



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

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February 6, 2008

ADVERSE DETERMINATION LETTER

BY FACSIMILE &
CERTIFIED MAIL
RETURNED RECEIPT REQUESTED

Mr. J. Chris Hrouda
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. Hrouda:

Paragraph X.A. of the Amended Consent Decree of Permanent Injunction (Decree) entered on April 15, 2003, provides the Food and Drug Administration (FDA) with authority to assess a penalty for "each unit of unsuitable blood or blood component that [the American Red Cross (ARC)] distributes after entry of [the Decree] for which FDA determines that the release was preventable by ARC...." Paragraph X.A.2. of the Decree provides that "[i]f FDA determines that use of, or exposure to, the product may cause temporary or medically reversible adverse health consequences or where the probability of serious adverse health consequences is remote, FDA may assess a penalty of up to \$5,000 for each such unit of blood or each such blood component. Notwithstanding the foregoing, FDA shall not assess ARC under this subparagraph (X.A.2) for the improper release of more than 100 units in any one event."

FDA has recently completed a review of its database and files to identify classified¹ recalls conducted by ARC. We focused on the recalls that occurred during the period of April 15, 2003, through April 15, 2006. However, several recall events involved the distribution of multiple unsuitable blood products over a period of time, and some of the individual distributions within such events fell outside the specified time frame. Such distributions and events are nevertheless included in this Adverse Determination Letter (ADL) but will not be revisited in future ADLs. In addition, this ADL does not

¹ Recall classifications are numerical designations assigned by FDA to indicate the relative degree of health hazard presented by the recalled product. 21 CFR § 7.3(m).

include any classified recalls previously identified in the May 16, 2005 or September 7, 2006 ADLs. Furthermore, this ADL includes only those recall events classified by FDA as of June 21, 2007, and, therefore, does not necessarily include all events that occurred during the specified time period. After FDA review, additional penalties may be assessed for events that occurred during the aforementioned time period but not included in this or other previous ADLs.

In FDA's review, we identified 113 events in which ARC reported to FDA that it retrieved unsuitable blood components. The unsuitable blood components are listed by event in the attachment to this letter. The events are identified by ARC-assigned biological product deviation numbers and FDA-assigned recall numbers and are arranged by ARC regions. FDA determined that all of these events were preventable by ARC, that they all meet the health hazard criteria of Paragraph X.A.2. of the Decree, and that no penalty exception listed in Paragraph X.B. of the Decree applies. These events involved a total of 4,094 unsuitable blood components. However, seven of the recall events involved distribution of more than 100 unsuitable blood components but were limited for penalty purposes to 100 units as provided by Paragraph X.A.2. of the Decree. Thus, the total number of unsuitable blood components for which FDA assessed a penalty under Paragraph X.A.2. of the Decree is 1,001.

Paragraph X.A.2. of the Decree sets forth three factors FDA must consider when determining whether to assess a penalty and the amount of a penalty: "(1) the potential effect of the event on the public health, e.g., the number and seriousness of exposures; (2) ARC's trends with respect to the same or similar events involving the release of unsuitable products; and (3) the degree to which ARC contributed to the improper release of the blood or blood components." FDA has considered these factors and has assessed penalties accordingly for each unsuitable blood component (see attached list). Some of the individual penalty amounts are higher than penalties assessed for similar events in earlier ADLs. FDA believes this adjustment is warranted based on the cumulative numbers of such events. The total penalty being assessed under Paragraph X.A.2. of the Decree is \$4,614,000.

Paragraph X.C. of the Decree provides that FDA "may assess an additional penalty of up to \$50,000 for each unit of unsuitable blood or blood component that was returned by a consignee and re-released for distribution by ARC, if ARC had the ability to determine that the blood or blood component was unsuitable, and failed to do so. ARC shall not be assessed the foregoing penalty if ARC demonstrates to FDA's satisfaction that ARC took appropriate steps to bring blood and blood components into compliance with the law, ARC SOPs, and this Order."

ARC reported to FDA that on July 2, 2004, it re-released a Red Blood Cell Leukocytes Reduced blood component that it had previously "recalled" from a consignee on June 25, 2004. ARC initially recalled the component from the consignee because required quality control steps were performed incorrectly on the microhematocrit centrifuge used during collection of the unit of whole blood.² ARC's problem report [REDACTED] indicates that after it notified the consignee of this component on June 25, 2004, the consignee returned the component to the ARC, instead of discarding it. ARC subsequently removed the computer hold applied to the unit, which resulted in ARC's re-releasing of

² Microhematocrit centrifuges are used to determine donor hematocrit levels and to verify qualitative donor hematocrit tests. Collecting blood from donors with low hematocrit levels could be detrimental to the donor and result in blood components that do not possess their purported quality or potency. Day-of-use quality control checks are required to ensure the functionality and accuracy of such equipment.

this unsuitable component to another consignee for transfusion purposes. FDA has assessed a \$35,000 fine under Paragraph X.C. of the Decree for the re-release of an unsuitable blood component.

Paragraph IX.F.5 of the Decree states that "All penalties assessed under this Order shall be based on the year in which the violative conduct occurred. The annual cap amounts described in paragraph IX.F.1 of this Order shall also be attributed solely to the year in which the violative conduct occurred." The penalty period described in this letter includes violations that occurred in 2003, 2004, 2005 and 2006. The penalty amounts assessed as a result of the violations for each of those years is \$793,000 in 2003, \$698,000 in 2004, \$3,090,000 in 2005 and \$68,000 in 2006.

The total fine that FDA is imposing is \$4,649,000. As provided in the Decree, if ARC agrees with this adverse determination, it must, within 20 days of receipt of this letter, notify FDA of its intent to come into compliance with the Decree, submit a plan to do so, and pay the penalty no later than thirty days (30) thereafter. If ARC disagrees with FDA's adverse determination, it shall respond in writing within 20 days of receipt of this letter, explaining the reason(s) for disagreeing with FDA's determination. The response 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, Suite 200N, Rockville, Maryland 20852.

Sincerely yours,



Evelyn Bonnin
Director, Baltimore District

Enclosure

cc: Mary Elcano
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AMERICAN RED CROSS: Certain Class II recalls for the period April 15, 2003 through April 15, 2006.

Several recall events listed below involved the distribution of multiple unsuitable blood products over a period of time, and some of the individual distributions within such events fell outside the April 15, 2003 through April 15, 2006 time frame. In addition, this chart does not include any classified recalls previously identified in the May 16, 2005 or September 7, 2006 Adverse Determination Letters (ADLs). Furthermore, this chart includes only those events classified by FDA as of June 21, 2007, and therefore does not necessarily include all events that occurred during the specified time period. After FDA review, additional penalties may be assessed for events that occurred during the aforementioned time period but not included in this or other previous ADLs. ARC did not identify to FDA any recalls that met the requirements for penalties under Paragraph X of the Decree for the following regions:

- Appalachian Region, FDA Registration 1173010
- Central Plains Region, FDA Registration 1973042
- Greater Alleghenies Region, FDA Registration 2573016
- Greater Ozarks-Arkansas, FDA Registration 2372998
- Gulf Coast, FDA Registration 1073005
- Heart of America, FDA Registration 1473043
- Midwest, FDA Registration 1973037
- New York-Penn, FDA Registration 2438445
- Northeastern Pennsylvania, FDA Registration 2573018
- Northern California, FDA Registration 2971430
- Penn Jersey, FDA Registration 2573021
- Puerto Rico, FDA Registration 2675945
- River Valley, FDA Registration 1073003
- Southwest, FDA Registration 1673040
- Western Lake Erie, FDA Registration 1573020

Region/FEI	Biological Product Deviation Number	Recall Number	Number of Recalled Products/Product Type	Reason for Recall	Penalty Amount	
					Per Blood Component	Total Penalty Amount
Alabama / 1073001	[REDACTED]	B-1261-07	2 - Red Blood Cells Pheresis Leukocytes Reduced	Donor eligibility (donor involved in a possible recipient transfusion transmitted infection case was not deferred)	\$5,000	\$10,000
Alabama / 1073001	[REDACTED]	B-1089-07	1 - Red Blood Cells Leukocytes Reduced	Donor eligibility (failure to defer donor for travel in a Creutzfeldt Jakob Disease (CJD) risk area)	\$4,000	\$8,000
		B-1090-07	1 - Recovered Plasma			

Alabama / 1073001	[REDACTED]	B-1626-05	7 - Fresh Frozen Plasma	Failure to control suspect blood component(s) (inappropriate release after discovering clots in red blood cells)	\$5,000	\$35,000
Arizona / 2072997	[REDACTED]	B-0464-06	1 - Red Blood Cells Leukocytes Reduced	Donor eligibility (failure to follow up on medications taken by donor)	\$4,000	\$4,000
Badger-Hawkeye / 2173028	[REDACTED]	B-0506-07	3 - Fresh Frozen Plasma	Failure to control suspect blood component(s) (inappropriate release after discovering clots in red blood cells)	\$5,000	\$40,000
		B-0507-07	3 - Cryoprecipitated AHF			
		B-0508-07	2 - Platelets Leukocytes Reduced			
Badger-Hawkeye / 2173028	[REDACTED]	B-0097-07	1 - Red Blood Cells Leukocytes Reduced	Donor eligibility (Blood Donation Record (BDR) question related to ongoing medical conditions was unanswered)	\$4,000	\$8,000
		B-0098-07	1 - Platelets Leukocytes Reduced			
Carolinas / 1073007	[REDACTED]	B-1284-06	1 - Red Blood Cells Leukocytes Reduced	Donor eligibility (incorrect identification used during deferral search for a donor previously deferred due to testing anti-HCV reactive)	\$5,000	\$10,000
		B-1285-06	1 - Recovered Plasma			
Carolinas / 1073007	[REDACTED]	B-0766-06	4 - Red Blood Cells Leukocytes Reduced	Failure to control suspect blood component(s) (inappropriate release of blood components that should have been discarded)	\$5,000	\$20,000
Carolinas / 1073007	[REDACTED]	B-0920-06	2 - Platelets Pheresis Leukocytes Reduced	Donor eligibility (BDR questions unanswered)	\$4,000	\$8,000
Carolinas / 1073007	[REDACTED]	B-0964-06	2 - Red Blood Cells Pheresis Leukocytes Reduced	Donor eligibility (BDR question related to current medication being taken was unanswered)	\$4,000	\$8,000
Carolinas / 1073007	[REDACTED]	B-1325-06	1 - Red Blood Cells Leukocytes Reduced	Failure to control suspect blood component(s) (release of blood components from a donor that was in a permanent deferral category)	\$5,000	\$5,000
Carolinas / 1073007	[REDACTED]	B-0934-06	1 - Red Blood Cells Leukocytes Reduced	Donor eligibility (unauthorized changes made to BDR questions)	\$4,000	\$4,000
Carolinas / 1073007	[REDACTED]	B-1089-06	1 - Red Blood Cells Leukocytes Reduced	Donor eligibility (BDR gender related questions were unanswered)	\$4,000	\$8,000
		B-1090-06	1 - Fresh Frozen Plasma			

Carolinas / 1073007	[REDACTED]	B-0929-06	1 - Red Blood Cells Leukocytes Reduced	Donor eligibility (failure to defer donor for travel in a malarial risk area)	\$4,000	\$4,000
Central Ohio / 1573013	[REDACTED]	B-1692-06	1 - Red Blood Cells Leukocytes Reduced	Donor eligibility (BDR question pertaining to high risk behavior was unanswered)	\$5,000	\$10,000
		B-1693-06	1 - Platelets Leukocytes Reduced			
Central Ohio / 1573013	[REDACTED]	B-1396-06	1 - Platelets Pheresis Leukocytes Reduced Irradiated	Failure to control suspect blood component(s) (product was not discarded after discovery that it should have been stored in two bags based on the platelet yield)	\$5,000	\$5,000
Central Ohio / 1573013	[REDACTED]	B-0987-06	1 - Red Blood Cells Leukocytes Reduced Irradiated	Donor eligibility (failure to defer donor for travel in a CJD risk area)	\$4,000	\$8,000
		B-0988-06	1 - Plasma Frozen			
Central Ohio / 1573013	[REDACTED]	B-0628-06	2 - Platelets Pheresis Leukocytes Reduced Irradiated	Component preparation (the manufacturing record was missing the time the apheresis machine was primed)	\$4,000	\$8,000
Connecticut / 1273014	[REDACTED]	B-1726-06	1 - Red Blood Cells Leukocytes Reduced	Donor eligibility (failure to defer donor for travel in a malarial risk area)	\$4,000	\$8,000
		B-1727-06	1 - Platelets Leukocytes Reduced			
Connecticut / 1273014	[REDACTED]	B-1154-06	1 - Red Blood Cells Leukocytes Reduced	Donor eligibility (failure to defer donor for travel in a malarial risk area)	\$4,000	\$4,000
Connecticut / 1273014	[REDACTED]	B-0951-06	1 - Red Blood Cells Leukocytes Reduced	Donor eligibility (failure to defer donor for travel in a malarial risk area)	\$4,000	\$8,000
		B-0952-06	1 - Platelets Leukocytes Reduced			
Great Lakes / 1873033	[REDACTED]	B-1348-06	872 - Platelets Leukocytes Reduced	Quality control and distribution (inappropriate release of platelet components with unacceptable product quality control)	\$4,000 for each of 100 blood components	\$400,000
Great Lakes / 1873033	[REDACTED]	B-1419-06	2 - Red Blood Cells Leukocytes Reduced	Donor eligibility (failure to defer donor for travel in a malarial risk area)	\$4,000	\$8,000

Great Lakes / 1873033	[REDACTED]	B-1420-06	2 – Red Blood Cells Leukocytes Reduced	Donor eligibility (failure to defer donor for travel in a malarial risk area)	\$4,000	\$8,000
Great Lakes / 1873033	[REDACTED]	B-1818-06 B-1819-06 B-1820-06 B-1821-06 B-1822-06	4 - Red Blood Cells 233 – Red Blood Cells Leukocytes Reduced 7 – Red Blood Cells Leukocytes Reduced Irradiated 2 – Cryoprecipitated AHF 33 – Fresh Frozen Plasma	Donor eligibility (inadequate donor screening related to high risk questions)	\$5,000 for each of 100 blood components	\$500,000
Great Lakes / 1873033	[REDACTED]	B-1825-06 B-1826-06 B-1827-06 B-1828-06 B-1829-06	448 – Red Blood Cells Leukocytes Reduced 1 – Red Blood Cells Leukocytes Reduced Washed 13 – Red Blood Cells Leukocytes Reduced Irradiated 5 – Cryoprecipitated AHF 41 – Fresh Frozen Plasma	Collection (sterility may have been compromised)	\$5,000 for each 100 blood components	\$500,000
Greater Chesapeake and Potomac / 1173011	[REDACTED]	B-0040-07	1 – Red Blood Cells Leukocytes Reduced	Donor eligibility (failure to defer donor for travel in a malarial risk area)	\$4,000	\$4,000
Greater Chesapeake and Potomac / 1173011	[REDACTED]	B-0080-07	1 – Platelets Pheresis Leukocytes Reduced	Storage/Shipping (shipment of products exceeded time allowed for shipping)	\$4,000	\$4,000
Greater Chesapeake and Potomac / 1173011	[REDACTED]	B-0082-07	1 – Red Blood Cells Leukocytes Reduced	Donor eligibility (failure to defer donor for travel in a malarial risk area)	\$4,000	\$4,000

Greater Chesapeake and Potomac / 1173011	[REDACTED]	B-0102-07	1 - Red Blood Cells Leukocytes Reduced	Donor eligibility (failure to defer donor for travel in a malarial risk area)	\$4,000	\$4,000
Greater Chesapeake and Potomac / 1173011	[REDACTED]	B-0103-07	1 - Red Blood Cells Leukocytes Reduced	Donor eligibility (failure to defer donor for travel in a malarial risk area)	\$4,000	\$4,000
Greater Chesapeake and Potomac / 1173011	[REDACTED]	B-0104-07	1 - Platelets Pheresis Leukocytes Reduced	Donor eligibility (failure to defer donor for travel in a malarial risk area)	\$4,000	\$4,000
Indiana-Ohio / 1873031	[REDACTED]	B-2286-05	6 - Red Blood Cells	Testing (failure to perform syphilis testing properly)	\$5,000 for each of 100 blood components	\$500,000
		B-2287-05	109 - Red Blood Cells Leukocytes Reduced			
		B-2288-05	1 - Red Blood Cells Leukocytes Reduced Irradiated			
		B-2289-05	6 - Red Blood Cells Pheresis Leukocytes Reduced			
		B-2290-05	6 - Platelets			
Lewis and Clark / 3072990	[REDACTED]	B-0334-06	1 - Platelets Pheresis Leukocytes Reduced	Collection (sterility may have been compromised)	\$5,000	\$10,000
		B-0335-06	1 - Platelets Pheresis Leukocytes Reduced Irradiated			
Lewis and Clark / 3072990	[REDACTED]	B-0338-06	1 - Platelets Pheresis	Failure to control suspect blood component(s) (sterility may have been compromised)	\$5,000	\$5,000
Lewis and Clark / 3072990	[REDACTED]	B-0981-07	1 - Red Blood Cells Leukocytes Reduced	Donor eligibility (failure to defer donor for residence in a malarial risk area)	\$4,000	\$4,000
Lewis and Clark / 3072990	[REDACTED]	B-0912-07	2 - Red Blood Cells Leukocytes Reduced	Donor eligibility (failure to defer donor for travel in a malarial risk area)	\$4,000	\$8,000

Lewis and Clark / [REDACTED] 3072990	B-1070-07	1 – Red Blood Cells Leukocytes Reduced	Donor eligibility (failure to defer donor for travel in a malarial risk area)	\$4,000	\$4,000
Mid-Atlantic / [REDACTED] 1173024	B-0110-07	1 - Red Blood Cells Leukocytes Reduced	Donor eligibility (failure to defer donor for travel in a malarial risk area)	\$4,000	\$4,000
Mid-Atlantic / [REDACTED] 1173024	B-0313-07	1 – Red Blood Cells Leukocytes Reduced	Donor eligibility (failure to defer donor for travel in a malarial risk area)	\$4,000	\$4,000
Missouri-Illinois / [REDACTED] 1973035	B-1289-06	1 – Red Blood Cells Leukocytes Reduced	Donor eligibility (failure to defer donor for travel in a malarial risk area)	\$4,000	\$8,000
	B-1290-06	1 – Platelets Leukocytes Reduced			
Missouri-Illinois / [REDACTED] 1973035	B-1457-06	138 – Red Blood Cells	Collection (sterility may have been compromised and failure to follow manufacturer's instructions)	\$5,000 for each of 100 blood components	\$500,000
	B-1458-06	657 – Red Blood Cells Leukocytes Reduced			
	B-1459-06	11 – Red Blood Cells Leukocytes Reduced Irradiated			
	B-1460-06	2 – Red Blood Cells Leukocytes Reduced Washed			
	B-1461-06	1 - Red Blood Cells Pheresis Leukocytes Reduced			
	B-1462-06	58 – Platelets Leukocytes Reduced			
	B-1463-06	204 – Fresh Frozen Plasma			
	B-1464-06	44 – Platelets Leukocytes Reduced			
	B-1465-06	53 – Plasma Frozen Cryoprecipitate Reduced			
	B-1466-06	172 – Cryoprecipitated AHF			
Missouri-Illinois / [REDACTED] 1973035	B-1511-06	1 – Red Blood Cells Leukocytes Reduced	Donor eligibility (failure to defer donor for travel in a malarial risk area)	\$4,000	\$8,000

	B-1512-06	1 – Platelets Leukocytes Reduced			
Missouri-Illinois / [REDACTED] 1973035	B-0394-07	1 – Red Blood Cells Leukocytes Reduced	Donor eligibility (failure to defer donor for travel in a malarial risk area)	\$4,000	\$4,000
Missouri-Illinois / [REDACTED] 1973035	B-1513-06	1 – Red Blood Cells Leukocytes Reduced	Donor eligibility (failure to defer donor for travel in a malarial risk area)	\$4,000	\$4,000
Missouri-Illinois / [REDACTED] 1973035	B-1520-06	1 – Red Blood Cells Leukocytes Reduced	Donor eligibility (failure to defer donor for travel in a malarial risk area)	\$4,000	\$4,000
New England / [REDACTED] 1270026	B-1935-05	1 – Red Blood Cells Leukocytes Reduced	Donor eligibility (failure to defer donor for CJD risk)	\$4,000	\$8,000
	B-1936-05	1 – Recovered Plasma			
New England / [REDACTED] 1270026	B-1967-05	1 – Red Blood Cells Leukocytes Reduced	Donor eligibility (failure to defer donor for travel in a malarial risk area)	\$4,000	\$4,000
New England / [REDACTED] 1270026	B-0131-06	12 – Red Blood Cells	Donor eligibility (inadequate donor screening related to high risk questions)	\$5,000 for each of 100 blood components	\$500,000
	B-0132-06	335 – Red Blood Cells Leukocytes Reduced			
	B-0133-06	27 – Red Blood Cells Leukocytes Reduced Irradiated			
	B-0134-06	5 - Red Blood Cells Pheresis			
	B-0135-06	37 – Fresh Frozen Plasma			
	B-0136-06	16 - Plasma			
New England / [REDACTED] 1270026	B-0231-06	1 – Red Blood Cells Leukocytes Reduced	Donor eligibility (failure to defer donor for travel in a malarial risk area)	\$4,000	\$4,000
New England / [REDACTED] 1270026	B-0232-06	2 – Red Blood Cells Leukocytes Reduced	Donor eligibility (failure to defer donor for travel in a malarial risk area)	\$4,000	\$8,000
New England / [REDACTED] 1270026	B-0284-06	1 – Red Blood Cells Leukocyte Reduced Irradiated	Donor eligibility (failure to defer donor for travel in a malarial risk area)	\$4,000	\$4,000

New England / 1270026	[REDACTED]	B-0545-06	1 – Red Blood Cells Leukocytes Reduced Irradiated	Labeling (product had an incorrect irradiation status label)	\$4,000	\$4,000
New England / 1270026	[REDACTED]	B-0586-06	1 – Red Blood Cells Leukocytes Reduced	Donor eligibility (failure to defer donor for travel in a malarial risk area)	\$4,000	\$4,000
New England / 1270026	[REDACTED]	B-0588-06	3 – Platelets Pheresis Leukocytes Reduced	Donor eligibility (failure to defer donor for travel in a malarial risk area)	\$4,000	\$16,000
		B-0589-06	1 – Platelet Pheresis Leukocytes Reduced Irradiated			
New England / 1270026	[REDACTED]	B-0603-06	1 - Red Blood Cells Pheresis Leukocytes Reduced	Failure to control suspect blood component(s) (failure to quarantine blood component due to contamination)	\$5,000	\$5,000
New England / 1270026	[REDACTED]	B-0629-06	1 – Red Blood Cells Leukocytes Reduced	Donor eligibility (failure to defer donor for travel in a malarial risk area)	\$4,000	\$4,000
New England / 1270026	[REDACTED]	B-0639-06	27 – Red Blood Cells Leukocytes Reduced	Collection (sterility may have been compromised)	\$5,000	\$135,000
New England / 1270026	[REDACTED]	B-0640-06	1 – Red Blood Cells Leukocytes Reduced	Donor eligibility (failure to defer donor for travel in a malarial risk area)	\$4,000	\$4,000
New England / 1270026	[REDACTED]	B-0641-06	2 – Platelets Pheresis Leukocytes Reduced	Donor eligibility (failure to defer donor for travel in a malarial risk area)	\$4,000	\$8,000
New England / 1270026	[REDACTED]	B-0675-06	1 – Red Blood Cells Leukocytes Reduced	Donor eligibility (failure to defer donor for travel in a malarial risk area)	\$4,000	\$4,000
New England / 1270026	[REDACTED]	B-0967-06	1 – Red Blood Cells Leukocytes Reduced	Donor eligibility (failure to defer donor for travel in a malarial risk area)	\$4,000	\$4,000
New England / 1270026	[REDACTED]	B-0968-06	1 – Red Blood Cells Leukocytes Reduced	Donor eligibility (failure to defer donor for travel in a malarial risk area)	\$4,000	\$4,000
New England / 1270026	[REDACTED]	B-1149-06	1 – Red Blood Cells Leukocytes Reduced	Donor eligibility (failure to defer donor for travel in a malarial risk area)	\$4,000	\$4,000

New England / 1270026	[REDACTED]	B-1260-07	1 – Red Blood Cells Leukocytes Reduced	Donor eligibility (failure to defer donor for travel in a malarial risk area)	\$4,000	\$4,000
New England / 1270026	[REDACTED]	B-1663-06	217 – Platelet Pheresis Leukocytes Reduced	Collection (failure to follow manufacturer's instructions)	\$4,000 for each of 100 blood components	\$400,000
		B-1664-06	16 – Platelet Pheresis Leukocytes Reduced Irradiated			
North Central / 2173038	[REDACTED]	B-1330-06	1 – Red Blood Cells	Failure to control suspect component(s) (failure to quarantine component from an overweight unit)	\$5,000	\$65,000
		B-1331-06	6 – Red Blood Cells Leukocytes Reduced			
		B-1334-06	4 – Platelets Leukocytes Reduced			
		B-1335-06	2 – Fresh Frozen Plasma			
North Central / 2173038	[REDACTED]	B-0986-07	10 – Red Blood Cells Leukocytes Reduced	Storage/Shipping (shipment of products exceeded time allowed for shipping)	\$4,000	\$40,000
Northern Ohio / 1573019	[REDACTED]	B-0769-06	1 – Red Blood Cells	Testing (failure to follow manufacturer's instructions for syphilis testing)	\$5,000	\$25,000
		B-0770-06	1 – Red Blood Cells Leukocytes Reduced			
		B-0771-06	3 - Red Blood Cells Pheresis Leukocytes Reduced			
Northern Ohio / 1573019	[REDACTED]	B-0144-07	1 – Red Blood Cells Leukocytes Reduces	Donor eligibility (failure to defer donor for travel in a malarial risk area)	\$4,000	\$4,000
Northern Ohio / 1573019	[REDACTED]	B-0146-07	1 – Red Blood Cells Leukocytes Reduced	Donor eligibility (failure to defer donor for travel in a malarial risk area)	\$4,000	\$4,000
Northern Ohio / 1573019	[REDACTED]	B-0232-07	1 – Red Blood Cells Leukocytes Reduced	Donor eligibility (BDR gender related questions were unanswered)	\$4,000	\$8,000
		B-0233-07	1 – Platelets Leukocytes Reduced			
Northern Ohio / 1573019	[REDACTED]	B-0237-07	2 – Platelet Pheresis Leukocytes Reduced Irradiated	Storage/shipping (products shipped under unacceptable temperatures)	\$4,000	\$8,000
Northern Ohio / 1573019	[REDACTED]	B-0271-07	2 – Red Blood Cells Leukocytes Reduced	Collection (sterility may have been compromised)	\$5,000	\$15,000

	B-0272-07	1 – Frozen Plasma			
Northern Ohio / 1573019	B-0275-07	2 – Red Blood Cells Leukocytes Reduced	Donor eligibility (failure to defer donor for travel in a malarial risk area)	\$4,000	\$16,000
	B-0276-07	2 – Platelets Leukocytes Reduced			
Northern Ohio / 1573019	B-0798-07	1 – Platelets Pheresis Leukocytes Reduced	Donor eligibility (failure to defer donor for travel in a malarial risk area)	\$4,000	\$4,000
Pacific Northwest / 3072996	B-1058-07	1 – Red Blood Cells Leukocytes Reduced	Donor eligibility (BDR gender related questions were unanswered)	\$4,000	\$4,000
Pacific Northwest / 3072996	B-1066-07	1 – Red Blood Cells Leukocytes Reduced	Failure to control suspect blood component(s) (failure to quarantine the product after receiving post donation information from the donor)	\$5,000	\$5,000
Pacific Northwest / 3072996	B-1304-07	18 – Red Blood Cells Leukocytes Reduced	Collection (sterility may have been compromised)	\$5,000	\$100,000
	B-1305-07	2 – Plasma Frozen			
South Carolina / 1073009	B-0953-06	1 - Red Blood Cells Leukocytes Reduced	Donor screening (incorrect merge of duplicate donor records performed for donor that was anti-HIV-1/2 reactive)	\$5,000	\$10,000
	B-0954-06	1 – Fresh Frozen Plasma			
South Carolina / 1073009	B-0961-06	2 – Platelets Pheresis Leukocytes Reduced Irradiated	Storage/shipping (product not packaged in accordance with specifications)	\$4,000	\$8,000
South Carolina / 1073009	B-0995-06	1 - Red Blood Cells Pheresis Leukocytes Reduced	Component preparation (inappropriate release of product with incorrect product quality control)	\$4,000	\$4,000
Southeastern / 1873044	B-1003-06	1 – Red Blood Cells Leukocytes Reduced	Donor eligibility (failure to defer donor for receiving tattoo)	\$4,000	\$8,000
	B-1004-06	1 – Recovered Plasma			
Southeastern / 1873044	B-1005-06	1 – Red Blood Cells Leukocytes Reduced	Donor eligibility (failure to defer donor for travel in a malarial risk area)	\$4,000	\$8,000
	B-1006-06	1 – Platelets Leukocytes Reduced			
Southeastern / 1873044	B-1019-06	4 – Platelets Pheresis Leukocytes Reduced Irradiated	Component preparation (irradiation not performed in accordance with specifications)	\$4,000	\$16,000

Southeastern / 1873044	2004-01-10-1030003	B-1615-06	1 - Red Blood Cells Leukocytes Reduced	Donor eligibility (failure to defer donor for travel in a malarial risk area)	\$4,000	\$4,000
Southeastern / 1873044	2004-01-10-1030003	B-0349-07	1 - Red Blood Cells Pheresis	Donor eligibility (failure to defer donor for travel in a malarial risk area)	\$4,000	\$8,000
		B-0350-07	1 - Platelets Pheresis Leukocytes Reduced			
Southern / 1073000	2004-01-10-1030003	B-0949-06	1 - Red Blood Cells Leukocytes Reduced	Donor eligibility (failure to defer donor for residence in a malarial risk area)	\$4,000	\$4,000
Southern / 1073000	2004-01-10-1030003	B-1078-06	1 - Red Blood Cells Leukocytes Reduced	Donor eligibility (failure to defer donor for increased risk of infection with hepatitis)	\$4,000	\$8,000
		B-1079-06	1 - Plasma Frozen			
Southern / 1073000	2004-01-10-1030003	B-1223-06	1 - Platelets Pheresis Leukocytes Reduced	Component preparation (platelet yield too high for storage in a single bag)	\$4,000	\$4,000
Southern / 1073000	2004-01-10-1030003	B-1279-06	1 - Red Blood Cells Leukocytes Reduced	Donor eligibility (BDR question related to AIDS or testing positive for the AIDS virus was unanswered)	\$5,000	\$10,000
		B-1280-06	1 - Cryoprecipitated AHF			
Southern / 1073000	2004-01-10-1030003	B-1292-06	1 - Red Blood Cells Leukocytes Reduced	Donor deferral (failure to defer donor who tested repeatedly reactive for anti- hepatitis B core on multiple occasions)	\$5,000	\$5,000
Southern / 1073000	2004-01-10-1030003	B-1313-06	1 - Platelets Pheresis Leukocytes Reduced Irradiated	Component preparation (platelet below minimum requirement)	\$4,000	\$4,000
Southern / 1073000	2004-01-10-1030003	B-1422-06	1 - Plasma Frozen	Donor eligibility (failure to defer donor for travel in a CJD risk area)	\$4,000	\$8,000
		B-1423-06	1 - Recovered Plasma			
Southern / 1073000	2004-01-10-1030003	B-1424-06	1 - Red Blood Cells Leukocytes Reduced	Donor eligibility (failure to defer donor for residence in a malarial risk area)	\$4,000	\$4,000
Southern / 1073000	2004-01-10-1030003	B-1429-06	1 - Red Blood Cells Leukocytes Reduced	Donor eligibility (failure to defer donor for travel in a malarial risk area)	\$4,000	\$4,000
Southern / 1073000	2004-01-10-1030003	B-1442-06	1 - Platelets Pheresis Leukocytes Reduced	Component preparation (platelet yield too high for storage in a single bag)	\$4,000	\$4,000

Southern / 1073000	2008-005-1551107	B-1509-06	6 - Red Blood Cells Pheresis Leukocytes Reduced	Quality control and distribution (quality control requirements were not met for Haemonetics Apheresis Red Blood Cells)	\$4,000	\$24,000
Southern / 1073000	2008-005-1551105	B-1651-06	1 - Red Blood Cells Leukocytes Reduced	Failure to control suspect component (failure to quarantine component that failed the inspection for the sterile tube welding)	\$5,000	\$5,000
Southern / 1073000	2008-005-1551102	B-1795-06	1 - Red Blood Cells Leukocytes Reduced	Collection (product collected in a 450 ml collection set instead of a 500 ml set)	\$4,000	\$4,000
Southern / 1073000	2008-005-1551102	B-1805-06	10 - Red Blood Cells Pheresis Leukocytes Reduced	Quality control and distribution (distribution of product collected using an instrument on which validation was not performed)	\$4,000	\$40,000
Southern / 1073000	2008-005-1551103	B-0101-08	1 - Red Blood Cells Leukocytes Reduced	Donor eligibility (BDR gender related questions were unanswered)	\$4,000	\$12,000
		B-0102-08	1 - Cryoprecipitated AHF			
		B-0103-08	1 - Plasma Cryoprecipitate Reduced			
Southern California / 2072994	2008-006-2083101	B-1085-06	1 - Platelets Pheresis Leukocytes Reduced Irradiated	Component preparation (platelet below minimum requirement)	\$4,000	\$4,000
Southern California / 2072994	2008-006-2083101	B-1161-06	2 - Red Blood Cells Leukocytes Reduced	Donor eligibility (failure to defer donor for travel in a malarial risk area)	\$4,000	\$12,000
		B-1162-06	1 - Platelets Pheresis Leukocytes Reduced			
Southern California / 2072994	2008-006-2083100	B-1317-06	1 - Platelets Pheresis Leukocytes Reduced	Donor eligibility (failure to defer donor for travel in a malarial risk area)	\$4,000	\$4,000
Southern California / 2072994	2008-006-2083100	B-1383-06	1 - Red Blood Cells Leukocytes Reduced	Donor eligibility (failure to defer donor for travel in a malarial risk area)	\$4,000	\$4,000
Southern California / 2072994	2008-006-2083104	B-1384-06	1 - Red Blood Cells Leukocytes Reduced	Donor eligibility (failure to defer donor for travel in a malarial risk area)	\$4,000	\$4,000

Southern California / 2072994	2003-09-02-09-09	B-1385-06	1 – Red Blood Cells Leukocytes Reduced	Donor eligibility (failure to defer donor for travel in a malarial risk area)	\$4,000	\$4,000
Southern California / 2072994	2003-06-05-07-01-05	B-1412-06	1 – Red Blood Cells Leukocytes Reduced	Donor eligibility (BDR question related to bovine insulin (CJD-related) was unanswered)	\$4,000	\$4,000
Tennessee Valley / 1073006	2003-09-02-09-09	B-0964-05	37 – Platelets Pheresis Leukocytes Reduced	Quality control and distribution (components collected using instruments whose quality control testing was not met for two months)	\$4,000	\$196,000
		B-0965-05	12 – Platelets Pheresis Leukocytes Reduced Irradiated			
Tennessee Valley / 1073006	2003-09-02-09-09	B-0966-05	1 – Red Blood Cells Leukocytes Reduced	Failure to control suspect blood component(s) (failure to quarantine components after receiving information about post donation illness)	\$5,000	\$10,000
		B-0967-05	1 – Fresh Frozen Plasma			
Tennessee Valley / 1073006	2003-01-02-03-04-08	B-0980-05	1 – Platelets Leukocytes Reduced	Failure to control suspect component(s) (failure to quarantine component from an overweight unit)	\$5,000	\$5,000
Tennessee Valley / 1073006	2003-01-02-03-04	B-0981-05	1 – Platelets Leukocytes Reduced	Failure to control suspect component(s) (failure to quarantine component from an overweight unit)	\$5,000	\$5,000