	\$36,000
Heart of America 1473043	2004-040-0643167 B-0465-5	1 – Platelets Pheresis Leukocytes Reduced	Failure to control suspect blood component(s) (sterility may have been compromised)	\$5,000	\$5,000
	2004-040-0642930 B-0466-5	3 – Red Blood Cells Leukocytes Reduced	Donor eligibility (travel in malarial risk area)	\$4,000	\$12,000
	2004-040-0642994 B-0467-5	3 – Red Blood Cells Leukocytes Reduced	Donor eligibility (travel in malarial risk area)	\$4,000	\$12,000
	2005-040-0804626 B-1327-5 B-1328-5	1 – Platelets Pheresis Leukocytes Reduced 1 – Platelets Pheresis Leukocytes Reduced Irradiated	Collection (failure to follow manufacturer's instructions)	\$3,000	\$6,000
	2005-040-0886454 B-1679-5	3 – Red Blood Cells Leukocytes Reduced	Donor eligibility (failure to document the hematocrit reading)	\$3,000	\$9,000
	2005-040-1175515 B-0728-6	1 – Red Blood Cells	Donor eligibility (travel in malaria risk area)	\$4,000	\$4,000

<u>Region/CFN</u>	<u>Biological Product Deviation Number/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>
Indiana-Ohio 1873031	2005-038-0799491 B-11104-5	1 - Red Blood Cells	Failure to control suspect blood component(s) (inappropriate release after receiving post donation information)	\$5,000	\$5,000
	2004-038-0348688 B-1114-5 B-1115-5 B-1116-5 B-1118-5 B-1119-5 B-1120-5	4 - Red Blood Cells 189 - Red Blood Cell, Leukocytes Reduced 18 - Platelets 1 - Platelets Irradiated 30 - Fresh Frozen Plasma 141 - Recovered Plasma	Donor eligibility (use of obsolete SOP for CJD risk)	\$4,000 for each of 100 blood components	\$400,000
	2005-038-0867114 B-1815-5	1 - Red Blood Cells Leukocytes Reduced	Donor eligibility (travel to malarial risk area)	\$4,000	\$4,000
Lewis and Clark 3072990	2003-020-0079860 B-0721-6	1 - Red Blood Cells Leukocytes Reduced	Donor eligibility (BDR question unanswered)	\$3,000	\$3,000
	2003-020-0221986 B-0211-6 B-0212-6 B-0213-6	2 - Fresh Frozen Plasma 1 - Plasma Cryoprecipitated Reduced 1 - Cryoprecipitated AHF	Failure to control suspect blood component(s) (inappropriate release after discovery of clots in red blood cells)	\$5,000	\$20,000
	2003-020-0279664 B-0630-6 B-0631-6	34 - Platelets Pheresis Leukocytes Reduced 5 - Platelets Pheresis Leukocytes Reduced Irradiated	Component preparation (failure to perform QC testing)	\$3,000	\$117,000
Mid-Atlantic 1173024	2004-029-0594370 B-0445-5	1 - Platelets Pheresis Leukocytes Reduced Irradiated	Component preparation (volume too great for one collection bag)	\$4,000	\$4,000
	2004-029-0606242 B-0461-5 B-0462-5	1 - Red Blood Cells Leukocytes Reduced 1 - Frozen Plasma	Donor eligibility (failure to defer donor for CJD risk)	\$4,000	\$8,000
	2004-029-0700521 B-1538-5	1 - Red Blood Cells Leukocytes Reduced	Donor eligibility (travel in malarial risk area)	\$4,000	\$4,000

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Missouri- Illinois 1973035	2005-011-0797069 B-0638-6	1 - Red Blood Cells Leukocytes Reduced	Donor eligibility (donor incorrectly removed from the National Donor Deferral Registry)	\$5,000	\$5,000
	2005-011-0793209 B-0684-6	1 - Red Blood Cells Leukocytes Reduced	Donor eligibility (travel in malaria risk area)	\$4,000	\$4,000
New England 1270026	B-1888-4	1 - Platelets Pheresis Leukocytes Reduced	Collection (failure to follow manufacturer's instructions)	\$3,000	\$3,000
	B-0501-5	1 - Red Blood Cells	Donor eligibility (travel in malarial risk area)	\$4,000	\$4,000
	B-0502-5	1 - Red Blood Cells Leukocytes Reduced	Donor eligibility (travel in malarial risk area)	\$4,000	\$4,000
	B-0670-5	1 - Platelets Pheresis Leukocytes Reduced Irradiated	Collection (sterility may have been compromised and failure to follow manufacturer's instruction)	\$5,000	\$5,000
	B-0723-5	1 - Red Blood Cells Leukocytes Reduced	Donor eligibility (travel in malaria risk area)	\$4,000	\$4,000
	B-0947-5	2 - Platelets Pheresis Leukocytes Reduced	Collection (sterility may have been compromised and failure to follow manufacturer's instructions)	\$5,000	\$10,000
	B-0951-5	1 - Red Blood Cells Leukocytes Reduced	Donor eligibility (travel in malarial risk area)	\$4,000	\$4,000
	B-0956-5	1 - Red Blood Cells	Donor eligibility (travel in malaria risk area)	\$4,000	\$4,000
	B-1006-5	1 - Red Blood Cells Leukocytes Reduced	Donor eligibility (travel in malaria risk area)	\$4,000	\$4,000
	B-1007-5	1 - Red Blood Cells Leukocytes Reduced	Donor eligibility (travel in malaria risk area)	\$4,000	\$4,000
	B-1009-5	1 - Platelets Pheresis Leukocytes Reduced	Donor eligibility (failure to defer donor for taking Proscar)	\$5,000	\$5,000
	B-1023-5	1 - Fresh Frozen Plasma	Failure to control suspect blood component(s) (inappropriate release after discovery of clots in red blood cells)	\$5,000	\$5,000
	B-1996-5 B-1997-5	2 - Red Blood Cells Leukocytes Reduced 1 - Fresh Frozen Plasma	Donor eligibility (failure to defer donor for taking Proscar)	\$5,000	\$15,000
	B-2005-5	1 - Red Blood Cells Leukocytes Reduced	Donor eligibility (travel in malaria risk area)	\$4,000	\$4,000

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	B-0625-6	1 – Red Blood Cells Leukocytes Reduced	Donor eligibility (travel in malaria risk area)	\$4,000	\$4,000
New York- Penn 2438445	2004-001-0532479 B-2253-5 B-2254-5	1 – Red Blood Cells Leukocytes Reduced 1 – Recovered Plasma	Donor eligibility (failure to defer donor for hepatitis risk)	\$4,000	\$8,000
North Central 2173038	2003-017-0112629 B-0424-6	1 – Platelets Leukocytes Reduced	Donor eligibility (failure to defer donor for HIV risk)	\$5,000	\$5,000
	2003-017-0114568 B-0503-6	1 – Platelets Leukocytes Reduced	Component preparation (sterility may have been compromised)	\$5,000	\$5,000
	2004-017-0320991 B-1097-6	1 – Red Blood Cells Leukocytes Reduced	Failure to control suspect blood component(s) (overweight unit)	\$5,000	\$5,000
	2004-017-0464920 B-1113-6	1 – Red Blood Cells Leukocytes Reduced	Donor eligibility (travel to malarial risk area)	\$4,000	\$4,000
	2004-017-0466796 B-1131-6	2 – Red Blood Cells Leukocytes Reduced	Component preparation (failure to assure leukoreduction)	\$4,000	\$8,000
Northeastern Pennsylvania 2573018	B-0069-5	1 – Red Blood Cells Leukocytes Reduced	Donor eligibility (hemoglobin not documented)	\$3,000	\$3,000
	B-0671-5	1 – Whole Blood	Donor eligibility (failure to defer donor for urinary tract infection)	\$4,000	\$4,000
	B-0656-5	2 – Red Blood Cells Leukocytes Reduced	Collections (error on daily quality control record)	\$3,000	\$6,000
	B-1853-5	1 – Red Blood Cells	Failure to control suspect blood component(s) (OC was not properly performed on the hematocrit centrifuge)	\$5,000	\$5,000
	B-1852-5	1 – Red Blood Cells Leukocytes Reduced	Donor eligibility (failure to have a hematocrit value on the BDR)	\$3,000	\$3,000
	B-2375-5 B-2376-5	1 – Red Blood Cells Leukocytes Reduced 1 – Cryoprecipitated AHF	Donor eligibility (failure to defer donor with melanoma)	\$4,000	\$8,000
	B-0233-6	1 – Red Blood Cells Leukocytes Reduced	Donor eligibility (travel in malarial risk area)	\$4,000	\$4,000

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Northern Ohio 1573019	2004-042-0686603 B-2141-5 B-2142-5 B-2143-5 B-2144-5 B-2145-5 B-2146-5 B-2147-5	6 – Red Blood Cells 719 – Red Blood Cells Leukocytes Reduced 1 – Red Blood Cells Leukocytes Reduced Washed 50 – Red Blood Cells Apheresis Leukocytes Reduced 249 – Platelets Leukocytes Reduced 107 – Fresh Frozen Plasma 15 – Plasma	Donor eligibility (inadequate donor screening)	\$5,000 for each of 100 blood components	\$500,000
	2005-042-0931991 B-0158-6	1 – Platelets Pheresis Leukocytes Reduced	Donor eligibility (travel in malarial risk area)	\$4,000	\$4,000
Pacific Northwest 3072996	2003-021-0223957 B-0492-5	1 – Red Blood Cells Leukocytes Reduced	Collection (sterility may have been compromised and failure to follow manufacturer's instructions)	\$5,000	\$5,000
	2004-021-0292966 B-1407-5	1 – Red Blood Cells Leukocytes Reduced	Donor eligibility (travel to malarial risk area)	\$4,000	\$4,000
	2004-021-0308462 B-1426-5	1 – Red Blood Cells Leukocytes Reduced	Donor eligibility (travel to malarial risk area)	\$4,000	\$4,000
	2004-021-0346465 B-0479-6 B-0480-6	1 – Red Blood Cells Leukocytes Reduced 5 – Platelets Pheresis Leukocytes Reduced	Donor eligibility (travel to malaria risk area)	\$4,000	\$24,000
Penn-Jersey 2573021	B-2037-4	1 – Red Blood Cells Pheresis	Component preparation (sterility may have been compromised and failure to follow manufacturer's instructions)	\$5,000	\$5,000
	B-2051-4	1 – Red Blood Cells Pheresis	Component preparation (sterility may have been compromised and failure to follow manufacturer's instructions)	\$5,000	\$5,000
	B-0834-5 B-0835-5	5 – Red Blood Cells Leukocytes Reduced Irradiated 6 – Platelets Pheresis Leukocytes Reduced Irradiated	Component preparation (discrepant irradiation times documented)	\$3,000	\$33,000

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	B-1434-5 B-1435-5	221 – Platelets Pheresis Leukocytes Reduced 27 – Platelet Pheresis Leukocytes Reduced Irradiated	Component preparation (monthly QC of pheresis products not performed)	\$3,000 for each of 100 blood components	\$300,000
	B-1531-5 B-1532-5 B-1533-5	1976 – Platelets Pheresis Leukocytes Reduced 736 – Platelets Pheresis Leukocytes Reduced Irradiated 1635 – Fresh Frozen Plasma	Component preparation (manufacturer's instructions were updated but written procedures had not been updated)	\$2,000 for each of 100 blood components	\$200,000
	2005-022-0839888 B-1637-5	1 – Fresh Frozen Plasma	Failure to control suspect blood component(s) (failure to quarantine components after receiving post donation information)	\$5,000	\$5,000
	B-1749-5	1 – Red Blood Cells	Failure to control suspect blood component(s) (overweight units)	\$5,000	\$5,000
	B-1881-5	1 – Red Blood Cells Leukocytes Reduced	Donor eligibility (travel to malarial risk area)	\$4,000	\$4,000
	B-1882-5	1 – Platelets Leukocytes Reduced	Donor eligibility (failure to defer donor for HIV risk)	\$5,000	\$5,000
	B-1906-5	13 – Platelets Pheresis Leukocytes Reduced	Storage/Shipping (shipment of products exceeded time allowed for shipping)	\$4,000	\$52,000
River Valley 1073003	2004-024-0324987 B-1759-5 B-1760-5	730 – Platelets Leukocytes Reduced 90 – Platelets Leukocytes Reduced Irradiated	Component preparation (low platelet yields)	\$4,000 for each of 100 blood components	\$400,000
South Carolina 1073009	2003-036-0157079 B-0965-6	1 – Red Blood Cells Leukocytes Reduced	Donor eligibility (failure to defer donor for taking Lupron)	\$2,000	\$2,000
	2005-036-0859145 B-1009-6	5 – Platelets Pheresis Leukocytes Reduced	Storage/Shipping (time in transit not documented)	\$2,000	\$10,000
	2005-036-0978405 B-0921-6	1 – Red Blood Cells Leukocytes Reduced	Donor eligibility (failure to defer donor for lymphoma)	\$4,000	\$4,000
Southeastern Michigan 1873044	2004-013-0403966 B-1424-5	1 – Red Blood Cells Leukocytes Reduced	Donor eligibility (travel to malarial risk area)	\$4,000	\$4,000
	2004-013-0652182 B-1425-5	1 – Red Blood Cells Leukocytes Reduced	Donor eligibility (travel to malarial risk area)	\$4,000	\$4,000

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	2004-013-0514574 B-1454-5 B-1455-5	1 - Red Blood Cells Leukocytes Reduced 1 - Platelets Leukocytes Reduced	Donor eligibility (failure to defer donor for human T lymphotropic virus (HTLV) risk)	\$4,000	\$8,000
	2004-013-0588706 B-1483-5	1 - Red Blood Cells Leukocytes Reduced	Donor eligibility (travel to malarial risk area)	\$4,000	\$4,000
	2005-013-0813171 B-2292-5 B-2293-5	1 - Red Blood Cells Leukocytes Reduced 1 - Fresh Frozen Plasma	Donor eligibility (failure to deter donor for taking Avodart)	\$5,000	\$10,000
	2005-013-0979194 B-0015-6	1 - Platelets Pheresis Leukocytes Reduced Irradiated	Donor eligibility (travel to malarial risk area)	\$4,000	\$4,000
	2005-013-0948006 B-0038-6 B-0039-6	1 - Red Blood Cells Leukocytes Reduced 1 - Platelets Leukocytes Reduced	Donor eligibility (travel to malarial risk area)	\$4,000	\$8,000
	2004-013-0414712 B-0124-6	1 - Red Blood Cells Leukocytes Reduced	Donor eligibility (failure to defer donor for HTLV risk)	\$4,000	\$4,000
Southern 1073000	2003-003-0268123 B-0445-6	3 - Red Blood Cells Leukocytes Reduced	Donor eligibility (travel in malarial risk area)	\$4,000	\$12,000
	2003-003-0137009 B-0447-6	10 - Red Blood Cells Leukocytes Reduced	Failure to control suspect blood component(s) (overweight unit)	\$5,000	\$50,000
	2003-003-0171218 B-0519-6	1 Red Blood Cells Leukocytes Reduced	Donor eligibility (travel in malarial risk area)	\$4,000	\$4,000
	2004-003-0655027 B-0736-6	1 - Platelets Pheresis Leukocytes Reduced	Component preparation (inappropriate release of unit with unacceptable platelet yield)	\$4,000	\$4,000
	2004-003-0362554 B-0737-6	1 - Platelets Pheresis	Component preparation (inappropriate release of unit with unacceptable platelet yield)	\$4,000	\$4,000
	2004-003-0508176 B-0762-6	1 - Platelets Pheresis Leukocytes Reduced	Component preparation (inappropriate release of unit with unacceptable platelet yield)	\$4,000	\$4,000

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	2004-003-0366103 B-0807-6	1 – Platelets Pheresis	Failure to control suspect blood component(s) (BDR questions related to HIV risk were unanswered)	\$5,000	\$5,000
	2004-003-0424198 B-0896-6	1 – Platelets Pheresis Leukocytes Reduced	Component preparation (inappropriate release of unit with unacceptable platelet yield)	\$4,000	\$4,000
	2004-003-0577474 B-0947-6	2 – Platelets Pheresis Leukocytes Reduced	Failure to control suspect blood component(s) (product did not meet product specifications)	\$5,000	\$10,000
	2004-003-0339931 B-1008-6	1 – Red Blood Cells Leukocytes Reduced	Failure to control suspect blood component(s) (BDR high risk question unanswered)	\$5,000	\$5,000
Southern California 2072994	2003-006-0186567 B-0624-4	1 – Red Blood Cells Leukocytes Reduced	Storage/Shipping (product stored at incorrect temperature)	\$4,000	\$4,000
	2004-006-036788 B-1045-5	2 – Red Blood Cells Leukocytes Reduced	Donor eligibility (travel to malarial risk area)	\$4,000	\$8,000
	2004-006-0360704 B-1049-5 B-1050-5	2 – Red Blood Cells 1 – Fresh Frozen Plasma	Donor eligibility (failure to defer donor for body piercing)	\$4,000	\$12,000
	2004-006-0325150 B-1768-5 B-1769-5	5 – Platelets Pheresis Leukocytes Reduced 1 – Platelets Pheresis Irradiated	Component preparation (failure to perform product QC testing)	\$3,000	\$18,000
	2004-006-0321033 B-1910-5	1 – Red Blood Cells Leukocytes Reduced	Donor eligibility (travel to malarial risk area)	\$4,000	\$4,000
	2003-006-0230785 B-0277-6	1 – Red Blood Cells Leukocytes Reduced	Donor eligibility (travel to malarial risk area)	\$4,000	\$4,000
	2004-006-0375556 B-0672-6	1 – Red Blood Cells Leukocytes Reduced	Donor eligibility (travel to malarial risk area)	\$4,000	\$4,000
	2003-006-0155824 B-0834-6	1 – Platelets Pheresis Irradiated	Failure to control suspect blood component(s) (inappropriate release-elevated platelet count)	\$5,000	\$5,000

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	2004-006-0501165 B-1176-6	1 – Red Blood Cells Leukocytes Reduced	Donor eligibility (travel to malarial risk area)	\$4,000	\$4,000
Southwest 1673040	2003-0490152156 B-1652-5 B-1653-5	1 – Red Blood Cells Leukocytes Reduced 1 – Recovered Plasma	Donor eligibility (failure to defer donor for taking Proscar)	\$5,000	\$10,000
	2003-049-0226992 B-1680-5	1 – Red Blood Cells Leukocytes Reduced	Donor eligibility (failure to defer donor for low Hct)	\$3,000	\$3,000
	2004-049-0709793 B-1698-5	1 – Platelets Pheresis Leukocytes Reduced	Collection (sterility may have been compromised)	\$5,000	\$5,000
	2003-049-0182598 B-1699-5	1 – Red Blood Cells Leukocytes Reduced	Donor eligibility (failure to defer donor for unacceptable hemoglobin level)	\$3,000	\$3,000
	2004-049-0564594 B-1726-5	1 – Red Blood Cells Leukocytes Reduced	Donor eligibility (travel to malarial risk area)	\$4,000	\$4,000
	2004-049-0620192 B-1739-5	2 – Platelets Pheresis Leukocytes Reduced	Failure to control suspect blood component(s) (product intended for validation study)	\$5,000	\$10,000
	2005-049-0819904 B-0877-6	1 – Red Blood Cells	Donor Eligibility (BDR question pertaining to CJD was unanswered)	\$4,000	\$4,000
Western Lake Erie 1573020	2004-050-0305012 B-0082-6 B-0083-6 B-0084-6	1 – Red Blood Cells Leukocytes Reduced 1 – Cryoprecipitated AHF 1 – Recovered Plasma	Donor eligibility (failure to defer donor for CJD risk)	\$4,000	\$12,000
	2004-050-0654999 B-1000-6 B-1001-6 B-1002-6	1 – Red Blood Cells Leukocytes Reduced 1 – Cryoprecipitated AHF 1 – Recovered Plasma	Donor eligibility (failure to defer donor for hepatitis risk)	\$4,000	\$12,000