

May 26, 2010

10-20

RECALLS AND FIELD CORRECTIONS: FOODS - CLASS I

PRODUCT

AAHU BARAH brand Dry Apricot, net wt. 0.5 lb., UPC 0 88247 50439 0, Product of Pakistan.
Nutrition Facts Information: Serving Size about 40 g -- Serving per Container about 5.5. Recall # F-2064-2010

CODE

Best Before: Dec. 2013

RECALLING FIRM/MANUFACTURER

Recalling Firm: Global Commodities Inc., Hicksville, NY, by press release on February 1, 2010.
Manufacturer: UNKNOWN. Firm initiated recall is complete.

REASON

The product contained undeclared sulfites (870.5 ppm) based on sampling and analysis by New York State Department of Agriculture & Markets.

VOLUME OF PRODUCT IN COMMERCE

18 cases (30 x 0.5 lbs. bags per case)

DISTRIBUTION

NY State

PRODUCT

Dulce Tipico de Coco, Coconut candy pieces with almonds, 2 oz. Recall # F-2065-2010

CODE

Manufacturing date: 11/27/2009

RECALLING FIRM/MANUFACTURER

Dulceria Gerardo, Moca, PR, by telephone and visit on December 11, 2009. Firm initiated recall is complete.

REASON

Undeclared almonds used in the production of candy.

VOLUME OF PRODUCT IN COMMERCE

65 pcs/2 oz each

DISTRIBUTION

PR

PRODUCT

1) Dry spaghetti sauce mix manufactured under the following product names and labels: (1) French's Thick Spaghetti Sauce Mix, packaged in 1.63-oz. pouches, UPC 041500058658; and (2) Durkee Thick & Rich Spaghetti Sauce Mix, packaged in 1.63-oz. pouches, UPC 047600083310. Recall # F-2066-2010;

2) Dry marinade mix packaged under the following product names and labels: (1) Weber Grill Creations Italian Herb Marinade Mix, packaged in 1.12-oz. pouches, UPC 0476000118100; and (2) Durkee Grill Creations Marinade Mix, Italian Herb, packaged in 1.12-oz. pouches. Recall # F-2067-2010

CODE

- 1) French's - OA14B53, Durkee - OA18B43;
- 2) Weber - OA18B43 and OA19B43; Durkee - 9K24B44 and 9K12B44

RECALLING FIRM/MANUFACTURER

Recalling Firm: Ach Food Companies Inc., Cordova, TN, by press release, e-mail and letter dated March 10, 2010.

Manufacturer: Ach Food Companies, Inc., Ankeny, IA. 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

1,315/12-package cases and 169/18-package cases

DISTRIBUTION

CA, FL, IA, IL, MI, MO, NC, NH, OK, PA, SD, UT, WI

PRODUCT

Kraft Tartar Sauce Tartare; tartar sauce in 355 mL plastic bottles, 12 bottles per case; The incorrect back label has the UPC is 0 683071 9, and the Ingredients: Glucose-Fructose, Water, Vinegar, Pineapple Juice Concentrate, Modified Cornstarch, Salt, Soybean Oil, Dried Red Bell and Green Bell Peppers, Spices. The correct back label has the UPC 0 683121 3, and the Ingredients: Soybean Oil, Relish (cucumbers, vinegar, salt, xanthan gum), Onion, Water, Vinegar, Egg Yolk, Sugar, Salt, Prepared Mustard, Olives, Dried Onion, Artificial Flavor, Spices, Xanthan Gum, Calcium Disodium EDTA. Recall # F-2068-2010

CODE

Best Before 10 OC 02 C xx and Best Before 10 OC 08 C xx

RECALLING FIRM/MANUFACTURER

Recalling Firm: Kraft Foods, Inc., Northfield, IL, by joint press release with the Canadian Food Inspection Agency on April 14, 2010, by memo, e-mail, fax or visit, and by letter dated April 14, 2010, and visit on April 16, 2010.

Manufacturer: Kraft Foods Inc-Enhancers Division, Champaign, IL. Firm initiated recall is ongoing.

REASON

Some of the Kraft Tartar Sauce bottles that are labeled for sale in Canada have the Kraft Sweet and Sour Sauce back labels and do not declare egg yolk which is in the Tartar Sauce.

VOLUME OF PRODUCT IN COMMERCE

1,572 cases

DISTRIBUTION

Canada

PRODUCT

Tom's Barbecue Potato Chips packaged in 1 oz, 2.25 oz and 8.5 oz size packages. Recall # F-2071-2010

CODE

Product with the following expiration dates: May 14 2010, May 21 2010, May 28 2010, Jun 4 2010, Jun 11 2010, Jun 18 2010, Jun 25 2010, Jul 2 2010, Jul 9 2010 and Jul 16 2010

RECALLING FIRM/MANUFACTURER

Recalling Firm: Lance Mfg LLC, Lance Manufacturing LLC, Charlotte, NC, by telephone and email on/about March 26, 2010 and by press release on March 29, 2010.

Manufacturers: Lance Mfg LLC, Lance Manufacturing LLC, Charlotte, NC;

Lance Inc., Perry, FL;

Lance, Inc., Corsicana, TX. 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 oz packed 48 count per case=320,736 packages; 2.25 oz packed 25 count per case=298,150 packages; and 8.5 oz packed 11 count per case=118,074 package

DISTRIBUTION

Nationwide

PRODUCT

David Michael & Co Natural and Artificial Vanilla Flavor #626 in 1 gallon containers. The product is 4 containers per box. Recall # F-2072-2010

CODE

Lot number 0H0991

RECALLING FIRM/MANUFACTURER

David Michael & Co., Philadelphia, PA, by telephone on April 16, 2010. Firm initiated recall is complete.

REASON

Positive *Salmonella* result.

VOLUME OF PRODUCT IN COMMERCE

16 gallons

DISTRIBUTION

IA

PRODUCT

1) Chicken Bouillon Type Flavor, item number 705700.47. 50 lb carton. Ingredients: Hydrolyzed Soy Protein, Natural Flavor, and Chicken Fat. Recall # F-2085-2010;

2) Natural Anchovy Type Flavor, item number 705783.47. 50 lb carton. Ingredients: Salt, Maltodextrin, Fish Powder, Hydrolyzed Soy Protein, Modified Food Starch, soy Lecithin, Partially Hydrogenated Vegetable Oil (Cottonseed and/or soybean), Vinegar Solids, Disodium Inosinate, Disodium Guanylate, and Silicon Dioxide (to prevent caking). Recall # F-2086-2010;

3) Natural Chicken Type Flavor, item number 705931.47. 50 lb carton. Ingredients: Maltodextrin, Hydrolyzed Soy Protein, Torula yeast, Natural Flavor, Chicken Fat, Disodium Inosinate and Disodium Guanylate. Recall # F-2087-2010;

4) Beef Flavor, item number 705937.47. 50 lb. carton. Ingredients: Dried Beef Stock, Hydrolyzed Soy Protein, Hydrolyzed Corn Gluten Protein (Salt), Autolyzed Yeast Extract, Dextrose, and Hydrolyzed Wheat Gluten Protein. Recall # F-2088-2010;

- 5) Roast Beef Type Flavor, item number 706868.47, 50 lb. carton. Ingredients: Hydrolyzed Corn, Soy, and Wheat Gluten Protein, Autolyzed Yeast Extract, Corn Syrup Solids, and Thiamine Hydrochloride. Recall # F-2089-2010;
- 6) Seafood Flavor Blend, item number 706881.47, 50 lb. carton. Ingredients: Lactose, Hydrolyzed Soy, Corn, and Wheat Protein, Natural Flavor, Lemon juice Solids, Canola Oil, Disodium Inosinate and Disodium Guanylate. Recall # F-2090-2010;
- 7) Roasted Garlic Flavor, item number 706889.47, 50 lb. carton. Ingredients: Salt, Maltodextrin, Natural Flavor, Hydrolyzed Soy Protein, Dehydrated Garlic, Partially Hydrogenated Vegetable Oil (Soybean and/or Cottonseed), Lipolyzed Butter Oil, Silicon Dioxide (to prevent caking), and Garlic Oil. Recall # F-2091-2010;
- 8) Roast Beef Type Flavor, item number 706893.49, 50 lb. carton. Ingredients: Hydrolyzed Soy, Corn, and Wheat Protein, Corn Syrup Solids, Thiamine Hydrochloride, Partially Hydrogenated Vegetable Oil (Soybean and/or Cottonseed), Disodium Inosinate and Disodium Guanylate. Recall # F-2092-2010;
- 9) HVP B-97 BFF, item number 716603.49, 55.12 lb. carton. Ingredients: Hydrolyzed Soy Protein, Corn Syrup Solids, Thiamine Hydrochloride, Partially Hydrogenated Soybean and Cottonseed Oil, Disodium Inosinate and Disodium Guanylate. Recall # F-2093-2010;
- 10) Rosemary Potato Seasoning, JRS 69GP1A30, item number 6020032.01, 50 lb. carton. Ingredients: Salt, Sugar, Butter Powder (Cream, Salt), Dehydrated Onion, Spices, Autolyzed Yeast Extract, Modified Potato Starch, Dehydrated Garlic, Sherry Wine Flavor (Maltodextrin, Sherry Wine Solids (prepared with Sulfur Dioxide)), Maltodextrin, Rendered Chicken Fat, Natural Flavors, Dried Chicken Meat, Dried Chicken Broth, Hydrolyzed Soy Protein, Citric Acid, Spice Extractive, Disodium Inosinate and Disodium Guanylate, and less than 2% Partially Hydrogenated Cottonseed and soybean Oils and Silicon Dioxide (processing aid.) Recall # F-2094-2010;
- 11) Ancho Chili Rub, item number 6970027.01, 2 lb bag. Ingredients: Chili Pepper and other Spices, Sugar, Salt, Dehydrated Onion and Garlic, Flavors (Salt, Maltodextrin, Hydrolyzed Soy Protein, Dried Garlic, Autolyzed Yeast Extract, Partially Hydrogenated Cottonseed and Soybean Oils Lipolyzed Butter Oil, Chicken Flavor, Chicken Stock, Natural Flavor, Chicken Fat), Hydrolyzed Corn Protein, Spice Extractive, and less than 2% Silicon Dioxide and Partially Hydrogenated Soybean and Cottonseed Oil (processing aid). Recall # F-2095-2010;
- 12) Roasted Chipotle Seas, item number 6980417.01, 50 lb carton. Ingredients: Spices, Salt, Sugar, Dehydrated Garlic, Dehydrated Red Bell Pepper, Natural and Artificial Flavors (contains Dairy), Molasses (Maltodextrin), Hydrolyzed Soy Protein, Yeast Extract, Citric Acid, Natural Smoke Flavor, Disodium Inosinate and Disodium Guanylate and less than 2% Silicon Dioxide and Partially Hydrogenated Cottonseed and Soybean Oils. Recall # F-2096-2010;
- 13) Instant Spicy Beef Broth Mix, item number 6980573.01, 75 g packet. Ingredients: Salt, Monosodium Glutamate, Onion Powder, Sugar, Yeast Extract, Natural Flavors (contains Milk, Soy,

Wheat), Rendered Beef Fat, Spices, Corn Starch, Silicon Dioxide (anti-caking), Extractives of Paprika, Hydrolyzed Soy Protein, Dehydrated Garlic. Recall # F-2097-2010;

14) Au Jus Mix, item number B00140.01. 200 lb drum. Ingredients: Salt, Hydrolyzed Protein (Soy, Whey {from Milk}, Wheat, Corn), Soybean Oil, Caramel Color, Modified Corn Starch, Sugar, Autolyzed Yeast Extract, Beef Fat (with Tocopherol and BHT used to protect quality), Silicon Dioxide (anti-caking agent), Onion Powder, Corn Syrup Solids, Sodium Tripolyphosphate, L-Cysteine Hydrochloride, Spices, Water, Disodium Inosinate, Disodium Guanylate, Yeast, Propylene Glycol, Natural Beef Flavor, Partially Hydrogenated Soybean and Cottonseed Oil, Thiamin Hydrochloride, Sodium Hexametaphosphate, Maltodextrin, Natural and artificial Flavors, Soybean Lecithin, Mixed Triglycerides, Calcium Disodium EDTA used to protect quality, Sodium Ascorbate. Recall # F-2098-2010;

15) Roast Beef Injection, item number B00474.01, 36 lb bag. Ingredients: Salt, Hydrolyzed Soy Protein, Sugar, Autolyzed Yeast, Flavor (Hydrolyzed Soy Protein, Corn Syrup Solids, Thiamin Hydrochloride, Partially Hydrogenated Soybean & Cottonseed Oil, Disodium Inosinate, Disodium Guanylate), Onion Powder, Garlic Powder, Spices, Natural Flavorings, Turmeric and Soy Lecithin, Soybean Oil and Silicon Dioxide added to prevent caking. Recall # F-2099-2010;

16) Chicken Gravy Mix 15964, S0042798-01, item number B15964.02, 46 lb bag. Ingredients: Modified Corn Starch, Flavor (Hydrolyzed Soy and Corn Protein, Dried Chicken Meat, Maltodextrin, Autolyzed Yeast, Natural Flavorings, Thiamin Hydrochloride, Partially Hydrogenated Soybean and/or Cottonseed Oil, Corn Syrup Solids, Disodium Inosinate, Disodium Guanylate), Wheat Flour, Whey, Salt, Sugar, Chicken Fat, Onion Powder, Xanthan Gum, Guar Gum, Caramel Color, Spice, Extractives of Spices including Turmeric; with less than 2% Silicon Dioxide added to prevent caking. Recall # F-2100-2010;

17) Chicken Gravy Flavor Seas, S0060186-00, item number B17707.01, 50 lb bag. Ingredients: Hydrolyzed Corn and Soy Protein, Onion Powder, Maltodextrin, Chicken Fat, Natural Flavors, Dextrose, Disodium Inosinate and Disodium Guanylate, Dried Chicken Meat, Salt, Autolyzed Yeast Extract, Thiamin Hydrochloride, Spice, Spice Extracts, and less than 2% Silicon Dioxide (to prevent caking). Recall # F-2101-2010;

18) Chicken Seasoning, item number B17810.01, 50 lb bag. Ingredients: Hydrolyzed Soy and Corn Gluten Protein, Salt, Maltodextrin, Sugar, Corn Syrup Solids, Wheat Flour, Citric Acid, sodium Diacetate, Dextrose, Lactose, Chicken Flavor, Partially Hydrogenated Soybean Oil (processing aid), Autolyzed Yeast Extract, Corn Starch, Natural and Artificial Flavors, Disodium Inosinate, Disodium Guanylate, Lactic Acid, Sesame Oil, and less than 2% Silicon Dioxide (to prevent caking). Recall # F-2102-2010;

19) Garlic and Herb Potato Seas, JRS 69DP1A30, item number B17918.01, 50 lb carton. Ingredients: Dehydrated Garlic, Sugar, Salt, Cultured Whey, Modified Potato Starch, Spices, Dehydrated Onion, Yeast, Natural Flavor (Salt, Maltodextrin, Hydrolyzed Soy Protein, Natural Flavors), Partially Hydrogenated Cottonseed and Soybean Oils, Citric Acid, Natural Flavors. Recall # F-2103-2010;

20) Garlic & Black Pepper Seas, JRS 773602, item number B18136.01, 50 lb carton. Ingredients: Salt, Natural Flavors (contains Dairy, Soy), Sugar, Garlic Powder, Yeast Extract, Onion Powder, Black Pepper, Vinegar Powder, (Maltodextrin, Modified Corn Starch, Vinegar), Safflower Oil , and less than 2% Silicon Dioxide (processing aid). Recall # F-2104-2010;

21) Chicken Seasoning, item number B18714.01, 50 lb bag. Ingredients: Hydrolyzed Soy and Corn Gluten Protein, Salt, Maltodextrin, Sugar, Corn Syrup Solids, Wheat Flour, Citric Acid, Sodium Diacetate, Dextrose, Lactose, Chicken Flavor, Partially Hydrogenated Soybean Oil (processing aid), Autolyzed Yeast Extract, Corn Starch, Natural and Artificial Flavors, Disodium Inosinate, Disodium Guanylate, Lactic Acid, and less than 2% Silicon Dioxide (to prevent caking). Recall # F-2105-2010;

22) Homestyle Gravy Mix S0060665-02, item number B18876.01, 38.33 lb bag. Ingredients: Modified Corn Starch, Nonfat Dry Milk, Maltodextrin, Hydrolyzed Soy and Corn Protein, Dried Butter (Cream, Salt), Dried Sour Cream (Cream, Nonfat Milk, Cultures), Whey Powder, Dried Onion, Cultured Nonfat Milk, Xanthan Gum, Salt, Autolyzed Yeast Extract, Citric Acid, Garlic Powder, Caramel (color), Spices, Dried Parsley, Disodium Phosphate, Disodium Inosinate and Disodium Guanylate, Paprika, Natural Flavors, Corn Syrup Solids, and Thiamine Hydrochloride. Recall # F-2106-2010;

23) Breader, item number G0098, 50 lb bag. Ingredients: Bleached Wheat Flour, Salt, Leavening (Sodium Bicarbonate, Sodium Aluminum Phosphate), Rice Flour, Spices, Partially Hydrogenated Soybean Oil, Dextrose, Monosodium Glutamate, Hydrolyzed Wheat Gluten, Autolyzed Yeast Extract, and Natural Flavors. Recall # F-2107-2010;

24) Predust, item number G0138, 50 lb bag. Ingredients: Bleached Wheat Flour, Food Starch - Modified Salt, Rice Flour, Leavening (Sodium Bicarbonate and Sodium Aluminum Phosphate), Spices, Partially Hydrogenated Soybean Oil, Dextrose, Monosodium Glutamate, Hydrolyzed Wheat Gluten, Autolyzed Yeast Extract, Lactic Acid, and Spice Extract. Recall # F-2108-2010;

25) Batter, item number G2769, 50 lb bag. Ingredients: Yellow Corn Flour, Modified Food Starch, Enriched Bleached Wheat Flour, (with Niacin, Ferrous Sulfate, Thiamine Mononitrate, Riboflavin, Folic Acid), Salt, Whey, Soy Flour, Garlic Powder, Leavening (Sodium Acid Pyrophosphate, Sodium Bicarbonate), Disodium Inosinate and Disodium Guanylate, Citric Acid, Guar Gum, Sodium Alginate, Methylcellulose, Nonfat Dry Milk, Spice Extractives, and Extractives of Paprika. Recall # F-2109-2010;

26) Batter, item number G3080.49, 50 lb bag. Ingredients: Yellow Corn Flour, Modified Corn Starch, Wheat Flour, Dextrose, Salt, Dried Whey, Hydrolyzed Soy Protein, Soy Flour, Garlic Powder, Leavening (Sodium Acid Pyrophosphate, Sodium Bicarbonate), Xanthan Gum, Disodium Inosinate and Disodium Guanylate, Methylcellulose, Sodium Alginate, Guar Gum, Citric Acid, Natural Flavor and Paprika Extract (color). Recall # F-2110-2010;

27) Batter, item number G3597.49, 50 lb bag. Ingredients: Yellow Corn Flour, Enriched Wheat Flour, (Wheat Flour, Niacin, Reduced Iron, Thiamine Mononitrate, Riboflavin, Folic Acid), Modified Food Starch, Salt, Dried Whey, Sugar, Methylcellulose, Garlic Powder, Disodium

Inosinate and Disodium Guanylate, Leavening (Sodium Acid Pyrophosphate, Sodium Bicarbonate), Soy Flour, Sodium Alginate, Citric Acid, and Oleoresin Paprika. Recall # F-2111-2010;

28) Batter, item number G3767.GF1, 50 lb bag. Ingredients: Bleached Wheat Flour, Modified Corn Starch, Salt, Hydrolyzed Soy Protein, Leavening (Sodium Acid Pyrophosphate, Sodium Bicarbonate, Monocalcium Phosphate), Monosodium Glutamate, Onion Powder, Garlic Powder, Corn Starch, Citric Acid, Spice and Disodium Inosinate and Disodium Guanylate. Recall # F-2112-2010;

29) Batter, item number G5052.49, 50 lb bag. Ingredients: Bleached Wheat Flour, Modified Corn Starch, Salt, Leavening (Sodium Acid Pyrophosphate, Sodium Bicarbonate, Monocalcium Phosphate), Hydrolyzed Soy Protein, Dried Garlic, Dried Onion, Citric Acid, Spice, Disodium Inosinate and Disodium Guanylate, Dried Whey, Dried Whole Egg, and Soy Flour. Recall # F-2113-2010;

30) Bar-B-Q Seas, item number I1036.465, 50 lb bag. Ingredients: Torula yeast, Salt, Spices, Corn Flour, Dextrose, Sucrose, Dried Onion, Dried Tomato, Corn Starch, Monosodium Glutamate, Hydrolyzed Corn/Soy Protein, Citric Acid, Natural Flavor, Paprika Extract (color), Tricalcium Phosphate and Silicon Dioxide (anti-caking agent), and Dried Garlic. Recall # F-2114-2010;

31) Chicken Flavor WONF EXCL-GOYA, P0600, item number P708718.01, 50 lb carton. Ingredients: Salt, Monosodium Glutamate, Sugar, Hydrolyzed Corn and Soy Protein, Maltodextrin, yeast Extract, Dried Onion, Chicken Fat, Dried Garlic, Non Fat. Recall # F-2115-2010;

32) CODE 5 BLEND Chicken, 1779 U10, item number P708763.01 50 lb bag. Ingredients: Hydrolyzed Corn and Soy Protein, Yeast Extract, Chicken Fat, Salt, Non Fat Dry Milk, Chicken Meal, Natural Flavor, L-Cysteine Hydrochloride, Disodium Inosinate and Disodium Guanylate, Lactic Acid, Calcium Lactate, and less than 2% Silicon Dioxide (to prevent caking). Recall # F-2116-2010;

33) N & A Ham Type LF 1746 U10800, item number P708794.01 50 lb carton. Ingredients: Hydrolyzed Soy Protein, Salt, Corn Syrup Solids, Hydrolyzed Corn Protein, Natural Flavor, Yeast Extract, Canola Oil, Artificial Flavor, Silicon Dioxide. Recall # F-2117-2010;

34) N&A Roast Ham Type FL 1747 U, item number P708795.01 50 lb carton. Ingredients: Hydrolyzed Soy and Corn Protein, Salt, Corn Syrup Solids, Yeast Extract, Canola Oil, Brown Sugar, Natural Flavor, Silicon Dioxide, Maltodextrin, Artificial Flavor, Disodium Inosinate, and Disodium Guanylate. Recall # F-2118-2010;

35) Nat BACON Type FL 1742 U10790, item number P708799.01 50 lb carton. Ingredients: Hydrolyzed Corn, Soy and Wheat Protein, Maltodextrin, Salt, Natural Flavors, Bacon Fat, Silicon Dioxide (prevent caking), Natural Smoke Flavor, Disodium Inosinate, and Guanylate. Recall # F-2119-2010;

36) Hot Sauce Seas 29270; item number I1923.465, 50 lb bag. Ingredients: Salt, Dextrose, Paprika, Maltodextrin, Food Starch - Modified, Citric Acid, Natural Flavor, Monosodium Glutamate, Red

40 Lake, Calcium Silicate (anti-caking agent), Sucrose, Hydrolyzed Corn/Soy/Wheat Protein, Carmel (color), dried Onion and Dried Garlic. Recall # F-2120-2010

CODE

- 1) Lot number: 118087601;
- 2) Lot number: 203087601;
- 3) Lot numbers: 212087901, 212087902, 1015987801, 1015987802, 1113987901, 1114987601, 1118987901, 1118987902, 1212987901, 1212987902, 1229987901, 1229987902;
- 4) Lot numbers: 219087901, 219087902, 219087903;
- 5) Lot numbers: 113087801, 223087602;
- 6) Lot number: 1120987601;
- 7) Lot numbers: 107087801, 203087801, 1005987505, 1005987506, 1005987507, 1005987508, 1005987801, 1005987802, 1005987803, 1005987804, 1005987805, 1005987806, 1005987807, 1005987808, 1106987601, 1106987602, 1222987901, 1222987902, 1222987903, 1222987904, 1228987801, 1228987802;
- 8) Lot number: 1231987601;
- 9) Lot numbers: 121039801, 203039801, 222039801;
- 10) Lot numbers: 021904401, 0120044101;
- 11) Lot numbers: 0013, 0048, 9309, 9341;
- 12) Lot numbers: 0121044002, 0129044101, 0212044101, 1112944103;
- 13) Lot number: 9324;
- 14) Lot numbers: 0211060102, 1119924303;
- 15) Lot numbers: 0106023810, 0218023807;
- 16) Lot numbers: 0121023801, 0205024102;
- 17) Lot numbers: 0111060001, 0127023803, 0218023808;
- 18) Lot numbers: 0201023806, 1207923802;
- 19) Lot numbers: 0212044003, 1111944201, 1201944204;
- 20) Lot number: 0112044101;

21) Lot numbers: 0104023808, 0120023809, 0216023808, 1023960103, 1104923805, 1120924101, 1207923803, 1214923810, 1214923811, 1229923804, 1229923808;

22) Lot numbers: 0121024304, 0224024104;

23) Lot number: 0122016103;

24) Lot numbers: 0122016104, 0211016110, 0218016108;

25) Lot numbers: 0211032202, 0104016010, 1103916002;

26) Lot numbers: 114032207, 127032207, 203032216, 1112932208, 1130932206, 1219932210;

27) Lot numbers: 0105016001, 0105016002, 0112016007, 0126016009, 0126016010, 0202016010, 0202016011, 0202016012, 0211032203, 0211032204, 0211032205, 0211032206, 1014916001, 1014916002, 1027916006, 1027916007, 1027916008, 1103916005, 1103916006, 1116916002, 1116916003, 1124916001, 1124916002, 1228916003, 1228916004, 1228916005, 1228916006, 211032202, 211032203, 211032204, 211032205, 211032206;

28) Lot numbers: 113032209, 126032206, 210032206, 224032211, 1003932207, 1028932201, 1112932213, 1118932212, 1202932204, 1202932205, 1213032209, 1216932209;

29) Lot numbers: 204032208, 218032202, 1007932215, 1020932214, 1202932209;

30) Lot numbers: 0211077101, 0211077102, 0211077103, 0211077104;

31) Lot numbers: 0104077101, 0104077102, 0104077103, 0104077104, 0104077105, 104077106, 0104077106, 0118077101, 0118077102, 0118077103, 0118077104, 0118077105, 0118077106, 203077101, 0203077101, 203077102, 0203077102, 203077103, 0203077103, 203077104, 0203077104, 203077105, 0203077105, 203077106, 0203077106, 204077101, 0204077101, 204077102, 0204077102, 204077103, 0204077103, 204077104, 0204077104, 204077105, 0204077105, 204077106, 0204077106, 222077101, 0222077101, 222077102, 0222077102, 222077103, 0222077103, 222077104, 0222077104, 222077105, 0222077105, 222077106, 0222077106, 1119977101, 1119977102, 1119977103, 1119977104, 1119977105, 1119977106, 1202977101, 1202977102, 1202977103, 1202977104, 1202977105, 1202977106;

32) Lot numbers: 0108076701, 0119076401, 0119076401, 119076402, 0119076402, 119076403, 0119076403, 119076404, 0119076404, 119076405, 0119076405, 0208076401, 208076402, 0208076402, 208076403, 0208076403, 208076404, 0208076404, 208076405, 0208076405, 1207977101, 1207977102, 1211976501, 1211976502, 1211976503;

33) Lot numbers: 212076601, 1222976501;

34) Lot numbers: 212076501, 1222976502;

35) Lot numbers: 212076501, 1222976502;

36) Lot number: 0126023804

RECALLING FIRM/MANUFACTURER

Recalling Firm: Kerry Inc., Beloit, WI, by letters on February 28, 2010 and March 16, 2010.

Manufacturers: Kerry, Inc., Jackson, WI;

Kerry Ingredients & Flavours Americas Region, Owen, WI;

Kerry Ingredients & Flavours, Sturtevant, WI;

Kerry, Inc., Waunakee, WI;

Kerry Ingredients and Flavours, Irving, TX;

Kerry Ingredients & Flavours, Kent, WA;

Kerry Inc., Evansville, IN;

Kerry Ingredients & Flavours Inc., Calhoun, GA;

Kerry Ingredients, Inc., Melrose Park, IL;

Kerry Ingredients & Flavours, Flemington, NJ;

Kerry Specialty, Fredericksburg, IA. Firm initiated recall is ongoing.

REASON

Kerry Ingredients is recalling products manufactured with HVP (hydrolyzed vegetable protein) supplied by Basic Food Flavors, Inc., Las Vegas, NV because it has the potential to be contaminated with *Salmonella*.

VOLUME OF PRODUCT IN COMMERCE

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DISTRIBUTION

AR, CA, FL, GA, IA, IL, IN, KS, MD, MI, MN, MS, NC, NJ, OH, TX, WA, WI

PRODUCT

1) Marco Polo Brand Shrimp Snacks Original, UPC Code 24628 92482, 2.5 oz plastic bag. Recall # F-2121-2010;

2) Marco Polo Brand Shrimp Snacks Onion & Garlic Flavored, UPC Code 24628 51183, 2.5 oz plastic bag. Recall # F-2122-2010;

3) Marco Polo Brand Shrimp Snacks Bar-B-Que Flavored, UPC Code 24628 51083, 2.5 oz plastic bag. Recall # F-2123-2010

CODE

All expiration dates of 08-13-10 and earlier.

RECALLING FIRM/MANUFACTURER

Golden Pacific Foods Inc., Chino, CA, by press release on April 2, 2010 and by letter on April 5, 2010. Firm initiated recall is ongoing.

REASON

The recall was initiated because the affected products may contain undeclared milk.

VOLUME OF PRODUCT IN COMMERCE

31,159 cases

DISTRIBUTION

Nationwide

PRODUCT

1) The Crushed Red Pepper product is packaged in a clear plastic bag which is placed inside of a cardboard box with an adhesive white label with a blue border and blue and black lettering; on certain occasions the adhesive white label would only contain black lettering. The brand name on the product labels is Wholesome Spices. The product name is listed as Crushed Red Pepper. Recall # F-2124-2010;

2) The Ground Red Pepper product is packaged in a clear plastic bag which is placed inside of 50 lb cardboard boxes with an adhesive white label with a blue border and blue and black lettering. The brand name on the product labels is Wholesome Spices. The product name is listed as Ground Red Pepper. Recall # F-2125-2010;

3) The Whole Black Pepper product is packaged in a clear plastic bag which is placed inside of 50 lb cardboard boxes with an adhesive white label with a blue border and blue and black lettering. The brand name on the product labels is Wholesome Spices. The product name is listed as Whole Black Pepper. Recall # F-2126-2010

CODE

1) All lots of Crushed Red Pepper packed in 25 pound boxes from 04/06/09 thru 01/20/10;

2) Lot - 092909-GR1;

3) Lot - 011810-WB1

RECALLING FIRM/MANUFACTURER

Recalling Firm: Superior Specialty Ingredients Inc., Brooklyn, NY, by telephone beginning on February 24, 2010, press release on February 25, 2010 and by letters on March 5, 2010.

Manufacturer: Phuc Sinh Co., Ltd, Hochiminh, Vietnam. Firm initiated recall is ongoing.

REASON

FDA testing determined that the products are contaminated with *Salmonella*.

VOLUME OF PRODUCT IN COMMERCE

???

DISTRIBUTION

RI, PA

PRODUCT

1) Cupcakes with a label for the cupcakes in dual languages: Chinese and English, 6 cupcakes per package, 15 packages per case, total Net. WT. 8 oz., in styrofoam tray with plastic wrapper. Recall # F-2127-2010;

2) Roasted Peanuts with a label for the roasted peanuts in dual languages: Chinese and English, Net Wt. 5 oz. in plastic container, 54 containers per case. Recall # F-2128-2010

CODE

None

RECALLING FIRM/MANUFACTURER

Shun Fung International Trading Inc., San Francisco, CA, by visit beginning April 6, 2010. Firm initiated recall is ongoing.

REASON

Undeclared allergen ingredients of wheat and soy on the finished product label to the roasted peanuts.

VOLUME OF PRODUCT IN COMMERCE

Unknown

DISTRIBUTION

CA

PRODUCT

Peony Mark brand Dried Date, net wt: 12 oz. (340g +-5g), UPC 6 86529 13005 5 – Product of China. Nutrition Facts: Serving Size 12 oz (340g) Serving Per Container 1. Recall # F-2129-2010

CODE

None

RECALLING FIRM/MANUFACTURER

Starway Inc. Brooklyn, NY, by press release on March 18, 2010. Firm initiated recall is complete.

REASON

The product contained undeclared sulfites (54.1 ppm) based on sampling and analysis by New York State Department of Agriculture & Markets.

VOLUME OF PRODUCT IN COMMERCE

176 cartons (50 - 12 oz bags per carton)

DISTRIBUTION

NY, NJ, PA, ME, CT, MA, OH, MD, VA, FL, NC, SC, IL

PRODUCT

Island Snacks Natures Mix trail mix (6.5 oz bag). Recall # F-2130-2010

CODE

Exp date: 07/24/2010

RECALLING FIRM/MANUFACTURER

Island Snacks, Buena Park, CA, by letter on August 24, 2009. Firm initiated recall is ongoing.

REASON

Island Snacks is initiating a recall on Island Snacks Natures Mix, 6.5 oz plastic bag, due to use of undeclared sulfites in Island Snacks Natures Mix trail mix.

VOLUME OF PRODUCT IN COMMERCE

756 units

DISTRIBUTION

NY

PRODUCT

Crown brand Cookie (Choco Sanddo), net wt 5.68 oz. (161gr), Product of Korea, UPC 8 801111 6 14436. The product is packaged in a waxed cardboard box with Korean labeling. --- A sticker with English label information is pasted on the box and labeled in part, " *** Cookie (Choco Sanddo)

*** Ingredients: Wheat Flour, Sugar, Glucose, Cocoa Mass, Cocoa Powder, Coconut Oil, Corn Syrup, Salt, Coconut Flavor, Chocolate Flavor, Contains: Wheat *** net wt: 5.68 oz. (161gr)".

Recall # F-2131-2010

CODE

Codes: 2008.12.01 followed by Korean characters, and 2009.11.30 followed by Korean characters

RECALLING FIRM/MANUFACTURER

Y S Trading Corp. Long Island City, NY, by press release on September 14, 2009. Firm initiated recall is complete.

REASON

The product contained undeclared milk allergens (>150 ppm) based on sampling and analysis by New York State Department of Agriculture and Markets.

VOLUME OF PRODUCT IN COMMERCE

1800 boxes

DISTRIBUTION

NY, NJ

RECALLS AND FIELD CORRECTIONS: FOODS - CLASS II

PRODUCT

1) BEEF BASE - N, Sales #, 328, Lot #, C3289350, 40 - 50 lbs, White HDPE, REFRIGERATE 2-10C (35-50F), 12/16/09. Recall # F-2073-2010;

2) BEEF BASE, Sales # 338, 40 - 50 lbs, White HDPE, REFRIGERATE 2-10C (35-50F), 1/13/2010, 1/27/2010, 12/2/2009. Recall # F-2074-2010;

3) BEEF BASE - ENZZ, Sales # 361, 40 - 50 lbs, White HDPE, REFRIGERATE 2-10C (35-50F) , 12/16/09. Recall # F-2075-2010;

4) BEEF BASE - E , Sales # 375, 40 - 50 lbs, White HDPE, REFRIGERATE 2-10C (35-50F) , 11/11/2009, 12/16/2009. Recall # F-2076-2010;

5) BEEF BASE - NSZ, Sales # 388, 40 - 50 lbs, White HDPE, REFRIGERATE 2-10C (35-50F) , 2/3/2010, 12/16/2009. Recall # F-2077-2010;

6) CHICKEN BASE - ENS, Sales # 461, 40 - 50 lbs, White HDPE, REFRIGERATE 2-10C (35-50F) , 11/23/09. Recall # F-2078-2010;

7) CHICKEN BASE - EN, Sales # 478, 40 - 50 lbs, White HDPE, REFRIGERATE 2-10C (35-50F), 1/18/2010, 12/7/2009. Recall # F-2079-2010;

8) TUSCAN CONDIMENT CONCENTRATE, Sales # 3009167, 40 - 50 lbs, White HDPE, REFRIGERATE 2-10C (35-50F), 11/11/09. Recall # F-2080-2010;

9) ANCHO FLAVOR BASE, Sales # 709, 40 - 50 lbs, White HDPE, REFRIGERATE 2-10C (35-50F), 1/12/2010, 1/19/2010, 12/8/2009. Recall # F-2081-2010;

10) BEEF AND BINDER PRODUCT, Sales # MP722, 40 - 50 lbs, White HDPE, REFRIGERATE 2-10C (35-50F), 11/4/2009, 12/16/2009. Recall # F-2082-2010;

11) BEEF BASE - N, Sales # 931, 40 - 50 lbs, White HDPE, REFRIGERATE 2-10C (35-50F) , 1/27/2010, 11/7/2009. Recall # F-2083-2010;

12) CHICKEN BASE - N, Sales # 942, 40 - 50 lbs, White HDPE, REFRIGERATE 2-10C (35-50F), 1/25/2010, 12/7/2009. Recall # F-2084-2010

CODE

- 1) Lot # C3289350;
- 2) Lot # C3380013, C3380027, C3389336;
- 3) Lot # C3619350;
- 4) Lot # C3759315, C3759350;
- 5) Lot # C3880034, C3889350;
- 6) Lot # C4619327;
- 7) Lot # C4780018, C4789341;
- 8) Lot # C6179315;
- 9) Lot # C7090012, C7090019, C7099342;
- 10) Lot # C7229308, C7229350;
- 11) Lot # C9310027, C9319321;
- 12) Lot # C9420025, C9429341

RECALLING FIRM/MANUFACTURER

Recalling Firm: Givaudan Flavors Corp., Cincinnati, OH, by letters on March 3, 2010.

Manufacturer: Nestle Professional, Cleveland OH. Firm initiated recall is ongoing.

REASON

Givaudan has been informed that Dry Powder and Paste HVP (Hydrolyzed Vegetable Protein) products manufactured by Basic Food Flavors, Inc. on or after September 17, 2009 are being recalled. A production lot within this time frame has tested positive for Salmonella and Basic Food Flavors and FDA has found Salmonella within the manufacturing facility.

VOLUME OF PRODUCT IN COMMERCE

166,862 pounds

DISTRIBUTION

CA, IA, ID, KY, LA, MN, NE, NY, OH, OR, TX, VA & WI

RECALLS AND FIELD CORRECTIONS: DRUGS - CLASS II

PRODUCT

Zyrtec Itchy Eye Drops (ketotifen fumarate) ophthalmic solution, 0.025%, 0.17 Fl oz (5 mL) bottle, NDC 50580-732-05, UPC 30045-208-057. Recall # D-542-2010

CODE

Lot numbers: JE2425, JE2425A, JE2426, JE2427, JE5608, JE6160, JE6160A, JG5286, JG5286A, JG5286B, JG7349, JJ6419, and JJ6422

RECALLING FIRM

McNeil Consumer Healthcare, Div of McNeil-PPC, Inc., Fort Washington, PA, by letter dated March 29, 2010.

REASON

Failed PH Specifications: out of specification (OOS) results for pH during stability testing.

VOLUME OF PRODUCT IN COMMERCE

1,183,614 bottles

DISTRIBUTION

Nationwide

PRODUCT

Rifampin USP, lyophilized powder for injection, 600 mg, sterile glass vial packaged in an individual carton, Rx only, NDC 55390-123-01. Recall # D-543-2010

CODE

Lot #1639562, Exp 01/11

RECALLING FIRM/MANUFACTURER

Ben Venue Laboratories Inc., Bedford, OH, by letters on February 4, 2010 and February 11, 2010. Firm initiated recall is ongoing.

REASON

Lack of assurance of sterility: Non-viable particulate (NVP) monitoring results exceeded action limits for approximately 40% of the filling operation which was not detected or corrected during the fill.

VOLUME OF PRODUCT IN COMMERCE

20,865 vials

DISTRIBUTION

Nationwide

PRODUCT

1) Fisiolin (sodium chloride), sterile nasal drops, supplied in 0.5 fl oz (15 mL) bottles packaged in individual boxes, NDC 66502-900-15. Recall # D-544-2010;

2) Camolyn, Homeopathic (Matricaria chamomilla tincture HPUS 3X, Hamamelis virginiana tincture HPUS 3X), eye drops, supplied in 0.5 fl oz (15 mL) bottles, NDC 66502-415-15. Recall # D-545-2010;

3) Camolyn-A (Naphazoline hydrochloride 0.025%, Pheniramine Maleate 0.3%), eye drops, supplied in 0.5 fl oz (15 mL) bottles packaged in individual boxes, NDC 66502-320-15. Recall # D-546-2010;

4) Camolyn Plus (Naphazoline Hydrochloride 0.012%, Matricaria Chamomile 0.2%, Virginian Hamamelis 0.1%), eye drops, supplied in 0.5 fl oz (15 mL) bottles packaged in individual boxes, NDC 66502-510-15. Recall # D-547-2010;

5) Camolyn Refresh (Dextran 70%, Hydroxypropyl Methylcellulose 0.3%), eye drops, supplied in 0.5 fl oz (15 mL) bottles packaged in individual boxes, NDC 66502-220-15. Recall # D-548-2010

CODE

1) All Lots: 028659, Exp 03/2011;

2) All Lots: 049036, Exp 05/2011; 087934, Exp 08/2009;

3) All Lots: 057063, Exp 5/2009; 058962, 04/2010; 106606, Exp 10/2008; 099487, Exp 09/2011;

4) All Lots: 037691, Exp 3/2010; 097420, Exp 10/2010;

5) All Lots: 16636, Exp 11/2009; 107610, Exp 11/2010

RECALLING FIRM/MANUFACTURER

US Recalling Firm: Oftalmi Corp., Hallandale Beach, FL, by letters on March 17, 2010.

Manufacturer: Laboratorios L.O. Oftalmi, C.A., Caracas, Venezuela. Firm initiated recall is ongoing.

REASON

Lack of Assurance of Sterility: Products were manufactured in conditions that compromised the sterility of the products.

VOLUME OF PRODUCT IN COMMERCE

45,842 bottles

DISTRIBUTION

Nationwide

RECALLS AND FIELD CORRECTIONS: BIOLOGICS - CLASS II

PRODUCT

Source Plasma. Recall # B-0678-10

CODE

Units: 0530606664, 0530605663, 0530604648, 0530607381

RECALLING FIRM/MANUFACTURER

CSL Plasma, Lexington, KY, by letters dated September 3, 2009. Firm initiated recall is complete.

REASON

Source Plasma, collected from a donor with an expired physical, was distributed.

VOLUME OF PRODUCT IN COMMERCE

4 units

DISTRIBUTION

Switzerland, IL

PRODUCT

Platelets Pheresis Leukocytes Reduced. Recall # B-1052-10

CODE

Unit: 267898443 (2 units)

RECALLING FIRM/MANUFACTURER

Recalling Firm: Blood Systems, Inc., Scottsdale, AZ, by facsimile on November 4, 2007.

Manufacturer: Blood Systems, Inc., Fort Smith, AR. Firm initiated recall is complete.

REASON

Blood products, which were possibly contaminated with Propionibacterium species, were distributed.

VOLUME OF PRODUCT IN COMMERCE

2 units

DISTRIBUTION

AR

PRODUCT

Red Blood Cells Leukocytes Reduced. Recall # B-1154-10

CODE

Units: 157038222, 157039083, 157046855, 157047230

RECALLING FIRM/MANUFACTURER

Recalling Firm: Blood Systems, Inc., Scottsdale, AZ, by telephone on March 23, 2007 or by letter dated July 25, 2007.

Manufacturer: Blood Systems, Inc - Lubbock Center, Lubbock, TX. Firm initiated recall is complete.

REASON

Blood products, collected from donors whose hemoglobin determinations were performed incorrectly, were distributed.

VOLUME OF PRODUCT IN COMMERCE

4 units

DISTRIBUTION

NM, TX

PRODUCT

Red Blood Cells Leukocytes Reduced. Recall # B-1244-10

CODE

Unit: W053309404614

RECALLING FIRM/MANUFACTURER

Community Blood Centers, Inc., Appleton, WI, by letter dated December 22, 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

WI

PRODUCT

1) Red Blood Cells Leukocytes Reduced. Recall # B-1245-10;

2) Plasma Frozen. Recall # B-1246-10

CODE

1) and 2) Unit: W053309800279

RECALLING FIRM/MANUFACTURER

Community Blood Center, Inc., Appleton, WI, by letter dated December 9, 2009 and by e-mail on December 9, 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

2 units

DISTRIBUTION

Switzerland, WI

PRODUCT

Red Blood Cells Leukocytes Reduced. Recall # B-1247-10

CODE

Unit: W035209331448W

RECALLING FIRM/MANUFACTURER

Carter BloodCare, Bedford, TX, by telephone on December 30, 2009 and by letter dated January 14, 2010. 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

TX

PRODUCT

- 1) Recovered Plasma. Recall # B-1248-10;
- 2) Red Blood Cells. Recall # B-1249-10;
- 3) Platelets Pooled Leukocytes Reduced. Recall # 1250-10

CODE

- 1) and 2) Unit: W120609243337;
- 3) Unit: W-120609383496

RECALLING FIRM/MANUFACTURER

Recalling Firm: Michigan Community Blood Centers, Saginaw, MI, by facsimile on December 23, 2009.

Manufacturer: Michigan Community Blood Centers, Midland, MI. Firm initiated recall is complete.

REASON

Blood products, collected from a donor who resided in an area considered at risk for human immunodeficiency virus (HIV) Group O, were distributed.

VOLUME OF PRODUCT IN COMMERCE

3 units

DISTRIBUTION

Switzerland, MI

PRODUCT

- 1) Platelets Pheresis Leukocytes Reduced Irradiated. Recall # B-1251-10;
- 2) Platelets Pheresis Leukocytes Reduced. Recall # B-1252-10

CODE

- 1) and 2) Unit: W036309020083K

RECALLING FIRM/MANUFACTURER

Recalling Firm: BloodCenter of Wisconsin, Inc., Milwaukee, WI, by facsimile on December 4, 2009.

Manufacturer: Blood Center of Wisconsin, Inc., Waukesha, WI. Firm initiated recall is complete.

REASON

Blood products, collected from a donor who had taken aspirin within 48 hours of donation, were distributed.

VOLUME OF PRODUCT IN COMMERCE

2 units

DISTRIBUTION

WI, KS

PRODUCT

Platelets Pheresis Leukocytes Reduced. Recall # B-1253-10

CODE

Unit: W125609619443

RECALLING FIRM/MANUFACTURER

Blood Bank Of San Bernardino and Riverside Counties, San Bernardino, CA, by e-mail on December 16, 2009. Firm initiated recall is complete.

REASON

Blood product, collected from a donor who took aspirin within 48 hours of donation, was distributed.

VOLUME OF PRODUCT IN COMMERCE

1 unit

DISTRIBUTION

CA

PRODUCT

Red Blood Cells Leukocytes Reduced. Recall # B-1254-10

CODE

Unit: 055FJ12421

RECALLING FIRM/MANUFACTURER

American Red Cross Blood Services, Saint Louis, MO, by telephone on December 1, 2009 and by letter dated December 1, 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

AR

PRODUCT

Red Blood Cells (Apheresis) Leukocytes Reduced. Recall # B-1256-10

CODE

Unit: W142809329396 (2 units)

RECALLING FIRM/MANUFACTURER

Tri-Counties Blood Bank, San Luis Obispo, CA, by letter dated January 8, 2010. 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

CA

PRODUCT

Recovered Plasma. Recall # B-1257-10

CODE

Units: W090709015225, W090709014250

RECALLING FIRM/MANUFACTURER

Blood Bank of the Redwoods, Santa Rosa, CA, by electronic notification on December 3, 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

2 units

DISTRIBUTION

Switzerland

PRODUCT

Source Plasma. Recall # B-1260-10

CODE

Unit: 0360131077

RECALLING FIRM/MANUFACTURER

Biomat USA, Inc., South Bend, IN, by letter dated December 7, 2007. Firm initiated recall is complete.

REASON

Blood product, which was not tested for viral markers, was distributed.

VOLUME OF PRODUCT IN COMMERCE

1 unit

DISTRIBUTION

Spain

PRODUCT

Platelets Pheresis Leukocytes Reduced Irradiated. Recall # B-1261-10

CODE

Unit: 032KP53833

RECALLING FIRM/MANUFACTURER

The American National Red Cross, Madison, WI, by facsimile on May 13, 2006. Firm initiated recall is complete.

REASON

Blood product, for which documentation of irradiation was not complete, was distributed.

VOLUME OF PRODUCT IN COMMERCE

1 unit

DISTRIBUTION

WI

PRODUCT

Recovered Plasma. Recall # B-1262-10

CODE

Units: W120609067635, W120609015974

RECALLING FIRM/MANUFACTURER

Michigan Blood, Grand Rapids, MI, by e-mail on February 9, 2010. 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

2 units

DISTRIBUTION

Switzerland

PRODUCT

Recovered Plasma. Recall # B-1263-10

CODE

Unit: W0425090897750N

RECALLING FIRM/MANUFACTURER

Recalling Firm: Blood Systems, Inc., Fargo, ND, by electronic notification on January 27, 2010.
Manufacturer: Blood Systems, Inc., Bismarck, ND. Firm initiated recall is complete.

REASON

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

VOLUME OF PRODUCT IN COMMERCE

1 unit

DISTRIBUTION

Switzerland

PRODUCT

- 1) Red Blood Cells Leukocytes Reduced. Recall # B-1264-10;
- 2) Recovered Plasma. Recall # B-1265-10

CODE

1) and 2) Unit: W125608416548

RECALLING FIRM/MANUFACTURER

Blood Bank of San Bernardino and Riverside Counties, San Bernardino, CA, by e-mail on January 21, 2010 and January 26, 2010. Firm initiated recall is complete.

REASON

Blood products, collected from a donor who resided in an area considered at risk for human immunodeficiency virus (HIV) Group O, were distributed.

VOLUME OF PRODUCT IN COMMERCE

2 units

DISTRIBUTION

Austria, CA

PRODUCT

- 1) Red Blood Cells (Apheresis) Leukocytes Reduced. Recall # B-1268-10;
- 2) Red Blood Cells Leukocytes Reduced. Recall # B-1269-10

CODE

1) Units: W091009175131 (2 units), 7879207 (2 units);

2) Unit: 7454100

RECALLING FIRM/MANUFACTURER

Oklahoma Blood Institute, Sylvan N Goldman Center, Oklahoma City, OK, by facsimile on January 8, 2010 and January 11, 2010. Firm initiated recall is complete.

REASON

Blood products, collected from a donor who was previously deferred for testing positive for the human immunodeficiency virus (HIV), were distributed.

VOLUME OF PRODUCT IN COMMERCE

5 units

DISTRIBUTION

IN, OK

PRODUCT

1) Red Blood Cells Leukocytes Reduced. Recall # B-1271-10;

2) Recovered Plasma. Recall # B-1272-10

CODE

1) and 2) Unit: W142808306794

RECALLING FIRM/MANUFACTURER

Tri-Counties Blood Bank, San Luis Obispo, CA, by telephone on January 12, 2010 and by letter dated February 8, 2010. Firm initiated recall is complete.

REASON

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

VOLUME OF PRODUCT IN COMMERCE

2 units

DISTRIBUTION

Switzerland, CA

PRODUCT

1) Fresh Frozen Plasma. Recall # B-1273-10;

2) Red Blood Cells Leukocytes Reduced. Recall # B-1274-10

CODE

1) Unit: W045909100198;

2) Units: W045909100198, 93GC11542

RECALLING FIRM/MANUFACTURER

Mercy Hospital, BB, Springfield, MA, by visit and facsimile on January 28, 2010 and by telephone on February 4, 2010. 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

MA

PRODUCT

Red Blood Cells Leukocytes Reduced. Recall # B-1275-10

CODE

Unit: W224309319693

RECALLING FIRM/MANUFACTURER

Houchin Blood Services, Bakersfield, CA, by facsimile on January 13, 2010, 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

1) Red Blood Cells Leukocytes Reduced. Recall # B-1277-10;

2) Fresh Frozen Plasma. Recall # B-1278-10

CODE

1) and 2) Unit: 1087081

RECALLING FIRM/MANUFACTURER

Hoxworth Blood Center UC Medical Center, Cincinnati, OH, by letter dated May 31, 2007. Firm initiated Recall is complete.

REASON

Blood products, collected from a donor who disclosed taking Imuran, were distributed.

VOLUME OF PRODUCT IN COMMERCE

2 units

DISTRIBUTION

OH

PRODUCT

1) Red Blood Cells (Apheresis) Leukocytes Reduced. Recall # B-1279-10;

2) Red Blood Cells Leukocytes Reduced. Recall # B-1280-10;

3) Plasma Frozen. Recall # B-1281-10

CODE

1) Units: 151704474 (part 1); 151704474 (part 2);151704482 (part 1); 151704482 (part 2);
151704483 (part 1); 151704483 (part 2); 151704487 (part 1); and 151704487 (part 2);

2)Units:151704472;151704473;151704481;151704469;151704476;151704478;151704479;151704480;151704484;151704485;151704490;

3) Unit: 151704480

RECALLING FIRM/MANUFACTURER

Recalling Firm: Blood Systems, Inc., Scottsdale, AZ, by facsimile on October 4, 2007.

Manufacturer: Blood Systems, Inc - Lubbock Center, Lubbock, TX. Firm initiated recall is complete.

REASON

Blood product, lacking assurance of having been maintained at an acceptable temperature during shipping, was distributed.

VOLUME OF PRODUCT IN COMMERCE

20 units

DISTRIBUTION

TX

PRODUCT

Platelets Pheresis Leukocytes Reduced. Recall # B-1282-10

CODE

Unit: 6055166

RECALLING FIRM/MANUFACTURER

Community Blood Center, Dayton, OH, by telephone on July 17, 2007. Firm initiated recall is complete.

REASON

Blood product, which did not meet acceptable product specifications, was distributed.

VOLUME OF PRODUCT IN COMMERCE

1 unit

DISTRIBUTION

OH

PRODUCT

1) Red Blood Cells Leukocytes Reduced. Recall # B-1288-10;

2) Recovered Plasma. Recall # B-1289-10;

3) Cryoprecipitated AHF. Recall # B-1290-10

CODE

1), 2), and 3) Unit: W149509908890

RECALLING FIRM/MANUFACTURER

Northern California Community Blood Bank, Eureka, CA, by fax and e-mail on October 23, 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

Austria, CA

PRODUCT

Platelets Pheresis Leukocytes Reduced. Recall # B-1292-10

CODE

Unit: 72M015638

RECALLING FIRM/MANUFACTURER

LifeSouth Community Blood Centers, Inc., Huntsville, AL, by fax on January 26, 2010. 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-1293-10

CODE

Unit: 72M74536X

RECALLING FIRM/MANUFACTURER

LifeSouth Community Blood Centers, Inc., Huntsville, AL, by fax on January 26, 2010. 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-1294-10

CODE

Unit: 72M797017

RECALLING FIRM/MANUFACTURER

LifeSouth Community Blood Centers, Montgomery Region, Montgomery, AL, by fax on January 20, 2010. 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-1295-10

CODE

Unit: 72M065709

RECALLING FIRM/MANUFACTURER

LifeSouth Community Blood Centers, Inc., Huntsville, AL, by fax on February 2, 2010. 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-1296-10

CODE

Unit: 72M741661

RECALLING FIRM/MANUFACTURER

LifeSouth Community Blood Centers, Inc., Huntsville, AL, by fax on January 26, 2010. 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-1297-10

CODE

Unit: 72M854250

RECALLING FIRM/MANUFACTURER

LifeSouth Community Blood Centers, Inc., Birmingham Region, Birmingham, AL, by fax on January 29, 2010. 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 Leukocytes Reduced. Recall # B-1301-10;

2) Platelets Pooled Leukocytes Reduced. Recall # B-1302-10

CODE

1) Unit: W120609016809;

2) Unit: W120609186568

RECALLING FIRM/MANUFACTURER

Michigan Community Blood Centers, Grand Rapids, MI, by fax on January 28, 2010. 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

MI

PRODUCT

Red Blood Cells Leukocytes Reduced. Recall # B-1303-10

CODE

Unit: W03941030111200

RECALLING FIRM/MANUFACTURER

Florida Blood Services, Inc., St Petersburg, FL, by fax on February 9, 2010. 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

FL

PRODUCT

1) Red Blood Cells Leukocytes Reduced. Recall # B-1304-10;

2) Platelets Pooled Leukocytes Reduced. Recall # B-1305-10

CODE

1) Units: W120609009417; W120609006351; W120609014930; W120609012556;

2) Units: W120609182382; W120609184489

RECALLING FIRM/MANUFACTURER

Michigan Community Blood Centers, Grand Rapids, MI, by fax on January 7, 2010 and January 8, 2010. 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

6 units

DISTRIBUTION

MI

PRODUCT

Red Blood Cells Leukocytes Reduced. Recall # B-1306-10

CODE

Unit: W137509206641

RECALLING FIRM/MANUFACTURER

Lane Memorial Blood Bank, Eugene, OR, by letter dated January 15, 2010. 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

FL

PRODUCT

Red Blood Cells. Recall # B-1307-10

CODE

Unit: W127809503072

RECALLING FIRM/MANUFACTURER

Tacoma Pierce County Blood Bank, Tacoma, WA, by letter dated December 8, 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 Leukocytes Reduced. Recall # B-1308-10

CODE

Unit: 2555857

RECALLING FIRM/MANUFACTURER

Central Kentucky Blood Center Inc., Lexington, KY, by letter dated December 31, 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

KY

PRODUCT

Platelets Pheresis Leukocytes Reduced Irradiated. Recall # B-1309-10

CODE

Units: W036809306420A; W036809306420C

RECALLING FIRM/MANUFACTURER

Community Blood Centers/S Florida, Inc., Lauderhill, FL, by telephone on September 4, 2009. Firm initiated recall is complete.

REASON

Blood products, which did not meet QC specifications for pH, were distributed.

VOLUME OF PRODUCT IN COMMERCE

2 units

DISTRIBUTION

FL

PRODUCT

Red Blood Cells (Apheresis) Leukocytes Reduced. Recall # B-1313-10

CODE

Unit: W036808162483

RECALLING FIRM/MANUFACTURER

Community Blood Centers/S Florida, Inc., Lauderhill, FL, by letter dated March 27, 2009. Firm initiated recall is complete.

REASON

Blood product, labeled leukoreduced but which did not meet the requirements for a leukoreduced product, was distributed.

VOLUME OF PRODUCT IN COMMERCE

1 unit

DISTRIBUTION

FL

PRODUCT

Red Blood Cells. Recall # B-1314-10

CODE

Unit: W047009139252

RECALLING FIRM/MANUFACTURER

New York Blood Center, Inc., Westbury, NY, by letter dated November 16, 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

NY

PRODUCT

1) Red Blood Cells Leukocytes Reduced. Recall # B-1326-10;

2) Cryoprecipitate AHF. Recall # B-1327-10

CODE

1) and 2) Unit: 16GY08249

RECALLING FIRM/MANUFACTURER

The American National Red Cross, Central Ohio Region, Columbus, OH, by telephone on January 21, 2008 and letter on January 24, 2008. 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

OH, MA

PRODUCT

Red Blood Cells Leukocytes Reduced. Recall # B-1355-10

CODE

Units: W044209575036; W044209545731; W044209545728; W044209575155; W044209575149; W044209575158; W044209575157; W044209575152; W044209575154; W044209575151; W044209575048; W044209575043; W044209575049; W044209575042; W044209575037

RECALLING FIRM/MANUFACTURER

San Diego Blood Bank, San Diego, CA, by telephone on November 13, 2009. Firm initiated recall is complete.

REASON

Blood products, possibly contaminated with air during collection, were distributed.

VOLUME OF PRODUCT IN COMMERCE

15 units

DISTRIBUTION

CA

PRODUCT

- 1) Liquid Plasma. Recall # B-1373-10;
- 2) Red Blood Cells. Recall # B-1374-10;
- 3) Fresh Frozen Plasma. Recall # B-1375-10

CODE

1) Units: W001708005659, W001708005630;

2) Units: W001708005630, W001708005631, W001708005632, W001708005636, W001708005639, W001708005640, W001708005641, W001708005642, W001708005643, W001708005644, W001708005645, W001708005649, W001708005650, W001708005652, W001708005653, W001708005654, W001708005655, W001708005656, W001708005658, W001708005660;

3) Units: W001708005631, W001708005632, W001708005633, W001708005639, W001708005640, W001708005641, W001708005642, W001708005644, W001708005646, W001708005648, W001708005652, W001708005653, W001708005654, W001708005655, W001708005660

RECALLING FIRM/MANUFACTURER

Department AF 81st Med. Group/SGSC Keesler AFB MC Blood Bank, Keesler AFB, MS, by telephone and facsimile on November 25, 2008 and by letter dated November 25, 2008. Firm initiated recall is complete.

REASON

Blood products, which were incorrectly tested for viral markers, were distributed.

VOLUME OF PRODUCT IN COMMERCE

37 units

DISTRIBUTION

NJ, LA, FL, D.C.

RECALLS AND FIELD CORRECTIONS: BIOLOGICS - CLASS III

PRODUCT

Recovered Plasma. Recall # B-1255-10

CODE

Unit: 055FJ12421

RECALLING FIRM/MANUFACTURER

American Red Cross Blood Services, Saint Louis, MO, by telephone on December 1, 2009 and by letter dated December 1, 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) Red Blood Cells Leukocytes Reduced. Recall # B-1266-10;

2) Platelets Pheresis Leukocytes Reduced. Recall # B-1267-10

CODE

1) Units: W040709178309, W040709334574;

2) Units: W040709681421 (2 units)

RECALLING FIRM/MANUFACTURER

Indiana Blood Center, Indianapolis, IN, by telephone on November 10, 2009. Firm initiated recall is complete.

REASON

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

VOLUME OF PRODUCT IN COMMERCE

4 units

DISTRIBUTION

IN

PRODUCT

Recovered Plasma. Recall # B-1270-10

CODE

Unit: 7454100

RECALLING FIRM/MANUFACTURER

Oklahoma Blood Institute, Sylvan N Goldman Center, Oklahoma City, OK, by facsimile on January 8, 2010 and January 11, 2010. Firm initiated recall is complete.

REASON

Blood product, collected from a donor who was previously deferred for testing positive for the human immunodeficiency virus (HIV), was distributed.

VOLUME OF PRODUCT IN COMMERCE

1 unit

DISTRIBUTION

IN, OK

PRODUCT

Red Blood Cells (Apheresis) Leukocytes Reduced. Recall # B-1283-10

CODE

Units: 264097522 Part 1 and Part 2

RECALLING FIRM/MANUFACTURER

Recalling Firm: Blood Systems, Inc., Scottsdale, AZ, by letters dated December 11, 2007, March 4, 2007 and March 25, 2008.

Manufacturer: Blood Systems, Inc., Texarkana, TX. Firm initiated recall is complete.

REASON

Blood products, collected under conditions where the sterility of the products may have been compromised, were distributed.

VOLUME OF PRODUCT IN COMMERCE

2 units

DISTRIBUTION

AR

PRODUCT

Red Blood Cells (Apheresis) Leukocytes Reduced. Recall # B-1287-10

CODE

Units: 16KY09557 Part 1; 16KY09557 Part 2

RECALLING FIRM/MANUFACTURER

American Red Cross Blood Services, Central Ohio Region, Columbus, OH, by telephone on September 22, 2008 and follow-up letter dated September 24, 2008. Firm initiated recall is complete.

REASON

Blood products, with RBC percent recovery rate below the specified minimum requirement, were distributed.

VOLUME OF PRODUCT IN COMMERCE

2 units

DISTRIBUTION

OH

PRODUCT

Red Blood Cells Leukocytes Reduced. Recall # B-1291-10

CODE

Unit: 011KN32369

RECALLING FIRM/MANUFACTURER

American Red Cross Blood Services, Saint Louis, MO, by telephone and fax on August 3, 2009. Firm initiated recall is complete.

REASON

Blood product, with insufficient red cell preservative solution added, was distributed.

VOLUME OF PRODUCT IN COMMERCE

1 unit

DISTRIBUTION

MO

PRODUCT

Red Blood Cells Leukocytes Reduced. Recall # B-1300-10

CODE

Units: 06GG00942; 06GG00943; 06GN00544; 06GS36368

RECALLING FIRM/MANUFACTURER

The American National Red Cross, Pomona, CA, by fax on October 5, 2009 and October 6, 2009 and letter dated October 5, 2009 and October 6, 2009. Firm initiated recall is complete.

REASON

Blood products, incorrectly labeled as containing additive solution and with an extended expiration date, were distributed

VOLUME OF PRODUCT IN COMMERCE

4 units

DISTRIBUTION

CA

PRODUCT

- 1) Red Blood Cells. Recall # B-1310-10;
- 2) Red Blood Cells Leukocytes Reduced. Recall # B-1311-10;
- 3) Red Blood Cells Leukocytes Reduced Irradiated . Recall # B-1312-10;

CODE

- 1) Unit: W036809125780;
- 2) Units: W036809125777; W036809125779; W036809125781;
- 3) Unit: W036809125778

RECALLING FIRM/MANUFACTURER

Community Blood Centers/S Florida, Inc., Lauderhill, FL, by letter dated March 10, 2009. Firm initiated recall is complete.

REASON

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

VOLUME OF PRODUCT IN COMMERCE

5 units

DISTRIBUTION

FL

PRODUCT

Recovered Plasma. Recall # B-1325-10

CODE

Unit: 16GY08249

RECALLING FIRM/MANUFACTURER

The American National Red Cross, Central Ohio Region, Columbus, OH, by telephone on January 21, 2008 and letter on January 24, 2008. 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

RECALLS AND FIELD CORRECTIONS: DEVICES - CLASS II

PRODUCT

PM1000 Flow Selector - An accessory to an emergency ventilator (resuscitator). The selector is attached to a flowmeter and is used to direct the outlet flow from any standard flowmeter to any one of the three outlets it provides. Recall # Z-1561-2010

CODE

Lot numbers 1209 and 0110

RECALLING FIRM/MANUFACTURER

Precision Medical, Inc., Northampton, PA, by letters on March 5, 2010. Firm initiated recall is ongoing.

REASON

The on/off outlet is mislabeled so that when a user/operator turns selector to "on", it actually may be turned "off".

VOLUME OF PRODUCT IN COMMERCE

1,361 units

DISTRIBUTION

Nationwide, Taiwan, Germany, Hong Kong, Canada

PRODUCT

1) Stryker Orthopaedics, Scorpio Ceramic 4:1 Guide Size 3; XCelerate cutting block for distal femur in orthopaedic surgery, Non Sterile. Catalog number: 8000-0003. Recall # Z-1574-2010;

2) Stryker Orthopedics, Scorpio Ceramic 4:1 Guide Size 4; XCelerate cutting block for distal femur in orthopedic surgery, Non Sterile. Catalog number: 8000-0004. Recall # Z-1575-2010;

3) Stryker Orthopedics, Scorpio Ceramic 4:1 Guide Size 5; XCelerate cutting block for distal femur in orthopaedic surgery, Non Sterile. Catalog Number: 8000-0005. Recall # Z-1576-2010;

4) Stryker Orthopaedics, Scorpio Ceramic 4:1 Guide Size 6; XCelerate cutting block for distal femur in orthopaedic surgery, Non Sterile. Catalog number: 8000-0006. Recall # Z-1577-2010;

5) Stryker Orthopaedics, Scorpio Ceramic 4:1 Guide Size 7; XCelerate cutting block for distal femur in orthopaedic surgery, Non Sterile. Catalog number: 8000-0007. Recall # Z-1578-2010;

6) Stryker Orthopaedics, Scorpio Ceramic 4:1 Guide Size 8; XCelerate cutting block for distal femur in orthopaedic surgery, Non Sterile. Catalog number: 8000-0008. Recall # Z-1579-201;

7) Stryker Orthopaedics, Scorpio Ceramic 4:1 Guide Size 9; XCelerate cutting block for distal femur in orthopaedic surgery, Non Sterile. Catalog number: 8000-0009. Recall # Z-1580-2010;

8) Stryker Orthopaedics, Scorpio Ceramic 4:1 Guide Size 11; XCelerate cutting block for distal femur in orthopaedic surgery, Non Sterile. Catalog number: 8000-0011. Recall # Z-1581-2010;

9) Stryker Orthopaedics, Scorpio Ceramic 4:1 Guide Size 13; XCelerate cutting block for distal femur in orthopaedic surgery, Non Sterile. Catalog number: 8000-0013. Recall # Z-1582-2010;

10) Stryker Orthopaedics, Duracon 4:1 Ceramic Cutting Block XS; XCelerate cutting block for distal femur in orthopaedic surgery, Non-Sterile. Catalog Number: 8000-7005. Recall # Z-1583-2010;

11) Stryker Orthopaedics, Duracon 4:1 Ceramic Cutting Block SM; XCelerate cutting block for distal femur in orthopaedic surgery, Non-Sterile. Catalog number: 8000-7010. Recall # Z-1584-2010;

12) Stryker Orthopaedics, Duracon 4:1 Ceramic Cutting Block MED; XCelerate cutting block for distal femur in orthopaedic surgery, Non-Sterile. Catalog number: 8000-7020. Recall # Z-1585-2010;

13) Stryker Orthopaedics, Duracon 4:1 Ceramic Cutting Block ML; XCelerate cutting block for distal femur in orthopaedic surgery, Non-Sterile. Catalog number: 8000-7030. Recall # Z-1586-2010;

14) Stryker Orthopaedics, Duracon 4:1 Ceramic Cutting Block LG; XCelerate cutting block for distal femur in orthopaedic surgery, Non-Sterile. Catalog number: 8000-7040. Recall # Z-1587-2010;

15) Stryker Orthopaedics, Duracon 4:1 Ceramic Cutting Block XL; XCelerate cutting block for distal femur in orthopaedic surgery, Non-Sterile. Catalog number: 8000-7050. Recall # Z-1588-2010;

16) Stryker Orthopaedics, Duracon 4:1 Ceramic Cutting Block XXL; XCelerate cutting block for distal femur in orthopaedic surgery, Non-Sterile. Catalog number: 8000-7060. Recall # Z-1589-2010

CODE

All lots

RECALLING FIRM/MANUFACTURER

Stryker Howmedica Osteonics Corp., Mahwah, NJ, by letters on December 3, 2009. Firm initiated recall is ongoing.

REASON

The ceramic guide rails, within the XCelerate 4:1 Ceramic Cutting Blocks, may fracture and displace from the block.

VOLUME OF PRODUCT IN COMMERCE

Scorpio: 9833; Duracon: 3056

DISTRIBUTION

Nationwide, Sweden, Ireland, Canada, Hong Kong, Germany, Spain, India, Australia, Italy, New Zealand, and United Kingdom

PRODUCT

1) Stryker Orthopaedics, Accolade Distal Centralizer 14 mm Large; Catalog No.: 1059-6714. For use with Accolade hip prosthesis. Recall # Z-1593-2010;

2) Stryker Orthopaedics, Accolade Distal Centralizer 13 mm Medium; Catalog No.: 1059-4513. For use with Accolade hip prosthesis. Recall # Z-1594-2010

CODE

1) Lot Code: WDYMLE;

2) Lot Code: WDXMLE

RECALLING FIRM/MANUFACTURER

Stryker Howmedica Osteonics Corp., Mahwah, NJ, by letters on March 31, 2010 and on April 1, 2010. Firm initiated recall is ongoing.

REASON

One lot of 13 mm medium distal ring centralizers and 14 mm large distal ring centralizer have been labeled incorrectly. The size 14 Large centralizers have been labeled as size 13 Medium centralizers and size 13 Medium centralizers have been labeled as size 14 Large centralizers.

VOLUME OF PRODUCT IN COMMERCE

1059-4513- 15 units; 1059-6714-17 units

DISTRIBUTION

MA, NJ, DC, MD, GA, FL, MA, CT, OH

PRODUCT

Basic Core Pack # OR1805, Sterile, Tri State Hospital Supply Corporation Manufacturers of Centurion Healthcare Products. Recall # Z-1595-2010

CODE

Lots: 2009100590, 2009110990, 2009121490, 2010011190 and 2010031590

RECALLING FIRM/MANUFACTURER

Recalling Firm: Centurion Medical Products, Howell, MI, by letter on April 9, 2010.

Manufacturer: Centurion Medical Products Corp., Yuma, AZ. Firm initiated recall is ongoing.

REASON

The firm is conducting a sub recall of kits containing ConMed Goldline Rocker Switch Pencils. The pencils activation switch may remain in the "on" position after the switch has been depressed with excessive force, thereby continuously activating the pencil.

VOLUME OF PRODUCT IN COMMERCE

74 kits

DISTRIBUTION

TX

PRODUCT

Vitrea 5.1. Vitrea fX 3.0, Vitrea Enterprise Suite 1.2 with the licensing of CT lung or CT Colon. Recall # Z-1600-2010

CODE

Vitrea 5.1. Vitrea fX 3.0, Vitrea Enterprise Suite 1.2

RECALLING FIRM/MANUFACTURER

Vital Images, Inc., Plymouth, MN, by letter dated 23 February 2010. Firm initiated recall is ongoing.

REASON

Vital images, Inc is issuing a recall notice on their medical device software in the use of CT Lung and CT Colon in Vitrea 5.1, Vitrea fX 3.0 or Vitre Enterprise Suite 1.2., because incorrect measurements may result.

VOLUME OF PRODUCT IN COMMERCE

95 units

DISTRIBUTION

Nationwide and Internationally

PRODUCT

1) Endotec, Prosthesis Knee, Patellofemorotibial, Semi-Constrained, Cemented, Polymer/Metal/Polymer, Titanium Alloy, Sterilized, (Beuchel-Pappas (BP)) The B-P Knee Replacement System is composed of several components used to provide surgeons with different intra-operative options. All metallic components are available in six sizes and are fabricated from Ti-6Al-4V titanium alloy by Endotec. BP Knee Replacement System Component, Modular Femoral Component: Size 5 Left Modular Femoral Component, Catalog: 04-31-2105, Lot No. 04-31-2105A; Size 4 Left Modular Femoral Component, Lot No. 04-31-2104A, Size 6 Left Femoral Component, Lot No. 04-31-2106A1. BP Knee Replacement System Component, Narrow Femoral Component: Size 3 Right Narrow Femoral Component Lot No. 04-31-1303C, Size 3 Left Narrow Femoral Component Lot No. 04-31-2303C, Size 4 Right Narrow Femoral Component Lot No. 04-31-1304C, Size 4 Left Narrow Femoral Component Lot No. 04-31-2304C. BP Knee Replacement System Component, All Poly Patella: Size 1 All Poly Patella Lot No. 04-34-0201B, 04-34-0201C, 04-34-0201D, 04-34-0201E. Size 2 All Poly Patella Lot No. 04-34-0202B, 04-34-0202C, 04-34-0202D, 04-34-0202E. BP Knee Replacement System Component, 3 Peg Patella: Size 4 3-Peg Patella Lot No. 04-34-0004H. BP Knee Replacement System Component, Conforming Bearing: 1x0mm Conforming Bearing Catalog: 04-33-001, 1x2.5mm Conforming Bearing Catalog: 04-33-0011, 1x5mm Conforming Bearing Catalog: 04-33-0021, 1x7.5mm Conforming Bearing Catalog: 04-33-0031, 2x0mm Conforming Bearing Catalog: 04-33-0002, 2x2.5mm Conforming Bearing Catalog: 04-33-0012, 2x5mm Conforming Bearing Catalog: 04-33-0022, 2x7.5mm Conforming Bearing Catalog: 04-33-0032, 3x0mm Conforming Bearing Catalog: 04-33-0003, 3x2.5mm Conforming Bearing Catalog: 04-33-0013, 3x5mm Conforming Bearing Catalog: 04-33-0023, 3x7.5mm Conforming Bearing Catalog: 04-33-0033, 4x0mm Conforming Bearing Catalog: 04-33-0004, 4x2.5mm Conforming Bearing Catalog: 04-33-0014, 4x5mm Conforming Bearing Catalog: 04-33-0024, 4x7.5mm Conforming Bearing Catalog: 04-33-0034, 5x0mm Conforming Bearing Catalog: 04-33-0005, 5x2.5mm Conforming Bearing Catalog: 04-33-0015 5x5mm Conforming Bearing Catalog: 04-33-0025, 5x7.5mm Conforming Bearing Catalog: 04-33-0035, 6x0mm Conforming Bearing Catalog: 04-33-0006, 6x2.5mm Conforming Bearing Catalog: 04-33-0016, BP Knee Replacement System Component, Screw Stop: Size 4-6 Screw Stop Catalog: 03-12-0036. BP Knee Replacement System Component, Tibial Component Type 1 w/o Biocoat: Size 1 Type 1 Tibial Component w/o Biocoat Catalog: 04-32-0401, Size 2 Type 1 Tibial Component w/o Biocoat Catalog: 04-32-0402, Size 3 Type 1 Tibial Component w/o Biocoat Catalog: 04-32-0403, Size 4 Type 1 Tibial Component w/o Biocoat Catalog: 04-32-0404, Size 5 Type 1 Tibial Component w/o Biocoat Catalog: 04-32-0405, Size 6 Type 1 Tibial Component w/o Biocoat Catalog: 04-32-0406. BP Knee Replacement System Component, Tibial Component Type 1: Size 1 Type 1 Tibial Component Catalog: 04-32-0001, Size 3 Type 1 Tibial Component Catalog: 04-32-0003, Size 4 Type 1 Tibial Component Catalog: 04-32-0004. BP Knee Replacement System Component, Tibial Component Type 2: Size 3 Type 2 Tibial Component Catalog: 04-32-0013. BP Knee Replacement

System Component, Tibial Component Type 0: Size 5 Type 0 Tibial Platform Catalog: 04-32-0065. BP Knee Replacement System Component, Femoral Component w/o Biocoat: Size 1 Right Femoral Component w/o Biocoat Catalog: 04-31-1201, Size 1 Left Femoral Component w/o Biocoat Catalog:04-31-2201, Size 2 Right Femoral Component w/o Biocoat Catalog: 04-31-1202, Size 2 Left Femoral Component w/o Biocoat Catalog:04-31-2202, Size 3 Right Femoral Component w/o Biocoat Catalog:04-31-1203, Size 3 Left Femoral Component w/o Biocoat Catalog:04-31-2203, Size 4 Right Femoral Component w/o Biocoat Catalog:04-31-1204, Size 4 Left Femoral Component w/o Biocoat Catalog: 04-31-2204, Size 5 Right Femoral Component w/o Biocoat Catalog: 04-31-1205, Size 5 Left Femoral Component w/o Biocoat Catalog: 04-31-2205, Size 6 Right Femoral Component w/o Biocoat Catalog: 04-31-1206, Size 6 Left Femoral Component w/o Biocoat Catalog: 04-31-2206. BP Knee Replacement System Component, Femoral Component: Size 3 Right Femoral Component Catalog: 04-31-1003, Size 3 Left Femoral Component Catalog: 04-31-2003, Size 4 Right Femoral Component Catalog: 04-31-1004, Size 5 Left Femoral Component Catalog: 04-31-2005, Size 6 Right Femoral Component Catalog: 04-31-1006. Size 1 Universal Tibial Component Catalog: 04-22-0001. Recall # Z-1621-2010;

2) Endotec Prosthesis Shoulder, Titanium Alloy, Sterilized Modular Femoral Stem BP Shoulder Component: 12mm Modular Femoral Stem, Catalog: 02-21-0103. Recall # Z-1622-2010;

3) Endotec Prosthesis Hip, Titanium Alloy, Sterilized. Acetabular Bearing, BP Hip System Component: 32x54 Acetabular Bearing, Catalog: 01-02-3254, 32x56 Acetabular Bearing, Catalog: 01-02-3256, Femoral Head Resurfacing Component, BP Hip System Component: 36.5mm Femoral Head Resurfacing Component:, Catalog: 01-03-0036, 38mm Femoral Head Resurfacing Component:, Catalog: 01-03-0038, 39.5mm Femoral Head Resurfacing Component:, Catalog: 01-03-0039, 41mm Femoral Head Resurfacing Component:, Catalog: 01-03-0041, 42.5mm Femoral Head Resurfacing Component:, Catalog: 01-03-0042, 44mm Femoral Head Resurfacing Component:, Catalog: 01-03-0044, 45.5mm Femoral Head Resurfacing Component:, Catalog: 01-03-0045, 47mm Femoral Head Resurfacing Component:, Catalog: 01-03-0047, 49mm Femoral Head Resurfacing Component:, Catalog: 01-03-0049, 51mm Femoral Head Resurfacing Component:, Catalog: 01-03-0051, 52mm Femoral Head Resurfacing Component:, Catalog: 01-03-0052. Femoral Stem BP Hip System Component: 10mm Femoral Stem Catalog: 01-04-0110, 11mm Femoral Stem Catalog: 01-04-0111, 12mm Femoral Stem Catalog: 01-04-0112. Recall # Z-1623-2010;

4) Endotec Prosthesis Ankle, Titanium Alloy, Sterilized. BP Ankle System, Talar Ankle Component: Size 2 Talar Component Catalog: 05-01-0002, Size 3 Talar Component Catalog: 05-01-0003, Size 4 Talar Component Catalog: 05-01-0004, Size 5 Talar Component Catalog: 05-01-0005, BP Ankle System, Thick Talar Ankle Component: Size 2 Thick Talar Component Catalog: 05-11-0002, Size 3 Thick Talar Component Catalog: 05-11-0003, Size 5 Thick Talar Component Catalog: 05-11-0005, B-P Ankle System, Tibial Component: Size 2 Tibial Component 05-03-0002, Size 3 Tibial Component 05-03-0003, Size 4 Tibial Component 05-03-0004, Size 5 Tibial Component 05-03-0005. Recall # Z-1624-2010;

5) Endotec Prosthesis Ankle, Titanium Alloy, Sterilized, BP Ankle System. BP Ankle System, F-P Type III Ankle Bearing Component: 2x5mm F-P Type III Ankle Bearing Catalog: 05-13-0532, 2x7mm F-P Type III Ankle Bearing Catalog: 05-13-0732, 8x3mm F-P Type III Ankle Bearing

Catalog: 05-13-0533, 8x1mm F-P Type III Ankle Bearing Catalog: 05-13-0731. BP Ankle System, F-P Type III Tibial Ankle Component: Size 1 F-P Type III Tibial Component Catalog: 05-12-0031, Size 2 F-P Type III Tibial Component Catalog: 05-12-0032, Size 3 F-P Type III Tibial Component Catalog: 05-12-0033. BP Ankle System, F-P Type III Talar Component: Size 1 F-P Type III Talar Component Catalog: 05-01-0031, Size 2 F-P Type III Talar Component Catalog: 05-01-0032, Size 3 F-P Type III Talar Component Catalog: 05-01-0033. Recall # Z-1625-2010;

6) TMJ Components: Right Ramus Component - DelCristo Catalog: 09-11-0215, TMJ - Shah Catalog: 09-42-0217, 09-11-0217. Left Fossa Component - DelCristo Catalog 09-42-0216, Left Ramus Component - DelCristo Catalog: 09-11-0216. Recall # Z-1626-2010;

7) Endotec Prothesis Ankle, Titanium Alloy, Sterilized, BP Ankle System. BP Ankle System, B-P Type II Talar Ankle Component: Size 1 B-P Type II Talar Ankle Component Catalog: 05-01-0101, Size 2 B-P Type II Talar Ankle Component Catalog: 05-01-0102, Size 3 B-P Type II Talar Ankle Component Catalog: 05-01-0103, Size 4 B-P Type II Talar Ankle Component Catalog: 05-01-0104, Size 5 B-P Type II Talar Ankle Component Catalog: 05-01-0105, Size 6 B-P Type II Talar Ankle Component Catalog: 05-01-0106. BP Ankle System, BP Type II Ankle Bearing: 3x5mm BP Type II Ankle Bearing Catalog: 05-02-0103, 3x6mm BP Type II Ankle Bearing Catalog: 05-02-0113, 3x7mm BP Type II Ankle Bearing Catalog: 05-02-0123, 3x9mm BP Type II Ankle Bearing Catalog: 05-02-0143, 3x11mm BP Type II Ankle Bearing Catalog: 05-02-0163, 3x13mm BP Type II Ankle Bearing Catalog: 05-02-0183, 4x5mm BP Type II Ankle Bearing Catalog: 05-02-0104, 4x6mm BP Type II Ankle Bearing Catalog: 05-02-0114, 4x7mm BP Type II Ankle Bearing Catalog: 05-02-0124, 5x5mm BP Type II Ankle Bearing Catalog: 05-02-0105, 5x7mm BP Type II Ankle Bearing Catalog: 05-02-0125, 5x9mm BP Type II Ankle Bearing Catalog: 05-02-0145. 5x6mm BP Type II Ankle Bearing Catalog 05-02-0106. 6x5mm BP Type II Ankle Bearing Catalog 05-02-0115. 6x6mm BP Type II Ankle Bearing Catalog 05-02-0116. 7x6mm BP Type II Ankle Bearing Catalog 05-02-0126. 9x6mm BP Type II Ankle Bearing Catalog 05-02-0146. 11x5mm BP Type II Ankle Bearing Catalog 05-02-0165. 11x6mm BP Type II Ankle Bearing Catalog 05-02-0166. 13x5mm BP Type II Ankle Bearing Catalog 05-02-0185. 13x6mm BP Type II Ankle Bearing Catalog 05-02-0186. BP Ankle System, B-P Type II Tibial Ankle Component Size 1 B-P Type II Tibial ankle Component Catalog: 05-03-0101, Size 2 B-P Type II Tibial ankle Component Catalog: 05-03-0102, Size 3 B-P Type II Tibial ankle Component Catalog: 05-03-0103, Size 4 B-P Type II Tibial ankle Component Catalog: 05-03-0104, Size 5 B-P Type II Tibial ankle Component Catalog: 05-03-0105, Size 6 B-P Type II Tibial ankle Component Catalog: 05-03-0106. Recall # Z-1627-2010

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6) Lot No: 09110215NN373 09110216NN373 09110217NN379 09420216NN373
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RECALLING FIRM/MANUFACTURER

Endotec, Inc., Orlando, FL, by letters on June 7, 2009. Firm initiated recall is Ongoing.

REASON

Products are recalled due to sterility issues involving validation, process variations and test results.

VOLUME OF PRODUCT IN COMMERCE

4000 total

DISTRIBUTION

OH, TX, CA, FL, NJ, TN, Korea, Australia, Switzerland, The Netherlands, Spain.

PRODUCT

Boston Scientific, LATITUDE Communicator, Models 6476 (USA) and 6468 (OUS). Recall # Z-1631-2010

CODE

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RECALLING FIRM/MANUFACTURER

Recalling Firm: Boston Scientific CRM Corp, St. Paul, MN, by letter dated September 9, 2009.
Manufacturer: Plexus Electronic Assembly, Penang, Malaysia. Firm initiated recall is ongoing.

REASON

Boston Scientific has determined that alert conditions for a limited subset of out-of-range Daily Measurements related to leads may not be recognized by Model 6476 (United States) or Model 6468 (Europe) LATITUDE in-home communicators. If a communicator fails to recognize a valid alert situation, notification for this or subsequent alerts for the same test will not be displayed for physician review on the LATITUDE Website. However, Daily Measurement values uploaded from the implanted defibrillator will be available from the ALL PATIENTS page after completion of the next full device interrogation, which occurs during Weekly Device Alert Interrogations and scheduled remote follow-ups. Although a limited subset of alerts may not display on the LATITUDE Website, it is important to note that all Daily Measurement tests within the implanted defibrillator function normally, and results will be displayed as designed when the defibrillator is interrogated with a programmer. The observed rate for a missed Red Alert (highest priority) has been approximately 0.01% per month of monitoring. No patient deaths or injuries have been associated with this communicator behavior.

VOLUME OF PRODUCT IN COMMERCE

26,046 units

DISTRIBUTION

Nationwide, United Kingdom, Switzerland, Netherlands, Italy, Germany, France, Finland, Denmark, Belgium, Austria

PRODUCT

1) Leica Footswitch, Type B used in conjunction with Leica Surgical Microscopes - Models M620, M844/820, M525 and M720; There are three cable connection footswitch models: a) MFS11, stock number 10445599, a 6 function footswitch type B with cross pedals; b) MFS12, stock number 10445600, a 12 function footswitch type B with cross pedals, XY-actuator 10717602 and screw 10630134 for dust protection enclosed; c) MFS18, stock number 10448164, a 16 function footswitch type B with cross pedals, XY-actuator 10717602 and screw 10630134 for dust protection enclosed. Recall # Z-1632-2010;

2) Leica Wireless Footswitch, Type B used in conjunction with Leica Surgical Microscopes - Models M620, M844/820, M525 and M720; There are two wireless models: a) MFS20, stock number 10448406, a 12 function wireless footswitch type B with cross pedals, XY-actuator 10717602 and screw 10630134 for dust protection enclosed; b) MFS21, stock number 10448407, a 16 function wireless footswitch type B with cross pedals, XY-actuator 10717602 and screw 10630134 for dust protection enclosed. Recall # Z-1633-2010

CODE

1) a) serial numbers 90909001 and 301109002; b) serial numbers 91009001, 81209001, 80909001, 8011001, 71009002, 71009001, 70110002, 61009002, 41209004, 41209002, 291009004, 271009004, 261109001, 250909001, 230909001, 211209005, 211209004, 211009004, 180909002, 180909001, 180110002, 171209002, 161209002, 160909001, 151209001, 140110001, 121009001, 120110002, 120110001, 111209002, 111209001, 110909003, 110909002, 110909001, 110909003,

101209003, 101209002, 101109002 and 100909001; c) serial numbers 80909001, 71209001, 70909002, 31209004, 31209003, 31209002, 31209001, 301009001, 300909001, 291009001, 290909002, 290909001, 240909002, 240909001, 230909001, 180909005, 180909004, 160909002, 100909002 and 100909001;

2) a) serial numbers 60110005, 60110004, 60110003, 60110002, 60110001, 50110001 and 120110001; b) serial numbers 80110003 and 221209001

RECALLING FIRM/MANUFACTURER

Leica Microsystems, Inc., Bannockburn, IL, by letters dated March 29, 2010.

Manufacturer: Leica Microsystems (Schweiz) Ag, Heerbrugg, Switzerland. Firm initiated recall is ongoing.

REASON

The pedals of the Footswitch Type B stick and the Zoom/Focus moves to the end position.

VOLUME OF PRODUCT IN COMMERCE

294 units

DISTRIBUTION

Nationwide, Canada, Australia, Europe and Asia

RECALLS AND FIELD CORRECTIONS: DEVICES - CLASS III

PRODUCT

One Touch Ping Insulin Pump using ezManager Max diabetes management software. Recall # Z-1560-2010

CODE

Pump serial numbers: 00-72187-15, 00-72194-15, 01-72188-15, 02-72196-15, 04-70673-15, 05-72199-15, 11-70768-15, 18-67503-15, 23-69304-15, 25-66538-15, 30-69170-15, 40-69613-15, 67-69696-15, 75-72201-15, 76-72202-15, 89-71176-15, 90-71177-15, 96-70468-15, 97-72191-15, 98-72192-15, and 99-72193-15

RECALLING FIRM/MANUFACTURER

Animas Corp., West Chester, PA, by letter dated December 22, 2009. Firm initiated recall is ongoing.

REASON

Software malfunction which disallows users to download, view and print information from their pump (including blood glucose, insulin delivery, carbohydrate and pump events). Additionally, users are unable to customize the built-in food database and pump settings using the software.

VOLUME OF PRODUCT IN COMMERCE

21units

DISTRIBUTION

CA, CT, FL, GA, ID, MA, MO, NJ, OH, OR, PA, TX, and WA

RECALLS AND FIELD CORRECTIONS: VETERINARY - CLASS II

PRODUCT

Datex-Ohmeda Trusat Pulse Oximeter and Accessories, Model 3500. Recall # V-186-2010

CODE

8136918 FCC06230063SA FCC06310007SA FCC06310008SA FCC06340088SA
FCC06370043SA FCC06370045SA FCC06380013SA FCC06380032SA FCC06380039SA

FCC06420052SA FCC06430029SA FCC06430029SA FCC07020024SA FCC07040117SA
FCC07050057SA FCC07070058SA FCC07140040SA FCE06360005SA FCC06340103SA

RECALLING FIRM/MANUFACTURER

Recalling Firm: GE Healthcare, LLC, Waukesha, WI, by letter dated April 22, 2010.

Manufacturer: GE Healthcare Finland Oy, Helsinki, Finland. Firm initiated recall is ongoing.

REASON

GE Healthcare has recently become aware that the TruSat Pulse Oximeter with external power supply does not comply with current safety standards. It is possible that the external power supply could leak electrical current. This current could cause third degree burns or an abnormal heart rhythm that, if untreated, could lead to death.

VOLUME OF PRODUCT IN COMMERCE

20 units

DISTRIBUTION

CA, TX, NC, LA, CT, OR, TX, MT, UT

END OF ENFORCEMENT REPORT FOR MAY 26, 2010

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