

November 11, 2009

09-45

RECALLS AND FIELD CORRECTIONS: COSMETICS - CLASS II

PRODUCT

Yes To Cucumber Calm Care Soothing Facial Cosmetic Mud Mask; Product # 391000.
Recall # F-1652-9

CODE

Batch # 592 11 EJ

RECALLING FIRM/MANUFACTURER

Recalling Firm: Yes To Inc., San Francisco, CA, by letter, e-mail and telephone on July 29, 2009.

Manufacturer: E. L. Erman, Ashdod, Israel. Firm initiated recall is ongoing.

REASON

The product is contaminated with Pseudomonas putida.

VOLUME OF PRODUCT IN COMMERCE

1,680 units

DISTRIBUTION

Nationwide

RECALLS AND FIELD CORRECTIONS: FOODS - CLASS I

PRODUCT

Product Label Reads in Part: "Home Made Wife Cake...Yummy from San Francisco...Ingredients: Bleached & Enriched Flour, Cotton Oil, Baking Powder, Sesame, Sugar...Net Wt.: 480g (17 oz) UPC 0 19151 00168 2". Individual cakes are sealed in clear plastic and packaged 6 to a box, 24 boxes per case. Most written information on the box is in Chinese. Recall # F-1632-9

CODE

None

RECALLING FIRM/MANUFACTURER

Shun Fung International Trading, Inc., San Francisco, CA, by telephone on July 23, 2009. Firm initiated recall is ongoing.

REASON

Product contains undeclared egg and wheat.

VOLUME OF PRODUCT IN COMMERCE

Approximately 964 cakes

DISTRIBUTION

WA, CA

PRODUCT

Green Jalapeno Peppers - De-stemmed, packaged in bulk cardboard bins, labeled in part: Rio Jalapeno Peppers Product of Mexico. Recall # F-1633-9

CODE

Lot #48734

RECALLING FIRM/MANUFACTURER

Recalling Firm: A & A Transportation, San Antonio, TX, by telephone on July 10, 2009.
Manufacturer: Agropecuaria El Consuelo, Meoqui, Mexico. Firm initiated recall is complete.

REASON

Green Jalapeno Peppers are contaminated with *Salmonella*.

VOLUME OF PRODUCT IN COMMERCE

20 bins (42,160 lbs)

DISTRIBUTION

TX

PRODUCT

HAIFA SMOKED FISH brand COLD SMOKED WHITEFISH, sold by weight, UPC 8 32007 00025 3 -- KEEP REFRIGERATED AT 38 F. OR BELOW UNTIL CONSUMED. The product is packaged in either vacuum-pack or air-pack. --- NOTE: The press release and recall letter lists the UPC as 832007000263 which was provided to the district by the firm before an original label was received. Recall # F-1634-9

CODE

No lot codes. Sold between 12/07/08 and 6/18/09

RECALLING FIRM/MANUFACTURER

Haifa Smoked Fish, Inc., Jamaica, NY, by press release on July 10, 2009 and letter dated July 14, 2009. Firm initiated recall is ongoing.

REASON

The product was found to be contaminated with *Listeria monocytogenes* based on sampling and analysis by the State of Florida.

VOLUME OF PRODUCT IN COMMERCE

Approximately 408 lbs

DISTRIBUTION

NY, FL

PRODUCT

1) Peregrina Cheese brand QUESO FRESCO Fresh Cheese, 14 Oz. (397g), UPC 8 17424 00024 6; and Chipilo brand MEXICAN CHEESE QUESO FRESCO - Fresh Cheese, Net Wt/Peso Neto 15 oz. (425g), UPC 8 17424 00028 4. The cheese is packaged in a foil wrapped package or a clam-shell container. Recall # F-1635-9;

2) Peregrina Cheese brand QUESO HEBRA Queso Oaxaca, Net Wt. 15 oz. (425g), UPC 8 17424. 00026 0. The cheese is vacuum packed in a plastic bag. Recall # F-1636-9;

3) Peregrina Cheese brand QUESO COTIJA MOLIDO, Net Wt. 15 oz. in plastic bags, UPC 8 17424 00027 7. The cheese is packed in a plastic bag. Recall # F-1637-9;

4) Peregrina Cheese brand CREMA MEXICANA Mexican Cream, Weight 16 oz, UPC 8 17424 00030 1. The product is packed in a plastic tub with a lid. This product was repacked by Peregrina Cheese. Recall # F-1638-9;

5) Peregrina Cheese brand Flan, Net Wt 8 oz. (227 mL), UPC 8 17424 00026 0. The product is packed in a plastic container with a lid. Recall # F-1639-9;

6) Peregrina Cheese brand GELATIN, Net Wt. 10 oz, Plant #36-8431, UPC 8 17424 00031 4. The product is packed in a plastic container with a lid. Recall # F-1640-9

CODE

All lot codes on the market produced since March 17, 2009

RECALLING FIRM/MANUFACTURER

Peregrina Cheese Corp., Brooklyn, NY, by letters on August 12, 2009 and by press release on August 13, 2009. Firm initiated recall is ongoing.

REASON

The products are being recalled as per the Consent Decree since they have the potential to be contaminated with *Listeria monocytogenes*.

VOLUME OF PRODUCT IN COMMERCE

Unknown

DISTRIBUTION

NY, PA

PRODUCT

Fresh Alfalfa Sprouts, 4 oz plastic containers. Recall # F-1641-9

CODE

Sell By: 072209

RECALLING FIRM/MANUFACTURER

Solar Farms, Inc., West Columbia, SC, by press release, telephone and e-mail on/about July 15, 2009. Firm initiated recall is ongoing.

REASON

The product may be contaminated with *Listeria monocytogenes*.

VOLUME OF PRODUCT IN COMMERCE

397 cases (12/4 oz containers per case)

DISTRIBUTION

NC, SC

RECALLS AND FIELD CORRECTIONS: FOODS - CLASS II

PRODUCT

Personal Care non-acetone nail polish remover, conditioner enriched with gelatin, 6 fl. oz., Manufactured in China; UPC 4815592076. Recall # F-032-9

CODE

All lots. (The bottles do not bear lot numbers)

RECALLING FIRM/MANUFACTURER

Recalling Firm: Personal Care Products Inc., Franklin, MI, by press release and letter dated April 28, 2009.

Manufacturer: Fayeshine D M Co. Ltd., Kowloon, Hong Kong SAR. Firm initiated recall is ongoing.

REASON

The product does not meet specifications, as it has a low pH and contains undeclared ingredients.

VOLUME OF PRODUCT IN COMMERCE

Approx. 300,000 bottles

DISTRIBUTION

Nationwide, Honduras and Nicaragua

PRODUCT

Organic Gold Rush Popcorn-brand Sea Salted flavor. Label reads in part: "Organic Gold Rush Popcorn Sea Salted Just Three Ingredients...Net Wt 5.5 oz (156g)...Ingredients: Organic Popcorn, Organic Expeller Pressed Soybean Oil, Sea Salt." UPC:

662118034416. Recall # F-033-9

CODE

Oct 9 09

RECALLING FIRM/MANUFACTURER

Gold Rush Kettle Korn LLC, Benicia, CA, by telephone and e-mail August 21, 2009. Firm initiated recall is ongoing.

REASON

The product contains undeclared sugar.

VOLUME OF PRODUCT IN COMMERCE

42 cases (10 bags per case)

DISTRIBUTION

WA

PRODUCT

Market pantry sugar free tea-to-go lemon iced tea mix, 10 0.07 oz. (2g) Packets, Net Wt 0.71 oz. (20g) 1 S (Display code and case code), 85241463114 (case stock no. or sku), 10085239150136 (case upc). Recall # F-034-9

CODE

Best by 12SEP2010

RECALLING FIRM/MANUFACTURER

Sturm Foods, Inc., Manawa, WI, by telephone on May 6, 2009. Firm initiated recall is ongoing.

REASON

The Ingredient Statement on the display carton incorrectly states Sucralose sweetener. The Ingredient Statement on the inner individual packets are correctly labeled as containing the sweetener Aspartame.

VOLUME OF PRODUCT IN COMMERCE

220 cases (12 display cartons/case; 10 packets/display carton)

DISTRIBUTION

MN, CA, GA, WI, OR, IN, VA, TX, NY, AL, AZ, PA, IA, SC, KS, OH, IL

PRODUCT

- 1) Unbleached Pastry Flour, packed in 50 lb. bags. Recall # F-1607-9;
- 2) Enriched Pastry Flour packed in 50 lb bags. Recall # F-1608-9;
- 3) Multi-Purpose Flour packed in 50 lb. bags; Recall # F-1609-9;

- 4) Seasoned Flour Mix packed in 25 lb. bags; Recall # F-1610-9;
- 5) Western Mix packed in 50 lb. bags. Recall # F-1611-9;
- 6) Batter Mix packed in 40 lb. bags. Recall # F-1612-9;
- 7) Breader Mix packed in 50 lb. bags. Recall # F-1613-9;
- 8) Chicken Breeding Mix packed in 25 lb. bags. Recall # F-1614-9;
- 9) Fish Breeding Mix packed in 25 lb bags. Recall # F-1615-9;
- 10) Lees Famous Mix packed in 40 lb. bags. Recall # F-1616-9;
- 11) Premium Breeding Mix packed in 50 lb. bags. Recall # F-1617-9;
- 12) Claim Jumper Mix packed in 50 lb. bags. Recall # F-1618-9;
- 13) Crispy Breaded Mix packed in 50 lb. bags. Recall # F-1619-9;
- 14) Funnel Cake Mix packed in 25 lb. bags. Recall # F-1620-9;
- 15) Hush Puppy Mix packed in 25 lb. bags. Recall # F-1621-9;
- 16) Pancake and Waffle Mix packed in 50 lb. bags. Recall # F-1622-9;
- 17) Potato Wedge Bread Mix packed in 50 lb. bags. Recall # F-1623-9;
- 18) Seasoned Chicken Mix packed in 25 lb. bags. Recall # F-1624-9;
- 19) Slim Chicken Mix packed in 50 lb. bags. Recall # F-1625-9;
- 20) Spicy Breeding Mix packed in 50 lb. bags. Recall # F-1626-9;
- 21) Yellow Corn Bread Mix packed in 44 lb. bags. Recall # F-1627-9

CODE

- 1) Lot Code: 154GC2;
- 2) Lot Code: 155CS1;
- 3) Lot Code: 147CF1
- 4) Lot Code: 149CS1;
- 5) Lot Code: 147CF1-2;
- 6) Lot Code: 152CS1-7;
- 7) Lot Codes: 148CS1-12 and 154CS1-4;
- 8) Lot Codes: 155CS1-4, 150CS1-3 and 155CS1;
- 9) Lot Codes: 150CS1 and 150CS2;
- 10) Lot Codes: 149CS1-4, 149CS4, 153CF1-3 and 153CF4;
- 11) Lot Codes: 149CS1-2 and 149CS3-5;
- 12) Lot Code: 148CS1-4;
- 13) Lot Code: 154CS-4;
- 14) Lot Code: 150CS1;
- 15) Lot Code: 149CS1-3;
- 16) Lot Code: 149CS1;
- 17) Lot Code: 153CF1;
- 18) Lot Code: 147CF1-2;
- 19) Lot Code: 146CS1;
- 20) Lot Code: 153CF1;
- 21) Lot Code: 149CS1

RECALLING FIRM/MANUFACTURER

H. Nagel and Son Co., Cincinnati, OH, by letter via FAX and/or E-mail on June 19, 2009. Firm initiated recall is ongoing.

REASON

Flour, batter, and various flour product mixes produced and distributed by the recalling firm, may contain metal fragments.

VOLUME OF PRODUCT IN COMMERCE

263,690 lbs

DISTRIBUTION

KY, WI, IN, OH, FL, TX

PRODUCT

1) Style 4 Macadamia Nuts; Dry Roasted/unsalted in 25 lb. boxes. Recall # F-1650-9;

2) Cashews and Macadamia nut mix in 8 oz. plastic stand up zip-lock bag, UPC 24295-13407. Recall # F-1651-9

CODE

1) Lot #D09210;

2) No code

RECALLING FIRM/MANUFACTURER

Orchard Valley Harvest, Inc., Patterson, CA, by telephone on August 14, 2009. Firm initiated recall is ongoing.

REASON

Raw Macadamia Nuts were contaminated with *Salmonella*.

VOLUME OF PRODUCT IN COMMERCE

80 cases Macadamia, 25 lbs. per case/ 60 cases mixed nuts, 6 lbs. per case

DISTRIBUTION

CO, CA

PRODUCT

Great Value Berry Crunch Sweetened Corn & Oat Cereal; Net Wt. 21 oz. (1 lb 5 oz) 595 g; fiberboard carton with inner plastic liner, 12 boxes per case; UPC 0 78742 08589 0.

Recall # F-1654-9

CODE

Lot # 07 21 10 N02

RECALLING FIRM/MANUFACTURER

Recalling Firm: Gilster-Mary Lee Corp., Chester, IL, by press release on September 15, 2009.

Manufacturer: Gilster-Mary Lee, Corp., McBride, MO. Firm initiated recall is ongoing.

REASON

Some units within the lot were found to contain undeclared almond slices, which were visible.

VOLUME OF PRODUCT IN COMMERCE

1,113 cases

DISTRIBUTION

Nationwide

RECALLS AND FIELD CORRECTIONS: FOODS - CLASS III

PRODUCT

Chopped Mustard Greens: Packaged in a 10 oz. plastic bag under the following labels: a) Seabrook Farms, UPC 0 41296-60360 2; b) Giant, UPC 6 88267-00974 7; c) White Rose,

UPC 0 11196 65144 0; d) Krasdale, UPC 0 75130 97715 7; e) Shop Rite, UPC 0 41190 40038. Packaged in 16 oz. plastic bags under the following labels: f) Best Yet, UPC 0 4218 20187 0; g) Southern Home, UPC 6 07880 01181 4; h) Safeway, UPC 0 21130 09122 5; i) Spartan, UPC 0 11213 35679 2; j) Super A, UPC 0 23627 53111 5; k) Harris Teeter, UPC 0 72036-53756; Packaged in 3 lb plastic bags under the following labels: l) Sysco Imperial, UPC 0 74865 52832 0; m) Monarch, UPC 7 58108 00557 0. Recall # F-1628-9

CODE

a) JUN0120SBGF, JUN1910SBSF, DEC0410SBSF, MAR3111SBSF; b) UN0120SBGF; NOV0110SBGF; DEC0510SBGF; c) JUN1910SBGO, DEC0110SBSF; d) JUN0210SBGF, DEC0110SBSF; e) JUN1919SBGF, JUN1919 SBSF, DEC0410SBSF, MAY2711SBGF. 16 oz: f) AUG2510SBBF, OCT0910SBBF, APR2211SBCF; g) JUL2310SBCF, AUG2610SBCF, OCT0910SBBF, OCT0910SBCF, JAN0711SBCF, APR0711SBCF; h) JUL2310SB1969BF, JUL2310SB1969CF, FEB2510SB1969BF, FEB2610SB1969CF, JUL0510SB1969CF, SEP2610SB1969CF, SEP2710SB1969BF; i) JUL2310SBCF, OCT0910SBBF, APR0711SBCF, JAN0711SBCF; j) JUL2310SBCF, OCT0910SBCF, MAR2611SBBF, MAR2711SBBF; k) AUG2610SBCF; 3 lb: l) JUN1710SB1CF; AUG1310SB1CF; DEC0510SB1BF; DEC0510SB1CF; MAR2611SB1CF; m) SB1548SF

RECALLING FIRM/MANUFACTURER

Seabrook Brothers & Sons, Inc., Seabrook, NJ, by letters, e-mail and telephone on July 7, 2009. Firm initiated recall is ongoing.

REASON

Unapproved pesticides: FDA sampling found a range of 0.86 to 4.0 ppm of Permethrin in Mustard Greens, where there is no tolerance for the chemical.

VOLUME OF PRODUCT IN COMMERCE

14,486 cases

DISTRIBUTION

AL, DE, MD, MI, NJ, NC, PA, SC, CT, VA

PRODUCT

Tetra Brik aseptically packed container labeled in part: "Pacific Natural Foods Barista Series Soy Blenders all natural non-dairy beverage Vanilla 32 fl. oz. (1 qt) 946mL". Product is packed 12 per case. Recall # F-1649-9

CODE

"BEST IF USED BY: 07OCT09 8281-N"

RECALLING FIRM/MANUFACTURER

Pacific Foods of Oregon, Inc., Tualatin, OR, by telephone on February 24, 2009. Firm initiated recall is ongoing.

REASON

Product is spoiled and contains high aerobic plate count.

VOLUME OF PRODUCT IN COMMERCE

2,209 cases, each containing 12.32 fl. oz packages

DISTRIBUTION

CA, NB, OR, TX, WA

RECALLS AND FIELD CORRECTIONS: DRUGS - CLASS II

PRODUCT

INVEGA (paliperidone) Extended-Release Tablets, 6 mg, 30-count bottle, Rx only, NDC 50458-551-01. Recall # D-030-2010

CODE

Lot # 9KG024, Exp 11/10

RECALLING FIRM/MANUFACTURER

Recalling Firm: Global Supply Pharmaceutical Gr, Titusville, NJ, by letters on October 20, 2009 and October 21, 2009.

Manufacturer: Janssen Cilag Manufacturing LLC, Gurabo, PR. Firm initiated recall is ongoing.

REASON

CGMP Deviations: One lot of INVEGA 6 mg was coated pink, when the approved color for the 6 mg tablets is beige.

VOLUME OF PRODUCT IN COMMERCE

19,668 bottles

DISTRIBUTION

Nationwide

RECALLS AND FIELD CORRECTIONS: DRUGS - CLASS III

PRODUCT

Twinject 0.3 mg Auto-Injector (epinephrine injection, USP 1:1000), Rx only, NDC 59630-802-01. Note that this lot of Twinject is labeled with the previous owner, Verus Pharmaceuticals', NDC # 13436-700-01. Recall # D-031-2010

CODE

Lot U081008A

RECALLING FIRM/MANUFACTURER

Recalling Firm: Sciele Pharma, Inc., Atlanta, GA, by letter on/about September 23, 2009.

Manufacturer: Philips Plastics, Corp., Menomonie, WI. Firm initiated recall is ongoing.

REASON

Defective Delivery System; High Force-To-Fire values for the 12 month pull performance testing of Twinject 2008 annual stability units.

VOLUME OF PRODUCT IN COMMERCE

5,988 units

DISTRIBUTION

AZ, CA, CO, CT, FL, LA, NC, OH, PA, SC, TX, WA, and WI

PRODUCT

EXE-FEN - IR, DECONGESTANT - ANTIHISTAMINIC, IMMEDIATE RELEASE TABLETS, Pseudoephedrine HCl 60mg, Guaifenesin 400mg, 100 count bottles, Rx only. Recall # D-032-2010

CODE

Lot# 091138, Exp. 07/31/2011

RECALLING FIRM/MANUFACTURER

Recalling Firm: Larken Laboratories, Inc., Canton, MI, by e-mail on October 22, 2009 and by letter on October 26, 2009.

Manufacturer: Contract Pharmacal Corp., Hauppauge NY. Firm initiated recall is ongoing.

REASON

Label Mix Up - Product is incorrectly labeled as a decongestant - antihistaminic, but should be labeled as decongestant - expectorant.

VOLUME OF PRODUCT IN COMMERCE

384 units

DISTRIBUTION

Nationwide

RECALLS AND FIELD CORRECTIONS: BIOLOGICS - CLASS II

PRODUCT

Red Blood Cells, Leukocytes Reduced. Recall # B-0030-10

CODE

Unit: 93FK00452

RECALLING FIRM/MANUFACTURER

Cooley Dickinson Hospital, BB, Northampton MA, by telephone on July 10, 2009 and by letter dated August 11, 2009. Firm initiated recall is complete.

REASON

Blood product, which tested negative for the antibodies to human T-lymphotropic virus types I and II (anti-HTLV-I/II), but was collected from a donor who previously tested positive for anti-HTLV-I/II, was distributed.

VOLUME OF PRODUCT IN COMMERCE

1 unit

DISTRIBUTION

MA

PRODUCT

Red Blood Cells, Leukocytes Reduced. Recall # B-0047-10

CODE

Units: 18GK67224, 18GL68730, 18GL70979

RECALLING FIRM/MANUFACTURER

American National Red Cross Great Lakes Region, Lansing, MI, facsimile on June 3, 2009 and July 15, 2009 and by the LOGIC system on June 3, 2009. 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

3 units

DISTRIBUTION

MI

PRODUCT

- 1) Red Blood Cells Leukocytes Reduced. Recall # B-0064-10;
- 2) Platelets Pooled Leukocytes Reduced. Recall # B-0065-10

CODE

- 1) Unit: W051709106147;
- 2) Unit: W051709801969

RECALLING FIRM/MANUFACTURER

Rhode Island Blood Center, Providence, RI, by letter dated July 1, 2009. Firm initiated recall is complete.

REASON

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

VOLUME OF PRODUCT IN COMMERCE

2 units

DISTRIBUTION

RI, MA

PRODUCT

Red Blood Cells Leukocytes Reduced. Recall # B-0066-10

CODE

Unit: W117008143411

RECALLING FIRM/MANUFACTURER

Blood Centers of the Pacific, San Francisco, CA, by telephone and by letter dated July 10, 2009. Firm initiated recall is complete.

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

CA

PRODUCT

Platelets Pheresis, Leukocytes Reduced. Recall # B-0067-10

CODE

Unit: 012KH21112

RECALLING FIRM/MANUFACTURER

Recalling Firm: American Red Cross Carolinas Blood Services Region, Charlotte, NC, by facsimile on June 10, 2009 and by letter dated June 12, 2009.

Manufacturer: American Red Cross Blood Services, Durham, NC. 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

NC

PRODUCT

- 1) Red Blood Cells Leukocytes Reduced. Recall # B-0068-10;
- 2) Recovered Plasma. Recall # B-0069-10

CODE

1) and 2) Unit: 5690205

RECALLING FIRM/MANUFACTURER

Recalling Firm: Florida's Blood Centers, Inc., Ormond Beach, FL, by e-mail and letter dated July 9, 2009.

Manufacturer: Florida's Blood Centers, Inc., Deland, FL. Firm initiated recall is complete.

REASON

Blood products, collected from a donor with a history of jaundice, were distributed.

VOLUME OF PRODUCT IN COMMERCE

2 units

DISTRIBUTION

Austria, FL

PRODUCT

Red Blood Cells Leukocytes Reduced. Recall # B-0083-10

CODE

Unit: 003GQ11700

RECALLING FIRM/MANUFACTURER

The American National Red Cross – Southern Region, Douglasville, GA, by fax on August 7, 2007 and by follow-up letter on August 8, 2007 and September 12, 2007. 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

GA

PRODUCT

Red Blood Cells Leukocytes Reduced. Recall # B-0087-10

CODE

Unit: 42K89666

RECALLING FIRM/MANUFACTURER

American Red Cross Blood Services, Cleveland, OH, by facsimile and electronic notification on May 27, 2009 and by letter dated August 25, 2009. 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

OH

PRODUCT

Red Blood Cells Leukocytes Reduced. Recall # B-0089-10

CODE

Unit: 012GM51999

RECALLING FIRM/MANUFACTURER

Recalling Firm: American Red Cross Carolinas Blood Services Region, Charlotte, NC, by facsimile and letter dated March 26, 2009.

Manufacturer: American Red Cross Blood Services, Asheville, NC. 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

GA

PRODUCT

Red Blood Cells Leukocytes Reduced. Recall # B-0092-10

CODE

Unit: 20X28619

RECALLING FIRM/MANUFACTURER

The American National Red Cross, Salt Lake City, UT, by electronic notification and facsimile on December 31, 2008 and by letters dated January 2, 2009 and February 11, 2009. 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

- 1) Platelets Leukocytes Reduced. Recall # B-0093-10;
- 2) Red Blood Cells Leukocytes Reduced. Recall # B-0094-10;
- 3) Platelets Leukocytes Reduced Irradiated. Recall # B-0095-10;
- 4) Fresh Frozen Plasma. Recall # B-0096-10

CODE

- 1) Unit: 19GY64937;
- 2) Units: 19GY64937, 19GY68284;
- 3) Unit: 19GY68284;
- 4) Units: 19GY64937, 19GY68284

RECALLING FIRM/MANUFACTURER

American Red Cross Blood Services, Tennessee Valley Region, Nashville, TN, by facsimile on June 16, 2009, and by letters dated June 16, 2009 and July 17, 2009. 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

6 units

DISTRIBUTION

TN, KY

PRODUCT

Red Blood Cells Leukocytes Reduced. Recall # B-0097-10

CODE

Units: 38FV58728, 38FV73467

RECALLING FIRM/MANUFACTURER

American National Red Cross, Indiana-Ohio Region, Fort Wayne, IN, by facsimile and electronic notification on July 15, 2009. 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

IN

PRODUCT

Red Blood Cells Leukocytes Reduced. Recall # B-0106-10

CODE

Unit: 50E60752

RECALLING FIRM/MANUFACTURER

American Red Cross Blood Services, Western Lake Erie Region, Toledo, OH, by facsimile and electronic notification on May 6, 2009. 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

MO

PRODUCT

Red Blood Cells Leukocytes Reduced. Recall # B-0107-10

CODE

Unit: 2545052

RECALLING FIRM/MANUFACTURER

Central Kentucky Blood Center, Inc., Lexington, KY, by letter dated July 2, 2009. Firm initiated recall is complete.

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

KY

PRODUCT

1) Red Blood Cells Leukocytes Reduced. Recall # B-0108-10;

2) Platelets Leukocytes Reduced. Recall # B-0109-10

CODE

1) and 2) Unit: 13FW42748

RECALLING FIRM/MANUFACTURER

American Red Cross, Southeastern Michigan Region, Detroit, MI, by telephone and electronic notification on June 4, 2009 and by letters dated June 4, 2009, June 10, 2009 and September 11, 2009. 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

MI

PRODUCT

Red Blood Cells Leukocytes Reduced. Recall # B-0111-10

CODE

Units: 2495601, 2517992

RECALLING FIRM/MANUFACTURER

Central Kentucky Blood Center, Inc., Lexington, KY, by letter dated July 9, 2009. Firm initiated recall is complete.

REASON

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

VOLUME OF PRODUCT IN COMMERCE

2 units

DISTRIBUTION

KY

PRODUCT

Red Blood Cells Leukocytes Reduced. Recall # B-0112-10

CODE

Unit: 7531811

RECALLING FIRM/MANUFACTURER

Central Kentucky Blood Center, Inc., Lexington, KY, by letter dated July 17, 2009. Firm initiated recall is complete.

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

KY

PRODUCT

Source Plasma. Recall # B-0116-10

CODE

Units: 365092887; 365080312; 365078372; 65076086; 365072469; 65069292;
365069252

RECALLING FIRM/MANUFACTURER

Telecris Plasma Resources, Roanoke, VA, by facsimile on April 21, 2008. Firm initiated recall is complete.

REASON

Blood products, collected from a donor who was permanently deferred for high risk behavior, were distributed.

VOLUME OF PRODUCT IN COMMERCE

7 units

DISTRIBUTION

NC

PRODUCT

Red Blood Cells Leukocytes Reduced. Recall # B-0126-10

CODE

Unit: 004L10739

RECALLING FIRM/MANUFACTURER

ARC Blood Services, New England Region, Dedham, MA, by facsimile on April 29, 2009 and follow-up letter on May 7, 2009. Firm initiated recall is complete.

REASON

Blood product, collected from an unsuitable donor, was distributed.

VOLUME OF PRODUCT IN COMMERCE

1 unit

DISTRIBUTION

MA

PRODUCT

Red Blood Cells (Apheresis). Recall # B-0127-10

CODE

Unit: 7526418 (Part A)

RECALLING FIRM/MANUFACTURER

Central Kentucky Blood Center, Inc., Lexington, KY, by letter dated June 4, 2009. Firm initiated recall is complete.

REASON

Blood product, which did not meet the minimum requirement for Red Blood Cell volume, was distributed.

VOLUME OF PRODUCT IN COMMERCE

1 unit

DISTRIBUTION

KY

PRODUCT

1) Red Blood Cells Leukocytes Reduced. Recall # B-0139-10;

2) Plasma Frozen within 24 hours (FP24). Recall # B-0140-10

CODE

1) and 2) Unit: 36FL34550

RECALLING FIRM/MANUFACTURER

Recalling Firm: American National Red Cross, Columbia, SC, by letter dated April 22, 2009.

Manufacturer: The American National Red Cross, South Carolina Region, Charleston, SC. 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, SC

PRODUCT

Red Blood Cells Leukocytes Reduced. Recall # B-0185-10

CODE

Unit: 01GG28191

RECALLING FIRM/MANUFACTURER

Recalling Firm: American Red Cross Blood Services, West Henrietta, NY, by electronic notification on February 24, 2009 and by letter dated February 24, 2009.

Manufacturer: American Red Cross Blood Services, Syracuse, NY. 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

NY

PRODUCT

Platelets Pheresis Leukocytes Reduced. Recall # B-0187-10

CODE

Unit: 36FM71531 (2 units)

RECALLING FIRM/MANUFACTURER

American National Red Cross, Columbia, SC, by telephone on March 9, 2009 and by facsimile April 16, 2009. Firm initiated recall is complete.

REASON

Blood products, which were labeled as leukoreduced, but were not tested to verify white blood cell count, were distributed.

VOLUME OF PRODUCT IN COMMERCE

2 units

DISTRIBUTION

SC

PRODUCT

Red Blood Cells Leukocytes Reduced. Recall # B-0188-10

CODE

Unit: 6190196

RECALLING FIRM/MANUFACTURER

South Texas Blood & Tissue Center, San Antonio, TX, by fax on May 18, 2009. Firm initiated recall is complete.

REASON

Blood product, collected from a donor taking the drug Evista, was distributed.

VOLUME OF PRODUCT IN COMMERCE

1 unit

DISTRIBUTION

TX

PRODUCT

Buffy Coat. Recall # B-0189-10

CODE

Unit: W149509302814

RECALLING FIRM/MANUFACTURER

Northern California Community Blood Bank, Eureka, CA, by telephone and fax on May 14, 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

Red Blood Cells Leukocytes Reduced. Recall # B-0190-10

CODE

Unit: 012LW35830

RECALLING FIRM/MANUFACTURER

Recalling Firm: American Red Cross Carolinas Blood Services Region, Charlotte, NC, by telephone, e-mail and letter on April 6, 2009.

Manufacturer: American Red Cross Blood Services Carolinas Region, Winston Salem, NC. 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

NC

PRODUCT

Red Blood Cells Leukocytes Reduced. Recall # B-0193-10

CODE

Unit: 012FX23590

RECALLING FIRM/MANUFACTURER

Recalling Firm: American Red Cross, Carolinas Blood Services Region, Charlotte, NC, by fax on June 6, 2009 and letter dated July 21, 2009.

Manufacturer: American Red Cross Blood Services, Durham, NC. 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

NC

PRODUCT

1) Red Blood Cells (Apheresis) Leukocytes Reduced. Recall # B-0194-10;

2) Red Blood Cells Leukocytes Reduced. Recall # B-0195-10

CODE

1) W037909137004 (part 1 and 2);

2) W037909121384

RECALLING FIRM/MANUFACTURER

Blood Center of Iowa, Des Moines, IA, by telephone on May 23, 2009. Firm initiated recall is complete.

REASON

Blood products, which were labeled as FY (-a) and JK(-a), but were subsequently found to be FY (a+) and JK (a+), were distributed.

VOLUME OF PRODUCT IN COMMERCE

3 units

DISTRIBUTION

IA

PRODUCT

- 1) Red Blood Cells. Recall # B-0196-10;
- 2) Recovered Plasma. Recall # B-0197-10

CODE

1) and 2) Unit: L33567

RECALLING FIRM/MANUFACTURER

Tacoma Pierce County Blood Bank, Tacoma, WA, by letter on August 3, 2009 and by email on August 4, 2009. Firm initiated recall is complete.

REASON

Blood products, collected from a donor who was previously deferred, were distributed.

VOLUME OF PRODUCT IN COMMERCE

2 units

DISTRIBUTION

Switzerland, WA

PRODUCT

- 1) Red Blood Cells Leukocytes Reduced. Recall # B-0198-10;
- 2) Plasma Frozen within 24 hours (FP24). Recall # B-0199-10

CODE

1) and 2) Unit: 01W47782

RECALLING FIRM/MANUFACTURER

American Red Cross Blood Services, West Henrietta, NY, by fax on February 9, 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

2 units

DISTRIBUTION

NY, PA

PRODUCT

Red Blood Cells (Apheresis) Leukocytes Reduced. Recall # B-0200-10

CODE

Unit: 01KT40202 (Part 1 and 2)

RECALLING FIRM/MANUFACTURER

American Red Cross Blood Services, West Henrietta, NY, by fax on January 29, 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

NY

PRODUCT

Platelets Pheresis Leukocytes Reduced. Recall # B-0209-10

CODE

Unit: W036509066845

RECALLING FIRM/MANUFACTURER

LifeShare Blood Centers, Baton Rouge, LA, by fax on July 31, 2009. Firm initiated recall is complete.

REASON

Blood product, that was not quarantined after receiving information concerning post-donation illness, was distributed.

VOLUME OF PRODUCT IN COMMERCE

1 unit

DISTRIBUTION

LA

PRODUCT

1) Plasma Frozen within 24 hours (FP24). Recall # B-0210-10;

2) Red Blood Cells Leukocytes Reduced. Recall # B-0211-10

CODE

1) and 2) Unit: 012FQ89247

RECALLING FIRM/MANUFACTURER

Recalling Firm: American Red Cross Carolinas Blood Services Region, Charlotte, NC, by fax and letter on April 16, 2009 and by follow-up letter on May 19, 2009.

Manufacturer: American Red Cross Blood Services, Durham NC. 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

NC, GA

PRODUCT

Red Blood Cells Leukocytes Reduced. Recall # B-0213-10

CODE

Unit: 03FJ95107

RECALLING FIRM/MANUFACTURER

The American National Red Cross - Southern Region, Douglasville, GA, by fax and letter on January 20, 2009 and by follow-up letter on January 21, 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

GA

PRODUCT

- 1) Red Blood Cells Leukocytes Reduced. Recall # B-0214-10;
- 2) Platelets Pooled Leukocytes Reduced. Recall # B-0215-10

CODE

1) and 2) Unit: 033GM65570

RECALLING FIRM/MANUFACTURER

American Red Cross Blood Services, Farmington, CT, by fax on January 20, 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

2 units

DISTRIBUTION

CT

PRODUCT

Red Blood Cells Leukocytes Reduced. Recall # B-0217-10

CODE

Units: 012FQ92207, 012FW35525

RECALLING FIRM/MANUFACTURER

Recalling Firm: American Red Cross Carolinas Blood Services Region, Charlotte, NC, by telephone, fax and letter on March 24, 2009.

Manufacturer: American Red Cross Blood Services, Durham NC. 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

SC, NC

PRODUCT

- 1) Red Blood Cells Leukocytes Reduced. Recall # B-0219-10;

- 2) Platelets Leukocytes Reduced. Recall # B-0220-10;
- 3) Recovered Plasma. Recall # B-0221-10

CODE

1), 2) and 3) Unit: 42GX10058

RECALLING FIRM/MANUFACTURER

American Red Cross Blood Services, Cleveland, OH, by email on June 2, 2009 and by fax on July 8, 2009 and August 17, 2009. Firm initiated recall is complete.

REASON

Blood products, collected from a donor considered to be at increased risk for variant Creutzfeldt-Jakob Disease (vCJD), were distributed.

VOLUME OF PRODUCT IN COMMERCE

3 units

DISTRIBUTION

OH

PRODUCT

Red Blood Cells. Recall # B-0222-10

CODE

Unit: W141608691220

RECALLING FIRM/MANUFACTURER

Recalling Firm: Puget Sound Blood Center and Program, Seattle, WA, by fax on April 1, 2009.

Manufacturer: Puget Sound Blood Center and Program, Silverdale, WA. 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

Austria

PRODUCT

1) Red Blood Cells Leukocytes Reduced. Recall # B-0223-10;

2) Plasma Frozen within 24 hours (FP24). Recall # B-0224-10

CODE

1) and 2) Unit: 012GS89850

RECALLING FIRM/MANUFACTURER

Recalling Firm: American Red Cross Carolinas Blood Services Region, Charlotte, NC, by fax on June 19, 2009.

Manufacturer: American Red Cross Blood Services, Durham NC. 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

NC

PRODUCT

Red Blood Cells. Recall # B-0235-10

CODE

Unit: 1290561

RECALLING FIRM/MANUFACTURER

Memorial Blood Centers, Saint Paul, MN, by email on August 5, 2009 and by letter on August 25, 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

MN

PRODUCT

1) Red Blood Cells Leukocytes Reduced Irradiated. Recall # B-0236-10;

2) Fresh Frozen Plasma. Recall # B-0237-10;

3) Red Blood Cells. Recall # B-0238-10

CODE

1) Unit: G37169;

2) Units: W127808503407, G37169;

3) Units: W127809700976, W127808503407, G32662, E10511

RECALLING FIRM/MANUFACTURER

Tacoma Pierce County Blood Bank, Tacoma, WA, by telephone on July 26, 2009 and letter on July 31, 2009. Firm initiated recall is complete.

REASON

Blood products, collected from a donor who was taking the drug Proscar, were distributed.

VOLUME OF PRODUCT IN COMMERCE

7 units

DISTRIBUTION

WA, PA

PRODUCT

Red Blood Cells Leukocytes Reduced Irradiated. Recall # B-0239-10

CODE

Unit: W127808504296

RECALLING FIRM/MANUFACTURER

Tacoma Pierce County Blood Bank, Tacoma, WA, by letter on July 13, 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

WA

PRODUCT

Red Blood Cells (Apheresis) Leukocytes Reduced. Recall # B-0240-10

CODE

Units: W037909122866 (Part 1 and 2)

RECALLING FIRM/MANUFACTURER

Blood Center of Iowa, Des Moines, IA, by letter dated August 14, 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

2 units

DISTRIBUTION

IA

PRODUCT

1) Platelets Leukocytes Reduced Irradiated. Recall # B-0241-10;

2) Platelets Pheresis Leukocytes Reduced. Recall # B-0242-10

CODE

1) Unit: W115909010494;

2) Units: W115909012396, W115909011073 (part 1 and 2), W115908029284

RECALLING FIRM/MANUFACTURER

Central California Blood Center, Fresno, CA, by e-mail and fax on August 3, 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

5 units

DISTRIBUTION

CA

RECALLS AND FIELD CORRECTIONS: BIOLOGICS - CLASS III

PRODUCT

1) Red Blood Cells Leukocytes Reduced. Recall # B-0001-10;

2) Platelets Leukocytes Reduced. Recall # B-0002-10;

3) Red Blood Cells Leukocytes Reduced Irradiated. Recall # B-0003-10;

4) Red Blood Cells (Apheresis) Leukocytes Reduced. Recall # B-0004-10

CODE

- 1) Unit: 022FZ67363;
- 2) Units: 022FQ76103, 022FS80951, 022GC10636, 022GH69205, 022LC65888, 022LC65943, 022LP52492, 022GV28838, 022GV28842, 022GV28857, 022GV28862, 022GV28865;
- 3) Units: 022FQ76103, 022LC65888;
- 4) Unit: 022GH68928

RECALLING FIRM/MANUFACTURER

American National Red Cross, Penn Jersey Region, Philadelphia, PA, by telephone on November 1, 2008 and by letter dated November 20, 2008. Firm initiated recall is complete.

REASON

Blood products, which were incorrectly tested for human T lymphotropic virus, types I and II (HTLV-I/II), were distributed.

VOLUME OF PRODUCT IN COMMERCE

16 units

DISTRIBUTION

PA, NJ, VA

PRODUCT

Source Plasma. Recall # B-0046-10

CODE

Unit: HP198254

RECALLING FIRM/MANUFACTURER

Interstate Blood Bank Inc. of Chicago, Chicago, IL, by facsimile and letter dated May 15, 2009, and by telephone on August 15, 2009. 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

IL

PRODUCT

Recovered Plasma. Recall # B-0048-10

CODE

Units: 18GK67224, 18GL68730, 18GL70979

RECALLING FIRM/MANUFACTURER

American National Red Cross Great Lakes Region, Lansing, MI, facsimile on June 3, 2009 and July 15, 2009 and by the LOGIC system on June 3, 2009. 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

3 units

DISTRIBUTION

CA

PRODUCT

Recovered Plasma. Recall # B-0061-10

CODE

Unit: W035208195424B

RECALLING FIRM/MANUFACTURER

Carter BloodCare, Bedford, TX, by e-mail on June 12, 2009 and August 17, 2009. 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

Austria

PRODUCT

Fresh Frozen Plasma. Recall # B-0082-10

CODE

Unit: 003GQ11700

RECALLING FIRM/MANUFACTURER

The American National Red Cross – Southern Region, Douglasville, GA, by fax on August 7, 2007 and by follow-up letter on August 8, 2007. 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

GA

PRODUCT

Recovered Plasma, Recall # B-0088-10

CODE

Unit: 42K89666

RECALLING FIRM/MANUFACTURER

American Red Cross Blood Services, Cleveland, OH, by facsimile and electronic notification on May 27, 2009 and by letter dated August 25, 2009. 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-0090-10

CODE

Unit: 012GM51999

RECALLING FIRM/MANUFACTURER

Recalling Firm: American Red Cross Carolinas Blood Services Region, Charlotte, NC, by facsimile and letter dated March 26, 2009.

Manufacturer: American Red Cross Blood Services, Asheville, NC. 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-0091-10;

CODE

Unit: 20X28619

RECALLING FIRM/MANUFACTURER

The American National Red Cross, Salt Lake City, UT, by electronic notification and facsimile on December 31, 2008 and by letters dated January 2, 2009 and February 11, 2009. 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-0098-10

CODE

Units: 38FV58728, 38FV73467

RECALLING FIRM/MANUFACTURER

American National Red Cross, Indiana-Ohio Region, Fort Wayne, IN, by facsimile and electronic notification on July 15, 2009. 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

CA

PRODUCT

Recovered Plasma. Recall # B-0105-10

CODE

Unit: 50E60752

RECALLING FIRM/MANUFACTURER

American Red Cross Blood Services, Western Lake Erie Region, Toledo, OH, by facsimile and electronic notification on May 6, 2009. 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-0110-10

CODE

Unit: 13FW42748

RECALLING FIRM/MANUFACTURER

American Red Cross, Southeastern Michigan Region, Detroit, MI, by telephone and electronic notification on June 4, 2009 and by letters dated June 4, 2009, June 10, 2009 and September 11, 2009. 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

Micro SSP Allele Specific HLA Class I DNA Typing Tray - A*03; Product Number: SSPI-03; Lot Number: 002, batch 002 and 003 Expiration Date: 31 Oct 2010; Product Insert Number: SSP-DNAT-PI-EN Rev 16. Recall # B-0179-10

CODE

Lot Number: 002

RECALLING FIRM/MANUFACTURER

One Lambda, Inc., Canoga Park, CA, by letters on September 9, 2009. Firm initiated recall is ongoing.

REASON

HLA Class I DNA Typing Trays, with incorrect internal control (IC) in well 3D , were distributed.

VOLUME OF PRODUCT IN COMMERCE

17 units

DISTRIBUTION

AL, NY, MS, Canada, Germany, Israel, Italy, Japan, Spain, China and Singapore

PRODUCT

Recovered Plasma. Recall # B-0184-10

CODE

Unit: 01GG28191

RECALLING FIRM/MANUFACTURER

Recalling Firm: American Red Cross Blood Services, West Henrietta, NY, by electronic notification on February 24, 2009 and by letter dated February 24, 2009.

Manufacturer: American Red Cross Blood Services, Syracuse, NY. 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-0191-10

CODE

Unit: 012LW35830

RECALLING FIRM/MANUFACTURER

Recalling Firm: American Red Cross Carolinas Blood Services Region, Charlotte, NC, by telephone, e-mail and letter on April 6, 2009.

Manufacturer: American Red Cross Blood Services Carolinas Region, Winston Salem, NC. 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

NC

PRODUCT

Recovered Plasma. Recall # B-0192-10

CODE

Unit: 012FX23590

RECALLING FIRM/MANUFACTURER

Recalling Firm: American Red Cross, Carolinas Blood Services Region, Charlotte, NC, by fax on June 6, 2009 and letter dated July 21, 2009.

Manufacturer: American Red Cross Blood Services, Durham, NC. 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

Recovered Plasma. Recall # B-0212-10

CODE

Unit: 03FJ95107

RECALLING FIRM/MANUFACTURER

The American National Red Cross - Southern Region, Douglasville, GA, by fax and letter on January 20, 2009 and by follow-up letter on January 21, 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

GA

PRODUCT

Recovered Plasma. Recall # B-0216-10

CODE

Unit: 033GM65570

RECALLING FIRM/MANUFACTURER

American Red Cross Blood Services, Farmington, CT, by fax on January 20, 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

C

PRODUCT

Recovered Plasma. Recall # B-0218-10

CODE

Units: 012FQ92207, 012FW35525

RECALLING FIRM/MANUFACTURER

Recalling Firm: American Red Cross Carolinas Blood Services Region, Charlotte, NC, by telephone, fax and letter on March 24, 2009.

Manufacturer: American Red Cross Blood Services, Durham NC. 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

SC, NC

PRODUCT

Recovered Plasma. Recall # B-0234-10

CODE

Unit: 1290561

RECALLING FIRM/MANUFACTURER

Memorial Blood Centers, Saint Paul, MN, by email on August 5, 2009 and by letter on August 25, 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

Switzerland

RECALLS AND FIELD CORRECTIONS: DEVICES - CLASS I

PRODUCT

1) PRO5100, PowerPro Battery Modular Handpiece. Drill mode Nominal Speed Range: 0-1250 rpm, PRO5200, PowerPro Battery Two Trigger Handpiece. Drill mode Nominal Speed Range: 0-1250 rpm, PRO5250, PowerPro Battery Two Trigger Handpiece. Drill mode Nominal Speed Range: 0-1250 rpm, PRO5300 PowerPro Battery Oscillator Handpiece. PRO 5300 Oscillator Speed Range: 0-11,000 cpm, and PRO5400 PowerPro Battery Reciprocator Handpiece. Speed Range: 0-14,500 cpm+/- 500 cpm. Recall # Z-1950-2009;

2) PowerProMax PRO5100M Battery Single Trigger, PowerProMax PRO5200M Battery Two Trigger, PowerProMax PRO5250M Battery Two-Trigger Standard, PowerProMax PRO5300M Battery Oscillator, PowerProMax PRO5400M Battery Reciprocator, and PowerProMax PRO6200 Battery Single Trigger. Recall # Z-1951-2009;

3) Mpower PRO6200 Single Trigger Modular Handpiece, Mpower PRO6202 Battery Two-Trigger Modular Handpiece, Mpower PRO6300 Battery Oscillating Saw, Mpower PRO6400 Battery Reciprocating Saw, and Mpower PRO6450 Battery Sternum Saw.
Recall # Z-1952-2009

CODE

1) 7265 BBC37268 BBC37270 BBC37498 BBC37499 BBC37500 BBC38926
BBC38927 BBC38928 BBC44299 BBC44300 BBC52023 BBC52024 BBC65032
BBC65033 BBC65034 BBC65917 BBC65918 BBC65919 BBC74607 BBC74739
BBC74740 BBC78501 BBC78502 BBC78504 BBC78505 BBC78655 BBC78656
BBC78657 BBC78658 BBC78659 BBC78905 BBC79215 BBC79216 BBC82293
BBC82294 BBC82295 BBC93885 BBC94440 BBC94441 BBD05152 BBD13486
BBD13487 BBD16488 BBD16489 BBD17968 BBD17969 BBD17970 BBD17971
BBD17972 BBD18366 BBD18367 BBD18370 BBD18371 BBD62831 BBD62832
BBD63893 BBD63894 BBD63895 BBD80892 BBD80893 BBD80894 PRO5400
PowerPro Battery Reciprocator Handpiece 00001021 00001023 00001024 00001025
00001026 00001027 00001035 00001036 00001038 00001039 00001040 00001041
00001044 00001045 00001046 00001047 00001048 00001050 00001053 00001055
00001056 00001064 00001065 00001066 00001067 00001069 00001072 00001073
00001074 00001077 00001079 00001080 00001081 00001082 00001085 00001088
00001089 00001100 00001101 00001103 00001104 00001105 00001119 00001122
00001123 00001124 00001126 00001127 00001128 00001129 00001130 00001131
00001132 00001133 00001134 00001135 00001158 00001159 00001160 00001162
00001164 00001165 00001166 00001180 00001191 00001196 00001198 00001199
00001201 00001209 00001210 00001211 00001212 00001213 00001214 00001216
00001217 00001218 00001227 00001228 00001229 00001230 00001231 00001232
00001233 00001234 00001235 00001236 00001237 00001238 00001239 00001240
00001241 00001242 00001247 00001248 00001249 00001253 00001254 00001255
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00001279 00001280 00001282 00001283 00001285 00001286 00001290 00001292
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00001306 00001308 00001309 00001310 00001312 00001313 00001315 00001316
BBB28679 BBB28681 BBB28683 BBB28684 BBB28687 BBB30799 BBB30800
BBB30801 BBB31931 BBB31932 BBB31933 BBB31934 BBB32104 BBB33252
BBB33254 BBB33255 BBB33257 BBB34512 BBB34513 BBB34514 BBB34515
BBB34516 BBB35098 BBB35099 BBB35100 BBB35694 BBB36068 BBB36071
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RECALLING FIRM/MANUFACTURER

Linvatec Corp. dba ConMed Linvatec, Largo, FL, by letter on July 31, 2009. Firm initiated recall is ongoing.

REASON

There is a potential the devices may self activate for their PowerPro, PowerProMax, and MPower Handpieces manufactured prior to June 1, 2008.

VOLUME OF PRODUCT IN COMMERCE

10,395 devices

DISTRIBUTION

Nationwide, United Arab Emirates, Austria, Australia, Bangladesh, Belgium, Canada, Switzerland, Chile, China, Czech Republic, Germany, Denmark, Egypt, Spain, Finland, France, United Kingdom, Greece, Guatemala, Hong Kong, Hungary, India, Italy, Japan, Republic of Korea, Kuwait, Lithuania, Luxembourg, Morocco, Netherlands, New Zealand, Panama, Pakistan, Poland, Portugal, Serbia, Russian Federation, Saudi Arabia, Singapore, El Salvador, Turkey, Taiwan, United States, Viet Nam, South Africa

PRODUCT

MC5057 12ft/3.6 meters Universal Cable. Made in USA. NON STERILE Rx Only. The MC5057 Universal Cable, 12 ft, is used to connect electric handpieces to the power source. The cable is designed with a button feature that allows the user to increase or decrease the operating speed of the handpiece in use. In select handpieces, the cord button feature can select the function, i.e. screw, tap, or drill mode. Recall # Z-2007-2009

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RECALLING FIRM/MANUFACTURER

Linvatec Corp. dba ConMed Linvatec, Largo, FL, by letter on July 31, 2009. Firm initiated recall is ongoing.

REASON

Sufficiently worn/damaged Universal Cable with product number MC5057, when used with various ConMed Linvatec electric Handpieces, may cause the handpiece to self activate.

VOLUME OF PRODUCT IN COMMERCE

12,205

DISTRIBUTION

Nationwide, United Arab Emirates, Argentina, Austria, Australia, Belgium, Canada, Switzerland, Chile, China, Colombia, Costa Rica, Czech Republic, Germany, Denmark, Egypt, Spain, Finland, France, United Kingdom, Guatemala, Hong Kong, Hungary, Ireland, India, Italy, Jordan, Japan, Republic of Korea, Kuwait, Lithuania, Morocco, Mexico, Netherlands, New Zealand, Panama, Pakistan, Poland, Portugal, Romania, Russian Federation, Saudi Arabia, Singapore, Tunisia, Turkey, Trinidad and Tobago, Taiwan, Venezuela, Viet Nam, and South Africa
United Arab Emirates, Argentina, Austria, Australia, Belgium, Canada, Switzerland, Chile, China, Colombia, Costa Rica, Czech Republic, Germany, Denmark, Egypt, Spain, Finland, France, United Kingdom, Guatemala, Hong Kong, Hungary, Ireland, India, Italy, Jordan, Japan, Republic of Korea, Kuwait, Lithuania, Morocco, Mexico, Netherlands, New Zealand, Panama, Pakistan, Poland, Portugal, Romania, Russian Federation, Saudi Arabia, Singapore, Tunisia, Turkey, Trinidad and Tobago, Taiwan, Venezuela, Viet Nam, and South Africa

RECALLS AND FIELD CORRECTIONS: DEVICES - CLASS II

PRODUCT

Whatman Body Fluid Collection Paper 903 The device is used by healthcare professionals in the collection and in-vitro storage of neonate blood. Recall # Z-1871-2009

CODE

Ref:/Lot number: 10534513 WO71 6794508 10534614 WO71 6795508 10534749 WO71 6795908 10534683 WO71 6800708 10534711 WO71 6807908 10534528 WO71 6800108 10534545 WO71 68235.008 10534578 WO71 6825608 10534782 WO71 6798908 10534640 WO71 6803208 10534639 WO71 6820908 10539765 WO71 6821008 10534523 WO71 6800208 10534524 WO71 6800308 10534691 WO71 6824408 10534523 WO71 6824508 10534611 WO71 6824108 10534647 WO71 6803708 10534648 WO71 6803808 10534735 WO71 6796508 10535643 WO71

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10534694 WO71 6813608 10534698 WO71 6813708 10535136 WO71 6823308
10534416 WO71 6822908 10534778 WO71 6830909 10534104 WO71 6810608
10537853 WO71 6602508 10534307 WO71 6808508

RECALLING FIRM/MANUFACTURER

Whatman, Inc., Sanford, ME, by letter on May 6, 2009. Firm initiated recall is ongoing.

REASON

The two portions of the card are coming apart prematurely.

VOLUME OF PRODUCT IN COMMERCE

2,853,410 cards

DISTRIBUTION

Nationwide

PRODUCT

BrightView Gamma Camera Radius Drive Assembly, 3/8" tilt, model number 4535604 34811, 3/4" tilt, model number 4535674 34801, and 3/8" fixed, model number 4535604 34781, all catalog number 882480 Medical device-- intended to produce images depicting anatomical distributions of single photon emitting radioisotopes within the human body for interpretation by medical personnel. Recall # Z-1892-2009

CODE

All units

RECALLING FIRM/MANUFACTURER

Recalling Firm: Phillips Nuclear Medicine, Milpitas, CA, by letter on July 6, 2009.
Manufacturer: Philips Medical Systems (Cleveland) Inc, Cleveland, OH. Firm initiated recall is ongoing.

REASON

Unexpected movement-- if the drive assembly is severely compromised, the detector may slide to its hardware limit.

VOLUME OF PRODUCT IN COMMERCE

288 units

DISTRIBUTION

Nationwide and Internationally

PRODUCT

Abiomed AB5000 Portable Driver Catalog number: 0025-0000 The AB5000 System is a mechanical circulatory support system for use in patients suffering from potentially reversible ventricular dysfunction. It can also be used to facilitate patient transport. The Driver is external to the patient and is intended for short-term use. Recall # Z-1914-2009

CODE

Serial numbers: AF0013 - AF0015, AF0017, AF0018, AF0020, AF0022-AF0024, AF0028, AF0030, AF0037, AF0038, AF0043, AF0049, and AF0053 - AF0055

RECALLING FIRM/MANUFACTURER

Abiomed, Inc., Danvers, MA, by letter on May 8, 2009. Firm initiated recall is complete.

REASON

The Emergency System Operation (ESO) mode may not provide adequate patient support under a specific operating condition

VOLUME OF PRODUCT IN COMMERCE

18 units

DISTRIBUTION

AL, IN, FL, NJ, NY, OH, Germany, Greece, and Sweden

PRODUCT

Chiba Needle Marked Model: CNM-2308, Size: 23 GA x 20 CM. General purpose aspiration Cytology Biopsy Needle. Recall # Z-1935-2009

CODE

Lot number 091386

RECALLING FIRM/MANUFACTURER

Remington Medical, Inc., Alpharetta, GA, by telephone on June 19, 2009 and by letter on June 30, 2009. Firm initiated recall is complete.

REASON

Two unsealed pouches were identified after product release, compromising product sterility.

VOLUME OF PRODUCT IN COMMERCE

50 units

DISTRIBUTION

CA, WI

PRODUCT

The BladderScan BVI 9400 is a portable ultrasound instrument that provides a noninvasive measurement of urinary bladder volume. The device consists of an ultrasound probe that scans the patient's bladder, and a battery operated console that provides measurement related information. The BVI 9400 measures ultrasonic reflections on multiple planes inside the body and produces a three dimensional image. Based on the image, the BVI 9400 calculates and displays bladder volume. Recall # Z-1939-2009;

CODE

Units with serial numbers ranging from 1000 to 3179 are affected. (Serial number 1564 was not used.) The serial number is assigned as a sequential number, with no breakdown.

RECALLING FIRM/MANUFACTURER

Verathon, Inc., Bothell, WA, by post card and telephone on or about May18, 2009. Firm initiated recall is ongoing.

REASON

Three specific issues are being addressed: 1. Calculation and use of an incorrect year in dates after 12/31/2009. 2. Double scans, continuous scans, and double printing. 3. Calibration sensitivity.

VOLUME OF PRODUCT IN COMMERCE

1,978 units

DISTRIBUTION

Nationwide, Canada, Malaysia, Hong Kong, Singapore, Argentina, New Zealand, Barbados, Dominican Republic, and Costa Rica

PRODUCT

Abbott AxSYM Cancer Assay Disk Version 5.0, for in vitro diagnostic use with the AxSYM System; List Number 3D50-05. AxSYM AFP is a Microparticle Enzyme Immunoassay (MEIA) for the quantitative determination of alpha-fetoprotein (AFP). Recall # Z-2222-2009

CODE

Version 5.0

RECALLING FIRM/MANUFACTURER

Abbott Laboratories, Abbott Park, IL, by letters dated February 2, 2009. Firm initiated recall is ongoing.

REASON

The AxSYM Cancer Assay Disk (LN 3D50-05 version 5.0) contains an AxSYM AFP assay file where the Low Concentration flag for the AFP 1:101 automated dilution protocol the instrument to report results between 0 ng/mL and 0.4 ng/mL (40.4 ng/mL accounting for the 1:101 dilution). The sensitivity of the assay is 0.4 ng/mL.

VOLUME OF PRODUCT IN COMMERCE

8,205 disks

DISTRIBUTION

Nationwide, Australia, Bahamas, Barbados, Bermuda, Brazil, Canada, Cayman Islands, Chile, Columbia, Costa Rica, Curacao (Neth Ant), Dominican Republic, Germany, Guatemala, Hong Kong, Jamaica, Japan, Mexico, New Zealand, Peru, Singapore, South Korea, Taiwan, Thailand, Trinidad and Tobago, Turks and Caicos and Venezuela

PRODUCT

3i Custom # 5753, OSCM2913, 2.9MMX 3.4MM X 13MM, Osseotite Custom, Micromini Implant, Lot # 470258, Sterile. Custom temporary cover screws are for use in maintaining the soft tissue during the healing process of a dental restoration. Recall # Z-2227-2009

CODE

Lot # 51298

RECALLING FIRM/MANUFACTURER

Biomet 3i, LLC, Palm Beach Gardens, FL, by telephone and follow- up faxed letter on or about July 28, 2009. Firm initiated recall is ongoing.

REASON

Healing Abutment was not made within required manufacturing specification. The product did not have the relief behind the thread, which does not allow proper seating.

VOLUME OF PRODUCT IN COMMERCE

24 units

DISTRIBUTION

Nationwide and Italy

PRODUCT

1) SKINTACT Electrodes for Defibrillation, 10X REF DF20, Rx only. The device is non-sterile and single use. For use on adults and children over eight years old for external defibrillation, pacing, monitoring, and cardioversion. Recall # Z-2233-2009;

2) S&W Electrodes for Defibrillation, 10 Defibrillation Electrodes, Reorder #90101. The device is non-sterile and single use. For use on adults and children over eight years old for external defibrillation, pacing, monitoring, and cardioversion. Recall # Z-2234-2009

CODE

1) Lot #'s 80506-0771, 80527-0776, 80628-0776, 80826-0773, 80911-0773;

2) Lot #'s 80505-0778, 80814-0773, 80930-0775, 81017-0777, 90226-0776, 90403-0779, 90420-0775

RECALLING FIRM/MANUFACTURER

Leonhard Lang Gmbh, Innsbruck, Austria, by letter dated June 9, 2009. Firm initiated recall is ongoing.

REASON

A potential risk was identified associated with the connectors of the defibrillation electrodes DF20. It was found that some of the connectors do not slip easily into the sockets of the defibrillator or an extension cord of the defibrillator. In such cases increased force or some wiggling is required to insert the connector fully. A potential risk for patients exist, if (a) such a connector (b) is used with the nearly brandnew defibrillator or extension cord (c) in a situation imposing extensive stress on a user.

VOLUME OF PRODUCT IN COMMERCE

4,477 units

DISTRIBUTION

FL, Austria, Germany, Romania, France, Dubai, Greece, Italy, South Korea, United Kingdom, Hungary, Latvia, Saudi Arabia and Lebanon

PRODUCT

ILUMAVision Software, version 2.1.0 Picture Archiving and Communication system Product used as a tool for the pre-surgical planning of the placement of dental implants and pre-surgical fabrication of stents to aid in dental implant insertion. In addition, it is used for diagnostics and treatment planning in orthodontic, ENT and similar applications. Recall # Z-2239-2009

CODE

ILUMA Vision Version 2.1.0

RECALLING FIRM/MANUFACTURER

IMTEC IMAGING L.L.C., Ardmore, OK, by letter on August 3, 2009. Firm initiated recall is ongoing.

REASON

Under certain circumstances, software Version 2.1.0 has potential for incorrect data imaging and patient identification.

VOLUME OF PRODUCT IN COMMERCE

223 units

DISTRIBUTION

Nationwide, Australia, Austria, Belgium, Bulgaria, Canada, Croatia, Egypt, France, Germany, Hong Kong, Italy Korea, Malaysia, Mexico, The Netherlands, Poland, Saudi Arabia, Spain, Turkey, and United Kingdom

PRODUCT

1) B. Braun Blistered Omnifix L.L. Syringe packaged in the Easypump LT 100-48, 100 ml x 2 ml/hr Used to provide an optional filling device for the Easypump. Recall # Z-2249-2009;

2) B. Braun Blistered Omnifix L.L. Syringe packaged in the Easypump LT 60-24, 60 ml x 2 ml/hr. Recall # Z-2250-2009

CODE

1) Lot Number: 7B2775;

2) Lot Numbers: 7B2868, 812193, 832357

RECALLING FIRM/MANUFACTURER

Recalling Firm: I-Flow Corp., Lake Forest, CA, by letter dated August 1, 2008.

Manufacturer: B. Braun Melsungen, Melsungen, Germany. Firm initiated recall is complete.

REASON

I-Flow identified a B. Braun syringe package that had a tear/hole in the paper portion of the primary package. Used to provide an optional filling device for the Easypump.

VOLUME OF PRODUCT IN COMMERCE

2,177 units

DISTRIBUTION

France

PRODUCT

Medtronic SynchroMed II Programmable Pump, 8637, Rx Only, Sterilized by ethylene oxide gas. (The SynchroMed II Pump is supplied in 20 ml or 40 ml reservoir size.)

Affected products are SynchroMed II Model 8637 pumps with batteries (MECC Lifetest Batteries) manufactured from April 9, 2002 through July 2, 2002 (internally defined as Time Period 1), and from August 15, 2003 to March 16, 2005 (internally defined as Time Period 3). The SynchroMed II Programmable Pump is indicated when patient therapy requires the chronic infusion of the certain drugs and fluids. Recall # Z-2276-2009

CODE

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RECALLING FIRM/MANUFACTURER

Recalling Firm: Medtronic Neuromodulation, Minneapolis, MN, by letter dated July 2009.

Manufacturer: Medtronic Neuromodulation, Columbia Heights, MN. Firm initiated recall is ongoing.

REASON

This recall is related to the potential for reduced battery performance in a small percentage of Medtronic Model 8637 SynchroMed II pumps with batteries manufactured during two distinct time periods prior to April 2005. Nature of the Device Issue: As part of ongoing analysis of returned explanted product, Medtronic has confirmed that reduced battery performance resulted in eight (8) occurrences of Low Battery Reset between 47 to 56 months implant duration, and one (1) occurrence of premature Elective Replacement Indicator (ERI) at 54 months implant duration. Of the eight (8) reports of Low Battery Reset (critical alarm), seven (7) were confirmed to have occurred when a bolus was given during priming or flex programming, which places additional demand on the battery. The single report of premature ERI (non-critical alarm) occurred during simple continuous drug delivery. Analysis of these pumps showed that the alarms were functional.

VOLUME OF PRODUCT IN COMMERCE

18,572 units

DISTRIBUTION

Nationwide, Australia, India, Canada, Hong Kong, Japan, Austria, Belgium Cyprus, Denmark, Egypt, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Luxembourg, Netherlands, Norway, Poland, Portugal, San Marino, Saudi Arabia, Slovakia, Slovenia, South Africa, Spain, Sweden, Switzerland, Tunisia, Turkey, United Arab Emirates, United Kingdom and Vatican City

PRODUCT

Penumbra Neuron Delivery Catheter 053, 115 cm/12 cm-- MP, Percutaneous Catheter, indicated for the introduction of interventional devices into the peripheral, coronary and neuro vasculature. Catalog number PND6F11512M. Recall # Z-2313-2009

CODE

Lot number: F14751

RECALLING FIRM/MANUFACTURER

Penumbra Inc., Alameda, CA, by letters on July 6, 2009 and July 7, 2009. Firm initiated recall is ongoing.

REASON

Misbranding--Some products may be identified with the wrong ID band content 'Neuron 6F 070' instead of 'Neuron 6F delivery'.

VOLUME OF PRODUCT IN COMMERCE

37 units

DISTRIBUTION

CA, FL, NC, MI, MO, VA, AZ, CT, IA, NY, CO, Germany and Australia

PRODUCT

Tandem Unipolar, 46 MM CO-CR, REF 126646, Sterile. Designed for use with femoral stems and acetabular components distributed by Smith & Nephew. Recall # Recall # Z-2314-2009

CODE

Lot Numbers: 08LM01326, 08LM01327, 08LM02210

RECALLING FIRM/MANUFACTURER

Smith & Nephew Inc., Memphis, TN, by letter, e-mail and telephone on January 12, 2009 and by letter on April 6, 2009. Firm initiated recall is ongoing.

REASON

46 mm Femoral head was mismarked and packaged as being 45 mm.

VOLUME OF PRODUCT IN COMMERCE

10 units

DISTRIBUTION

CA, FL, MI, and Canada

PRODUCT

Martel Printer Accessory to i-STAT Portable Clinical Analyzer, rechargeable battery pack. Printing results of clinical chemistry tests and test panels contained in the i-STAT test cartridges. Printer i-STAT Catalog number 06723-91; battery pack catalog number 06F21-35. Martel Printers with. Repaired printers received since November 4, 2008;

Replacement chargeable battery packs received since October 30, 2008. Recall # Z-2328-2009

CODE

Serial numbers: 281071578 to 281071977; 281174571 to 281174970; 281276302 to 281276701 and 290178290 to 290178689

RECALLING FIRM/MANUFACTURER

Abbott Point of Care, Inc., East Windsor, NJ, by letters dated April 2009. Firm initiated recall is ongoing.

REASON

It appears that the rechargeable battery pack is overheating with or without the presence of smoke.

VOLUME OF PRODUCT IN COMMERCE

2552 units

DISTRIBUTION

Nationwide and Internationally

RECALLS AND FIELD CORRECTIONS: DEVICES - CLASS III

PRODUCT

Sensititre Mueller-Hinton Broth w/Lysed Horse Blood (MHB w/LHB), Model Number: CP112-10. In vitro diagnostic products for clinical susceptibility testing of H. influenza and Streptococcus spp. can provide both qualitative and quantitative results. Recall # Z-2324-2009

CODE

Lot number: 150444SA

RECALLING FIRM/MANUFACTURER

Recalling Firm: Trek Diagnostic Systems, Cleveland, OH, by telephone on June 4, 2009. Manufacturer: Trek Diagnostics Systems Inc., Sun Prairie, WI. Firm initiated recall is ongoing.

REASON

Thirty-one boxes of unapproved quarantine product, CP112-10 MHB w/LHB, Lot # 150444SA, were inadvertently shipped to customers on 6/2/09 instead of shipping approved Lot # 150344SA.

VOLUME OF PRODUCT IN COMMERCE

31 boxes 10/11 ml tubes

DISTRIBUTION

PA, VA, WA

RECALLS AND FIELD CORRECTIONS: VETERINARY - CLASS III

PRODUCT

Vitamin E 20,000, Animal Feed Premix; Vitamin E (min.) 20,000 IU per pound; Ingredients: Calcium Carbonate, Roughage Products, Vitamin E Supplement, Crystalline Silica, Sodium Bentonite; For Use in Manufacture of Animal Feeds Only. Recall # V-006-2010

CODE

50 lb. bags, lot numbers 0307219 and 0407179, printed on the white tape stitched to close the bag.

RECALLING FIRM/MANUFACTURER

Recalling Firm: Tri Ag Supply Inc., Harvard, IL, by telephone on September 11, 2009.

Manufacturer: Hubbard Feeds Inc. dba Ridley Feed Ingredients, Mendota, IL. Firm initiated recall is complete.

REASON

Misbranding of product by partial label removal to hide original source of materials.

Removal of partial label also removed weight and BSE statement and in some cases may remove a portion of the ingredient statement.

VOLUME OF PRODUCT IN COMMERCE

95 bags

DISTRIBUTION

IL, OH and WI

END OF ENFORCEMENT REPORT FOR NOVEMBER 11, 2009

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