RECALLS AND FIELD CORRECTIONS: FOODS - CLASS I

PRODUCT
1) Great Value Half & Half 32 fl oz (1 qt) 946mL Product # 1871600, UPC: 605388187161; IMS Plant code: 21-031. Recall # F-0969-2010;

2) Great Value Heavy Whipping Cream Net 32 fl oz (1 qt) 946mL, Product # 1871800, UPC: 605388187185; IMS Plant Code: 21-031. Recall # F-0970-2010;

3) Kroger Heavy Whipping Cream One Quart-946mL, Product #4382900, UPC: 011110438287; IMS Plant Code 21-031. Recall # F-0971-2010;

4) Wholesome Farms Chocolate Reduced Fat Ice Cream, Net 64 fl oz (1.89L) Keep Refrigerated 33-40 F, Product #5798300, Carton UPC: 074865579834. Recall # F-0972-2010

CODE
1) Lot code: Dec169YD30, Expiration date: 12/16/09;

2) Lot codes: DEC169YB39 and DEC169YC27, Expiration date: 12/16/09;

3) Lot codes: DEC169YB40, DEC179YB42, DEC179YC44, DEC179YD43, Expiration date: 12/16/09 & 12/17/09;

4) Lot Code: JAN070YM37, Expiration date: 01/07/10

RECALLING FIRM/MANUFACTURER
Recalling Firm: Morningstar Foods LLC, Murray, KY, by letters on November 2, 2009. Manufacturer: Dean Foods Branded Products, Murray, KY. Firm initiated recall is complete.

REASON
The product contains undeclared soy protein.

VOLUME OF PRODUCT IN COMMERCE
110,418 gable top cartons

DISTRIBUTION
AL, FL, IL, IN, KY, MO, SC, TN, VA & WI

PRODUCT
Trader Joe's Chocolate Chip Chewy Coated Granola Bars, UPC: 82818. Recall # F-1537-2010

CODE
Use by Dates/Lot Codes: 24DEC09H1, 24DEC09H2, 25DEC09H1, 01JAN10H2, 02JAN10H1, 02JAN10H2, 15JAN10H1, 15JAN10H2, 21JAN10H1, 21JAN10H2, 01FEB10H1, 01FEB10H2, 02FEB10H1, 02FEB10H2, 03FEB10H1, 12FEB10H1, 16FEB10H1, 16FEB10H2, 17FEB10H1, 08MAR10H1, 23MAR10H1, 23MAR10H2, 09APR10H2, 10APR10H1, 10APR10H1, 03MAY10H1, 28MAY10H1, 28MAY10H2,
RECALLING FIRM/MANUFACTURER
Manufacturer: Lovin Oven, LLC, Azusa, CA. Firm initiated recall is ongoing.

REASON
The recall was initiated because the affected product has the potential to be contaminated with *Salmonella*.

VOLUME OF PRODUCT IN COMMERCE
Approximately 75,000 cases

DISTRIBUTION
Nationwide

PRODUCT
Jenny's Cuisine Chocolate Chip Trail Mix Bar, Net Wt 1.09 oz (31g), Unit UPC Code: 655447-00892-0. Recall # F-1538-2010

CODE
BEST BEFORE DATE AUG302010A

RECALLING FIRM/MANUFACTURER
Recalling Firm: Jenny Craig Inc., Carlsbad, CA, by e-mail on January 29, 2010.
Manufacturer: Lovin Oven, LLC, Azusa, CA. Firm initiated recall is ongoing.

REASON
The recall was initiated because the contract manufacturer of Jenny Craig's Chocolate Chip Trail Mix Bars has alerted Jenny Craig that an ingredient utilized in the production of a specific batch of Jenny Craig Chocolate Chip Trail Mix Bars may have been contaminated with *Salmonella*.

VOLUME OF PRODUCT IN COMMERCE
927.1 cases

DISTRIBUTION
Nationwide and Puerto Rico

PRODUCT
1) Health Valley Organic Peanut Crunch Chewy Granola Bars, 6.1 oz box, SKU Number: 0-35742-15483-4. Recall # F-1539-2010;

2) Health Valley Organic Dutch Apple Chewy Granola Bars, 6.1 oz box, SKU Number: #0-35742-15482-7. Recall # F-1540-2010;

3) Health Valley Organic Wildberry Chewy Granola Bars, 6.1 oz box, SKU Number: #0-35742-15481-0. Recall # F-1541-2010

CODE
1) Lot Numbers: 07DEC09, 15JAN10, 09FEB10, 23FEB10, 28FEB10, 28MAR10, 29MAR10, 13APR10, 16SEP10, and 06NOV10;
2) Lot Numbers: 03JAN10, 05FEB10, 28MAR10 and 17AUG10;

3) Lot Numbers: 05JAN10, 15JAN10, 08MAR10, 12APR10 and 06JUL10

**RECALLING FIRM/MANUFACTURER**
Lovin Oven, LLC, Azusa, CA, by press release, e-mail, and telephone on February 19, 2010. Firm initiated recall is ongoing.

**REASON**
The recall was initiated because the bars contain organic toasted soy grits, supplied by Thumb Oilseed Producers Cooperative, have the potential to be contaminated with *Salmonella*.

**VOLUME OF PRODUCT IN COMMERCE**
3,938 cases

**DISTRIBUTION**
Nationwide, to Israel, Jordan

---

**PRODUCT**
Fresh & easy Chewy Chocolate Chip Granola Bars 6 count/7.4 oz carton, 10 units/case, Barcode: 5051379001377. Recall # F-1542-2010

**CODE**

**RECALLING FIRM/MANUFACTURER**
Recalling Firm: Fresh And Easy, El Segundo, CA, by press release and e-mail on February 18, 2010.
Manufacturer: Lovin Oven, LLC, Azusa, CA. Firm initiated recall is complete.

**REASON**
The recall was initiated as a result of a recall initiated by Thumb Oilseed Producers. This company supplies an ingredient that has the potential to be contaminated with *Salmonella* that was utilized in the manufacturing process.

**VOLUME OF PRODUCT IN COMMERCE**
14,242 cases

**DISTRIBUTION**
CA, NV, AZ

---

**PRODUCT**
1) Gluten Free Naturals Light & Moist Yellow Cake Mix. Recall # F-1543-2010;
2) Gluten Free Naturals Pancake Mix. Recall # F-1544-2010;
3) Gluten Free Naturals Cookie Blend. Recall # F-1545-2010

**CODE**
1) Lot 09083, Exp 09/24/10; Lot 09322, Exp 5/18/12;
2) Lot 09159, Exp 12/08/10; Lot 09320, Exp 5/16/12; Lot 09322, Exp 5/18/12;
3) Lot 09086, Exp 06/24/10; Lot 09219, Exp 11/17/10; Lot 10035, Exp 5/04/11

**RECALLING FIRM/MANUFACTURER**
Manufacturer: Good Food Inc., Honey Brook, PA. Firm initiated recall is ongoing.
REASON
Food products were manufactured with soy flour supplied by Thumb Oilseed Producers Cooperative that was recalled due to the possibility of contamination with salmonella.

VOLUME OF PRODUCT IN COMMERCE
5798 boxes

DISTRIBUTION
Nationwide

PRODUCT
1) Non-GMO Low Fat Soy Grits, Net weight 40 lbs. packaged in brown paper bags. Sold under the Soy Beginnings Brand, Product code 285818-NGB, and Nexsoy brand. Recall # F-1546-2010;

2) Organic Soy Grits, Net weight 40 lbs. packaged in brown paper bags. Sold under the Soy Beginnings Brand Product code 258818-OGB and Nexsoy Organic Low-Fat Soy Grits brand. Recall # F-1547-2010;

3) Non- GMO Low Fat Soy Flour Net weight 40 lbs. packaged in brown paper bags. Sold under the Soy Beginnings Brand Product code 285100-NFB and Nexsoy Certified Non-GMO Low-Fat Soy Flour. Recall # F-1548-2010;

4) Organic Low Fat Soy Flour Net weight 40 lbs. packaged in brown paper bags. Sold under the Soy Beginnings Brand Product code 285100-OFB, and Nexsoy. Recall # F-1549-2010;

5) Soy Beginnings Non GMO Low Fat soy flour feed grade Product code 285100-NFT, sold in 1,500 pound bulk white mesh tote. Recall # F-1550-2010

CODE
1) TG010709, TG012209, TG021809, TG032109, TG040109, TG040909, TG042309, TG050109, TG052609, TG060409, TG061209, TG062309 TG070709, TG072109, TG082209, TG090209, TG092409, TG092509 TG102609, TG110209, TG111609, TG111709, TG111809, TG113009 and TG121608;

2) TOG021209, TOG022309, TOG031209, TOG032709, TOG041709, TOG061009 TOG072009, TOG090109, TOG092509, TOG110909 and TOG121509;

3) TF062309, TF062509, TF072109, TF081209, TF091809, TF092909, TF102009, TF111809, TF121509, TF121608, TF121808, TF121809 and TF010510;

4) TOF041709, TOF061009, TOF072009, TOF072209, TOF092509, TOF110909;

5) TF010709, TF020209, TF060209, TF082009, TF082709, TF090909, TF091809, TF092409, TF101309, TF111609, TF113009, TF121609, TF122909 and TF011110

RECALLING FIRM/MANUFACTURER
Manufacturer: Thumb Oilseed Producers' Cooperative, Ubly, MN. Firm initiated recall is ongoing.

REASON
Environmental samples and product samples are contaminated with Salmonella.

VOLUME OF PRODUCT IN COMMERCE
Unknown

DISTRIBUTION
PA, CA, NC, IL, AL, MN and Japan

PRODUCT
Hulled Sesame Seeds, 1 and 5 lb plastic bags (heat-sealed) with no label. Recall # F-1555-2010

CODE
MFG Lot Number: C# 34626, SCI Lot Number: 27631

RECALLING FIRM/MANUFACTURER
Recalling Firm: Mount Hope Wholesale, Inc., Cottonwood, AZ, by letter on February 18, 2010
Manufacturer: Specialty Commodities, Inc., Fargo, ND. Firm initiated recall is ongoing.

REASON
Product has the potential of being contaminated with Salmonella. Seeds were recalled by firm's supplier Specialty Commodities.

VOLUME OF PRODUCT IN COMMERCE
200 lbs, distributed in 1 lb. & 5 lb. packages

DISTRIBUTION
Nationally: AZ, TX, WA, OR, CA, NM, CO, FL, IN, UT, MA

PRODUCT
Sesame Hulled Net Wt 5 lbs and 25 lbs. Product of India. Recall # F-1556-2010

CODE
No Codes – All Product recalled

RECALLING FIRM/MANUFACTURER
Manufacturer: Specialty Commodities, Inc., Fargo, ND. Firm initiated recall is completed.

REASON
Santa Maura has decided to recall Hulled Sesame Seeds because they were notified by Specialty Commodities of potential Salmonella contamination.

VOLUME OF PRODUCT IN COMMERCE
850 lbs

DISTRIBUTION
CA

RECALLS AND FIELD CORRECTIONS: FOODS - CLASS II

PRODUCT
1) Mushroom Base – PN, 40 – 50 lbs, White HDPE; Mushroom Base - N, 40 - 50 pounds, White HDPE; Mushroom Base - FNZZ, 40 - 50 pounds, White HDPE. Store at: Refrigerate 2-10C (35-50F). Recall # F-1532-2010;


3) Chicken (No Added MSG), 40 - 50 pounds, White HDPE pails. Store at: Refrigerate 2-10C (35-50F). Recall # F-1534-2010;

4) Clam Base (No Added MSG), 40 - 50 pounds, White HDPE pails; Clam Base - N, 40 - 50 pounds, White HDPE pails. Store at: Refrigerate 2-10C (35-50F). Recall # F-1535-2010

CODE
1) Lot # C3049280, Mfr. 7-Oct-09, Lot # C3049308, Mfr. 4-Nov-09, Lot # C3089315, Mfr. 11-Nov-09 & Lot # C2859328, Mfr. 24-Nov-09;

2) Lot # C2239302 Mfr. 29-Oct-09, Lot # C2239328, Mfr. 24-Nov-09, Lot # C2239356, Mfr. 22-Dec-09;

3) Lot # C9419341, Mfr. 7-Dec-09;

4) Lot # C9999309, Mfr. 5-Nov-09, Lot # C9999348, Mfr. 14-Dec-09, Lot # C9990012, Mfr. 12-Jan-10; Lot # C6480012, Mfr. 12-Jan-10.

RECALLING FIRM/MANUFACTURER
Recalling Firm: Givaudan Flavors Corp., Cincinnati, OH, by e-mail on February 6, 2010, and letters on February 8, 2010. Manufacturer: Nestle Professional, Cleveland, OH. Firm initiated recall is ongoing.

REASON
Givaudan Flavors received a notice from their food base toll manufacturer, Nestle Professional (LJ Minor) that related to an ingredient (hydrolyzed vegetable protein) used in their products that are identified on the list above. Givaudan Flavors were notified that a presumptive (+) result for Salmonella was obtained in a food base product that Nestle Professional produced. This result was confirmed Feb 5, 2010. Nestle Professional advised that they have narrowed the source to one raw material lot that was also used in the products listed above.

VOLUME OF PRODUCT IN COMMERCE
12,800 Pounds

DISTRIBUTION
CA, ID, IL, LA, MN, OH & PA

PRODUCT
Castella brand Chicken Flavored Soup Base, a) Net Wt 1 lb packaged in an opaque plastic jar with a white cap, a gold seal, a light yellow label, and UPC code 7 50144 33000 5. b) Net Wt 25 lb is packed in an all white bucket, a yellow label, and UPC code
The product is best used by 1 year from the manufactured date. Recall # F-1536-2010

**CODE**

a) Lots: 0912039918, 1001121915, 1002013074, 194266; exp. dates 12-3-2010 through 2-28-2011; b) Lots: 0911259508, 0911259508A, 0912150738, 0912180973, 0912211087, 1001192342, 1001282925, 1002194267; exp. dates 11-25-2010 through 2-28-2011

**RECALLING FIRM/MANUFACTURER**

Manufacturer: Basic Food Flavors, Inc., North Las Vegas, NV. Firm initiated recall is ongoing.

**REASON**

The product was manufactured using hydrolyzed vegetable protein recalled by Basic Food Flavors, Inc. because it has the potential to be contaminated with *Salmonella*.

**VOLUME OF PRODUCT IN COMMERCE**

1 lb - 76 cases; 25 lb - 627 cases

**DISTRIBUTION**

Nationwide

---

**PRODUCT**

1) China Garden Almond Sauce in 5 lb packages in heat sealed bags in cardboard boxes, Net Wt 20 lb, labeled For Institutional Use Only. Recall # F-1551-2010;

2) China Garden General TSO'S Sauce in 5 lb packages in heat sealed bags in cardboard boxes, Net Wt 20 lb, labeled For Institutional Use Only. Recall # F-1552-2010;

3) China Garden Sweet and Sour Sauce in 5 lb packages in heat sealed bags in cardboard boxes, Net Wt 20 lb labeled For Institutional Use Only. Recall # F-1553-2010;

4) China Garden Hunan Sauce in 5 lb packages in heat sealed bags in cardboard boxes, Net Wt 20 lb labeled For Institutional Use Only. F-1554-2010

**CODE**

1) Label Code: 2/22/10 and Computer Code: 018428;  
2) Label Code: 2/22/10 and Computer Code: 018429;  
3) Label Code: 2/22/10 and Computer Code: 018430;  
4) Label Code: 2/22/10 and Computer Code: 018432

**RECALLING FIRM/MANUFACTURER**

Sunrise Foods, Columbus, OH, by telephone and letter on March 4, 2010. Firm initiated recall is ongoing.

**REASON**

The product was manufactured using hydrolyzed vegetable protein recalled by Basic Food Flavors, Inc. because it has the potential to be contaminated with *Salmonella*.

**VOLUME OF PRODUCT IN COMMERCE**

162 Cases

**DISTRIBUTION**
RECALLS AND FIELD CORRECTIONS: FOODS - CLASS III

PRODUCT
Wanley Noodles (Raw Wide Noodle, Thick Egg Noodle, Egg Noodle, Wide Egg Noodle, LoMein Egg Noodle, Wonton Noodle, and Thin Noodle), packaged in 40-pound boxes. Each box contains 8 bags with 5 lbs of noodles per bag. Manufacturing date is black inked-stamped on each box. Recall # F-0873-2010

CODE
Product manufactured before 12/3/2009

RECALLING FIRM/MANUFACTURER
Quality Noodle, Inc., Plano, TX by telephone on December 3, 2009. Firm initiated recall is complete.

REASON
Product contains undeclared color red #40.

VOLUME OF PRODUCT IN COMMERCE
306 boxes

DISTRIBUTION
TX

RECALLS AND FIELD CORRECTIONS: DRUGS - CLASS I

PRODUCT
1) Slimbionic Capsules, 350 mg of a proprietary herbal blend, packaged in 30 count boxes. Recall # D-379-2010;

2) One Weight Loss Pill, 990 mg of a proprietary herbal blend, packaged in 30 capsule bottles. Recall # D-380-2010;

3) SlimDemand Capsules, with FeiHua formula, 350 mg of a proprietary herbal blend, 30 count bottles. Recall # D-381-2010;

4) Botanical Weight Loss Capsules, 350 mg herbal blend, 30 count bottles. Recall # D-382-2010

CODE
All lots

RECALLING FIRM/MANUFACTURER

REASON
Marketed Without an Approved NDA/ANDA: product contains undeclared Sibutramine.

VOLUME OF PRODUCT IN COMMERCE
Unknown

DISTRIBUTION
Nationwide and Switzerland, Azerbaijan, Cayman Islands, Greece, United Kingdom, Norway, Australia, Ireland, Israel, Denmark, France, Canada, Sweden, Netherlands

**RECALLS AND FIELD CORRECTIONS: DRUGS - CLASS II**

**PRODUCT**
Cleviprex (clevidipine butyrate) injectable emulsion (0.5 mg/mL); 25 mg/50 mL single use vials (NDC 65293-002-50) packaged in a 10-count carton (NDC 65293-002-55); 50 mg/100 mL single use vials (NDC 65293-002-00) packaged in a 10-count carton (NDC 65293-002-11); Rx only. Recall # D-371-2010

**CODE**
Lot #: 61-978-DW, 61-979-DW, and 61-980-DW, Exp 01/10; 68-404-DJ, 68-405-DJ, and 68-406-DJ, Exp 08/10; 69-830-DJ, 63-385-DJ, 63-386-DJ, and 63-266-DJ, Exp 03/11; and 64-453-DJ, Exp 04/11

**RECALLING FIRM/MANUFACTURER**
Manufacturer: Hospira, Inc., Clayton, NC. Firm initiated recall is ongoing.

**REASON**
Presence of Particulate Matter: Visible particulate matter was observed in certain lots of Cleviprex 0.5 mg/mL.

**VOLUME OF PRODUCT IN COMMERCE**
7,492 cartons

**DISTRIBUTION**
Nationwide

---

**PRODUCT**
Demser (Metyrosine) capsules, 250 mg; 100 capsules per bottle; Rx only; NDC: 25010-305-15; UPC 325010305151. Recall # D-373-2010

**CODE**
Lot number: 9F661, Exp. 5/2012

**RECALLING FIRM/MANUFACTURER**
Manufacturer: Merck & Company, Inc., West Point, PA. Firm initiated recall is ongoing.

**REASON**
Failed USP Dissolution Test Requirements. Samples have failed to meet dissolution specifications.

**VOLUME OF PRODUCT IN COMMERCE**
317 bottles of 100 capsules

**DISTRIBUTION**
Nationwide, Canada, Spain, France, New Zealand, UK

---

**RECALLS AND FIELD CORRECTIONS: DRUGS - CLASS III**

---

**PRODUCT**
Cortamox Lotion (hydrocortisone/pramoxine HCl/chloroxylenol), in each mL: 10 mg/10 mg/1 mg, 60 mL (2 fl oz) dropper bottle, Rx Only; NDC 68032-206-02. Recall # D-372-2010

**CODE**
Lot # F07G011, Exp 6/30/2009

**RECALLING FIRM/MANUFACTURER**
Recalling Firm: River’s Edge Pharmaceuticals, LLC, Suwanee, GA, by e-mail on/about August 11, 2008.
Manufacturer: Harmony Labs, Inc., Landis, NC. Firm initiated recall is complete.

**REASON**

**VOLUME OF PRODUCT IN COMMERCE**
7,103 dropper bottles

**DISTRIBUTION**
Nationwide

**PRODUCT**
1) Clearasil Ultra (2% Salicylic Acid) Overnight Wash, 6.78 fl. oz (200 mL), Item 39977-00613-00; UPC 8 39977 00939 1. Recall # D-374-2010;

2) Clearasil Ultra (2% Salicylic Acid) Acne Clearing Gel Wash, 6.78 fl. oz. (200mL), Item 39977-00939-15; UPC 8 39977 00939 2. Recall # D-375-2010

**CODE**
1) Lot numbers: 01 C9296, 02 C9296, 02 C9297, 07 C9303, 02 C9299, 03 C9299, 04 C9301, 05 C9301, 05 C9302, and 06 C9302;

2) Lot number 02 C9317

**RECALLING FIRM/MANUFACTURER**
Reckitt Benckiser, Fort Worth, TX, by letter on February 4, 2010. Firm initiated recall is ongoing.

**REASON**
Product has potential for losing lot code information when unwrapped.

**VOLUME OF PRODUCT IN COMMERCE**
84,432 units

**DISTRIBUTION**
Nationwide

**PRODUCT**
Fluocinonide Ointment USP, 0.05%, For external use only, not for ophthalmic use, a) Net Wt 15 grams (NDC 0168-0140-15); b) Net Wt 30 grams (NDC 0168-0140-30); c) Net Wt 60 grams (NDC 0168-0140-60), Rx only. Recall # D-376-2010

**CODE**
a) batch 902A (exp 9/11); b) batch 982A (exp 10/11); c) batch 111B (exp 10/11)

**RECALLING FIRM/MANUFACTURER**
Manufacturer: Nycomed Us Inc., Hicksville, NY. Firm initiated recall is ongoing.
**REASON**
Out-of-specification result for a known degradant was obtained for a previous batch of Fluocinonide Ointment USP, 0.05%. The firm is recalling the three batches as a precaution.

**VOLUME OF PRODUCT IN COMMERCE**
52,156 units

**DISTRIBUTION**
Nationwide

---

**PRODUCT**
Selenium Sulfide Shampoo, 2.25%, 180 mL bottle, Rx Only, NDC 68032-127-18. Recall # D-377-2010

**CODE**
Lot #s: 94200, Exp 8/31/2010; F08B056, Exp 2/28/2010; F07K014, Exp 10/31/2009

**RECALLING FIRM/MANUFACTURER**
Recalling Firm: River’s Edge Pharmaceuticals, LLC, Suwanee, GA, by e-mail on/about August 28, 2009.
Manufacturer: Harmony Labs, Inc., Landis, NC. Firm initiated recall is ongoing.

**REASON**

**VOLUME OF PRODUCT IN COMMERCE**
21,603 bottles

**DISTRIBUTION**
Nationwide

---

**PRODUCT**
RE Pramoxine-HC (hydrocortisone/chloroxylenol/pramoxine HCl), Otic drops, 10 mg/1 mg/10 mg, 10 mL dropper bottle, Rx Only, NDC 68032-379-97. Recall # D-378-2010

**CODE**
Lot # 6191, Exp 2/28/2011

**RECALLING FIRM/MANUFACTURER**
Recalling Firm: River’s Edge Pharmaceuticals, LLC, Suwanee, GA, by e-mail on/about August 28, 2009.
Manufacturer: Sonar Products, Inc., Carlstadt, NJ. Firm initiated recall is ongoing.

**REASON**
Product lacks stability.

**VOLUME OF PRODUCT IN COMMERCE**
9,552 dropper bottles

**DISTRIBUTION**
Nationwide

---

**RECALLS AND FIELD CORRECTIONS: BIOLOGICS - CLASS II**

**PRODUCT**
Recovered Plasma. Recall # B-0507-10

**CODE**
RECALLING FIRM/MANUFACTURER
Southeastern Community Blood Center, Tallahassee, FL, by e-mail on June 24, 2009.
firm initiated recall is complete.
REASON
Blood product, which was collected from a donor whose suitability pertaining to risk factors for Creutzfeldt-Jakob Disease (vCJD) was not adequately determined, was distributed.
VOLUME OF PRODUCT IN COMMERCE
1 unit
DISTRIBUTION
Austria

PRODUCT
Red Blood Cells Leukocytes Reduced. Recall # B-0511-10
CODE
Units: 003FM27873 and 003FM21935
RECALLING FIRM/MANUFACTURER
Recalling Firm: The American National Red Cross, Douglasville, GA, by telephone and e-mail on November 1, 2007 and by letter on November 2, 2007.
Manufacturer: The American National Red Cross – Southern Region, Douglasville, GA.
Firm initiated recall is complete.
REASON
Blood products, collected from a donor for whom donor suitability was not adequately determined, were distributed.
VOLUME OF PRODUCT IN COMMERCE
2 units
DISTRIBUTION
GA

PRODUCT
Source Plasma. Recall # B-0672-10
CODE
Unit: 09OUTB1154
RECALLING FIRM/MANUFACTURER
BioLife Plasma Service, LP, Van Nuys, CA, by e-mail on June 3, 2009. Firm initiated recall is complete.
REASON
Blood product, collected from a donor with a recent tattoo history, was distributed.
VOLUME OF PRODUCT IN COMMERCE
1 unit
DISTRIBUTION
CA

PRODUCT
1) Red Blood Cells Leukocytes Reduced. Recall # B-0673-10
2) Red Blood Cells Leukocytes Reduced Irradiated. Recall # B-0674-10

CODE
1) Units: 06FW35951, 06FW37598;
2) Unit: 06FW39125

RECALLING FIRM/MANUFACTURER
The American National Red Cross, Pomona, CA, by telephone, e-mail and letter on April 24, 2009. Firm initiated recall is complete.

REASON
Blood products, collected from an ineligible donor, were distributed.

VOLUME OF PRODUCT IN COMMERCE
3 units

DISTRIBUTION
CA

___________________________________

PRODUCT
1) Red Blood Cells. Recall # B-0691-10;
2) Platelets. Recall # B-0692-10;
3) Recovered Plasma. B-0693-10

CODE
1), 2) and 3) Unit: 1730137

RECALLING FIRM/MANUFACTURER
Blood Bank of Hawaii, Honolulu, HI, by letter on September 23, 2009. Firm initiated recall is complete.

REASON
Blood products, that tested negative for hepatitis, but were collected from an ineligible donor due to a history of jaundice, were distributed.

VOLUME OF PRODUCT IN COMMERCE
3 units

DISTRIBUTION
NY, HI

___________________________________

PRODUCT
1) Red Blood Cells Leukocytes Reduced. Recall # B-0695-10;
2) Fresh Frozen Plasma. Recall # B-0696-10

CODE
1) and 2) Unit: 7701752

RECALLING FIRM/MANUFACTURER

REASON
Blood products, which was collected from an unsuitable donor based on risk factors for variant Creutzfeldt-Jakob Disease (vCJD), were distributed.

VOLUME OF PRODUCT IN COMMERCE
2 units

DISTRIBUTION
NJ
PRODUCT
Platelets Pheresis Leukocytes Reduced. Recall # B-0697-10
CODE
Unit: 01P03423
RECALLING FIRM/MANUFACTURER
American Red Cross Blood Services, West Henrietta, NY, by facsimile on August 27, 2009. Firm initiated recall is complete.
REASON
Blood product, collected from a donor in which donor suitability was not adequately determined, was distributed.
VOLUME OF PRODUCT IN COMMERCE
1 unit
DISTRIBUTION
NY

PRODUCT
1) Platelets. Recall # B-0700-10;
2) Red Blood Cells Leukocytes Reduced. Recall # B-0701-10
CODE
1) Units: 2534262 and 2468743;
2) Units: 2520737, 2468743, 2534262, 2338710, 2364638, 2435168 and 2492282
RECALLING FIRM/MANUFACTURER
Central Kentucky Blood Center, Inc., Lexington, KY, by letter on October 6, 2009. Firm initiated recall is complete.
REASON
Blood products, which were collected from a donor who had traveled to a malarial endemic area, were distributed.
VOLUME OF PRODUCT IN COMMERCE
9 units
DISTRIBUTION
KY

PRODUCT
Source Plasma. Recall # B-0776-10
CODE
Unit: 08GNDH1832
RECALLING FIRM/MANUFACTURER
BioLife Plasma Services, L.P., Grand Forks, ND, by fax on October 12, 2009. Firm initiated recall is complete.
REASON
Blood product, collected from a donor whose suitability to donate was not adequately determined, was distributed.
VOLUME OF PRODUCT IN COMMERCE
1 unit
DISTRIBUTION
Austria

**PRODUCT**
Source Plasma. Recall # B-0777-10

**CODE**
Unit: 08MMTF2077

**RECALLING FIRM/MANUFACTURER**
BioLife Plasma Services, L.P., Missoula, MT, by fax on October 1, 2009. Firm initiated recall is complete.

**REASON**
Blood product, collected from a donor whose suitability to donate was not adequately determined, was distributed.

**VOLUME OF PRODUCT IN COMMERCE**
1 unit

**DISTRIBUTION**
Austria

---

**PRODUCT**
1) Red Blood Cells Leukocytes Reduced Irradiated. Recall # B-0780-10;  
2) Platelets Pooled Irradiated. Recall # B-0781-10

**CODE**
1) Unit: W141609155275;  
2) Unit: W141609395385

**RECALLING FIRM/MANUFACTURER**
Manufacturer: Puget Sound Blood Center and Program, Renton, WA. Firm initiated recall is complete.

**REASON**
Blood products, not tested for cytomegalovirus (CMV) but labeled as CMV negative, were distributed.

**VOLUME OF PRODUCT IN COMMERCE**
2 units

**DISTRIBUTION**
WA

---

**PRODUCT**
Source Plasma. Recall # B-0782-10

**CODE**
Unit: 09FINA2522

**RECALLING FIRM/MANUFACTURER**
BioLife Plasma Services, L.P., Fort Wayne, IN, by fax on August 10, 2009. Firm initiated recall is complete.

**REASON**
Blood product, collected from a donor whose suitability to donate was not adequately determined, was distributed.
VOLUME OF PRODUCT IN COMMERCE
1 unit
DISTRIBUTION
CA

PRODUCT
Platelets Pheresis Leukocytes Reduced. Recall # B-0783-10
CODE
Units: W051509087555 (split product); W051509087599
RECALLING FIRM/MANUFACTURER
Manufacturer: Memorial Blood Centers, Plymouth, MN. Firm initiated recall is complete.
REASON
Blood products, labeled as leukoreduced, but which may not meet the criteria for leukoreduced products, were distributed.

VOLUME OF PRODUCT IN COMMERCE
3 units
DISTRIBUTION
NY, OH, NC

PRODUCT
Red Blood Cells Leukocytes Reduced. Recall # B-0784-10
CODE
Unit: 49LH79802
RECALLING FIRM/MANUFACTURER
American National Red Cross SW Region – HT, Tulsa, OK, by telephone on September 30, 2009. Firm initiated recall is complete.
REASON
Blood product, collected from a donor who reported post donation illness, was distributed.

VOLUME OF PRODUCT IN COMMERCE
1 unit
DISTRIBUTION
OK

PRODUCT
Red Blood Cells Leukocytes Reduced. Recall # B-0785-10
CODE
Unit: W137509204509
RECALLING FIRM/MANUFACTURER
Lane Memorial Blood Bank, Eugene, OR, by letter dated September 3, 2009. Firm initiated recall is complete.
REASON
Blood product, collected from a donor who visited a malarial endemic area, was distributed.
VOLUME OF PRODUCT IN COMMERCE
1 unit
DISTRIBUTION
OR

PRODUCT
Source Plasma. Recall # B-0786-10
CODE
Unit: 08GND13758
RECALLING FIRM/MANUFACTURER
REASON
Blood product, collected from a donor who reported high risk behavior, was distributed.

VOLUME OF PRODUCT IN COMMERCE
1 unit
DISTRIBUTION
KY

PRODUCT
1) Recovered Plasma. Recall # B-0787-10;
2) Red Blood Cells Leukocytes Reduced. Recall # B-0788-10
CODE
1) and 2) Unit: W115909025767
RECALLING FIRM/MANUFACTURER
Central California Blood Center, Fresno, CA, by fax on August 19, 2009 and August 24, 2009. Firm initiated recall is complete.
REASON
Blood products, collected from a donor who had a blood exposure, were distributed.

VOLUME OF PRODUCT IN COMMERCE
2 units
DISTRIBUTION
Austria, CA

PRODUCT
Red Blood Cells Leukocytes Reduced. Recall # B-0791-10
CODE
Unit: 53FL70940
RECALLING FIRM/MANUFACTURER
REASON
Blood product, collected from a donor who visited a HIV Group O risk area, was distributed.

VOLUME OF PRODUCT IN COMMERCE
PRODUCT
Platelets Pheresis Leukocytes Reduced. Recall # B-0792-10

CODE
Unit: 72L366625

RECALLING FIRM/MANUFACTURER

REASON
Blood product, with platelet count below the specified minimum requirement, was distributed.

VOLUME OF PRODUCT IN COMMERCE
1 unit

DISTRIBUTION
MD

PRODUCT
1) Platelets Pheresis Leukocytes Reduced. Recall # B-0793-10;
2) Platelets Pheresis Leukocytes Reduced Irradiated. Recall # B-0794-10

CODE
1) Unit: W038309077314;
2) Units: W038309077314; W038309077325 (split product)

RECALLING FIRM/MANUFACTURER
Mississippi Valley Regional Blood Centers, Davenport, IA, by fax on August 3, 2009 and telephone on August 4, 2009. Firm initiated recall is complete.

REASON
Blood products, labeled leukoreduced without the assurance that they met the criteria for leukoreduced products, were distributed.

VOLUME OF PRODUCT IN COMMERCE
4 units

DISTRIBUTION
FL, MO, IA, IL

PRODUCT
Platelets Pheresis Leukocytes Reduced. Recall # B-0795-10

CODE
Unit: 72K732804

RECALLING FIRM/MANUFACTURER

REASON
Blood product, with platelet count below the specified minimum requirement, was distributed.
VOLUME OF PRODUCT IN COMMERCE
1 unit
DISTRIBUTION
AL

PRODUCT
Source Plasma. Recall # B-0796-10
CODE
Units: HS0198296; HS0198526; HS0199072; HS0199358
RECALLING FIRM/MANUFACTURER
DCI Biologicals Hot Springs, Inc, Hot Springs, AR, by fax on July 30, 2009 and e-mail on July 31, 2009. Firm initiated recall is complete.
REASON
Blood products, collected from a donor who received a tattoo within 12 months of donating, were distributed.
VOLUME OF PRODUCT IN COMMERCE
4 units
DISTRIBUTION
UK

PRODUCT
Red Blood Cells Leukocytes Reduced. Recall # B-0797-10
CODE
Units: W071209031310; W071209030902
RECALLING FIRM/MANUFACTURER
REASON
Blood products, leukoreduced after the allowable post collection time limit, were distributed.
VOLUME OF PRODUCT IN COMMERCE
2 units
DISTRIBUTION
TN

PRODUCT
Source Plasma. Recall # B-0798-10
CODE
Units: NG0224214; NG0224668; NG0224841; NG0225321
RECALLING FIRM/MANUFACTURER
DCI Biologicals Nacogdoches, LLC, Nacogdoches, TX, by fax on July 20, 2009 and e-mail on October 23, 2009. Firm initiated recall is complete.
REASON
Blood products, collected from a donor who received ear piercings within 12 months of donating, were distributed.
VOLUME OF PRODUCT IN COMMERCE
4 units
**DISTRIBUTION**
UK

**PRODUCT**
Platelets Pheresis Leukocytes Reduced. Recall # B-0799-10

**CODE**
W067109703310 (split product)

**RECALLING FIRM/MANUFACTURER**
The Blood Center, New Orleans, LA, by telephone on August 4, 2009. Firm initiated recall is complete.

**REASON**
Blood products, with platelet count below the specified minimum requirement, were distributed.

**VOLUME OF PRODUCT IN COMMERCE**
2 units

**DISTRIBUTION**
LA

**PRODUCT**
Red Blood Cells Leukocytes Reduced. Recall # B-0800-10

**CODE**
Unit: 50LW80199

**RECALLING FIRM/MANUFACTURER**
American Red Cross Blood Services, Western Lake Erie Region, Toledo, OH, by telephone and electronically (Logic) on August 11, 2009 and follow-up letter dated August 13, 2009. Firm initiated recall is complete.

**REASON**
Blood product, collected from a donor whose suitability to donate was not adequately determined, was distributed.

**VOLUME OF PRODUCT IN COMMERCE**
1 unit

**DISTRIBUTION**
OH

**PRODUCT**
Fresh Frozen Plasma (Apheresis). Recall # B-0802-10

**CODE**
Units: W120609402488; W120609402113; W120609401719

**RECALLING FIRM/MANUFACTURER**
Michigan Community Blood Center, Traverse City, MI, by fax on August 6, 2009 and August 10, 2009. Firm initiated recall is complete.

**REASON**
Blood products, collected from a donor taking the drug finasteride, were distributed.

**VOLUME OF PRODUCT IN COMMERCE**
3 units
PRODUCT
Red Blood Cells Leukocytes Reduced. Recall # B-0803-10
CODE
Unit: W068508402737
RECALLING FIRM/MANUFACTURER
REASON
Blood product, collected from a donor who reported travel to an area that was potentially endemic for malaria, was distributed.
VOLUME OF PRODUCT IN COMMERCE
1 unit
DISTRIBUTION
WA

PRODUCT
Source Plasma. Recall # B-0804-10
CODE
Units: GN0206116; GN0206276; GN0207310; GN0208240; GN0208370; GN0209382; GN0209523
RECALLING FIRM/MANUFACTURER
DCI Biologicals, Orlando LLC, Gainesville, FL, by fax on May 30, 2009 and e-mail on October 23, 2009. Firm initiated recall is complete.
REASON
Blood products, collected from a donor who received a tattoo within 12 months of donating, were distributed.
VOLUME OF PRODUCT IN COMMERCE
7 units
DISTRIBUTION
CA

PRODUCT
Platelets Pheresis Leukocytes Reduced. Recall # B-0805-10
CODE
Unit: FE22232
RECALLING FIRM/MANUFACTURER
Children’s Hospital Orange County, Orange, CA, by telephone on July 25, 2009 and follow-up letter dated August 6, 2009. Firm initiated recall is complete.
REASON
Blood product, labeled leukoreduced without the assurance that it met the criteria for a leukoreduced product, was distributed.
VOLUME OF PRODUCT IN COMMERCE
1 unit
DISTRIBUTION
CA

PRODUCT
Platelets Pheresis Leukocytes Reduced Irradiated. Recall # B-0807-10
CODE
Unit: W142809328291 (split unit)
RECALLING FIRM/MANUFACTURER
Manufacturer: Tri-Counties Blood Bank, San Luis Obispo, CA. Firm initiated recall is complete.
REASON
Blood products, with insufficient plasma to support the platelet concentration, were distributed.
VOLUME OF PRODUCT IN COMMERCE
2 units
DISTRIBUTION
CA

PRODUCT
1) Red Blood Cells Leukocytes Reduced. Recall B-0808-10
2) Platelets Leukocytes Reduced. Recall # B-0810-10
CODE
1) and 2) Unit: 017KM71111
RECALLING FIRM/MANUFACTURER
REASON
Blood products, collected from a donor whose suitability to donate was not adequately determined, were distributed.
VOLUME OF PRODUCT IN COMMERCE
2 units
DISTRIBUTION
MA, MN

PRODUCT
Red Blood Cells (Apheresis) Leukocytes Reduced. Recall # B-0811-10
CODE
Unit: 03FH44968
RECALLING FIRM/MANUFACTURER
The American National Red Cross – Southern Region, Douglasville, GA, by fax and follow up letter on July 24, 2009. Firm initiated recall is complete.
REASON
Blood product, with an unacceptably low volume, was distributed.
VOLUME OF PRODUCT IN COMMERCE
1 unit
DISTRIBUTION
GA

PRODUCT
Platelets Pheresis Leukocytes Reduced. Recall # B-0812-10

CODE
Unit: W040709450989 (2 units)

RECALLING FIRM/MANUFACTURER
Indiana Blood Center, Indianapolis, IN, by telephone on October 2, 2009. Firm initiated recall is complete.

REASON
Blood products, which were labeled as leukoreduced, but exceeded the acceptable limit for white blood cell count, were distributed.

VOLUME OF PRODUCT IN COMMERCE
2 units
DISTRIBUTION
IN

PRODUCT
Recovered Plasma. Recall # B-0813-10

CODE
Units: 7061264, 7024801, 6961797

RECALLING FIRM/MANUFACTURER
Community Blood Center of the Ozarks, Springfield, MO, by e-mail on October 26, 2009. Firm initiated recall is complete.

REASON
Blood products, collected from a donor who was at risk for variant Creutzfeldt-Jakob Disease (vCJD), were distributed.

VOLUME OF PRODUCT IN COMMERCE
3 units
DISTRIBUTION
Austria

PRODUCT
1) Platelets. Recall # B-0814-10;
2) Red Blood Cells Leukocytes Reduced. Recall # B-0815-10

CODE
1) Unit: 2418494;
2) Units: 2418494, 2449866, 2465140

RECALLING FIRM/MANUFACTURER

REASON
Blood products, collected from a donor who traveled to an area considered endemic for malaria, were distributed.

**VOLUME OF PRODUCT IN COMMERCE**
4 units

**DISTRIBUTION**
KY

**PRODUCT**
Red Blood Cells. Recall # B-0816-10

**CODE**
Unit: W120609204576

**RECALLING FIRM/MANUFACTURER**

**REASON**
Blood product, collected from a donor who traveled to an area considered endemic for malaria, was distributed.

**VOLUME OF PRODUCT IN COMMERCE**
1 unit

**DISTRIBUTION**
MI

---

**PRODUCT**
Red Blood Cells Leukocytes Reduced. Recall # B-0818-10

**CODE**
Unit: W137509202306

**RECALLING FIRM/MANUFACTURER**

**REASON**
Blood product, collected from a donor who traveled to an area considered endemic for malaria, was distributed.

**VOLUME OF PRODUCT IN COMMERCE**
1 unit

**DISTRIBUTION**
OR

---

**PRODUCT**
Platelets Pheresis Leukocytes Reduced Irradiated. Recall # B-0819-10

**CODE**
Unit: W037909561268

**RECALLING FIRM/MANUFACTURER**
Blood Center of Iowa, Des Moines, IA, by telephone on November 10, 2009. Firm initiated recall is complete.

**REASON**
Blood product, which was labeled as leukoreduced, but was not tested to verify white blood cell count, was distributed.

**VOLUME OF PRODUCT IN COMMERCE**
1 unit

**DISTRIBUTION**
IA

**PRODUCT**
Red Blood Cells (Apheresis) Leukocytes Reduced. Recall # B-0820-10

**CODE**
Unit: W067109705813

**RECALLING FIRM/MANUFACTURER**
The Blood Center, New Orleans, LA, by telephone on September 9, 2009. Firm initiated recall is complete.

**REASON**
Blood product, which was incorrectly labeled as negative for the Fyb red cell antigen, was distributed.

**VOLUME OF PRODUCT IN COMMERCE**
1 unit

**DISTRIBUTION**
LA

**PRODUCT**
1) Recovered Plasma. Recall # B-0821-10;
2) Red Blood Cells, Leukocytes Reduced. Recall # B-0822-10

**CODE**
1) and 2) Unit: W224309312893

**RECALLING FIRM/MANUFACTURER**
Houchin Blood Services, Bakersfield, CA, by facsimile on October 19, 2009. Firm initiated recall is complete.

**REASON**
Blood products, collected from a donor who received a piercing within one year of donation, were distributed.

**VOLUME OF PRODUCT IN COMMERCE**
2 units

**DISTRIBUTION**
Austria, CA

**PRODUCT**
1) Cryoprecipitated AHF. Recall # B-0824-10;
2) Recovered Plasma. Recall # B-0825-10

**CODE**
1) and 2) Unit: W035209146913U
Carter BloodCare, Bedford, TX, by telephone on October 14, 2009, by facsimile on November 17, 2009, and by letter dated November 17, 2009, Firm initiated recall is complete.

**REASON**
Blood products, collected from a donor who was exposed to someone else's blood, were distributed.

**VOLUME OF PRODUCT IN COMMERCE**
2 units

**DISTRIBUTION**
Austria, TX

---

**PRODUCT**
Platelets Pheresis Leukocytes Reduced Irradiated. Recall # B-0826-10

**CODE**
Unit: W037909561118 (2 units)

**RECALLING FIRM/MANUFACTURER**
Blood Center of Iowa, Des Moines, IA, by letter dated November 18, 2009. Firm initiated recall is complete.

**REASON**
Blood products, which were labeled as leukoreduced, but exceeded the acceptable limit for white blood cell count, were distributed.

**VOLUME OF PRODUCT IN COMMERCE**
2 units

**DISTRIBUTION**
NE, IA

---

**PRODUCT**
Platelets Pheresis Leukocytes Reduced. Recall # B-0827-10

**CODE**
Unit: W03940973572300

**RECALLING FIRM/MANUFACTURER**
Florida Blood Services, Inc., St Petersburg, FL, by telephone and facsimile on November 29, 2009. Firm initiated recall is complete.

**REASON**
Blood product, which was labeled as leukoreduced, but exceeded the acceptable limit for white blood cell count, was distributed.

**VOLUME OF PRODUCT IN COMMERCE**
1 unit

**DISTRIBUTION**
FL

---

**PRODUCT**
Platelets Pheresis Leukocytes Reduced. Recall # B-0828-10

**CODE**
Unit: 72M449778

**RECALLING FIRM/MANUFACTURER**
Lifesouth Community Blood Centers, Mobile, AL, by facsimile on December 16, 2009. Firm initiated recall is complete.

**REASON**
Blood product, with a low platelet count, was distributed.

**VOLUME OF PRODUCT IN COMMERCE**
1 unit

**DISTRIBUTION**
AL

---

**PRODUCT**
1) Red Blood Cells Leukocytes Reduced. Recall # B-0830-10;
2) Cryoprecipitated AHF. Recall # B-0831-10
3) Plasma Frozen Cryoprecipitate Reduced. Recall # B-0832-10

**CODE**
1) 2) and 3) Unit: 368514792

**RECALLING FIRM/MANUFACTURER**

**REASON**
Blood products, collected from a donor who previously tested positive for Hepatitis C, were distributed.

**VOLUME OF PRODUCT IN COMMERCE**
3 units

**DISTRIBUTION**
CA

---

**PRODUCT**
Red Blood Cells Deglycerolized. Recall # B-0833-10

**CODE**
Unit: W121609107424

**RECALLING FIRM/MANUFACTURER**

**REASON**
Blood product, labeled with an extended expiration date, was distributed.

**VOLUME OF PRODUCT IN COMMERCE**
1 unit

**DISTRIBUTION**
SC

---

**PRODUCT**
1) Red Blood Cells. Recall # B-0837-10;
2) Fresh Frozen Plasma. Recall # B-0838-10

**CODE**
1) and 2) Unit: 4255177

**RECALLING FIRM/MANUFACTURER**
Community Blood Center, Dayton, OH, by letter dated September 1, 2009. Firm initiated recall is complete.

**REASON**
Blood products, collected from a donor taking the drug Finasteride, were distributed.

**VOLUME OF PRODUCT IN COMMERCE**
2 units

**DISTRIBUTION**
OH

**PRODUCT**
Platelets Pheresis Leukocytes Reduced. Recall # B-0839-10

**CODE**
Unit: 72L32837X

**RECALLING FIRM/MANUFACTURER**

**REASON**
Blood product, with platelet count below the specified minimum requirement, was distributed.

**VOLUME OF PRODUCT IN COMMERCE**
1 unit

**DISTRIBUTION**
AL

**PRODUCT**
Red Blood Cells. Recall # B-0840-10

**CODE**
Unit: 16774361257379

**RECALLING FIRM/MANUFACTURER**
Department of Army William Beaumont Army Medical Center, El Paso, TX, by letter dated March 10, 2009 and by telephone on July 14, 2009. Firm initiated recall is complete.

**REASON**
Blood product, collected from a donor considered to be at increased risk for variant Creutzfeldt-Jakob Disease (vCJD), was distributed.

**VOLUME OF PRODUCT IN COMMERCE**
1 unit

**DISTRIBUTION**
NJ

**PRODUCT**
Platelets Pheresis Leukocytes Reduced. Recall # B-0841-10

**CODE**
Units: W050909027815 (Split unit)

**RECALLING FIRM/MANUFACTURER**
HCSC Blood Center, Bethlehem, PA, by telephone on April 14, 2009. Firm initiated recall is complete.

**REASON**
Blood products, which did not undergo quality control testing, were distributed.

**VOLUME OF PRODUCT IN COMMERCE**
2 units

**DISTRIBUTION**
PA

**PRODUCT**
1) Fresh Frozen Plasma. Recall # B-0843-10;  
2) Red Blood Cells. Recall # B-0844-10

**CODE**
1) Units: 1278370; 1417620;  
2) Units: 1173670; 1278370; 1349426; 1417620

**RECALLING FIRM/MANUFACTURER**
Manufacturer: Memorial Blood Centers - Duluth, Duluth, MN. Firm initiated recall is complete.

**REASON**
Blood products, collected from a donor whose suitability to donate was not adequately determined, were distributed.

**VOLUME OF PRODUCT IN COMMERCE**
6 units

**DISTRIBUTION**
MN, PA

**PRODUCT**
Plasma Frozen. Recall # B-0846-10

**CODE**
Unit: 003FX57563

**RECALLING FIRM/MANUFACTURER**

**REASON**
Blood product, associated with a red cell component which contained clots, was distributed.

**VOLUME OF PRODUCT IN COMMERCE**
1 unit

**DISTRIBUTION**
GA

**PRODUCT**
Red Blood Cells Leukocytes Reduced. Recall # B-0849-10
CODE
Units: 06LG50594, 06GP74376, 06LG42861

RECALLING FIRM/MANUFACTURER
The American National Red Cross, Pomona, CA, by telephone on May 15, 2009 and by letters dated May 18, 2009 and June 26, 2009. Firm initiated recall is complete.

REASON
Blood products, collected from a donor who lived in an area considered endemic for malaria, were distributed.

VOLUME OF PRODUCT IN COMMERCE
3 units

DISTRIBUTION
CA

________________________________________________________________________

PRODUCT
Platelets Pheresis Leukocytes Reduced Irradiated. Recall # B-0852-10

CODE
Unit: W041209051382T

RECALLING FIRM/MANUFACTURER

REASON
Blood product, with platelet concentration below the specified minimum requirement, was distributed.

VOLUME OF PRODUCT IN COMMERCE
1 unit

DISTRIBUTION
NM

________________________________________________________________________

PRODUCT
Source Plasma. B-0853-10

CODE
Units: 2090091973; 2090091116; 2090090586; 2090090392; 2090091375

RECALLING FIRM/MANUFACTURER
Plasma Care, Inc., Richmond, VA, by fax on March 6, 2009. Firm initiated recall is complete.

REASON
Blood products, collected from a donor who received a tattoo within 12 months of donating, were distributed.

VOLUME OF PRODUCT IN COMMERCE
5 units

DISTRIBUTION
CA

________________________________________________________________________

PRODUCT
Source Plasma. Recall # B-0854-10

CODE
RECALLING FIRM/MANUFACTURER

REASON
Blood products, collected from a donor whose physical exam was incomplete, were distributed.

VOLUME OF PRODUCT IN COMMERCE
6 units
DISTRIBUTION
IL

PRODUCT
Source Plasma. B-0855-10
CODE
Units: 7020806680; 7020800756
RECALLING FIRM/MANUFACTURER

REASON
Blood products, collected from a donor whose physical exam was incomplete, were distributed.

VOLUME OF PRODUCT IN COMMERCE
2 units
DISTRIBUTION
IL

PRODUCT
Platelets Pheresis Leukocytes Reduced. Recall # B-0856-10
CODE
Unit: 72M363412
RECALLING FIRM/MANUFACTURER
Lifesouth Community Blood Centers Inc - Birmingham Region, Birmingham, AL, by fax on November 25, 2009. Firm initiated recall is complete.

REASON
Blood product, with platelet count below the specified minimum requirement, was distributed.

VOLUME OF PRODUCT IN COMMERCE
1 unit
DISTRIBUTION
AL

PRODUCT
1) Platelets Pooled Leukocytes Reduced Irradiated. Recall # B-0857-10;
2) Red Blood Cells. Recall # B-0858-10
CODE
1) and 2) Unit: W141609375213

**RECALLING FIRM/MANUFACTURER**
Manufacturer: Puget Sound Blood Center and Program, Federal Way, WA. Firm initiated recall is complete.

**REASON**
Blood products, collected from a donor who reported travel to a malarial endemic area, were distributed.

**VOLUME OF PRODUCT IN COMMERCE**
2 units

**DISTRIBUTION**
WA

**PRODUCT**
Platelets Pheresis Leukocytes Reduced. Recall # B-0859-10

**CODE**
Unit: 72M068306

**RECALLING FIRM/MANUFACTURER**
LifeSouth Community Blood Centers Inc., Huntsville, AL, by fax on November 24, 2009. Firm initiated recall is complete.

**REASON**
Blood product, with platelet count below the specified minimum requirement, was distributed.

**VOLUME OF PRODUCT IN COMMERCE**
1 unit

**DISTRIBUTION**
AL

**PRODUCT**
Platelets Pheresis Leukocytes Reduced. Recall # B-0860-10

**CODE**
Units: W142809333253 (split unit)

**RECALLING FIRM/MANUFACTURER**
Manufacturer: Tri-Counties Blood Bank, San Luis Obispo, CA. Firm initiated recall is complete.

**REASON**
Blood products, collected from a donor who reported travel to a malarial endemic area, were distributed.

**VOLUME OF PRODUCT IN COMMERCE**
2 units

**DISTRIBUTION**
AZ
PRODUCT
Platelets Pheresis Leukocytes Reduced. Recall # B-0862-10

CODE
Unit: 72L953752

RECALLING FIRM/MANUFACTURER
LifeSouth Community Blood Centers Inc., Huntsville, AL, by fax on November 17, 2009. Firm initiated recall is complete.

REASON
Blood product, with platelet count below the specified minimum requirement, was distributed.

VOLUME OF PRODUCT IN COMMERCE
1 unit

DISTRIBUTION
AL

PRODUCT
1) Red Blood Cells (Apheresis) Leukocytes Reduced. Recall # B-0865-10;

2) Platelets Pheresis Leukocytes Reduced Irradiated. Recall # B-0866-10;

CODE
1) and 2) Unit: W117009122912;

RECALLING FIRM/MANUFACTURER
Manufacturer: Blood Centers Of The Pacific - Marin Center, San Rafael, CA. Firm initiated recall is complete.

REASON
Blood products, collected from a donor who reported travel to a malarial endemic area, were distributed.

VOLUME OF PRODUCT IN COMMERCE
2 units

DISTRIBUTION
CA

PRODUCT
1) Recovered Plasma. Recall # B-0873-10;
2) Red Blood Cells Leukocytes Reduced. Recall # B-0874-10;
3) Plasma Cryoprecipitated Reduced. Recall # B-0875-10;
4) Cryoprecipitated AHF, Pooled. Recall # B-0876-10;
5) Plasma Frozen. Recall # B-0877-10

CODE
1) Units: 003LC36109, 003GF30610, 003GT78728, 003GT77793 and 003FY08162;

2) Units: 003FQ69159, 003KH36107, 003FQ67312, 003LC36109, 003GF30610, 003GT78728, 003GT77793 and 003FY08162;
3) and 4) Unit: 003KH36107;

5) Unit: 003FQ67312

RECALLING FIRM/MANUFACTURER
Manufacturer: The American National Red Cross – Southern Region, Douglasville, GA. Firm initiated recall is complete.

REASON
Blood products, that tested negative for hepatitis, but were collected from an ineligible donor due to a history of jaundice, were distributed.

VOLUME OF PRODUCT IN COMMERCE
16 units

DISTRIBUTION
AL, GA, PA

____________________________
PRODUCT
Red Blood Cells Leukocytes Reduced. Recall # B-0878-10
CODE
Units: W137509201624, W137508207731, W137508205541, W137508204528

RECALLING FIRM/MANUFACTURER
Lane Memorial Blood Bank, Eugene, OR, by letter on September 21, 2009. Firm initiated recall is complete.

REASON
Blood products, collected from a donor who reported travel to a malarial endemic area, were distributed.

VOLUME OF PRODUCT IN COMMERCE
4 units

DISTRIBUTION
KY, FL and OR

____________________________
PRODUCT
Red Blood Cells Leukocytes Reduced. Recall # B-0879-10
CODE
Unit: W115909251924

RECALLING FIRM/MANUFACTURER
Central California Blood Center, Fresno, CA, by e-mail on October 6, 2009. Firm initiated recall is complete.

REASON
Blood product, collected from a donor who reported travel to a malarial endemic area, was distributed.

VOLUME OF PRODUCT IN COMMERCE
1 unit

DISTRIBUTION
CA
PRODUCT
1) Red Blood Cells Leukocytes Reduced. Recall # B-0881-10;
2) Recovered Plasma. Recall # B-0882-10
CODE
1) and 2) Unit: W036508078821
RECALLING FIRM/MANUFACTURER
LifeShare Blood Centers, Alexandria, LA, by letter and e-mail on April 7, 2009. Firm initiated recall is complete.
REASON
Blood products, collected from a donor who received a tattoo within 12 months of donating, were distributed.
VOLUME OF PRODUCT IN COMMERCE
2 units
DISTRIBUTION
Austria, LA

PRODUCT
Aldagen, Aldecount, 20 Tests, Recall # B-0949-10
CODE
Lot numbers: 081203040004, 09050704005, 090701040006
RECALLING FIRM/MANUFACTURER
Aldagen, Inc., Durham, NC, by e-mail on July 30, 2009. Firm initiated recall is complete.
REASON
Aldagen, Aldecout Tests, associated with complaints of loss of activity in Reagent tubes, were distributed.
VOLUME OF PRODUCT IN COMMERCE
6 kits
DISTRIBUTION
NC, WA

PRODUCT
Clearlink System Y-Type Blood/Solution Set with Standard Blood Filter (170 to 260 micron) and 1 Clearlink Valve 6" from Male Luer Lock Adapter; approx. drops per mL 10, approx overall length 112" (2.8 m); an Rx, single use device; product code 2C8750. Recall # B-0950-10
CODE
Lot numbers: UR09G21135, UR09H03156, UR09G21094, UR09G31175, UR09H03016, UR09G31043
RECALLING FIRM/MANUFACTURER
Manufacturer: Baxter Healthcare Corp., of Puerto Rico S.A., Aibonito, PR. Firm initiated recall is ongoing.
REASON
Blood filters, containing fiber-like particulate, which have the potential to be infused into the patient, were distributed.
VOLUME OF PRODUCT IN COMMERCE
37,776 sets
DISTRIBUTION
Nationwide and Canada

RECALLS AND FIELD CORRECTIONS: BIOLOGICS - CLASS III

| PRODUCT | Recovered Plasma. Recall # B-0510-10 |
| CODE | Unit: 003FM21935 |
| RECALLING FIRM/MANUFACTURER | Recalling Firm: The American National Red Cross, Douglasville, GA, by telephone and e-mail on November 1, 2007 and by letter on November 2, 2007. Manufacturer: The American National Red Cross – Southern Region, Douglasville, GA. Firm initiated recall is complete. |
| REASON | Blood product, collected from a donor for whom donor suitability was not adequately determined, was distributed. |
| VOLUME OF PRODUCT IN COMMERCE | 1 unit |
| DISTRIBUTION | CA |

| PRODUCT | Recovered Plasma. Recall # B-0675-10 |
| CODE | Units: 06FW35951, 06FW37598, 06FW39125 |
| RECALLING FIRM/MANUFACTURER | The American National Red Cross, Pomona, CA, by telephone, e-mail and letter on April 24, 2009. Firm initiated recall is complete. |
| REASON | Blood products, collected from an ineligible donor, were distributed. |
| VOLUME OF PRODUCT IN COMMERCE | 3 units |
| DISTRIBUTION | CA |

| PRODUCT | 1) Red Blood Cells Leukocytes Reduced. Recall # B-0698-10; 2) Plasma Frozen. Recall # B-0699-10 |
| CODE | 1) and 2) Unit: W040709170029 |
| RECALLING FIRM/MANUFACTURER | Indiana Blood Center, Indianapolis, IN, by letter on August 25, 2009. Firm initiated recall is complete. |
REASON
Blood products, collected from an unsuitable donor due to a history of hemochromatosis, were distributed.

VOLUME OF PRODUCT IN COMMERCIA
2 units

DISTRIBUTION
IN

PRODUCT
Red Blood Cells Leukocytes Reduced. Recall # B-0703-10

CODE
Units: 29GH53830; 29GH53832; 29GH53833; 29GL92921; 29GL92923; 29GL92928; 29GH53837

RECALLING FIRM/MANUFACTURER
American National Red Cross Mid Atlantic Region, Norfolk, VA, by telephone on November 1, 2008 and follow up letter dated November 19, 2008. Firm initiated recall is complete.

REASON
Blood products, incorrectly tested for Human Lymphotropic Virus I/II, were distributed.

VOLUME OF PRODUCT IN COMMERCIA
7 units

DISTRIBUTION
VA, PA

PRODUCT
1) Red Blood Cells, Leukocytes Reduced. Recall # B-0769-10;

2) Plasma, Frozen. Recall # B-0770-10;

3) Platelets, Pheresis, Leukocytes Reduced. Recall # B-0771-10;

4) Cryoprecipitated AHF. Recall # B-0772-10;

5) Plasma, Cryoprecipitate Reduced. Recall # B-0773-10;

6) Red Blood Cells, Leukocytes Reduced, Irradiated. Recall # B-0774-10;

7) Platelet, Pheresis, Leukocytes reduced, irradiated. Recall # B-0775-10

CODE
1) Units: 1164280, 1164281, 1164282, 1164288, 1164289, 1164290, 1164308, 1164309, 1164311, 1164313, 1457241, 1457242, 1457243, 1457244, 1457247, 1457248, 1457249, 1458936, 1458938, 1459233, 1459236, 1459238, 1459239, 1459240, 1459244, 1459245, 1459249, 1459276, 1459278, 1459280, 1459281, 1459382, 1459383, 1459384, 1459385, 1459387, 1459436, 1459502, 1459505, 1459506, 1459507, 1459745, 1459746, 1459747, 1459748, 1460001, 1460004, 1460008, 1460019, 1460020, 1460023, 1460026, 1460029, 1460030, 1460033, 1460037, 1460039, 1460040, 1460043, 1460047, 1460660, 1460662,
2) Units: 1460664, 1460666, 1460670, 1460674, 1460678, 1460682, 1461074, 1461075, 1461076, 1461081, 1461085, 1461089, 1461106, 1461108, 1461111, 1461114, 1461118, 1461122, 1461123, 1461124, 1461126, 1461127, 1461136, 1461166, 1461168, 1461171, 1461172, 1461173, 1461176, 1461177, 1461182, 1461186, 1461191, 1461201, 1461202, 1461204, 1461228, 1461230, 1461579, 1461618, 1461638, 1461639, 1461641, 1461763, 1461765, 1462015, 1462020, 1462028, 1462035, 1462036, 1462037, 1462040, 1462041, 1462074, 1580250, 1580505, 1580507, 1580514, 1580515, 1580532, 1580533, 1580535, 1580537, 1580538, 1580539, 1580540, 1580543, 1580544, 1580546, 1580549, 1580553, 1580554, 1580566, 1580569, 1580579, 1580591, 1580596, 1580603, 1580607, 1580611, 1580616, 1580617, 1580618, 1580627, 1580632, 1580643, 1580645, 1580652, 1580656, 1580667, 1580671, 1580678, 1580709, 1580711, 1580713, 1580715, 1580717, 1580721, 1580728, 1582307, 1582308, 1582309, 1582310, 1582311, 1582312, 1582314, 1582315, 1582316, 1582317, 1582391, 1582394, 1582396, 1582398, 1582430, 1582431, 1582432, 1582434, 1582436, 1582437, 1582439, 1582440, 1582442, 1582444, 1582446, 1582453, 1582455, 1582460, 1582462, 1582463, 1582465, 1582480, 1582481, 1582482, 1582483, 1582773, 1582774, 1582775, 1582776, 1582777, 1582779, 1582780, 1582781, 1582784, 1582786, 1582804, 1582809, 1582810, 1582812, 1582813, 1582815, 1582816, 1582817, 1583308, 1583313, 1583316, 1583321, 1583322, 1583324, 1584089, 1584106, 1584108, 1584192, 1584194, 1584197, 1584200, 1584202, 1584211, 1584224, 1584245, 1584246, 1584835, 1584838, 1584841, 1584843, 1585107, 1585109, 1585111, 1585125, 1585130, 1585131, 1585242, 1585243, 1585251, 1585254, 1585259, 1585260, 1585262, 1585313, 1585319, 1585321, 1585323, 1586024, 1586026, 1588767, 1588772, 1588779, 1588782, 1588792, 1588793, 1588794 and 3320942;

3) Units 1409178 (bags 1 and 2), 1409240, 1409243, 1409244, 1409282, 1409420, 1409421 (bags 1 and 2), 1409435 (bags 1 and 2), 1409436, 1409438 (bags 1 and 2), 1409442, 1409446, 1409457 (bags 1 and 2), 1409461, 1409466 (bags 1 and 2), 1409467, 1409485 (bags 1 and 2), 1409486, 1409496 (bags 1 and 2), 1409497 (bags 1 and 2), 1409518, 1409521, 1409522, 1409539 (bags 1 and 2), 1409541 (bags 1 and 2), 1545010 (bags 1 and 2), 1545011, 1545101, 1545102, 1545251 (bags 1 and 2), 1545253, 1545259, 1545278, 1545342, 1545345 bags 1 and 2), 1545357 and W040709610017;

4) Units: 1460662, 1460674, 1460677, 1461637, 1461641 and 1461765;

5) Unit: 1584839;

6) Units: 1459277, 1580574, 1582429, 1582433, 1586001, 1588759 and 1588765;
7) Units: 1409420, 1409423, 1409462, 1409463, and 1545384

**RECALLING FIRM/MANUFACTURER**
Indiana Blood Center, Indianapolis, IN, by letter on March 3, 2009. Firm initiated recall is complete.

**REASON**
Blood products, collected from a donor whose temperature was not determined, were distributed.

**VOLUME OF PRODUCT IN COMMERCE**
391 units

**DISTRIBUTION**
FL, IN, KY, NJ, OH, PA, WA

---

**PRODUCT**
Source Plasma. Recall # B-0779-10

**CODE**
Units: 07MOHH0744; 07MOHG9692; 07MOHF8605; 07MOHF7620; 07MOHF6979; 07MOHF5602; 07MOHF3752; 07MOHF2647; 07MOHF1959; 07MOHG2012; 07MOHH2545; 07MOHH1509

**RECALLING FIRM/MANUFACTURER**
BioLife Plasma Services LP, Lima, OH, by fax on September 3, 2009 and by e-mail on September 4, 2009. Firm initiated recall is complete.

**REASON**
Blood products, collected from a donor whose suitability to donate was not adequately determined, were distributed.

**VOLUME OF PRODUCT IN COMMERCE**
12 units

**DISTRIBUTION**
Austria, CA

---

**PRODUCT**
Recovered Plasma. Recall # B-0801-10

**CODE**
Unit: 50LW80199

**RECALLING FIRM/MANUFACTURER**
American Red Cross Blood Services, Western Lake Erie Region, Toledo, OH, by telephone and electronically (Logic) on August 11, 2009 and follow-up letter dated August 13, 2009. Firm initiated recall is complete.

**REASON**
Blood product, collected from a donor whose suitability to donate was not adequately determined, was distributed.

**VOLUME OF PRODUCT IN COMMERCE**
1 unit

**DISTRIBUTION**
CA

---

**PRODUCT**
Red Blood Cells Leukocytes Reduced Irradiated. Recall # B-0806-10

**CODE**
Units: 2007848; 2507803

**RECALLING FIRM/MANUFACTURER**

**REASON**
Blood products, which were not maintained at an acceptable temperature during shipping, were distributed.

**VOLUME OF PRODUCT IN COMMERCE**
2 units

**DISTRIBUTION**
NY

**PRODUCT**
Recovered Plasma. B-0809-10

**CODE**
Unit: 017KM71111

**RECALLING FIRM/MANUFACTURER**

**REASON**
Blood product, collected from a donor whose suitability to donate was not adequately determined, was distributed.

**VOLUME OF PRODUCT IN COMMERCE**
1 unit

**DISTRIBUTION**
CA

**PRODUCT**
Platelets Pheresis Leukocytes Reduced. Recall # B-0823-10

**CODE**
Unit: W091009283391

**RECALLING FIRM/MANUFACTURER**
Recalling Firm: Oklahoma Blood Institute - Sylvan N Goldman Center, Oklahoma City, OK, by telephone on October 19, 2009 and by facsimile on November 6, 2009. Manufacturer: Oklahoma Blood Institute, Northwest Oklahoma Blood Institute, Enid, OK. Firm initiated recall is complete.

**REASON**
Blood product, for which the viral marker testing was performed incorrectly, was distributed.

**VOLUME OF PRODUCT IN COMMERCE**
1 unit

**DISTRIBUTION**
OK
PRODUCT
1) Platelets Pheresis Leukocytes Reduced. Recall # B-0834-10;
2) Platelets Pheresis Leukocytes Reduced Irradiated. Recall # B-0835-10

CODE
1) Units: 2547798, 2547790, 2547790, 2547787, 2547787, 25477800, 2547796, 2547796,
2547789, 2547791, 2547791, 2547797, 2547799;
2) Unit: 2547793

RECALLING FIRM/MANUFACTURER
Central Texas Regional Blood and Tissue Center, Austin, TX, by fax on November 13,
2007. Firm initiated recall is complete.

REASON
Blood products, with platelet counts determined using controls that were out of range,
were distributed.

VOLUME OF PRODUCT IN COMMERCE
14 units

DISTRIBUTION
TX

PRODUCT
Recovered Plasma. Recall # B-0842-10

CODE
Units: 1173670; 1349426

RECALLING FIRM/MANUFACTURER
Recalling Firm: Memorial Blood Centers, Saint Paul, MN, by letter dated October 15,
2009.
Manufacturer: Memorial Blood Centers - Duluth, Duluth, MN. Firm initiated recall is
complete.

REASON
Blood products, collected from a donor whose suitability to donate was not adequately
determined, were distributed.

VOLUME OF PRODUCT IN COMMERCE
2 units

DISTRIBUTION
Switzerland

PRODUCT
Source Plasma. Recall # B-0845-10

CODE
Unit: 4040161544

RECALLING FIRM/MANUFACTURER
recall is complete.

REASON
Blood product, collected from a donor whose suitability to donate was not adequately determined, was distributed.

**VOLUME OF PRODUCT IN COMMERCE**
1 unit

**DISTRIBUTION**
IL

**PRODUCT**
1) Red Blood Cells Leukocytes Reduced. Recall # B-0847-10
2) Recovered Plasma. Recall # B-0848-10

**CODE**
1) and 2) Unit: W042309052914

**RECALLING FIRM/MANUFACTURER**

**REASON**
Blood products, collected from a donor who previously tested positive on an HIV antigen test, were distributed.

**VOLUME OF PRODUCT IN COMMERCE**
2 units

**DISTRIBUTION**
MT, Switzerland

---

Red Blood Cells Leukocytes Reduced. Recall # B-0850-10

**CODE**
Unit: W125609466774

**RECALLING FIRM/MANUFACTURER**

**REASON**
Blood product, which was not quarantined after receiving post donation information concerning the donor having received a shingles vaccination, was distributed.

**VOLUME OF PRODUCT IN COMMERCE**
1 unit

**DISTRIBUTION**
CA

---

Red Blood Cells Leukocytes Reduced Irradiated. Recall # B-0851-10

**CODE**
Units: W224309317020; W224309318408; W224309318344; W224309702826; W224309319157; W224308303814; W224308306000; W224308308255; W224308308313; W224309311381; W224309312211; W224309313902; W224309314009; W224309316794

**RECALLING FIRM/MANUFACTURER**
Houchin Blood Services, Bakersfield, CA, by fax on December 7, 2009. Firm initiated recall is complete.

**REASON**
Blood products, labeled with an extended expiration date, were distributed.

**VOLUME OF PRODUCT IN COMMERCE**
14 units

**DISTRIBUTION**
CA

---

**PRODUCT**
Platelets Pooled Leukocytes Reduced. Recall # B-0861-10

**CODE**
Unit: W120609383470

**RECALLING FIRM/MANUFACTURER**
Michigan Community Blood Centers, Saginaw, MI, by fax on November 6, 2009 and November 10, 2009. Firm initiated recall is complete.

**REASON**
Blood product, collected from a donor who reported post donation illness, was distributed.

**VOLUME OF PRODUCT IN COMMERCE**
1 unit

**DISTRIBUTION**
MI

---

**PRODUCT**
1) Red Blood Cells, Leukocytes Reduced. Recall # B-0867-10;

2) Plasma, Frozen. Recall # B-0868-10;

3) Platelets, Pheresis, Leukocytes Reduced. Recall # B-0869-10;

4) Red Blood Cells, Leukocytes Reduced, Irradiated. Recall # B-0870-10;

5) Red Blood Cells (Apheresis), Leukocytes Reduced. Recall # B-0871-10;

6) Plasma, Cryoprecipitate Reduced. Recall # B-0872-10

**CODE**
1) Units: 1166526, 1166527, 1166531, 1166537, 1168154, 1168155, 1168157, 1168161, 1168163, 1168164, 1168165, 1168786, 1168805, 1168807, 1459786, 1459787, 1459789, 1459791, 1459793, 1459877, 1459879, 1459880, 1459881, 1459883, 1459884, 1459885, 1580733, 1580735, 1580885, 1580886, 1580893, 1580899, 1580900, 1580920, 1580923, 1583746, 1583748, 1585402, 1593007, 1593012, 1593016, 1593022, 1593027, 1593041, 1593045, 1593427, 1593430, 1593432, 1593443, 1593463, 1593466, 1593467, 1593483, 1593486, 1594038, 1594042, 1594049, 1594067, 1594076, 1594239, 1594247, 1595393, 1595761, 1595775, 1595779, 1595794, 1595795, 1595797, 1595799, 1595802, 1595842, 1595845, 1595847, 1595849, 1595853, 1595855, 1595858, 1595863, 1595869, 1595872,
1595874, 1595875, 1596030, 1596035, 1596037, 1596039, 1596041, 1596043, 1596197, 1596200, 1596201, 1596202, 1596209, 1596211, 1596213, 1596218, 1596221, 1596222, 1863184, 1863189, 1863191, 1863192, 1863194, 1863319, 1863321, 1863325, 1863365, 1863366, 1863381, 1863383, 3205325, 3205327, 3205329, 3516923, 3516924, 3516926, 3516928, 3516930, 3516932, 3516935, 3516936, 3516937 and 4181709;

2) Units: 1166531, 1580885, 1580920, 1594076, 1594042, 1595781, 1595875, 1596041 and 1596221;

3) Units: 1120030, 1120031 and 1661307 (split);

4) Units: 1168158, 1168159, 1168160, 1580731, 1595781, 1596203 and 3516931;

5) Units: 1970119 (split);

6) Units: 1168165 and 1594038

RECALLING FIRM/MANUFACTURER
Indiana Blood Center, Indianapolis, IN, by telephone on December 12, 2008 and by e-mail on January 14, 2009. Firm initiated recall is complete.

REASON
Blood products, collected from a donor whose temperature was not determined, were distributed.

VOLUME OF PRODUCT IN COMMERCE
147 units

DISTRIBUTION
IN, OH, PA, TN

RECALLS AND FIELD CORRECTIONS: DEVICES - CLASS I

PRODUCT
1) Cardiac Science Powerheart 9300A automated external defibrillator. This fully automatic model does not require the user to press a shock button in order for the device to deliver therapy (when appropriate). Intended for use in either in-hospital or out-of-hospital settings for emergency treatment of victims exhibiting symptoms of sudden cardiac arrest who are unresponsive and not breathing. Recall # Z-0765-2010;

2) Cardiac Science Powerheart 9300C automated external defibrillator. This semi-automatic model requires the user to press a shock button in order for the device to deliver defibrillation energy (when appropriate). Intended for use in either in-hospital or out-of-hospital settings for emergency treatment of victims exhibiting symptoms of sudden cardiac arrest who are unresponsive and not breathing. Recall # Z-0766-2010;

3) Cardiac Science Powerheart 9300D automated external defibrillator. This semi-automatic model requires the user to press a shock button in order for the device to deliver defibrillation energy (when appropriate). Intended for use in either in-hospital or
out-of-hospital settings for emergency treatment of victims exhibiting symptoms of sudden cardiac arrest who are unresponsive and not breathing. Recall # Z-0767-2010;

4) Cardiac Science Powerheart 9300E automated external defibrillator. This semi-automatic model requires the user to press a shock button in order for the device to deliver defibrillation energy (when appropriate). Intended for use in either in-hospital or out-of-hospital settings for emergency treatment of victims exhibiting symptoms of sudden cardiac arrest who are unresponsive and not breathing. Recall # Z-0768-2010;

5) Cardiac Science Powerheart 9300P automated external defibrillator. This semi-automatic model requires the user to press a shock button in order for the device to deliver defibrillation energy (when appropriate). Intended for use in either in-hospital or out-of-hospital settings for emergency treatment of victims exhibiting symptoms of sudden cardiac arrest who are unresponsive and not breathing. Recall # Z-0769-2010;

6) Cardiac Science Powerheart 9390A automated external defibrillator. This fully automatic model does not require the user to press a shock button in order for the device to deliver therapy (when appropriate). Intended for use in either in-hospital or out-of-hospital settings for emergency treatment of victims exhibiting symptoms of sudden cardiac arrest who are unresponsive and not breathing. Recall # Z-0770-2010;

7) Cardiac Science Powerheart 9390E automated external defibrillator. This semi-automatic model requires the user to press a shock button in order for the device to deliver defibrillation energy (when appropriate). Intended for use in either in-hospital or out-of-hospital settings for emergency treatment of victims exhibiting symptoms of sudden cardiac arrest who are unresponsive and not breathing. Recall # Z-0771-2010;

8) Burdick Cardiovive 92531 automated external defibrillator. This semi-automatic model requires the user to press a shock button in order for the device to deliver defibrillation energy (when appropriate). Intended for use in either in-hospital or out-of-hospital settings for emergency treatment of victims exhibiting symptoms of sudden cardiac arrest who are unresponsive and not breathing. Recall # Z-0772-2010;

9) Burdick Cardiovive 92532 automated external defibrillator. This semi-automatic model requires the user to press a shock button in order for the device to deliver defibrillation energy (when appropriate). Intended for use in either in-hospital or out-of-hospital settings for emergency treatment of victims exhibiting symptoms of sudden cardiac arrest who are unresponsive and not breathing. Recall # Z-0773-2010;

10) Burdick Cardiovive 92533 automated external defibrillator. This semi-automatic model requires the user to press a shock button in order for the device to deliver defibrillation energy (when appropriate). Intended for use in either in-hospital or out-of-hospital settings for emergency treatment of victims exhibiting symptoms of sudden cardiac arrest who are unresponsive and not breathing. Recall # Z-0774-2010;

11) GE Responder 2019198 automated external defibrillator. This semi-automatic model requires the user to press a shock button in order for the device to deliver defibrillation
energy (when appropriate). Intended for use in either in-hospital or out-of-hospital settings for emergency treatment of victims exhibiting symptoms of sudden cardiac arrest who are unresponsive and not breathing. Recall # Z-0775-2010;

12) GE Responder 2023440 automated external defibrillator. This semi-automatic model requires the user to press a shock button in order for the device to deliver defibrillation energy (when appropriate). Intended for use in either in-hospital or out-of-hospital settings for emergency treatment of victims exhibiting symptoms of sudden cardiac arrest who are unresponsive and not breathing. Recall # Z-0776-10;

13) NK 9231 CardioLife automated external defibrillator. This semi-automatic model requires the user to press a shock button in order for the device to deliver defibrillation energy (when appropriate). Intended for use in either in-hospital or out-of-hospital settings for emergency treatment of victims exhibiting symptoms of sudden cardiac arrest who are unresponsive and not breathing. Recall # Z-0777-2010;

14) NK 9200G. CardioLife automated external defibrillator. This semi-automatic model requires the user to press a shock button in order for the device to deliver defibrillation energy (when appropriate). Intended for use in either in-hospital or out-of-hospital settings for emergency treatment of victims exhibiting symptoms of sudden cardiac arrest who are unresponsive and not breathing. Recall # Z-0778-2010

CODE
1) Serial Numbers: 9300A, 366730, 365060AB, 364566A, 365143, 364965AB, 364993A, 360361, 378677, 378649, 379267, 382912, 381076, 380427, 390981, 365269, 365268, 365266, 365265, 365263, 365262, 365271, 365258, 365277, 365257, 365256, 365255, 365260, 365282, 365293, 365292, 365289, 365288, 365287, 365275, 365283, 365273, 365281, 365280, 365279, 365252, 365276, 365294, 365284, 365218, 365226, 365225, 365224, 365223, 365222, 365221, 365254, 365219, 365230, 365217, 365216, 365215, 365214, 365213, 365212, 365220, 365238, 365327, 365250, 365248, 365246, 365245, 365243, 365227, 365239, 365229, 365236, 365235, 365234, 365233, 365232, 365231, 365253, 365241, 365369, 365377, 365376, 365375, 365374, 365372, 365325, 365370, 365381, 365367, 365366, 365365, 365364, 365363, 365362, 365371, 365389, 365398, 365397, 365396, 365395, 365394, 365392, 365378, 365390, 365379, 365388, 365387, 365384, 365383, 365382, 365358, 365391, 365332, 365361, 365339, 365338, 365337, 365336, 365335, 365341, 365333, 365342, 365331, 365330, 365329, 365328, 365206, 365326, 365334, 365349, 365211, 365357, 365356, 365355, 365353, 365352, 365340, 365350, 365360, 365348, 365347, 365346, 365345, 365344, 365343, 365351, 365108, 365115, 365114, 365113, 365112, 365111, 365099, 365109, 365118, 365106, 365105, 365103, 365102, 365101, 365135, 365110, 365125, 365209, 365133, 365131, 365130, 365129, 365128, 365126, 365116, 365117, 365124, 365123, 365121, 365120, 365119, 365097, 365127, 365069, 365077, 365076, 365075, 365074, 365073, 365100, 365070, 365081, 365068, 365067, 365066, 365065, 365063, 365062, 365072, 365088, 365096, 365095, 365094, 365093, 365092, 365091, 365090, 365089, 365080, 365087, 365085, 365084, 365083, 365082, 365136, 365090, 365182, 365190, 365188, 365187, 365186, 365185, 365174, 365183, 365193, 365181, 365179, 365178, 365177, 365176, 365134, 365184, 365199, 365061, 365207, 365402, 365205, 365204, 365203, 365191,
2) Serial Numbers: 330941, 330942, 330944, 330945, 330947, 330948, 330950, 330951, 330952, 330954, 330956, 330958, 330959, 330960, 330962, 330963, 330964, 330965, 330966, 330967, 330968, 330969, 330970, 330972, 330973, 330975, 330976, 330977, 330978, 330979, 330980, 330981, 330983, 330985, 330986, 330987, 330988, 330989, 330990, 330992, 330993, 330994, 330995, 330996, 330997, 330998, 330999, 331001, 331002, 331004, 331005, 331006, 331009, 331010, 331011, 331012, 331013, 331016, 331017, 331018, 331019, 331020, 331261, 331262, 331263, 331266, 331267, 331268, 331269, 331270, 331271, 331272, 331273, 331274, 331275, 331277, 331280, 331281, 331282, 331283, 331284, 331285, 331286, 331287, 331288, 331289, 331290, 331291, 331292, 331293, 331294, 331295, 331296, 331297, 331298, 331299, 331300, 331301, 331302, 331303, 331304, 331305, 331306, 331307, 331308, 331310, 331311, 331312, 331313, 331315, 331316, 331319, 331320, 331321, 331322, 331323, 331325, 331326, 331328, 331329, 331330, 331331, 331332, 331333, 331334, 331336, 331337, 331338, 331339, 331340, 332181, 332182, 332183, 332184, 332185, 332186, 332187, 332189, 332190, 332191, 332192, 332193, 332194, 332195, 332196, 332197, 332198, 332199, 332200, 332201, 332202, 332203, 332204, 332206, 332207, 332208, 332209, 332210, 332211, 332212, 332213, 332214, 332215, 332216, 332217, 332218, 332219, 332220, 332221, 332222, 332223, 332224, 332225, 332226, 332227, 332228, 332229, 332230, 332231, 332232, 332233, 332234, 332235, 332236, 332237, 332238, 332239, 332240, 332241, 332242, 332243, 332244, 332245, 332246, 332247, 332249, 332250, 332251, 332252, 332253, 332254, 332255, 332256, 332257, 332258, 332259, 332260, 332261, 332262, 332263, 332264, 332266, 332267, 332268, 332269, 332270, 332271, 332273, 332274, 332275, 332276, 332277, 332278, 332281, 332284, 332285, 332286, 332287, 332288, 332290, 332291, 332292, 332293, 332295, 332296, 332297, 332298, 332299, 332300, 332302, 332303, 332304, 332305, 332306, 332307, 332309, 332310, 332311, 332313, 332314, 332315, 332316, 332318, 332319, 332320, 332321, 332322, 332324, 332325, 332327, 332328, 332329, 332330, 332331, 332332, 332333, 332334, 332335, 332336, 332337, 332338, 332339, 332340, 332341, 332342, 332343, 332344,
3) Serial Numbers: 378784, 378785, 378786, 378787, 378788, 378789, 378790, 378791, 378792, 378793, 378794, 378795, 378796, 378797, 378798, 378799, 378800, 378801, 378802, 378803, 378804, 378805, 378806, 378807, 378808, 378809, 378810, 378811, 378812, 378813, 378814, 378815, 378816, 378817, 378818, 378819, 378820, 378821, 378822, 378823, 378824, 378825, 378826, 378827, 378828, 378829, 378830, 378831, 378832, 378833, 378834, 378835, 378836, 378837, 378838, 378839, 378840, 378841, 378842, 378843, 378844, 378845, 378846, 378847, 378848, 378849, 378850, 378851, 378852, 378853, 378854, 378855, 378856, 378857, 378858, 378859, 378860, 378861, 378862, 378863, 378864, 378865, 378866, 378867, 378868, 378869, 378870, 378871, 378872, 378873, 378874, 378875, 378876, 378877, 378878, 378879, 378880, 378881, 378882, 378883, 378884, 378885, 378886, 378887, 378888, 378889, 378890, 378891, 378892, 378893, 378894, 378895, 378896, 378897, 378898, 378899, 378900, 378901, 378902, 378903, 378904, 378905, 378906, 378907, 378908, 378909, 378910, 378911, 378912, 378913, 378914, 378915, 378916, 378917, 378918, 378919, 378920, 378921, 378922, 378923, 378924, 378925, 378926, 378927, 378928, 378929, 378930, 378931,
4) Serial Numbers: 364187, 368050, 368195, 356572, 355815, 355804, 363695, 360983, 356902, 359149, 354826, 357973, 354955, 356263, 354748, 357825, 363207, 357345, 354660, 359982, 359618, 363759, 357351, 356050, 360381, 355758, 359493, 354731, 362105, 329074, 329051, 329426, 329049, 329422, 329069, 329437, 329057, 329082, 379032, 379033, 379034, 379035, 379036, 379037, 379038, 379039, 379040, 379041, 379042, 379043, 379044, 379045, 379046, 379047, 379048, 379049, 379050, 379051, 379052, 379053, 379054, 379055, 379056, 379057, 379058, 379059, 379060, 379061, 379062, 379063, 379064, 379065, 379066, 379067, 379068, 379069, 379070, 379071, 379072, 379073, 379074, 379075, 379076, 379077, 379078, 379079, 379080, 379081, 379082, 379083;
5) Serial Numbers: 391776, 393102, 402793, 404926, 900002, 900003, 900004, 900005,
900006, 900007, 900008, 900009, 900010, 900011, 900012, 900013, 900014, 900015,
900016, 900017, 900018, 900019, 900020, 900021, 900022, 900023, 900024, 900025,
900026, 900027, 900028, 900029, 900030, 900035, 900036, 900037, 900038, 900039,
900040, 900041, 900042, 900044, 900045, 900046, 900047, 900048, 900049, 900050,
900051, 900052, 900053, 900054, 900055, 900056, 900057, 900058, 900059, 900060,
900062, 900063, 900064, 900065, 900066, 900067, 900068, 900069, 900070, 900071,
900072, 900073, 900075, 900076, 900077, 900078, 900079, 900080, 900081, 900082,
900083, 900084, 900085, 900086, 900087, 900088, 900089, 900090, 900091, 900092,
900093, 900094, 900096, 900097, 900099, 900100, 900102, 900103, 900104, 900105,
900106, 900107, 900108, 900109, 900121, 900123, 900124, 900126, 900127, 900128,
900129, 900131, 900132, 900133, 900134, 900135, 900136, 900138, 900139, 900140,
900142, 900143, 900144, 900145, 900146, 900147, 900148, 900149, 900150, 900151,
900152, 900153, 900154, 900156, 900158, 900159, 900160, 900161, 900162, 900165,
900166, 900168, 900169, 900170, 900172, 900173, 900174, 900176, 900177, 900178,
900179, 900180, 900181, 900182, 900183, 900184, 900185, 900186, 900187, 900188,
900189, 900190, 900191, 900192, 900193, 900194, 900195, 900196, 900197, 900199,
900200, 900201, 900202, 900203, 900205, 900206, 900207, 900211, 900212, 900214,
900216, 900217, 900218, 900219, 900220, 900222, 900223, 900224, 900226, 900227,
900228, 900229, 900230, 900231, 900232, 900233, 900234, 900235, 900237, 900238,
900241, 900242, 900243, 900244, 900245, 900246, 900247, 900248, 900249, 900250,
900251, 900252, 900254, 900256, 900257, 900259, 900260, 900261, 900262, 900263,
900264, 900265, 900266, 900268, 900269, 900270, 900271, 900272, 900273, 900274,
900276, 900277, 900278, 900279, 900280, 900281, 900283, 900284, 900288, 900289,
900290, 900291, 900294, 900295, 900297, 900298, 900299, 900300, 900301, 900302,
900305, 900307, 900308, 900309, 900310, 900311, 900312, 900313, 900314, 900315,
900316, 900317, 900318, 900319, 900321, 900322, 900323, 900324, 900325, 900326,
900327, 900328, 900329, 900330, 900331, 900333, 900334, 900335, 900336, 900337,
900338, 900341, 900342, 900343, 900344, 900345, 900346, 900347, 900348, 900349,
900350, 900351, 900352, 900353, 900354, 900356, 900357, 900358, 900360, 900361,
900362, 900363, 900364, 900365, 900366, 900367, 900368, 900369, 900370, 900371,
900372, 900373, 900374, 900375, 900376, 900377, 900378, 900380, 900381, 900382,
900383, 900384, 900388, 900390, 900391, 900394, 900395, 900396, 900397, 900399,
900401, 900402, 900403, 900404, 900405, 900406, 900407, 900409, 900412, 900414,
900418, 900420, 900421, 900422, 900423, 900425, 900426, 900427, 900428, 900429,
900430, 900433, 900434, 900435, 900437, 900439, 900440, 900441, 900444, 900447,
900448, 900449, 900450, 900452, 900453, 900455, 900456, 900457, 900458, 900464,
900467, 900468, 900471, 900473, 900474, 900475, 900480, 900481, 900485, 900488,
900491, 900493, 900495, 900497, 900498, 900501, 900502, 900504, 900506, 900507,
900508, 900510, 900512, 900513, 900514, 900518, 900519, 900520, 900521, 900522,
900523, 900524, 900525, 900527, 900528, 900531, 900532, 900533, 900537, 900538,
900539, 900540, 900541, 900542, 900545, 900546, 900548, 900549, 900550, 900551,
900552, 900553, 900555, 900556, 900557, 900559, 900560, 900561, 900562, 900563,
900565, 900568, 900569, 900570, 900571, 900572, 900573, 900574, 900575, 900576,
900578, 900579, 900580, 900581, 900582, 900584, 900585, 900586, 900587, 900589,
900592, 900593, 900594, 900595, 900596, 900598, 900599, 900600, 900601, 900603,


Serial Numbers: 4191354, 4191355, 4191357, 4191358, 4191359, 4191360, 4191361,
4141844, 4141837, 4141842, 4141843, 4141836, 4141827, 4141804, 4141803, 4165594, 4165595, 4165596, 4165592, 4165685, 4165593, 4165684, 4165670, 4165671, 4165672, 4165673, 4165699, 4165676, 4165701, 4165695, 4165693, 4165691, 4165690, 4165687, 4165708, 4175252, 4175254, 4175255, 4175214, 4175260, 4175253, 4175213, 4175212, 4175211, 4175208, 4175251, 4175217, 4175207, 4175040, 4175210, 4175220, 4175250, 4175243, 4175241, 4175242, 4175244, 4175245, 4175247, 4175249, 4129219, 4129229, 4129228, 4129136, 4129227, 4129225, 4129224, 4129223, 4129222, 4129220, 4129232, 4124054, 4124053, 4129201, 4129221, 4129377, 4129391, 4129233, 4129373, 4129390, 4129374, 4129375, 4129376, 4129231, 4129379, 4129391, 4129378, 4175250, 4175243, 4175241, 4175242, 4175244, 4175245, 4175247, 4175249, 4129219, 4129229, 4129228, 4129136, 4129227, 4129225, 4129224, 4129223, 4129222, 4129220, 4129232, 4124054, 4124053, 4129201, 4129221, 4129377, 4129391, 4129378, 4129373, 4129376, 4129231, 4129379, 4129230, 4129378, 4259189 and 4268760;

8) Serial Numbers: 331327, 331014, 331000, 331317, 330984, 341805, 341827, 341306, 341912, 338527, 331683, 335085, 338117, 3340263, 3341818, 3341820, 341821, 341791, 341890, 338113, 338059, 331944, 338039, 338041, 335057, 331438, 338084, 338053, 331782, 338060, 331923, 338073, 338075, 331316, 3340255, 338050, 3340365, 341787, 341732, 341729, 341726, 340354, 338078, 331717, 338916, 334882, 341703, 341263, 341706, 335258, 338142, 341775, 334945, 341750, 341749, 338035, 334402, 335413, 341497, 338024, 335457, 341966, 341534, 338002, 341518, 341430, 338017, 341511, 338027, 341548, 341566, 341567, 341542, 341434, 335449, 341549, 381727, 381729, 381724, 341888, 341806, 341901, 338079 and 341790;

9) Serial Numbers: 4022185, 92532-0001124, 4022096, 4022095, 4022094, 4022093, 4022092, 4022091, 4022089, 4022088, 4022087, 4022086, 4022085, 4022084, 4022233, 4022234, 4022235, 4022236, 4022090, 4022112, 4022126, 4022125, 4022124, 4022123, 4022122, 4022121, 4022120, 4022119, 4022118, 4022117, 4022116, 4022115, 4022099, 4022113, 4022098, 4022111, 4022110, 4022109, 4022108, 4022107, 4022106, 4022105, 4022104, 4022103, 4022102, 4022101, 4022250, 4022100, 4022114, 4022268, 4022248, 4022278, 4022277, 4022276, 4022275, 4022274, 4022273, 4022272, 4022271, 4022280, 4022269, 4022258, 4022267, 4022266, 4022265, 4022264, 4022263, 4022262, 4022261, 4022260, 4022127, 4022203, 4022202, 4022201, 4022200, 4022199, 4022198, 4022197, 4022196, 4022195, 4022194, 4022192, 4022191, 4022189, 4022187, 4022184, 4022183, 4022182, 4022181, 4022179, 4022178, 4022177, 4022176, 4022175, 4022173, 4022171, 4022170, 4022169, 4022168, 4022167, 4022166, 4022164, 4022163, 4022162, 4022161, 4022160, 4022159, 4022158, 4022157, 4022156, 4022155, 4022154, 4035467, 4035457, 4035458, 4035459, 4035460, 4035461, 4035462, 4035463, 4035464, 4037389, 4035466, 4035454, 4035458, 4035468, 4035469, 4035470, 4035471, 4035472, 4035473, 4035474, 4035465, 4035445, 4035435,
10) Serial Numbers: 4107816, 4025272, 4025260, 4025300, 4025299, 4025296, 4025295, 4025293, 4025292, 4025291, 4025290, 4025284, 4025277, 4025283, 4025280, 4025279, 4025301, 4025266, 4025275, 4025274, 4025273, 4025271, 4025270, 4025267, 4025259, 4025265, 4025264, 4025262, 4025261, 4025285, 4025268, 4018981, 4018974, 4018988, 4018976, 4018977, 4018978, 4018970, 4018980, 4018989,
11) Serial Numbers: 331444, 331468, 331488, 331493, 331496, 331511, 331519, 336294, 336304, 336310, 337095, 337114, 337115, 337120, 337121, 337122, 337123, 337124, 337126, 337127, 337128, 337129, 337130, 337131, 337132, 337133, 337134, 337135, 337136, 337137, 337138, 337139, 337140, 337143, 337145, 337152, 337156, 337165, 337168, 337169, 337170, 337171, 337172, 337173, 337174, 337175, 337176, 337177, 337178, 337179, 337180, 337181, 337182, 337183, 337184, 337185, 337186, 337187, 337188, 337189, 337190, 337191, 337192, 337193, 337194, 337195, 337196, 337197, 337198, 337199, 337200, 337201, 337202, 337203, 337204, 337205, 337206, 337207, 337208, 337209, 337210, 337211, 337212, 337213, 337214, 337215, 337216, 337217, 337218, 337219, 337220, 337221, 337222, 337223, 337224, 337225, 337226, 337227, 337228, 337229, 337230, 337231, 337232, 337233, 337234, 337235, 337236, 337237,
12) Serial Numbers: 900650, 900651, 900652, 900653, 900654, 900655, 900656, 900658, 900659, 900660, 900661, 900662, 900663, 900664, 900665, 900666, 900667, 900668, 900670, 900671, 900672, 900673, 900675, 900677, 900678, 900679, 900680, 900681, 900682, 900683, 900684, 900685, 900686, 900687, 900688, 900689, 900690, 900691, 900692, 900693, 900694, 900695, 900696, 900697, 900698, 900940, 900941,
14) Serial Numbers: 4033818, 4033811, 4033812, 4033813, 4033814, 4033815, 4034542, 4034543, 4033817, 4034546, 4033819, 4033820, 4033821, 4033822, 4033824, 4034541, 4033825, 4033826, 4033827, 4033816, 4034550, 4034553, 4033795, 4033796, 4033797, 4033798, 4034552, 4033800, 4033801, 4034551, 4033802, 4034545, 4033804, 4034544, 4033805, 4034549, 4033806, 4034548, 4033807, 4034547, 4033808, 4033809, 4033810, 4034540, 4033803, 4034660, 4033828, 4034658, 4033849, 4033850, 4033851, 4033852, 4033853, 4033854, 4033855, 4033856, 4033847, 4033659, 4033846, 4034661, 4034662, 4034663, 4034664, 4034665, 4033858, 4034666, 4033859, 4033860, 4033861, 4033857, 4033838, 4034652, 4034556, 4034653, 4033829, 4033831, 4034654, 4033832, 4033833, 4034539, 4033834, 4033848, 4033837, 4033794, 4033839, 4033840, 4033841, 4034655, 4033842, 4034538, 4033843, 4033844, 4033845, 4034656, 4033835, 4034595, 4034606, 4034605, 4034604, 4034603, 4034602, 4034601, 4034600, 4034599, 4034598, 4034585, 4034596, 4034609, 4034593, 4034592, 4034591, 4034589, 4034588, 4034587,
RECALLING FIRM/MANUFACTURER

REASON
Potential for devices not to deliver therapy.

VOLUME OF PRODUCT IN COMMERCE
284,800 units

DISTRIBUTION
Nationwide and Internationally
Micron Bobbin Vent Tube, 1.27 MM I.D., Titanium, REF 145281-ENT, qty 1, Sterile EO. Intended to be implanted for ventilation or drainage of the middle ear. Recall # Z-0797-2010

**CODE**
Lot Number: MH136952

**RECALLING FIRM/MANUFACTURER**
Manufacturer: Gyrus ENT LLC Sub of Gyrus ACMI, Inc., Memphis, TN. Firm initiated recall is ongoing.

**REASON**
Product may have been shipped without being sterilized.

**VOLUME OF PRODUCT IN COMMERCE**
19 boxes /6 units

**DISTRIBUTION**
FL, GA, OH, TX, RI, IL, MI

**PRODUCT**
StatSpin Express 4 Horizontal Centrifuge Model # M510. Intended Use: Rapid Separation of plasma and serum from primary gel collection tubes. Recall # Z-0807-2010

**CODE**
Serial Numbers: 00100 through 001679

**RECALLING FIRM/MANUFACTURER**

**REASON**
Centrifuge shield micro-switch failed due to damage, and the unit opened, ejecting pieces.

**VOLUME OF PRODUCT IN COMMERCE**
1,511 units

**DISTRIBUTION**
Nationwide and Internationally

**PRODUCT**
Beckman Coulter UniCel DxC Synchron Clinical Systems. PN Numbers: A10405 (UniCel DxC 600); A11810 (UniCel DxC 600 PRO); A27318 (UniCel DxC 600i); A11816 (UniCel DxC 800); A11812 (UniCel DxC 800 PRO); A59102 (UniCel DxC 880i); A64903 (UniCel DxC 680i); A64871 (UniCel DxC 660i); A64871 (UniCel DxC 860i). Intended for the in vitro determination of a variety of general chemistries, therapeutic drugs, and other chemistries of clinical interest in biological fluids such as serum, plasma, urine, or cerebrospinal fluid. Recall # Z-0863-2010

**CODE**
All serial numbers

**RECALLING FIRM/MANUFACTURER**
REASON
Excessive Buildup of protein, bacteria and sample tube additives in the ISE flow cell may cause erroneous NA (sodium) results.

VOLUME OF PRODUCT IN COMMERCE
2,630 units

DISTRIBUTION
Nationwide and Canada

RECALLS AND FIELD CORRECTIONS: DEVICES - CLASS II

---------------------------------------------------------------------------------------------------------------

PRODUCT
Auto Suture ProTack Fixation 5 mm Product Catalogue # 174006. Has application in endoscopic surgery procedures. Recall # Z-1157-2010

CODE

RECALLING FIRM/MANUFACTURER

REASON
Fixation device may fail to fire and staple.

VOLUME OF PRODUCT IN COMMERCE
5,638 units

DISTRIBUTION
Nationwide

---------------------------------------------------------------------------------------------------------------

PRODUCT
Leksell Gamma Knife Perfexion, Article #715000. Teletherapy device intended for stereotactic irradiation of head structures ranging from very small target sizes of a few millimeters to several centimeters. Recall # Z-1158-2010

CODE
Serial Numbers: 6002, 6003, 6004, 6006, 6008, 6009, 6010, 6011, 6012, 6014, 6015, 6016, 6020, 6021, 6022, 6023, 6025, 6029, and 6030

RECALLING FIRM/MANUFACTURER

REASON
Need to modify the closing speed of the shielding doors in the event of an emergency exit.

VOLUME OF PRODUCT IN COMMERCE
19 units

DISTRIBUTION
AR, AZ, CA, FL, IL, MI, MN, MS, NJ, OH, OR, PA, UT, VA, France and United Kingdom
PRODUCT
SilverHawk Peripheral Cutter Driver Plaque Excision System REF Catalog No: FG 02550, Sterilized with gamma radiation. Intended for use in atherectomy of the peripheral vasculature. The catheter is NOT intended for use in the coronary or carotid vasculature. Recall # Z-1162-2010

CODE
Lot Numbers: 7341279, 7426555, 7516513, 7584246, 7366716, 7470350, 7526519, 7696072, 7373759, 7481467, 753644, 7381976, 7497872, 7555071, 7408387, 7505507, 7574961, 7341279, 7505507, 7555071, 7381976, 7516513, 7574961, 7408387, 753644, 7696072, 7426555, 7481467, 7470350, and 7497872

RECALLING FIRM/MANUFACTURER
Manufacturer: Ev3, Inc., Irvine, CA. Firm initiated recall is ongoing.

REASON
ev3 Inc. is conducting a voluntary recall of specific lots of the SilverHawk Cutter Drivers (Model Number FG 02550) because of damage to the packaging.

VOLUME OF PRODUCT IN COMMERCE
8,330 units

DISTRIBUTION
Nationwide and Internationally

PRODUCT
1) Aplio 50; SSA-700A; software version 5.5r002. Recall # Z-1171-2010;
2) Aplio 80; SSA-770A; software version 5.5r002. Z-1172-2010;
3) Xario; SSA-660A; software version 1.0 and later. Recall # Z-1173-2010

CODE

2) F4603656, F4603654, F4613731, F5513813, F4613730, F4613732, G5523875, G5523871, A2542234, F4603309, F450331, F4603314, F4603317, D3622941,
RECALLING FIRM/MANUFACTURER
Firm initiated recall is ongoing.

REASON
Toshiba America Medical System Inc initiated a field corrective action on Aplio 50; SSA-700A; software version 5.5r002 and later, Aplio 80; SSA-700A; software version 5.5r002 and later, and Xario; SSA-660A; software version 1.0 and later, because the product does not meet the Safety Standard requirements.

VOLUME OF PRODUCT IN COMMERCE
200 units

DISTRIBUTION
Nationwide
**PRODUCT**
1) AOS Trochanteric Nail, 9mm x 17cm x 130, Product Part Number: 1034-170. Recall # Z-1181-2010;

2) AOS Trochanteric Nail, 9mm x 20cm x 130, Product Part Number: 1034-200. Recall # Z-1182-2010;

3) AOS Trochanteric Nail, 11mm x 17cm x 130, Product Part Number: 1036-170. Recall # Z-1183-2010;

4) AOS Trochanteric Nail, 11mm x 20cm x 130, Product Part Number: 1036-200. Recall # Z-1184-2010;

5) AOS Trochanteric Nail, 13mm x 20cm x 130, Product Part Number: 1037-200. Recall # Z-1185-2010;

6) AOS Trochanteric Nail, 11mm x 20cm x 135, Product Part Number: 1038-200. Recall # Z-1186-2010;

7) AOS Trochanteric Nail, 10mm x 17cm x 130, Product Part Number: 1040-170. Recall # Z-1187-2010;

8) AOS Trochanteric Nail, 10mm x 20cm x 130, Product Part Number: 1040-200. Recall # Z-1188-2010;

9) AOS Trochanteric Nail, 12mm x 17cm x 130, Product Part Number: 1041-170. Recall # Z-1189-2010;

10) AOS Trochanteric Nail, 12mm x 20cm x 130, Product Part Number: 1041-200. Recall # Z-1190-2010;

11) AOS Trochanteric Nail, 10mm x 20cm x 135, Product Part Number: 1042-200. Recall # Z-1191-2010;

12) AOS Trochanteric Nail, 12mm x 20cm x 135, Product Part Number: 1043-200. Recall # Z-1192-2010

**CODE**
1) Lot Numbers: 08558, 09000, & 09001;
2) Lot Number: 09010;
3) Lot Numbers: 08559, 09003, & 09004;
4) Lot Numbers: 08092, 08372, 08625, 09012, & 09013;
5) Lot Numbers: 08373, 09015, & 09034;
6) Lot Number: 09017;
7) Lot Numbers: 08370, 08560, 08635, 09005, & 09006;
8) Lot Numbers: 08374, 08593, & 09018;
9) Lot Numbers: 08371, 08561, & 09008;
10) Lot Numbers: 08375, 08594, 09020, 09021, & 09022;
11) Lot Number: 09023;
12) Lot Numbers: 09024 & 09082

RECALLING FIRM/MANUFACTURER
Manufacturer: JMG Machine Inc., La Mirada, CA. Firm initiated recall is ongoing.

REASON
The recall was initiated after Advanced Orthopaedic Solutions (AOS) became aware of a manufacturing defect involving the short Trochanteric Nail, where one piece was found to be incorrectly bent.

VOLUME OF PRODUCT IN COMMERCE
1,822 units

DISTRIBUTION
Nationwide and Japan

PRODUCT
Avanta Fluid Management Injection System, Avanta Multi-Patient Disposable Set (MPAT) High Pressure Check Valve, Catalog number AVA 500 MPAT, Material number 3018231. Recall # Z-1199-2010

CODE
Lot numbers: 820007 and 820008

RECALLING FIRM/MANUFACTURER

REASON
The product may be defective resulting in a reduction of the saline delivery rate and inadequate air purging.

VOLUME OF PRODUCT IN COMMERCE
2,625 units

DISTRIBUTION
AL, AZ, CA, DC, FL, GA, IL, KS, MD, MO, NM, NY, OH, OK, PA, TN, TX, and WI, Belgium, Germany, and Italy

RECALLS AND FIELD CORRECTIONS: VETERINARY - CLASS II

PRODUCT
Convenia (cefovecin sodium) sterile powder for reconstitution, Injectable, 80 mg/mL, in 10 mL vials. NADA 141-285. Recall # V-060-2010

CODE
Lot number: 0A6C2; expiration date 05/2011

RECALLING FIRM/MANUFACTURER

REASON
Product label has incorrect expiry date. Lot 0A6C2 was incorrectly labeled with an expiration date of 05/2012. The expiration date should be 05/2011.

VOLUME OF PRODUCT IN COMMERCE
5,326 vials
DISTRIBUTION
Nationwide

PRODUCT
NicoletOne vEEG System. Recall # V-061-2010
CODE
n/a
RECALLING FIRM/MANUFACTURER
REASON
CareFusion NeuroCare is voluntarily implementing a field correction to delete certain NicoletOne software protocols, which users may interpret incorrectly when conducting patient evaluations. The field correction involves providing users with instructions for removing the subject protocols and verifying the deletion has been properly conducted. CareFusion NeuroCare believes that the products in the field with the original configuration are not likely to cause any adverse events for patients.
VOLUME OF PRODUCT IN COMMERCE
6 units
DISTRIBUTION
FL, NJ, PA

END OF ENFORCEMENT REPORT FOR MARCH 31, 2010