



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
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June 17, 2010

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:

On October 30, 2009, the Food and Drug Administration (FDA) issued the American National Red Cross (ARC) an Adverse Determination Letter (ADL) under Paragraph X.A. of the Amended Consent Decree of Permanent Injunction (Decree) entered on April 15, 2003.

Paragraph X.A. provides the FDA with authority to assess a penalty for “each unit of *unsuitable blood or blood component*¹ 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 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 also stated in its October 30, 2009 ADL that we were continuing to evaluate assessment of fines and alternate or additional regulatory measures and that the decision on those matters would be communicated by FDA to ARC separately. The purpose of this letter is to notify ARC of FDA’s decision. For your convenience, we are resending the list of recalls cited in the ADL, now including the penalty amounts assessed for each.

¹ The italics in the quotations from the Decree are in the original and indicate that the italicized word was defined in Paragraph III of the Decree.

In the October 30, 2009 ADL, FDA explained that its review of the database and files identified classified² recalls conducted by ARC that occurred from April 15, 2003, through September 30, 2008, and that the October 30, 2009 ADL did not include any classified recalls previously identified in the May 16, 2005, September 7, 2006, or February 6, 2008 ADLs. FDA also explained that only those recall events classified by FDA as of September 30, 2008 were included in the October 30, 2009 ADL; that the ADL did not necessarily include all events that occurred during the specified time period; and that after further FDA review, additional recall events may be identified that occurred during the aforementioned time period but are not included in the October 30, 2009 ADL or previous ADLs.

FDA has incorporated ARC's concerns with some of the recall events discussed on Bates page 088904 of its November 19, 2009 letter. As such, FDA has identified 230 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 number or Problem Report Number and FDA-assigned recall numbers and are arranged by ARC region. 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 7,359 unsuitable blood components. However, thirteen of the recall events involved distribution of more than 100 unsuitable blood components but were limited for penalty purposes to 100 units per event as provided by Paragraph X.A.2. of the Decree. Thus, the total number of unsuitable blood components for which FDA is assessing a penalty under Paragraph X.A.2. of the Decree is 2,096.

Paragraph X.A.2. of the Decree sets forth three non-exhaustive factors FDA considers 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 under the second factor. The total penalty being assessed under Paragraph X.A.2 is \$9,776,000.00.

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 through 2008. The penalty amounts assessed as a result of the violations for each of those years is \$525,000 in 2003, \$2,302,000 in 2004, \$2,019,000 in 2005, \$3,122,000 in 2006, \$1,728,000 in 2007 and \$80,000 in 2008.

The total fine that FDA is imposing is \$9,776,000. Payment of that amount is due no later than thirty days from the date of receipt of this letter.

In accordance with paragraph IX.F.7. of the Decree, we are attaching instructions for the electronic transfer of this payment to the United States Treasury. ARC must, contemporaneous with the electronic

² 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).

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transfer, provide written notification to the FDA Director, Baltimore District and the Associate Commissioner of Regulatory Affairs that payment has been made.

If you have any questions regarding this response, please contact Nancy Rose, Compliance Officer, at (410) 779-5415, or Linda Mattingly, Consumer Safety Officer, at (410) 779-5443.

Sincerely yours,

A handwritten signature in black ink, appearing to read 'E. Bonnin', written in a cursive style.

Evelyn Bonnin
Director, Baltimore District

Enclosures

cc: Ms. Gail McGovern
President and CEO
American National Red Cross
2025 E Street, N.W.
Washington, D.C. 20006

Eva Quinley
Senior Vice President for Quality
and Regulatory Affairs
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2025 E Street, N.W.
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Bonnie McElveen-Hunter
Chairman, Board of Governors
American National Red Cross
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Washington, D.C. 20006

AMERICAN RED CROSS: Certain Class II recalls for the period April 15, 2003 through September 30, 2008

This chart does not include any classified recalls previously identified in the May 16, 2005, September 7, 2006 or February 6, 2008 Adverse Determination Letters (ADLs). Furthermore, this chart includes only those events classified by FDA as of September 30, 2008, 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 that are not included in this or previous ADLs. FDA did not classify any recalls that met the requirements for penalties under Paragraph X of the Decree for the following regions:

- Appalachian Region, FDA Registration 1173010
- Arizona Region, FDA Registration 2072997
- Midwest Region, FDA Registration 1973037
- Missouri-Illinois Region, FDA Registration 1973035
- New York-Penn Region, FDA Registration 2438445
- Pacific Northwest Region, FDA Registration 3072996
- River Valley Region, FDA Registration 1073003
- Western Lake Erie Region, FDA Registration 1573020

Region/FEI	BPDR Number or ARC Problem Report Number	Recall Number	Number of Recalled Products/Product Type	Reason for Recall	Penalty Amount Per Blood Component	Total Penalty Amount
Alabama/ 1073001	(b) (4)	B-0711-08	1 – Red Blood Cells	Collection (inadequate arm prep; sterility may have been compromised)	\$5,000	\$250,000
		B-0712-08	43 – Red Blood Cells Leukocytes Reduced			
		B-0713-08	1 – Red Blood Cells Leukocytes Reduced Irradiated			
		B-0714-08	5 – Fresh Frozen Plasma			

Region/FEI	BPDR Number or ARC Problem Report Number	Recall Number	Number of Recalled Products/Product Type	Reason for Recall	Penalty Amount Per Blood Component	Total Penalty Amount
Alabama/ 1073001	(b) (4)	B-1800-08	633 – Red Blood Cells Leukocytes Reduced	Collection (inadequate arm prep; sterility may have been compromised)	\$5,000 for each of 100 blood components	\$500,000
		B-1801-08	19 – Fresh Frozen Plasma			
		B-1802-08	5- Red Blood Cells Leukocytes Reduced Irradiated			
		B-1803-08	2 – Red Blood Cells			
		B-1804-08	37 – Plasma Frozen			
Alabama/ 1073001	(b) (4)	B-1911-08	2 – Red Blood Cells (Apheresis) Leukocytes Reduced	Donor eligibility (incorrect gender assigned; incorrect Blood Donation Record (BDR) gender-specific questions were answered)	\$5,000	\$10,000
Alabama/ 1073001	(b) (4)	B-1947-08	1 – Red Blood Cells Leukocytes Reduced	Donor eligibility (incorrect gender assigned; incorrect BDR gender- specific questions were answered)	\$5,000	\$10,000
		B-1948-08	1 – Red Blood Cells Leukocytes Reduced Irradiated			
Alabama/ 1073001	(b) (4)	B-1951-08	1 - Red Blood Cells Leukocytes Reduced	Donor eligibility (incorrect gender assigned; incorrect BDR gender- specific questions were answered)	\$5,000	\$5,000
Alabama/ 1073001	(b) (4)	B-1979-08	1 – Red Blood Cells Leukocytes Reduced	Donor eligibility (incorrect gender assigned; incorrect BDR gender- specific questions were answered)	\$5,000	\$5,000

Region/FEI	BPDR Number or ARC Problem Report Number	Recall Number	Number of Recalled Products/Product Type	Reason for Recall	Penalty Amount Per Blood Component	Total Penalty Amount
Badger Hawkeye/ 2173028	(b) (4)	B-1434-07	166 – Platelets Pheresis Leukocytes Reduced	Quality control and distribution (inappropriate release of platelet components with unacceptable quality control)	\$4,000 for each of 100 blood components	\$400,000
		B-1435-07	16 – Platelets Pheresis Leukocytes Reduced Irradiated			
		B-1436-07	4 – Platelets Pheresis Leukocytes Reduced Washed			
Badger Hawkeye/ 2173028	(b) (4)	B-1141-08	53 – Platelets Leukocytes Reduced	Labeling (failure to properly label platelet products ‘Donor took aspirin’)	\$4,000	\$212,000
Badger Hawkeye/ 2173028	(b) (4)	B-1416-08	1 – Fresh Frozen Plasma Pheresis	Donor eligibility (failure to defer two donors when an obsolete version of a reference for tattoos was utilized)	\$4,000	\$12,000
		B-1417-08	1 – Platelets Pheresis Leukocytes Reduced Irradiated			
		B-1418-08	1 – Platelets Pheresis Leukocytes Reduced			
Badger Hawkeye/ 2173028	(b) (4)	B-1464-08	1 – Red Blood Cells Leukocytes Reduced	Donor eligibility (failure to defer donor for travel in a Creutzfeldt Jakob Disease (CJD) risk area)	\$4,000	\$12,000
		B-1465-08	1 - Platelets			
		B-1466-08	1 - Recovered Plasma			
Carolinas/ 1073007	(b) (4)	B-0061-08	1 – Red Blood Cells Leukocytes Reduced	Donor eligibility (incorrect gender assigned; incorrect BDR gender- specific questions were answered)	\$5,000	\$5,000

Region/FEI	BPDR Number or ARC Problem Report Number	Recall Number	Number of Recalled Products/Product Type	Reason for Recall	Penalty Amount Per Blood Component	Total Penalty Amount
Carolinas/ 1073007	(b) (4)	B-0063-08	1 – Fresh Frozen Plasma	Donor eligibility (incorrect gender assigned; incorrect BDR gender-specific questions were answered)	\$5,000	\$20,000
		B-0064-08	2 – Red Blood Cells Leukocytes Reduced			
		B-0065-08	1 – Plasma Frozen			
Carolinas/ 1073007	(b) (4)	B-0069-08	1 – Red Blood Cells Leukocytes Reduced	Donor eligibility (failure to defer donor for travel to a malarial risk area)	\$5,000	\$5,000
Carolinas/ 1073007	(b) (4)	B-0076-08	2 – Fresh Frozen Plasma	Collection (inadequate arm prep; sterility may have been compromised)	\$5,000	\$35,000
		B-0077-08	4 – Red Blood Cells Leukocytes Reduced			
		B-0078-08	1 – Plasma Frozen			
Carolinas/ 1073007	(b) (4)	B-0082-08	1 – Cryoprecipitated AHF	Donor eligibility (incorrect gender assigned; incorrect BDR gender-specific questions were answered)	\$5,000	\$10,000
		B-0084-08	1 – Red Blood Cells Leukocytes Reduced			
Carolinas/ 1073007	(b) (4)	B-0113-08	2 – Red Blood Cells (Apheresis) Leukocytes Reduced	Quality control and distribution (failure to perform quality control testing on product)	\$4,000	\$8,000
Carolinas/ 1073007	(b) (4)	B-0135-08	16 – Red Blood Cells Leukocytes Reduced	Failure to control to control suspect blood component(s) (inappropriate release of blood components that should have been discarded for unacceptable shipping temperatures)	\$5,000	\$80,000

Region/FEI	BPDR Number or ARC Problem Report Number	Recall Number	Number of Recalled Products/Product Type	Reason for Recall	Penalty Amount Per Blood Component	Total Penalty Amount
Carolinas/ 1073007	(b) (4)	B-0163-08	237 – Red Blood Cells Leukocytes Reduced	Testing (failure to perform syphilis testing properly)	\$5,000 for each of 100 blood components	\$500,000
		B-0164-08	26 – Red Blood Cells (Apheresis) Leukocytes Reduced			
		B-0165-08	15 – Platelets Pheresis Leukocytes Reduced			
		B-0166-08	73 – Fresh Frozen Plasma			
		B-0167-08	27 – Cryoprecipitated AHF			
		B-0168-08	16 – Plasma Cryoprecipitate Reduced			
Carolinas/ 1073007	(b) (4)	B-0304-08	1 – Red Blood Cells Leukocytes Reduced	Donor eligibility (incorrect gender assigned; incorrect BDR gender-specific questions were answered)	\$5,000	\$10,000
		B-0305-08	1 – Plasma Frozen			
Carolinas/ 1073007	(b) (4)	B-0319-08	2 – Red Blood Cells Leukocytes Reduced	Donor eligibility (incorrect gender assigned; incorrect BDR gender-specific questions were answered)	\$5,000	\$10,000
Carolinas/ 1073007	(b) (4)	B-0321-08	1 – Cryoprecipitated AHF	Donor eligibility (incorrect gender assigned; incorrect BDR gender-specific questions were answered)	\$5,000	\$20,000
		B-0322-08	1 – Fresh Frozen Plasma			
		B-0323-08	2 - Red Blood Cells Leukocytes Reduced			
Carolinas/ 1073007	(b) (4)	B-0326-08	1 – Red Blood Cells Leukocytes Reduced	Donor eligibility (incorrect gender assigned; incorrect BDR gender-specific questions were answered)	\$5,000	\$5,000
Carolinas/ 1073007	(b) (4)	B-0330-08	1 – Red Blood Cells Leukocytes Reduced	Donor eligibility (incorrect gender assigned; incorrect BDR gender-specific questions were answered)	\$5,000	\$5,000
Carolinas/ 1073007	(b) (4)	B-0332-08	1 – Red Blood Cells Leukocytes Reduced	Donor eligibility (incorrect gender assigned; incorrect BDR gender-specific questions were answered)	\$5,000	\$5,000
Carolinas/ 1073007	(b) (4)	B-0420-08	1 – Red Blood Cells Leukocytes Reduced	Donor eligibility (failure to defer donor for travel to a malarial risk area)	\$4,000	\$4,000

Region/FEI	BPDR Number or ARC Problem Report Number	Recall Number	Number of Recalled Products/Product Type	Reason for Recall	Penalty Amount Per Blood Component	Total Penalty Amount
Carolinas/1073007	(b) (4)	B-0572-08	2 – Red Blood Cells (Apheresis)	Quality control and distribution (product did not meet specifications)	\$4,000	\$8,000
Carolinas/1073007	(b) (4)	B-0693-08	1 – Red Blood Cells (Apheresis) Leukocytes Reduced	Component preparation (distribution of low volume unit)	\$4,000	\$4,000
Carolinas/1073007	(b) (4)	B-0696-08	2 – Red Blood Cells (Apheresis) Leukocytes Reduced	Donor eligibility (incorrect gender assigned; incorrect BDR gender-specific questions were answered)	\$5,000	\$10,000
Carolinas/1073007	(b) (4)	B-0698-08	1 – Red Blood Cells Leukocytes Reduced	Donor eligibility (incorrect gender assigned; incorrect BDR gender-specific questions were answered)	\$5,000	\$5,000
Carolinas/1073007	(b) (4)	B-0699-08	2 – Red Blood Cells Leukocytes Reduced	Donor eligibility (incorrect gender assigned; incorrect BDR gender-specific questions were answered)	\$5,000	\$20,000
		B-0700-08	2 – Fresh Frozen Plasma			
Carolinas/1073007	(b) (4)	B-0715-08	1 – Red Blood Cells Leukocytes Reduced	Donor eligibility (failure to defer donor for residence in a malarial risk area)	\$5,000	\$5,000
Carolinas/1073007	(b) (4)	B-0728-08	2 – Red Blood Cells Leukocytes Reduced	Donor eligibility (failure to defer donor for travel to a malarial risk area)	\$5,000	\$10,000
Carolinas/1073007	(b) (4)	B-1088-08	1 – Fresh Frozen Plasma	Donor eligibility (incorrect gender assigned; incorrect BDR gender-specific questions were answered)	\$5,000	\$10,000
		B-1089-08	1 – Red Blood Cells Leukocytes Reduced			
Carolinas/1073007	(b) (4)	B-1472-08	1 – Red Blood Cells Leukocytes Reduced	Donor eligibility (incorrect gender assigned; incorrect BDR gender-specific questions were answered)	\$5,000	\$5,000
Carolinas/1073007	(b) (4)	B-1476-08	1 – Platelets Pheresis Leukocytes Reduced	Donor eligibility (incorrect gender assigned; incorrect BDR gender-specific questions were answered)	\$5,000	\$5,000
Carolinas/1073007	(b) (4)	B-1480-08	1 – Red Blood Cells Leukocytes Reduced	Donor eligibility (incorrect gender assigned; incorrect BDR gender-specific questions were answered)	\$5,000	\$5,000

Region/FEI	BPDR Number or ARC Problem Report Number	Recall Number	Number of Recalled Products/Product Type	Reason for Recall	Penalty Amount Per Blood Component	Total Penalty Amount
Carolinas/1073007	(b) (4)	B-1497-08	1 – Red Blood Cells Leukocytes Reduced	Donor eligibility (failure to defer donor for travel to a malarial risk area)	\$5,000	\$5,000
Carolinas/1073007	(b) (4)	B-1526-08	1 – Fresh Frozen Plasma	Failure to control suspect blood component(s) (inappropriate release after discovering clots in red blood cells)	\$5,000	\$5,000
Central Ohio/1573013	(b) (4)	B-1999-08	1 – Red Blood Cells Leukocytes Reduced	Donor eligibility (failure to defer donor for travel to a malarial risk area)	\$5,000	\$5,000
Central Plains/1973042	(b) (4)	B-0417-08	1 – Red Blood Cells Leukocytes Reduced	Donor eligibility (failure to defer donor for receiving tattoo)	\$4,000	\$8,000
		B-0418-08	1 – Recovered Plasma			
Connecticut/1273014	(b) (4)	B-0277-7	1 – Red Blood Cells Leukocytes Reduced	Donor eligibility (failure to defer donor for travel to a malarial risk area)	\$5,000	\$10,000
		B-0278-7	1 – Platelets Leukocytes Reduced			
Connecticut/1273014	(b) (4)	B-0538-7	1 – Red Blood Cells Leukocytes Reduced	Component preparation (product manufactured from an overweight unit of Whole Blood)	\$4,000	\$4,000
Connecticut/1273014	(b) (4)	B-0694-07	4 – Red Blood Cells (Apheresis) Leukocytes Reduced	Component preparation (failure to perform required product quality control testing)	\$4,000	\$16,000
Connecticut/1273014	(b) (4)	B-0845-08	1 – Red Blood Cells Leukocytes Reduced	Donor eligibility (incorrect gender assigned; incorrect BDR gender-specific questions were answered)	\$5,000	\$5,000
Connecticut/1273014	(b) (4)	B-0924-08	1 – Red Blood Cells Leukocytes Reduced	Donor eligibility (failure to defer donor for travel to a malarial risk area)	\$5,000	\$10,000
		B-0925-08	1 – Platelets Leukocytes Reduced			
Connecticut/1273014	(b) (4)	B-1068-08	1 – Red Blood Cells Leukocytes Reduced	Component preparation (product manufactured from an overweight unit of Whole Blood)	\$4,000	\$4,000

Region/FEI	BPDR Number or ARC Problem Report Number	Recall Number	Number of Recalled Products/Product Type	Reason for Recall	Penalty Amount Per Blood Component	Total Penalty Amount
Great Lakes/ 1873033	(b) (4)	B-1579-6	3 – Red Blood Cells Leukocytes Reduced	Donor eligibility (failure to defer donor for increased risk of infection with hepatitis)	\$4,000	\$32,000
		B-1582-6	2 – Cryoprecipitated AHF			
		B-1585-6	2 – Plasma Frozen Cryoprecipitate Reduced			
		B-1586-6	1 – Recovered Plasma			
Great Lakes/ 1873033	(b) (4)	B-0566-08	1 – Red Blood Cells Leukocytes Reduced	Donor eligibility (failure to defer donor for travel to a malarial risk area)	\$5,000	\$5,000
Great Lakes/ 1873033	(b) (4)	B-1329-08	1 – Red Blood Cells Leukocytes Reduced	Donor eligibility (incorrect gender assigned; incorrect BDR gender-specific questions were answered)	\$5,000	\$5,000
Great Lakes/ 1873033	(b) (4)	B-1331-08	1 – Fresh Frozen Plasma	Donor eligibility (incorrect gender assigned; incorrect BDR gender-specific questions were answered)	\$5,000	\$10,000
		B-1332-08	1 – Red Blood Cells Leukocytes Reduced			
Great Lakes/ 1873033	(b) (4)	B-1333-08	1 – Red Blood Cells Leukocytes Reduced	Donor eligibility (incorrect gender assigned; incorrect BDR gender-specific questions were answered)	\$5,000	\$5,000
Great Lakes/ 1873033	(b) (4)	B-1335-08	1 – Red Blood Cells Leukocytes Reduced	Donor eligibility (incorrect gender assigned; incorrect BDR gender-specific questions were answered)	\$5,000	\$5,000
Great Lakes/ 1873033	(b) (4)	B-1358-08	2 – Red Blood Cells (Apheresis) Leukocytes Reduced	Component preparation (failure to perform required product quality control testing)	\$4,000	\$8,000
Great Lakes/ 1873033	(b) (4)	B-1477-08	1 – Red Blood Cells Leukocytes Reduced	Donor eligibility (incorrect gender assigned; incorrect BDR gender-specific questions were answered)	\$5,000	\$5,000
Great Lakes/ 1873033	(b) (4)	B-1695-08	1 – Red Blood Cells Leukocytes Reduced	Donor eligibility (incorrect gender assigned; incorrect BDR gender-specific questions were answered)	\$5,000	\$5,000
Great Lakes/ 1873033	(b) (4)	B-1697-08	2 – Red Blood Cells Leukocytes Reduced	Donor eligibility (incorrect gender assigned; incorrect BDR gender-specific questions were answered)	\$5,000	\$10,000

Region/FEI	BPDR Number or ARC Problem Report Number	Recall Number	Number of Recalled Products/Product Type	Reason for Recall	Penalty Amount Per Blood Component	Total Penalty Amount
Greater Alleghenies/ 2573016	(b) (4)	B-0785-6	1 – Red Blood Cells Leukocytes Reduced	Donor eligibility (BDR question related to CJD was unanswered)	\$4,000	\$4,000
Greater Alleghenies/ 2573016	(b) (4)	B-0805-6	1 – Red Blood Cells Leukocytes Reduced	Failure to control suspect blood component(s) (inappropriate release of blood components that should have been discarded)	\$5,000	\$10,000
		B-0806-6	1 – Cryoprecipitated AHF			
Greater Alleghenies/ 2573016	(b) (4)	B-1640-6	1 – Red Blood Cells Leukocytes Reduced	Donor eligibility (incorrect gender assigned; incorrect BDR gender-specific questions were answered)	\$4,000	\$4,000
Greater Alleghenies/ 2573016	(b) (4)	B-1787-6	1 – Red Blood Cells (Apheresis) Leukocytes Reduced	Collection (sterility may have been compromised)	\$5,000	\$5,000

Region/FEI	BPDR Number or ARC Problem Report Number	Recall Number	Number of Recalled Products/Product Type	Reason for Recall	Penalty Amount Per Blood Component	Total Penalty Amount
Greater Alleghenies/ 2573016	(b) (4)	B-0285-7	1 – Platelets Pheresis Leukocytes Reduced	Failure to control suspect blood component(s) (supervisory review did not identify that the products failed the pH requirement)	\$5,000	\$10,000
		B-0286-7	1 – Platelets Pheresis Leukocytes Reduced Irradiated			
Greater Alleghenies/ 2573016	(b) (4)	B-0255-08	2 – Red Blood Cells (Apheresis) Leukocytes Reduced	Quality control and distribution (failure to perform QC on the pheresis machine)	\$4,000	\$8,000
Greater Alleghenies/ 2573016	(b) (4)	B-0361-08	1 – Red Blood Cells Leukocytes Reduced	Donor eligibility (incorrect gender assigned; incorrect BDR gender-specific questions were answered)	\$5,000	\$10,000
		B-0362-08	1 – Platelets Leukocytes Reduced			
Greater Alleghenies/ 2573016	(b) (4)	B-0398-08	4 – Red Blood Cells (Apheresis) Leukocytes Reduced	Quality control and distribution (failure to perform quality control testing on product)	\$4,000	\$16,000
Greater Alleghenies/ 2573016	(b) (4)	B-1440-08	1 – Red Blood Cells Leukocytes Reduced	Donor eligibility (incorrect gender assigned; incorrect BDR gender-specific questions were answered)	\$5,000	\$10,000
		B-1441-08	1 – Cryoprecipitated AHF			
Greater Alleghenies/ 2573016	(b) (4)	B-1765-08	3 – Platelets Pheresis Leukocytes Reduced	Quality control and distribution (failure to perform platelet count)	\$4,000	\$12,000
Greater Chesapeake and Potomac/ 1173011	(b) (4)	B-1707-6	2 – Platelets Pheresis Leukocytes Reduced	Component preparation (plateletpheresis product did not meet specification for platelet yield)	\$4,000	\$8,000
Greater Chesapeake and Potomac/ 1173011	(b) (4)	B-0002-7	1 – Platelets Pheresis Leukocytes Reduced	Component preparation (product had insufficient plasma to support the platelet yield and therefore did not meet specification)	\$4,000	\$4,000
Greater Chesapeake and Potomac/ 1173011	(b) (4)	B-0006-7	1 – Red Blood Cells Leukocytes Reduced	Donor eligibility (failure to defer donor for residence in a malarial risk area)	\$4,000	\$4,000

Region/FEI	BPDR Number or ARC Problem Report Number	Recall Number	Number of Recalled Products/Product Type	Reason for Recall	Penalty Amount Per Blood Component	Total Penalty Amount
Greater Chesapeake and Potomac/ 1173011	(b) (4)	B-0007-7	1 – Platelets Pheresis Leukocytes Reduced	Donor eligibility (failure to defer donor for travel to a malarial risk area)	\$4,000	\$4,000
Greater Chesapeake and Potomac/ 1173011	(b) (4)	B-0012-7	1 – Red Blood Cells Leukocytes Reduced	Donor eligibility (failure to assure that donor met acceptance criteria for hematocrit & body temperature)	\$3,000	\$3,000
Greater Chesapeake and Potomac/ 1173011	(b) (4)	B-0020-7	1 – Red Blood Cells Leukocytes Reduced	Donor eligibility (failure to defer donor for medication use)	\$2,000	\$4,000
		B-0021-7	1 – Platelets			
Greater Chesapeake and Potomac/ 1173011	(b) (4)	B-0026-7	138 – Platelets Pheresis	Component preparation (plateletpheresis product did not meet specification for platelet yield)	\$4,000 for each of 100 blood components	\$400,000
		B-0027-7	25 – Platelets Pheresis Irradiated			
Greater Chesapeake and Potomac/ 1173011	(b) (4)	B-1438-07	3 – Platelets Pheresis Leukocytes Reduced	Quality control and distribution (blood products were collected on equipment that was not validated)	\$4,000	\$12,000
Greater Chesapeake and Potomac/ 1173011	(b) (4)	B-1439-07	2 – Platelets Pheresis Leukocytes Reduced	Quality control and distribution (blood products were collected on equipment that was not validated)	\$4,000	\$8,000
Greater Chesapeake and Potomac/ 1173011	(b) (4)	B-1526-07	1 – Red Blood Cells Leukocytes Reduced	Donor eligibility (incorrect gender assigned; incorrect BDR gender-specific questions were answered)	\$5,000	\$5,000
Greater Chesapeake and Potomac/ 1173011	(b) (4)	B-0754-08	1 – Red Blood Cells (Apheresis) Leukocytes Reduced	Quality control and distribution (failure to test for White Blood Cell count; product mislabeled)	\$4,000	\$4,000

Region/FEI	BPDR Number or ARC Problem Report Number	Recall Number	Number of Recalled Products/Product Type	Reason for Recall	Penalty Amount Per Blood Component	Total Penalty Amount
Greater Chesapeake and Potomac/ 1173011	(b) (4)	B-0755-08	1 – Platelets Pheresis Leukocytes Reduced	Failure to control suspect blood component(s) (failure to quarantine the product due to potential contamination)	\$5,000	\$5,000
Greater Ozark-Arkansas/ 2372998	(b) (4)	B-0049-08	1 – Red Blood Cells Leukocytes Reduced	Testing (failure to perform anti-HIV 1/2 testing correctly)	\$5,000	\$5,000
Greater Ozark-Arkansas/ 2372998	(b) (4)	B-0221-08	1 – Red Blood Cells Leukocytes Reduced	Donor eligibility (incorrect gender assigned; incorrect BDR gender-specific questions were answered)	\$5,000	\$5,000
Greater Ozark-Arkansas/ 2372998	(b) (4)	B-0424-08	1 – Red Blood Cells Leukocytes Reduced	Donor eligibility (incorrect gender assigned; incorrect BDR gender-specific questions were answered)	\$5,000	\$5,000
Gulf Coast/1073005	(b) (4)	B-1234-07	1 – Red Blood Cells Leukocytes Reduced	Failure to control suspect blood component(s) (release of blood component from a donor who was previously incarcerated)	\$5,000	\$10,000
		B-1235-07	1 - Recovered Plasma			
Heart of America/ 1473043	(b) (4)	B-0802-6	2 – Platelets Pheresis Leukocytes Reduced	Collection (products collected using apheresis kits that had exceed the acceptable time period for use)	\$4,000	\$8,000
Heart of America/ 1473043	(b) (4)	B-0844-6	1 - Red Blood Cells Leukocytes Reduced	Donor eligibility (failure to defer donor for travel to a malarial risk area)	\$4,000	\$8,000
		B-0845-6	1 - Platelets Pheresis Leukocytes Reduced			
Heart of America/ 1473043	(b) (4)	B-0950-6	1 - Platelets Pheresis Leukocytes Reduced	Donor eligibility (failure to defer donor for travel to a malarial risk area)	\$4,000	\$4,000
Heart of America/ 1473043	(b) (4)	B-1144-6	1 - Red Blood Cells Leukocytes Reduced	Collection (inadequate arm prep; sterility may have been compromised)	\$5,000	\$5,000
Heart of America/ 1473043	(b) (4)	B-1730-6	1 - Red Blood Cells Leukocytes Reduced	Donor eligibility (incorrect gender assigned; incorrect BDR gender-specific questions were answered)	\$5,000	\$10,000

Region/FEI	BPDR Number or ARC Problem Report Number	Recall Number	Number of Recalled Products/Product Type	Reason for Recall	Penalty Amount Per Blood Component	Total Penalty Amount
		B-1731-6	1 – Plasma Frozen			
Heart of America/1473043	(b) (4)	B-0182-7	1 – Red Blood Cells Leukocytes Reduced	Donor eligibility (incorrect gender assigned; incorrect BDR gender-specific questions were answered)	\$5,000	\$10,000
		B-0183-7	1 – Fresh Frozen Plasma			
Heart of America/1473043	(b) (4)	B-0671-07	3 – Red Blood Cells Leukocytes Reduced	Donor eligibility (failure to defer donor for travel to a malarial risk area)	\$5,000	\$15,000
Heart of America/1473043	(b) (4)	B-1308-07	1 – Platelets Pheresis Leukocytes Reduced	Collection (products collected using apheresis kits that had exceed the acceptable time period for use)	\$4,000	\$4,000
Heart of America/1473043	(b) (4)	B-1573-07	10 – Cryoprecipitated AHF	Component preparation (failure to freeze blood components within the required one hour following manufacture)	\$4,000	\$40,000
Heart of America/1473043	(b) (4)	B-0087-08	1 – Platelets Pheresis Leukocytes Reduced Irradiated	Component preparation (irradiation not performed in accordance with specifications)	\$4,000	\$4,000
Heart of America/1473043	(b) (4)	B-0089-08	1 – Red Blood Cells Leukocytes Reduced Irradiated	Component preparation (irradiation not performed in accordance with specifications)	\$4,000	\$4,000

Region/FEI	BPDR Number or ARC Problem Report Number	Recall Number	Number of Recalled Products/Product Type	Reason for Recall	Penalty Amount Per Blood Component	Total Penalty Amount
Heart of America/ 1473043	(b) (4)	B-0268-08	118 – Cryoprecipitated AHF	Collection (inadequate arm prep; sterility may have been compromised)	\$5,000 for each of 100 blood components	\$500,000
		B-0269-08	84 – Red Blood Cells			
		B-0270-08	229 – Red Blood Cells Leukocytes Reduced			
		B-0271-08	17 – Plasma Frozen			
		B-0272-08	8 – Red Blood Cells Leukocytes Reduced Irradiated			
		B-0273-08	71 – Fresh Frozen Plasma			
Heart of America/ 1473043	(b) (4)	B-1387-08	1 – Red Blood Cells Leukocytes Reduced	Donor eligibility (failure to defer donor for travel in a CJD risk area)	\$5,000	\$20,000
		B-1388-08	1 – Frozen Plasma			
		B-1389-08	2 – Recovered Plasma			
Heart of America/ 1473043	(b) (4)	B-1558-08	2 – Red Blood Cells	Collection (inadequate arm prep; sterility may have been compromised)	\$5,000	\$70,000
		B-1559-08	9 – Red Blood Cells Leukocytes Reduced			
		B-1560-08	1 – Cryoprecipitated AHF			
		B-1561-08	1 – Cryoprecipitated AHF, Pooled			
		B-1562-08	1 – Frozen Plasma			
Heart of America/ 1473043	(b) (4)	B-1973-08	1 – Red Blood Cells Leukocytes Reduced	Donor eligibility (incorrect gender assigned; incorrect BDR gender-specific questions were answered)	\$5,000	\$5,000
Heart of America/ 1473043	(b) (4)	B-1974-08	1 – Red Blood Cells Leukocytes Reduced	Donor eligibility (incorrect gender assigned; incorrect BDR gender-specific questions were answered)	\$5,000	\$10,000
		B-1975-08	1 – Fresh Frozen Plasma			
Indiana-Ohio/ 1873031	(b) (4)	B-0708-07	1 – Platelets Pheresis Leukocytes Reduced	Component preparation (irradiation not performed in accordance with specifications)	\$4,000	\$4,000

Region/FEI	BPDR Number or ARC Problem Report Number	Recall Number	Number of Recalled Products/Product Type	Reason for Recall	Penalty Amount Per Blood Component	Total Penalty Amount
Indiana-Ohio/ 1873031	(b) (4)	B-2050-08	1 – Red Blood Cells Leukocytes Reduced	Donor eligibility (incorrect gender assigned; incorrect BDR gender-specific questions were answered)	\$5,000	\$5,000
Lewis and Clark/ 3072990	(b) (4)	B-0979-07	1 – Red Blood Cells Leukocytes Reduced	Donor eligibility (failure to follow up on medications taken by donor)	\$2,000	\$2,000
Mid Atlantic/ 1173024	(b) (4)	B-0244-7	1 – Red Blood Cells Leukocytes Reduced	Donor eligibility (failure to perform a hematocrit after donor failed hemoglobin acceptance criteria)	\$4,000	\$4,000
Mid Atlantic/ 1173024	(b) (4)	B-1388-07	1 – Red Blood Cells	Donor eligibility (incorrect gender assigned; incorrect BDR gender-specific questions were answered)	\$5,000	\$5,000
Mid Atlantic/ 1173024	(b) (4)	B-1433-07	1 – Red Blood Cells Leukocytes Reduced	Collection (inadequate arm prep; sterility may have been compromised)	\$5,000	\$5,000
Mid Atlantic/ 1173024	(b) (4)	B-1427-08	14 – Red Blood Cells Leukocytes Reduced	Collection (sterility may have been compromised)	\$5,000	\$70,000
Mid Atlantic/ 1173024	(b) (4)	B-1513-08	1 – Red Blood Cells	Donor eligibility (incorrect gender assigned; incorrect BDR gender-specific questions were answered)	\$5,000	\$5,000
Mid Atlantic/ 1173024	(b) (4)	B-1580-08	1 – Red Blood Cells Leukocytes Reduced	Collection (inadequate arm prep; sterility may have been compromised)	\$5,000	\$5,000
New England/ 1270026	(b) (4)	B-1801-6	1 – Platelets Pheresis Leukocytes Reduced	Component preparation (platelet yield too high for storage in a single bag)	\$4,000	\$4,000
New England/ 1270026	(b) (4)	B-1612-6	2 – Red Blood Cells Leukocytes Reduced	Collection (sterility may have been compromised)	\$5,000	\$15,000
		B-1613-6	1 – Plasma Frozen			
New England/ 1270026	(b) (4)	B-0753-07	1 – Red Blood Cells Leukocytes Reduced	Donor eligibility (failure to defer donor for residence in a malarial risk area)	\$5,000	\$5,000
New England/ 1270026	(b) (4)	B-0786-07	1 – Platelets Pheresis Leukocytes Reduced	Collection (inadequate arm prep; sterility may have been compromised)	\$5,000	\$10,000

Region/FEI	BPDR Number or ARC Problem Report Number	Recall Number	Number of Recalled Products/Product Type	Reason for Recall	Penalty Amount Per Blood Component	Total Penalty Amount
		B-0787-07	1 – Platelets Pheresis Leukocytes Reduced Irradiated			
New England/ 1270026	(b) (4)	B-1310-7	1 – Platelets Pheresis Leukocytes Reduced	Component preparation (plateletpheresis product did not meet specification for platelet yield)	\$4,000	\$4,000
New England/ 1270026	(b) (4)	B-1334-07	1 – Red Blood Cells	Donor eligibility (failure to defer donor for travel to a malarial risk area)	\$5,000	\$5,000
New England/ 1270026	(b) (4)	B-1370-07	1 – Red Blood Cells Leukocytes Reduced	Donor eligibility (failure to defer donor for travel to a malarial risk area)	\$5,000	\$5,000
New England/ 1270026	(b) (4)	B-0635-08	3 – Red Blood Cells	Donor eligibility (incorrect gender assigned; incorrect BDR gender- specific questions were answered)	\$5,000	\$55,000
		B-0636-08	2 – Fresh Frozen Plasma			
		B-0637-08	5 – Red Blood Cells Leukocytes Reduced			
		B-0638-08	1 – Plasma Frozen			
New England/ 1270026	(b) (4)	B-0701-08	3 – Red Blood Cells	Failure to control suspect blood component(s) (donor was not properly deferred after testing anti-HIV reactive on a previous donation)	\$5,000	\$110,000
		B-0702-08	8 – Red Blood Cells Leukocytes Reduced			
		B-0703-08	1 – Red Blood Cells Irradiated			
		B-0704-08	2 – Red Blood Cells Leukocytes Reduced Irradiated			
		B-0705-08	4 – Platelets			
		B-0706-08	3 – Fresh Frozen Plasma			
		B-0707-08	1 – Plasma Frozen			

Region/FEI	BPDR Number or ARC Problem Report Number	Recall Number	Number of Recalled Products/Product Type	Reason for Recall	Penalty Amount Per Blood Component	Total Penalty Amount
New England/ 1270026	(b) (4)	B-0716-08	1 – Red Blood Cells Leukocytes Reduced	Donor eligibility (failure to defer donor for travel to a malarial risk area)	\$5,000	\$5,000
New England/ 1270026	(b) (4)	B-0725-08	2 – Red Blood Cells (Apheresis)	Donor eligibility (failure to defer donor for travel to a malarial risk area)	\$5,000	\$30,000
		B-0726-08	4 – Platelets Pheresis Leukocytes Reduced			
New England/ 1270026	(b) (4)	B-0742-08	1 – Red Blood Cells Leukocytes Reduced	Donor eligibility (failure to defer donor for residence in a malarial risk area)	\$5,000	\$10,000
		B-0743-08	1 – Red Blood Cells Leukocytes Reduced Irradiated			
New England/ 1270026	(b) (4)	B-0785-08	1 – Red Blood Cells Leukocytes Reduced	Donor eligibility (incorrect gender assigned; incorrect BDR gender-specific questions were answered)	\$5,000	\$5,000
New England/ 1270026	(b) (4)	B-0808-08	1 – Red Blood Cells Leukocytes Reduced	Failure to control suspect blood component(s) (failure to quarantine components from a donor with a questionable donation status)	\$5,000	\$5,000
New England/ 1270026	(b) (4)	B-0824-08	2 – Red Blood Cells Leukocytes Reduced	Donor eligibility (incorrect gender assigned; incorrect BDR gender-specific questions were answered)	\$5,000	\$10,000
New England/ 1270026	(b) (4)	B-0843-08	3 – Platelets Pheresis Leukocytes Reduced	Quality control and distribution (failure to test for White Blood Cell count; product mislabeled)	\$4,000	\$12,000
New England/ 1270026	(b) (4)	B-0917-08	2 – Red Blood Cells	Donor eligibility (incorrect gender assigned; incorrect BDR gender-specific questions were answered)	\$5,000	\$50,000
		B-0918-08	5 – Red Blood Cells Leukocytes Reduced			
		B-0919-08	2 – Plasma Frozen			
		B-0920-08	1 – Red Blood Cells Leukocytes Reduced Irradiated			

Region/FEI	BPDR Number or ARC Problem Report Number	Recall Number	Number of Recalled Products/Product Type	Reason for Recall	Penalty Amount Per Blood Component	Total Penalty Amount
New England/ 1270026	(b) (4)	B-0926-08	2 – Platelets Pheresis Leukocytes Reduced Irradiated	Failure to control suspect blood component(s) (product was not discarded after discovery that it should have been discarded based on platelet yield)	\$5,000	\$20,000
		B-0927-08	2 – Platelets Pheresis Leukocytes Reduced			
New England/ 1270026	(b) (4)	B-1081-08	2 – Red Blood Cells	Donor eligibility (incorrect gender assigned; incorrect BDR gender-specific questions were answered)	\$5,000	\$35,000
		B-1082-08	3 – Red Blood Cells Leukocytes Reduced			
		B-1083-08	2 – Fresh Frozen Plasma			
New England/ 1270026	(b) (4)	B-1087-08	1 – Recovered Plasma	Donor eligibility (failure to defer donor for travel in a CJD risk area)	\$5,000	\$5,000
New England/ 1270026	(b) (4)	B-1109-08	15 – Platelets Pheresis Leukocytes Reduced	Quality control and distribution (failure to perform quality control testing on product)	\$4,000	\$60,000
New England/ 1270026	(b) (4)	B-1188-08	1 – Red Blood Cells	Failure to control suspect blood component(s) (failure to quarantine component from an overweight unit)	\$5,000	\$5,000
New England/ 1270026	(b) (4)	B-2037-08	1 – Red Blood Cells Leukocytes Reduced	Donor eligibility (incorrect gender assigned; incorrect BDR gender-specific questions were answered)	\$5,000	\$5,000
New England/ 1270026	(b) (4)	B-2042-08	1 – Red Blood Cells Leukocytes Reduced	Donor eligibility (incorrect gender assigned; incorrect BDR gender-specific questions were answered)	\$5,000	\$5,000
North Central/ 2173038	(b) (4)	B-1596-07	6 – Red Blood Cells Leukocytes Reduced	Donor eligibility (failure to defer donor who reported a positive test result for hepatitis)	\$5,000	\$75,000
		B-1597-07	4 – Platelets Leukocytes Reduced			
		B-1599-07	3 – Recovered Plasma			
		B-1598-07	2 – Frozen Plasma			
North Central/ 2173038	(b) (4)	B-0059-08	9 – Red Blood Cells (Apheresis) Leukocytes Reduced	Failure to control suspect blood component(s) (sterility may have been compromised)	\$5,000	\$45,000

Region/FEI	BPDR Number or ARC Problem Report Number	Recall Number	Number of Recalled Products/Product Type	Reason for Recall	Penalty Amount Per Blood Component	Total Penalty Amount
North Central/ 2173038	(b) (4)	B-1045-08	1 – Red Blood Cells Leukocytes Reduced	Donor eligibility (failure to defer donor for travel to a malarial risk area)	\$4,000	\$4,000
North Central/ 2173038	(b) (4)	B-1458-08	1 – Red Blood Cells Leukocytes Reduced	Donor eligibility (failure to defer donor for travel to a malarial risk area)	\$4,000	\$4,000
North Central/ 2173038	(b) (4)	B-1463-08	1 – Red Blood Cells	Donor eligibility (failure to defer donor for residence in a malarial risk area)	\$4,000	\$4,000
North Central/ 2173038	(b) (4)	B-1495-08	1 – Red Blood Cells Leukocytes Reduced	Donor eligibility (failure to defer donor for reporting history of hepatitis)	\$4,000	\$8,000
		B-1496-08	1 – Recovered Plasma			
North Central/ 2173038	(b) (4)	B-1508-08	1 – Red Blood Cells Leukocytes Reduced	Donor eligibility (failure to defer donor for residence in a malarial risk area)	\$4,000	\$8,000
		B-1509-08	1 – Platelets Leukocytes Reduced			
North Central/ 2173038	(b) (4)	B-1514-08	1 – Platelets Pheresis Leukocytes Reduced Irradiated	Quality control and distribution (failure to test for White Blood Cell count; product mislabeled)	\$4,000	\$4,000
Northeastern/ 2573018	(b) (4)	B-1320-07	4 – Red Blood Cells Leukocytes Reduced	Collection (hematocrit quality control was not acceptable)	\$4,000	\$16,000
Northeastern/ 2573018	(b) (4)	B-0129-08	1 – Red Blood Cells Leukocytes Reduced	Donor eligibility (failure to defer donor for travel to a malarial risk area)	\$5,000	\$5,000
Northeastern/ 2573018	(b) (4)	B-0248-08	1 – Red Blood Cells Leukocytes Reduced	Donor eligibility (incorrect gender assigned; incorrect BDR gender-specific questions were answered)	\$5,000	\$5,000
Northeastern/ 2573018	(b) (4)	B-1091-08	1 – Red Blood Cells Leukocytes Reduced	Donor eligibility (failure to defer donor for travel to a malarial risk area)	\$5,000	\$5,000
Northeastern/ 2573018	(b) (4)	B-1424-08	1 – Red Blood Cells Leukocytes Reduced	Donor eligibility (failure to defer donor for travel to a malarial risk area)	\$5,000	\$5,000

Region/FEI	BPDR Number or ARC Problem Report Number	Recall Number	Number of Recalled Products/Product Type	Reason for Recall	Penalty Amount Per Blood Component	Total Penalty Amount
Northeastern/ 2573018	(b) (4)	B-1432-08	1 – Red Blood Cells Leukocytes Reduced	Donor eligibility (incorrect gender assigned; incorrect BDR gender-specific questions were answered)	\$5,000	\$5,000
Northeastern/ 2573018	(b) (4)	B-1625-08	1 – Red Blood Cells Leukocytes Reduced	Donor eligibility (incorrect gender assigned; incorrect BDR gender-specific questions were answered)	\$5,000	\$5,000
Northeastern/ 2573018	(b) (4)	B-1628-08	1 – Red Blood Cells Leukocytes Reduced	Donor eligibility (incorrect gender assigned; incorrect BDR gender-specific questions were answered)	\$5,000	\$5,000
Northeastern/ 2573018	(b) (4)	B-1678-08	1 – Red Blood Cells Leukocytes Reduced	Donor eligibility (incorrect gender assigned; incorrect BDR gender-specific questions were answered)	\$5,000	\$5,000
Northern California/ 2971430	(b) (4)	B-1601-08	1 – Red Blood Cells Leukocytes Reduced	Donor eligibility (failure to defer donor for travel to a malarial risk area)	\$4,000	\$4,000
Northern California/ 2971430	(b) (4)	B-1602-08	2 – Red Blood Cells Leukocytes Reduced	Donor eligibility (failure to defer donor for travel to a malarial risk area)	\$4,000	\$8,000
Northern California/ 2971430	(b) (4)	B-1603-08	1 – Red Blood Cells Leukocytes Reduced	Donor eligibility (failure to defer donor for travel to a malarial risk area)	\$4,000	\$4,000

Region/FEI	BPDR Number or ARC Problem Report Number	Recall Number	Number of Recalled Products/Product Type	Reason for Recall	Penalty Amount Per Blood Component	Total Penalty Amount
Northern Ohio/ 1573019	(b) (4)	B-0235-7	10 – Platelets Pheresis Leukocytes Reduced	Storage/shipping (blood components may have been shipped at unacceptable temperatures)	\$4,000	\$52,000
		B-0236-7	3 – Platelets Pheresis Leukocytes Reduced Irradiated			
Penn Jersey/ 2573021	(b) (4)	B-1644-6	2 – Platelets Pheresis Leukocytes Reduced	Donor eligibility (BDR question related to CJD was unanswered)	\$4,000	\$8,000
Penn Jersey/ 2573021	(b) (4)	B-1676-6	1 – Platelets Pheresis Leukocytes Reduced	Failure to control suspect blood component(s) (product distributed prior to resolution of a quality control failure for platelet yield)	\$5,000	\$5,000
Penn Jersey/ 2573021	(b) (4)	B-1717-6	1 – Red Blood Cells Leukocytes Reduced	Donor eligibility (failure to defer donor for travel to a malarial risk area)	\$4,000	\$8,000
		B-1718-6	1 – Platelets Leukocytes Reduced			
Penn Jersey/ 2573021	(b) (4)	B-0139-7	1 – Red Blood Cells Leukocytes Reduced	Donor eligibility (failure to defer donor for travel to a malarial risk area)	\$5,000	\$10,000
		B-0140-7	1 – Platelets Leukocytes Reduced			
Penn Jersey/ 2573021	(b) (4)	B-0321-7	1 – Red Blood Cells Leukocytes Reduced	Donor eligibility (failure to defer donor for travel to a malarial risk area)	\$5,000	\$5,000
Penn Jersey/ 2573021	(b) (4)	B-0352-7	2 - Red Blood Cells	Collection (inadequate arm prep; sterility may have been compromised)	\$5,000	\$325,000
		B-0353-7	35 – Red Blood Cells Leukocytes Reduced			
		B-0354-7	17 – Platelets Leukocytes Reduced			
		B-0355-7	11 – Fresh Frozen Plasma			

Region/FEI	BPDR Number or ARC Problem Report Number	Recall Number	Number of Recalled Products/Product Type	Reason for Recall	Penalty Amount Per Blood Component	Total Penalty Amount
Penn Jersey/ 2573021	(b) (4)	B-0550-07	1 – Red Blood Cells Leukocytes Reduced Irradiated	Donor eligibility (BDR questions unanswered)	\$4,000	\$4,000
Penn Jersey/ 2573021	(b) (4)	B-0756-07	141 – Red Blood Cells Leukocytes Reduced	Collection (inadequate arm prep; sterility may have been compromised)	\$5,000 for each of 100 blood components	\$500,000
		B-0757-07	5 – Red Blood Cells			
		B-0758-07	2 – Red Blood Cells Leukocytes Reduced Irradiated			
		B-0759-07	13 – Whole Blood			
		B-0760-07	51 – Cryoprecipitated AHF			
		B-0761-07	8 – Platelets Leukocytes Reduced			
		B-0762-07	123 – Fresh Frozen Plasma			
		B-0763-07	29 – Plasma Frozen Within 24 Hours			
		B-0764-07	7 – Plasma Cryoprecipitate Reduced			

Region/FEI	BPDR Number or ARC Problem Report Number	Recall Number	Number of Recalled Products/Product Type	Reason for Recall	Penalty Amount Per Blood Component	Total Penalty Amount
Penn Jersey/ 2573021	(b) (4)	B-0876-07	42 – Red Blood Cells	Collection (inadequate arm prep; sterility may have been compromised)	\$5,000 for each of 100 blood components	\$500,000
		B-0877-07	1 – Red Blood Cells (Apheresis)			
		B-0878-07	30 – Red Blood Cells Leukocytes Reduced			
		B-0879-07	1 – Red Blood Cells Leukocytes Reduced Irradiated			
		B-0880-07	2 – Platelets Leukocytes Reduced			
		B-0881-07	8 – Platelets Pheresis Leukocytes Reduced			
		B-0882-07	434 – Fresh Frozen Plasma			
		B-0883-07	85 – Cryoprecipitated AHF			
		B-0884-07	42 – Plasma Frozen Within 24 Hours			
		B-0885-07	25 - Plasma Frozen Cryoprecipitate Reduced			
Penn Jersey/ 2573021	(b) (4)	B-0905-07	1600 – Platelets Leukocytes Reduced	Quality control and distribution (product with unacceptable product quality control)	\$4,000 for each of 100 blood components	\$400,000
		B-0906-07	55 – Platelets Leukocytes Reduced Irradiated			
Penn Jersey/ 2573021	(b) (4)	B-1257-07	893 – Platelets Leukocytes Reduced	Component preparation (plateletpheresis product did not meet specification for platelet yield)	\$4,000 for each of 100 blood components	\$400,000
Penn Jersey/ 2573021	(b) (4)	B-1298-07	1 – Red Blood Cells Leukocytes Reduced	Donor eligibility (failure to defer donor for travel to a malarial risk area)	\$5,000	\$5,000
Penn Jersey/ 2573021	(b) (4)	B-1363-07	1 – Red Blood Cells Leukocytes Reduced	Donor eligibility (failure to defer donor who was previous HIV positive)	\$5,000	\$15,000

Region/FEI	BPDR Number or ARC Problem Report Number	Recall Number	Number of Recalled Products/Product Type	Reason for Recall	Penalty Amount Per Blood Component	Total Penalty Amount
		B-1364-07	1 – Cryoprecipitated AHF			
		B-1365-07	1 – Plasma Frozen Cryoprecipitate Reduced			
Penn Jersey/ 2573021	(b) (4)	B-0348-08	1 – Fresh Frozen Plasma	Donor eligibility (incorrect gender assigned; incorrect BDR gender-specific questions were answered)	\$5,000	\$10,000
		B-0349-08	1 – Red Blood Cells Leukocytes Reduced			
Penn Jersey/ 2573021	(b) (4)	B-0350-08	1 – Cryoprecipitated AHF	Donor eligibility (incorrect gender assigned; incorrect BDR gender-specific questions were answered)	\$5,000	\$20,000
		B-0351-08	2 – Red Blood Cells Leukocytes Reduced			
		B-0352-08	1 – Platelets Leukocytes Reduced			
Penn Jersey/ 2573021	(b) (4)	B-0354-08	1 – Red Blood Cells Leukocytes Reduced	Donor eligibility (failure to defer donor who was previous HIV positive)	\$5,000	\$10,000
		B-0355-08	1 – Platelets Leukocytes Reduced			

Region/FEI	BPDR Number or ARC Problem Report Number	Recall Number	Number of Recalled Products/Product Type	Reason for Recall	Penalty Amount Per Blood Component	Total Penalty Amount
Penn Jersey/ 2573021	(b) (4)	B-0357-08	1 – Red Blood Cells Leukocytes Reduced	Donor eligibility (incorrect gender assigned; incorrect BDR gender-specific questions were answered)	\$5,000	\$10,000
		B-0358-08	1 – Platelets Leukocytes Reduced			
Penn Jersey/ 2573021	(b) (4)	B-0400-08	2 – Red Blood Cells Leukocytes Reduced Irradiated	Component preparation (irradiation not performed in accordance with specifications)	\$4,000	\$8,000
Penn Jersey/ 2573021	(b) (4)	B-0406-08	2 – Red Blood Cells (Apheresis) Leukocytes Reduced	Quality control and distribution (failure to perform quality control testing on product)	\$4,000	\$8,000
Penn Jersey/ 2573021	(b) (4)	B-0487-08	1 – Cryoprecipitated AHF	Donor eligibility (incorrect gender assigned; incorrect BDR gender-specific questions were answered)	\$5,000	\$15,000
		B-0488-08	1 – Red Blood Cells Leukocytes Reduced			
		B-0489-08	1 – Plasma Cryoprecipitate Reduced			
Penn Jersey/ 2573021	(b) (4)	B-0610-08	1 – Red Blood Cells Leukocytes Reduced	Donor eligibility (incorrect gender assigned; incorrect BDR gender-specific questions were answered)	\$5,000	\$10,000
		B-0611-08	1 – Fresh Frozen Plasma			
Penn Jersey/ 2573021	(b) (4)	B-0661-08	1 – Red Blood Cells Leukocytes Reduced	Donor eligibility (incorrect gender assigned; incorrect BDR gender-specific questions were answered)	\$5,000	\$5,000
Penn Jersey/ 2573021	(b) (4)	B-0679-08	1 – Red Blood Cells Leukocytes Reduced	Donor eligibility (incorrect gender assigned; incorrect BDR gender-specific questions were answered)	\$5,000	\$5,000
Penn Jersey/ 2573021	(b) (4)	B-0681-08	1 – Fresh Frozen Plasma	Donor eligibility (incorrect gender assigned; incorrect BDR gender-specific questions were answered)	\$5,000	\$15,000
		B-0682-08	1 – Red Blood Cells Leukocytes Reduced			
		B-0683-08	1 – Platelets Leukocytes Reduced			

Region/FEI	BPDR Number or ARC Problem Report Number	Recall Number	Number of Recalled Products/Product Type	Reason for Recall	Penalty Amount Per Blood Component	Total Penalty Amount
Penn Jersey/ 2573021	(b) (4)	B-1004-08	108 – Fresh Frozen Plasma	Collection (inadequate arm prep; sterility may have been compromised)	\$5,000 for each of 100 blood components	\$500,000
		B-1005-08	192 – Red Blood Cells Leukocytes Reduced			
		B-1006-08	80 – Platelets Leukocytes Reduced			
		B-1007-08	7 – Red Blood Cells Leukocytes Reduced Irradiated			
		B-1008-08	7 – Red Blood Cells			
		B-1009-08	4 – Whole Blood CPD			
		B-1010-08	6 – Whole Blood CPDA-1			
		B-1011-08	44 – Cryoprecipitated AHF			
		B-1012-08	12 – Platelets Pooled Leukocytes Reduced			
		B-1013-08	5 – Plasma Frozen Within 24 Hours			
		B-1014-08	1 – Plasma Cryoprecipitate Reduced			
Penn Jersey/ 2573021	(b) (4)	B-1156-08	1 – Red Blood Cells Leukocytes Reduced	Donor eligibility (incorrect gender assigned; incorrect BDR gender-specific questions were answered)	\$5,000	\$10,000
		B-1157-08	1 – Platelets Leukocytes Reduced			
Penn Jersey/ 2573021	(b) (4)	B-1636-08	2 – Red Blood Cells Leukocytes Reduced	Donor eligibility (incorrect gender assigned; incorrect BDR gender-specific questions were answered)	\$5,000	\$15,000
		B-1637-08	1 – Cryoprecipitated AHF			
Penn Jersey/ 2573021	(b) (4)	B-1674-08	1 – Red Blood Cells Leukocytes Reduced	Donor eligibility (incorrect gender assigned; incorrect BDR gender-specific questions were answered)	\$5,000	\$15,000
		B-1675-08	1 – Fresh Frozen Plasma			
		B-1676-08	1 – Platelets Leukocytes Reduced			
Penn Jersey/ 2573021	(b) (4)	B-2043-08	1 – Red Blood Cells Leukocytes Reduced	Donor eligibility (incorrect gender assigned; incorrect BDR gender-specific questions were answered)	\$5,000	\$10,000
		B-2044-08	1 – Plasma Frozen			

Region/FEI	BPDR Number or ARC Problem Report Number	Recall Number	Number of Recalled Products/Product Type	Reason for Recall	Penalty Amount Per Blood Component	Total Penalty Amount
Puerto Rico/2675945	(b) (4)	B-1873-08	51 – Red Blood Cells Leukocytes Reduced	Donor eligibility (failure to defer donor for travel to a malarial risk area)	\$4,000	\$208,000
		B-1874-08	1 – Platelets Pheresis Leukocytes Reduced			
Puerto Rico/2675945	(b) (4)	B-1916-08	1 – Red Blood Cells Leukocytes Reduced	Donor eligibility (BDR question related to HIV high risk behavior was unanswered)	\$5,000	\$5,000
Puerto Rico/2675945	(b) (4)	B-1917-08	1 – Recovered Plasma	Donor eligibility (BDR question related to exposure to another person’s blood was unanswered)	\$4,000	\$4,000
South Carolina/1073009	(b) (4)	B-0096-08	1 – Fresh Frozen Plasma	Donor eligibility (inadequate donor screening related to gender-specific questions and travel in a CJD risk area)	\$4,000	\$12,000
		B-0097-08	2 – Red Blood Cells Leukocytes Reduced			
South Carolina/1073009	(b) (4)	B-0469-08	1 – Red Blood Cells Leukocytes Reduced Irradiated	Storage/shipping (product may have been out of controlled storage for greater than 30 minutes)	\$4,000	\$4,000
Southeastern/1873044	(b) (4)	B-1545-08	2 – Red Blood Cells Leukocytes Reduced	Donor eligibility (incorrect gender assigned; incorrect BDR gender-specific questions were answered)	\$5,000	\$10,000
Southeastern/1873044	(b) (4)	B-1722-08	1 – Red Blood Cells Leukocytes Reduced	Donor eligibility (failure to defer donor for travel in malarial risk area)	\$5,000	\$10,000
		B-1723-08	1 – Platelets Leukocytes Reduced			
Southern/1073000	(b) (4)	B-1682-6	1 – Red Blood Cells Leukocytes Reduced	Donor eligibility (donor’s hemoglobin was unacceptable and the hematocrit determination was not performed)	\$4,000	\$4,000
Southern/1073000	(b) (4)	B-0066-08	1 – Red Blood Cells Leukocytes Reduced	Donor eligibility (incorrect gender assigned; incorrect BDR gender-specific questions were answered)	\$5,000	\$10,000
		B-0067-08	1 – Plasma Frozen			
Southern/1073000	(b) (4)	B-0085-08	1 – Red Blood Cells Leukocytes Reduced	Donor eligibility (incorrect gender assigned; incorrect BDR gender-specific questions were answered)	\$5,000	\$5,000

Region/FEI	BPDR Number or ARC Problem Report Number	Recall Number	Number of Recalled Products/Product Type	Reason for Recall	Penalty Amount Per Blood Component	Total Penalty Amount
Southern/1073000	(b) (4)	B-0280-08	1 – Red Blood Cells Leukocytes Reduced	Donor eligibility (failure to defer donor for travel to a malarial risk area)	\$5,000	\$5,000
Southern/1073000	(b) (4)	B-0306-08	1 – Red Blood Cells Leukocytes Reduced	Donor eligibility (incorrect gender assigned; incorrect BDR gender-specific questions were answered)	\$5,000	\$10,000
		B-0307-08	1 – Plasma Frozen			
Southern/1073000	(b) (4)	B-0308-08	5 – Red Blood Cells Leukocytes Reduced	Donor eligibility (failure to defer donor for travel to a malarial risk area)	\$5,000	\$25,000
Southern/1073000	(b) (4)	B-0325-08	1 – Red Blood Cells Leukocytes Reduced	Donor eligibility (incorrect gender assigned; incorrect BDR gender-specific questions were answered)	\$5,000	\$5,000
Southern/1073000	(b) (4)	B-0570-08	1 – Red Blood Cells Leukocytes Reduced	Donor eligibility (incorrect gender assigned; incorrect BDR gender-specific questions were answered)	\$5,000	\$5,000
Southern/1073000	(b) (4)	B-0573-08	1 – Red Blood Cells Leukocytes Reduced	Donor eligibility (incorrect gender assigned; incorrect BDR gender-specific questions were answered)	\$5,000	\$10,000
		B-0574-08	1 – Plasma Frozen			
Southern/1073000	(b) (4)	B-1325-08	1 – Red Blood Cells Leukocytes Reduced	Donor eligibility (inadequate donor screening)	\$5,000	\$5,000
Southwest/1673040	(b) (4)	B-0186-08	1 – Red Blood Cells Leukocytes Reduced	Donor eligibility (incorrect gender assigned; incorrect BDR gender-specific questions were answered)	\$5,000	\$5,000
Southwest/1673040	(b) (4)	B-0410-08	1 – Red Blood Cells Leukocytes Reduced	Donor eligibility (failure to defer donor for travel to a malarial risk area)	\$5,000	\$5,000
Southwest/1673040	(b) (4)	B-0419-08	1 – Platelets Pheresis Leukocytes Reduced Irradiated	Collection (sterility may have been compromised)	\$5,000	\$5,000

Region/FEI	BPDR Number or ARC Problem Report Number	Recall Number	Number of Recalled Products/Product Type	Reason for Recall	Penalty Amount Per Blood Component	Total Penalty Amount
Southwest/ 1673040	(b) (4)	B-0516-08	93 – Red Blood Cells Leukocytes Reduced	Collection (sterility may have been compromised and failure to follow manufacturer’s instructions)	\$5,000 for each of 100 blood components	\$500,000
		B-0517-08	72 – Fresh Frozen Plasma			
		B-0518-08	53 – Platelets Leukocytes Reduced			
		B-0519-08	1 – Red Blood Cells Leukocytes Reduced Irradiated			
Southwest/ 1673040	(b) (4)	B-0520-08	62 – Red Blood Cells Leukocytes Reduced	Collection (sterility may have been compromised and failure to follow manufacturer’s instructions)	\$5,000 for each of 100 blood components	\$500,000
		B-0521-08	40 – Fresh Frozen Plasma			
		B-0522-08	31 – Platelets Leukocytes Reduced			
		B-0523-08	5 – Red Blood Cells Leukocytes Reduced Irradiated			
Southwest/ 1673040	(b) (4)	B-0524-08	1 – Platelets Pheresis Leukocytes Reduced	Donor eligibility (failure to defer donor for travel to a malarial risk area)	\$5,000	\$5,000
Southwest/ 1673040	(b) (4)	B-0526-08	1 – Red Blood Cells Leukocytes Reduced	Donor eligibility (failure to defer donor for travel to a malarial risk area)	\$4,000	\$4,000
Southwest/ 1673040	(b) (4)	B-0528-08	1 – Red Blood Cells Leukocytes Reduced	Donor eligibility (incorrect gender assigned; incorrect BDR gender-specific questions were answered)	\$5,000	\$10,000
		B-0529-08	1 – Plasma Frozen			
Southwest/ 1673040	(b) (4)	B-0553-08	1 – Red Blood Cells Leukocytes Reduced	Donor eligibility (incorrect gender assigned; incorrect BDR gender-specific questions were answered)	\$5,000	\$5,000
Southwest/ 1673040	(b) (4)	B-0555-08	1 – Red Blood Cells Leukocytes Reduced	Donor eligibility (incorrect gender assigned; incorrect BDR gender-specific questions were answered)	\$5,000	\$5,000
Southwest/ 1673040	(b) (4)	B-0557-08	1 – Platelets Pheresis Leukocytes Reduced	Component preparation (platelet yield too high for storage in a single bag)	\$4,000	\$4,000

Region/FEI	BPDR Number or ARC Problem Report Number	Recall Number	Number of Recalled Products/Product Type	Reason for Recall	Penalty Amount Per Blood Component	Total Penalty Amount
Southwest/1673040	(b) (4)	B-0561-08	1 – Red Blood Cells Leukocytes Reduced	Donor eligibility (incorrect gender assigned; incorrect BDR gender-specific questions were answered)	\$5,000	\$5,000
Southwest/1673040	(b) (4)	B-0590-08	1 – Red Blood Cells Leukocytes Reduced	Donor eligibility (incorrect gender assigned; incorrect BDR gender-specific questions were answered)	\$5,000	\$5,000
Southwest/1673040	(b) (4)	B-0648-08	1 – Red Blood Cells Leukocytes Reduced	Donor eligibility (incorrect gender assigned; incorrect BDR gender-specific questions were answered)	\$5,000	\$5,000
Southwest/1673040	(b) (4)	B-0787-08	1 – Red Blood Cells Leukocytes Reduced	Donor eligibility (failure to defer donor for travel to a malarial risk area)	\$4,000	\$4,000
Southwest/1673040	(b) (4)	B-1069-08	42 – Platelets Pheresis Leukocytes Reduced	Collection (products collecting using apheresis kits that had exceeded the acceptable time period for use)	\$4,000	\$188,000
		B-1070-08	5 – Platelets Pheresis Leukocytes Reduced Irradiated			
Tennessee Valley/1073006	(b) (4)	B-1449-07	2 – Red Blood Cells Leukocytes Reduced	Donor eligibility (failure to defer donor for travel to a malarial risk area)	\$5,000	\$10,000
Tennessee Valley/1073006	(b) (4)	B-1499-07	2 – Red Blood Cells (Apheresis) Leukocytes Reduced	Collection (products collected using apheresis kits that had exceed the acceptable time period for use)	\$4,000	\$8,000
Tennessee Valley/1073006	(b) (4)	B-0176-08	1 – Platelets Leukocytes Reduced Irradiated	Collection (inadequate arm prep; sterility may have been compromised)	\$5,000	\$5,000
Tennessee Valley/1073006	(b) (4)	B-0654-08	1 – Fresh Frozen Plasma	Donor eligibility (incorrect gender assigned; incorrect BDR gender-specific questions were answered)	\$5,000	\$15,000
		B-0655-08	1 – Red Blood Cells Leukocytes Reduced			
		B-0656-08	1 - Platelets Leukocytes Reduced			
Tennessee Valley/1073006	(b) (4)	B-0722-08	4 – Red Blood Cells Leukocytes Reduced	Donor eligibility (failure to defer donor for travel to a malarial risk area)	\$5,000	\$40,000

Region/FEI	BPDR Number or ARC Problem Report Number	Recall Number	Number of Recalled Products/Product Type	Reason for Recall	Penalty Amount Per Blood Component	Total Penalty Amount
		B-0723-08	4 – Platelets Leukocytes Reduced			
Tennessee Valley/1073006	(b) (4)	B-0749-08	5 – Red Blood Cells Leukocytes Reduced	Collection (inadequate arm prep; sterility may have been compromised)	\$5,000	\$25,000
Tennessee Valley/1073006	(b) (4)	B-0750-08	10 – Red Blood Cells Leukocytes Reduced	Collection (inadequate arm prep; sterility may have been compromised)	\$5,000	\$110,000
		B-0751-08	11 – Platelets			
		B-0752-08	1 – Fresh Frozen Plasma			
Tennessee Valley/1073006	(b) (4)	B-0853-08	1 – Red Blood Cells Leukocytes Reduced	Donor eligibility (incorrect gender assigned; incorrect BDR gender-specific questions were answered)	\$5,000	\$5,000
Tennessee Valley/1073006	(b) (4)	B-1392-08	1 – Red Blood Cells Leukocytes Reduced	Failure to control suspect blood component(s) (inappropriate release of blood components that should have been discarded because donor was taking Coumadin)	\$5,000	\$5,000
Tennessee Valley/1073006	(b) (4)	B-1398-08	1 – Red Blood Cells Leukocytes Reduced	Donor eligibility (incorrect gender assigned; incorrect BDR gender-specific questions were answered)	\$5,000	\$5,000

Region/FEI	BPDR Number or ARC Problem Report Number	Recall Number	Number of Recalled Products/Product Type	Reason for Recall	Penalty Amount Per Blood Component	Total Penalty Amount
Tennessee Valley/ 1073006	(b) (4)	B-1412-08	1 – Fresh Frozen Plasma	Donor eligibility (incorrect gender assigned; incorrect BDR gender-specific questions were answered)	\$5,000	\$10,000
		B-1413-08	1 – Red Blood Cells Leukocytes Reduced			
Tennessee Valley/ 1073006	(b) (4)	B-1829-08	112 – Red Blood Cells Leukocytes Reduced	Collection (inadequate arm prep; sterility may have been compromised)	\$5,000 for each of 100 blood components	\$500,000
		B-1830-08	42 – Platelets Leukocytes Reduced			
		B-1831-08	24 – Fresh Frozen Plasma			
Tennessee Valley/ 1073006	(b) (4)	B-2032-08	1 – Red Blood Cells Leukocytes Reduced	Failure to control suspect blood component(s) (failure to quarantine component after discovery that donor had traveled to a malarial risk area)	\$5,000	\$5,000
Tennessee Valley/ 1073006	(b) (4)	B-2064-08	1 – Fresh Frozen Plasma	Donor eligibility (incorrect gender assigned; incorrect BDR gender-specific questions were answered)	\$5,000	\$25,000
		B-2065-08	2 – Red Blood Cells Leukocytes Reduced			
		B-2066-08	2 – Platelets Leukocytes Reduced			
Tennessee Valley/ 1073006	(b) (4)	B-2067-08	1 – Fresh Frozen Plasma	Donor eligibility (incorrect gender assigned; incorrect BDR gender-specific questions were answered)	\$5,000	\$10,000
		B-2068-08	1 – Red Blood Cells Leukocytes Reduced			
Tennessee Valley/ 1073006	(b) (4)	B-2070-08	1 – Fresh Frozen Plasma	Donor eligibility (incorrect gender assigned; incorrect BDR gender-specific questions were answered)	\$5,000	\$20,000
		B-2071-08	3 – Red Blood Cells Leukocytes Reduced			
						\$9,776,000