



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Baltimore District Office
Central Region
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October 30, 2009

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*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 has recently completed a review of its database and files to identify classified² recalls conducted by ARC. We focused on the recalls that occurred from April 15, 2003, through September 30, 2008. This Adverse Determination Letter (ADL) does not include any classified recalls previously identified in the May 16, 2005, September 7, 2006, or February 6, 2008 ADLs. Furthermore, this ADL includes only those recall events classified by FDA as of September 30, 2008; therefore, this ADL does not necessarily include all events that occurred during the specified time period. After further FDA review, we may

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.

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).

identify additional recall events that occurred during the aforementioned time period but are not included in this or previous ADLs.

FDA's review identified 231 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 7,363 unsuitable blood components.

FDA regards the violations discussed in this letter to be significant. We are continuing our evaluation of fines and alternate or additional regulatory measures, and our decision on those matters will be communicated to you separately. However, we decided to send you this ADL at this time to notify you of the violations that we found so that you would take appropriate action to address them.

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 and submit a plan to do so. If ARC disagrees with FDA's adverse determination, it shall respond in writing within twenty (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 Karen Midthun, M.D., Acting Director, Center for Biologics Evaluation and Research, 1401 Rockville Pike, Suite 200N, Rockville, Maryland 20852.

Sincerely yours,



Evelyn Bonnin
Director, Baltimore District

Enclosure

cc: Ms. Gail McGovern
President and CEO
American National Red Cross
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Eva Quinley
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Bonnie McElveen-Hunter
Chairman, Board of Governors
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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 further FDA review, we may identify additional recall 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
Alabama/ 1073001	(b) (4)	B-0711-08	1 – Red Blood Cells	Collection (inadequate arm prep; sterility may have been compromised)
		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	
Alabama/ 1073001	(b) (4)	B-1800-08	633 – Red Blood Cells Leukocytes Reduced	Collection (inadequate arm prep; sterility may have been compromised)
		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)
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)
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)
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)
		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’)
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)
		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)
		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)
Carolinas/ 1073007	(b) (4)	B-0063-08	1 – Fresh Frozen Plasma	Donor eligibility (incorrect gender assigned; incorrect BDR gender-specific questions were answered)
		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)
Carolinas/ 1073007	(b) (4)	B-0076-08	2 – Fresh Frozen Plasma	Collection (inadequate arm prep; sterility may have been compromised)
		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)
		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)

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)
Carolinas/ 1073007	(b) (4)	B-0163-08	237 – Red Blood Cells Leukocytes Reduced	Testing (failure to perform syphilis testing properly)
		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)
		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)
Carolinas/ 1073007	(b) (4)	B-0321-08	1 – Cryoprecipitated AHF	Donor eligibility (incorrect gender assigned; incorrect BDR gender-specific questions were answered)
		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)

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)
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)
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)
Carolinas/ 1073007	(b) (4)	B-0572-08	2 – Red Blood Cells (Apheresis)	Quality control and distribution (product did not meet specifications)
Carolinas/ 1073007	(b) (4)	B-0693-08	1 – Red Blood Cells (Apheresis) Leukocytes Reduced	Component preparation (distribution of low volume unit)
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)
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)
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)
		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)
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)
Carolinas/ 1073007	(b) (4)	B-1088-08	1 – Fresh Frozen Plasma	Donor eligibility (incorrect gender assigned; incorrect BDR gender-specific questions were answered)
		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)
Carolinas/ 1073007	(b) (4)	B-1476-08	1 – Platelets Pheresis Leukocytes Reduced	Donor eligibility (incorrect gender assigned; incorrect BDR gender-specific questions were answered)
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)
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)
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)
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)
Central Plains/1973042	(b) (4)	B-0417-08	1 – Red Blood Cells Leukocytes Reduced	Donor eligibility (failure to defer donor for receiving tattoo)
		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)
		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)

Connecticut/ 1273014	(b) (4)	B-0694-07	4 – Red Blood Cells (Apheresis) Leukocytes Reduced	Component preparation (failure to perform required product quality control testing)
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)
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)
		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)
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)
		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)
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)
Great Lakes/ 1873033	(b) (4)	B-1331-08	1 – Fresh Frozen Plasma	Donor eligibility (incorrect gender assigned; incorrect BDR gender-specific questions were answered)
		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)
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)
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)
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)
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)
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)
Greater Alleghenies/ 2573016	(b) (4)	B-0785-6	1 – Red Blood Cells Leukocytes Reduced	Donor eligibility (BDR question related to CJD was unanswered)
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)
		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)

Greater Alleghenies/ 2573016	(b) (4)	B-1787-6	1 – Red Blood Cells (Apheresis) Leukocytes Reduced	Collection (sterility may have been compromised)
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)
		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)
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)
		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)
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)
		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)
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)

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)
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)
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)
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)
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)
		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)
		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)
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)

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)
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)
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)
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)
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)
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)
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)
		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)
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)

		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)
Heart of America/ 1473043	(b) (4)	B-1144-6	1 - Red Blood Cells Leukocytes Reduced	Collection (inadequate arm prep; sterility may have been compromised)
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)
		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)
		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)
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)
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)
Heart of America/ 1473043	(b) (4)	B-0087-08	1 - Platelets Pheresis Leukocytes Reduced Irradiated	Component preparation (irradiation not performed in accordance with specifications)

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)
Heart of America/ 1473043	(b) (4)	B-0268-08	118 – Cryoprecipitated AHF	Collection (inadequate arm prep; sterility may have been compromised)
		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)
		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)
		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)
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)

		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)
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)
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)
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)
Mid Atlantic/ 1173024	(b) (4)	B-1388-07	1 – Red Blood Cells	Donor eligibility (incorrect gender assigned; incorrect BDR gender-specific questions were answered)
Mid Atlantic/ 1173024	(b) (4)	B-1433-07	1 – Red Blood Cells Leukocytes Reduced	Collection (inadequate arm prep; sterility may have been compromised)
Mid Atlantic/ 1173024	(b) (4)	B-1427-08	14 – Red Blood Cells Leukocytes Reduced	Collection (sterility may have been compromised)
Mid Atlantic/ 1173024	(b) (4)	B-1513-08	1 – Red Blood Cells	Donor eligibility (incorrect gender assigned; incorrect BDR gender-specific questions were answered)
Mid Atlantic/ 1173024	(b) (4)	B-1580-08	1 – Red Blood Cells Leukocytes Reduced	Collection (inadequate arm prep; sterility may have been compromised)
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)
New England/ 1270026	(b) (4)	B-1612-6	2 – Red Blood Cells Leukocytes Reduced	Collection (sterility may have been compromised)

		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)
New England/ 1270026	(b) (4)	B-0786-07	1 – Platelets Pheresis Leukocytes Reduced	Collection (inadequate arm prep; sterility may have been compromised)
		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)
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)
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)
New England/ 1270026	(b) (4)	B-0635-08	3 – Red Blood Cells	Donor eligibility (incorrect gender assigned; incorrect BDR gender-specific questions were answered)
		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)
		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	
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)
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)
		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)
		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)
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)
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)
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)
New England/ 1270026	(b) (4)	B-0917-08	2 – Red Blood Cells	Donor eligibility (incorrect gender assigned; incorrect BDR gender-specific questions were answered)
		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	
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)
		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)
		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)
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)
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)
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)
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)
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)
		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)
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)
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)
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)
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)
		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)
		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)
Northeastern/ 2573018	(b) (4)	B-1320-07	4 – Red Blood Cells Leukocytes Reduced	Collection (hematocrit quality control was not acceptable)
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)
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)

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)
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)
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)
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)
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)
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)
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)
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)
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)
Northern Ohio/ 1573019	(b) (4)	B-0235-7	10 – Platelets Pheresis Leukocytes Reduced	Storage/shipping (blood components may have been shipped at unacceptable temperatures)
		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) [REDACTED]
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)
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)
		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)
		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)
Penn Jersey/ 2573021	(b) (4)	B-0352-7	2 - Red Blood Cells	Collection (inadequate arm prep; sterility may have been compromised)
		B-0353-7	35 – Red Blood Cells Leukocytes Reduced	
		B-0354-7	17 – Platelets Leukocytes Reduced	
		B-0355-7	11 – Fresh Frozen Plasma	
Penn Jersey/ 2573021	(b) (4)	B-0550-07	1 – Red Blood Cells Leukocytes Reduced Irradiated	Donor eligibility (BDR questions unanswered)
Penn Jersey/ 2573021	(b) (4)	B-0756-07	141 – Red Blood Cells Leukocytes Reduced	Collection (inadequate arm prep; sterility may have been compromised)
		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	
Penn Jersey/ 2573021	(b) (4)	B-0876-07	42 – Red Blood Cells	Collection (inadequate arm prep; sterility may have been compromised)
		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)
		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)
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)
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)
		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)
		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)
		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)

		B-0355-08	1 – Platelets Leukocytes Reduced	
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)
		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)
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)
Penn Jersey/ 2573021	(b) (4)	B-0487-08	1 – Cryoprecipitated AHF	Donor eligibility (incorrect gender assigned; incorrect BDR gender-specific questions were answered)
		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)
		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)
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)
Penn Jersey/ 2573021	(b) (4)	B-0681-08	1 – Fresh Frozen Plasma	Donor eligibility (incorrect gender assigned; incorrect BDR gender-specific questions were answered)
		B-0682-08	1 – Red Blood Cells Leukocytes Reduced	

		B-0683-08	1 – Platelets Leukoctyes Reduced	
Penn Jersey/ 2573021	(b) (4)	B-1004-08	108 – Fresh Frozen Plasma	Collection (inadequate arm prep; sterility may have been compromised)
		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)
		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)
		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)
		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)
		B-2044-08	1 – Plasma Frozen	
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)
		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)
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)
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)
		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)
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)
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)
		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)
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)
		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)
Southern/ 1073000	(b) (4)	B-0101-08	1 – Red Blood Cells Leukocytes Reduced	Donor eligibility (incorrect gender assigned; incorrect BDR gender-specific questions were answered)
		B-0102-08	1 – Cryoprecipitated AHF	
		B-0103-08	1 – Plasma Cryoprecipitate Reduced	
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)
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)
		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)
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)
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)

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)
		B-0574-08	1 – Plasma Frozen	
Southern/ 1073000	(b) (4)	B-1325-08	1 – Red Blood Cells Leukocytes Reduced	Donor eligibility (inadequate donor screening)
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)
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)
Southwest/ 1673040	(b) (4)	B-0419-08	1 – Platelets Pheresis Leukocytes Reduced Irradiated	Collection (sterility may have been compromised)
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)
		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)
		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)
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)
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)
		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)
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)
Southwest/ 1673040	(b) (4)	B-0557-08	1 – Platelets Pheresis Leukocytes Reduced	Component preparation (platelet yield too high for storage in a single bag)
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)
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)
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)
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)
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)

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)
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)
Tennessee Valley/ 1073006	(b) (4)	B-1412-08	1 – Fresh Frozen Plasma	Donor eligibility (incorrect gender assigned; incorrect BDR gender-specific questions were answered)
		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)
		B-1830-08	42 – Platelets Leukocytes Reduced	
		B-1831-08	24 – Fresh Frozen Plasma	
Tennessee Valley/ 1073006	(b) (4)	B-1947-08	1 – Red Blood Cells Leukocytes Reduced	Donor eligibility (incorrect gender assigned; incorrect BDR gender-specific questions were answered)
		B-1948-08	1 – Red Blood Cells Leukocytes Reduced Irradiated	
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)
Tennessee Valley/ 1073006	(b) (4)	B-2064-08	1 – Fresh Frozen Plasma	Donor eligibility (incorrect gender assigned; incorrect BDR gender-specific questions were answered)
		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)