The FDA Enforcement Report is published weekly by the Food and Drug Administration, Department of Health and Human Services. It contains information on actions taken in connection with agency Regulatory activities.

June 24, 2009
09-25

RECALLS AND FIELD CORRECTIONS: FOODS - CLASS I

PRODUCT
1) Galliker brand Rocky Road Ice Cream in 3 gallon containers. Recall # F-361-9;
2) Galliker brand Sundae Nut Cones sold in 24 pack paperboard boxes. Recall # F-362-9
CODE
1) Lot numbers 008-08, 086-08, and 176-08;
2) Product with dates prior to 01/29/10
RECALLING FIRM/MANUFACTURER
Galliker Dairy Co, Inc, by press release on January 30, 2009 and visits and by letter dated April 2, 2009. Firm initiated recall is complete.
REASON
The products were manufactured using peanuts recalled by Peanut Corporation of America because they have the potential to be contaminated with *Salmonella*.
VOLUME OF PRODUCT IN COMMERCE
1,979 units
DISTRIBUTION
PA, VA, and WV

PRODUCT
1) Peanut Butter Cookie Dough, 240/1.5-oz. frozen cookies per case (net wt. 22 lbs. 8 oz.), Item 43101. Recall # F-363-9;

2) Monster Cookie Dough, 240/1.5-oz. frozen cookies per case (net wt. 22 lbs. 8 oz.), Item #43113. Recall # F-364-9;

3) Peanut Butter Reese's Pieces, 240/1.5-oz. frozen cookies per case (net wt. 22 lbs. 8 oz.), Item 43112. Recall # F-365-9;

4) Peanut Butter Chocolate Chip Cookie Dough, 240/1.5-oz. frozen cookies per case (net wt. 22 lbs. 8 oz.), Item 43107. Recall # F-366-9;

5) Lunchbox Reese's Pieces Cookie Dough, 480/.75-oz. frozen cookies per case (net wt. 22 lbs. 8 oz.), Item 43127. Recall # F-367-9;

6) Lunchbox Peanut Butter Cookie Dough, 480/.75-oz. frozen cookies per case (net wt. 22 lbs. 8 oz.), Item 43121. Recall # F-368-9;

7) People Chow, packaged in bulk 15-lb. cases. Recall # F-369-9;

8) Assorted Cookie Pallet, 240/1.5-oz. frozen cookies per case (net wt. 22 lbs. 8 oz.), Item 43900. Each pallet contains five cases of Peanut Butter Cookies cookie dough; 2 cases of Monster Cookies cookie Dough; one case of Reese's Pieces Cookies cookie

dough, and 34 other cases of cookies that do not contain peanut butter. Recall # F-370-9;

9) Assorted Truffle Fudge, 3/8-lb. individually wrapped trays each containing a different type of fudge, one of which is peanut butter, net wt. 24 lbs., Item #43255. Recall # F-371-9;

10) Peanut Brittle, net weight 10 lbs, Item No. 43001. Recall # F-372-9;

11) Party Mix, 12 lbs, Item 43005. Recall # F-373-9

CODE

All Sell-by dates

RECALLING FIRM/MANUFACTURER

Recalling Firm: Hy-Vee Stores Inc, West Des Moines, IA, by letter and e-mail on January 16, 2009 and by press release on January 17, 2009 and January 29, 2009. Manufacturer: Hy-Vee Bakery Manufacturing, Des Moines, IA. Firm initiated recall is ongoing.

REASON

The products were manufactured using peanut butter recalled by Peanut Corporation of America because it has the potential to be contaminated with *Salmonella*.

VOLUME OF PRODUCT IN COMMERCE

Approximately 33,925 cases

DISTRIBUTION

IA, IL, MO, KS, NE, SD, and MN

PRODUCT

Hebert's Fully Loaded Peanut Butter Crunch miniBARS. Individually wrapped minBARS 128 g Gourmet Milk Chocolate with Chewy Peanut Butter Pieces and Crunch White Candy Chips. Recall # F-374-9

CODE

Lot # 082608 and 090908

RECALLING FIRM/MANUFACTURER

Hebert Confections, LLC, Shrewsbury, MA, by e-mail on January 19, 2009. Firm initiated recall is ongoing.

REASON

The product was manufactured using peanut butter and /or peanut paste recalled by Peanut Corporation of America because they have the potential to be contaminated with *Salmonella*.

VOLUME OF PRODUCT IN COMMERCE

900 cases (12 boxes/case/10 bars)

DISTRIBUTION

Canada

PRODUCT

Peanut Butter Base packaged in 450-lb. containers, for use in further manufacture. Recall # F-376-9

CODE

Lot 6508082315 and 2008-1210

RECALLING FIRM/MANUFACTURER

SensoryEffects Flavor Systems, Bridgeton MO, by e-mail on January 19, 2009. Firm initiated recall is ongoing.

REASON
The product was manufactured using peanut butter recalled by Peanut Corporation of America because it has the potential to be contaminated with *Salmonella.*
VOLUME OF PRODUCT IN COMMERCE
2 – 450 lb drums
DISTRIBUTION
UT

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PRODUCT
1) Jenny's Cuisine ANYTIME BAR Peanut Butter Flavor Nutritional Bar - Retail Unit UPC Code 6 55447-00934 7 " (7-1.16 oz Bars, Net Wt 8.14 oz) " Each retail unit consists of one fully labeled paperboard carton containing seven individually wrapped bars not labeled for retail sale. Recall # F-377-9;

2) Jenny's Delites Chocolate Caramel Peanut Bar, 3.5g (1.23 oz), a) UPC 655447008364 & b) UPC 655447108361. Each bar is individually wrapped. Recall # F-378-9;

3) Jenny's Cuisine Peanut Butter Bar Naturally and Artificially Flavored, Net Wt 1.23 oz (36 g), UPC 655447-08111. Each bar is individually wrapped. Recall # F-379-9
CODE
1) Best Before date codes: SEP0308 ALO SEP0308 BLO SEP0508 BLO SEP0608 ALO SEP0608 BLO SEP1508 ALO SEP1508 BLO SEP2908 ALO SEP2908 BLO OCT1408 ALO OCT1408 BLO NOV0908 ALO NOV0908 BLO NOV1008 ALO NOV1008 BLO NOV1108 ALO DEC2408 ALO DEC2408 BLO DEC2508 ALO DEC2508 BLO DEC2608 ALO JAN1109 ALO JAN1109 BLO JAN1209 ALO JAN1209 BLO JAN1309 ALO FEB0109 ALO FEB0109 BLO FEB1109 BLO FEB1209 ALO FEB1209 BLO FEB2309 ALO FEB2309 BLO FEB2409 ALO FEB2409 BLO FEB2509 ALO MAR0509 ALO MAR0509 BLO MAY1209 ALO* MAY1209 BLO* MAY2409 BLO* MAY2509 BLO* MAY2509 ALO* MAY2609 ALO* MAY2609 BLO* *represents product originally recalled in accordance with the January 20, 2009 submission;

2) (a) Best Before Dates Codes: JAN 05 07A, JAN 25 07B, APR 27 07B, MAY 23 08A, Dec 26 08A, NOV 06 09A, MAY 06 07A, MAY 0908A, MAR 11 09A, OCT 28 09A, FEB 07 07A, MAY 15 07A, MAR 11 09B, JAN 05 10A, MAR 01 07A, MAY 29 07B, JUN 20 08B, APR 24 09A, JAN 05 10B, MAR 01 07B, FEB 27 08A, JUL 16 08A, MAY 30 09A, JAN 26 10A, MAR 25 07A, MAR 28 08A, AUG 24 08A, JUN 25 09A, MAR 25 07B, MAR 30 08A, SEP 25 08A, AUG 05 09A, MAR 26 07A, APR 26 08B, OCT 25 08A, AUG 05 09A, AUG 05 09B, APR 27 07A, APR 30 08A, NOV 12 08B, AUG 26 09A. (b) Best Before Dates Codes: JAN 25 07A, MAY 15 07A, JUN 20 08B, MAR 11 09A, NOV 06 09A, MAR 01, 07A, FEB 27 08A, AUG 24 08A, MAY 30 09A, MAR 25 07A, MAR 28 08A, SEP 25 08A, JUN 25 09A, APR 27 07A, JUN 20 08A, OCT 25 08A, OCT 28 09A;

3) Best Before Date Codes: DEC 02 06B, MAY 27 07B, JAN 12 08B, AUG 25 08A, APR 13 09A, DEC 23 06B, AUG 22 07A, FEB 21 08B, AUG 25 08B, MAY 12 09B, JAN 14 07A, AUG 22 07B, MAR 25 08B, OCT 01 08A, JUN 23 09A, MAR 26 07A, OCT 28 07B, APR 26 08A, OCT 01 08B, APR 30 07A, DEC 21 07B, JUN 26 08A, OCT 25 08A, APR 30 07B, JAN 12 08A, JUNE 26 08B, FEB 05 09B
RECALLING FIRM/MANUFACTURER

Recalling Firm: Jenny Craig Inc, Carlsbad, CA, by telephone, fax and corporate intranet posting on January 20, 2009 and by a press release on January 27, 2009 and March 4, 2009.
Manufacturer: Lovin Oven, LLC, Azusa, CA. Firm initiated recall is ongoing.
REASON
The product was manufactured using peanut butter recalled by Peanut Corporation of America because it has the potential to be contaminated with *Salmonella*.
VOLUME OF PRODUCT IN COMMERCE
218,774 cases/11,978,988 bars
DISTRIBUTION
Nationwide

PRODUCT
White Herring, Net Wt: 16 oz (454G) --- PRODUCT OF CHINA --- UPC 6 922868 289066 --- KEEP FROZEN --- INGREDIENTS FISH, SALT --- The product is packed in a sealed flexible plastic bag. According to the State Lab Report, the 2 partial fish measured at 9 inches and 11 1/2 inches in length. Recall # F-380-9
CODE
UPC Code only
RECALLING FIRM/MANUFACTURER
S&M (USA) Enterprise Corporation, Brooklyn, NY, by press release on February 23, 2009. Firm initiated recall is complete.
REASON
The processed fish was found to be uneviscerated based on sampling and analysis by New York State Department of Agriculture & Markets.
VOLUME OF PRODUCT IN COMMERCE
Unknown
DISTRIBUTION
NYC area

PRODUCT
Atlantis Foods Smoked Fish Dip, packaged in 7 oz., 32 oz, and 5 lb clear plastic containers with snap on lid. Recall # F-381-9
CODE
Lot No. 048
RECALLING FIRM/MANUFACTURER
Neco Foods, LLC, Lantana FL, by e-mail, faxes, and letters on March 12, 2009. Firm initiated recall is ongoing.
REASON
Product that was returned due to heat abuse was found to be contaminated with *Listeria monocytogenes* based on Acam Laboratories, LLC's analysis.
VOLUME OF PRODUCT IN COMMERCE
271 cases
DISTRIBUTION
FL

PRODUCT
Dried Chechon -- Product of Russia --- Ingredients: fish, salt. The fish is vacuum packed in plastic bags of varying weights (0.66 lbs. average). According to New York State Department of Agriculture & Market's Lab Report, each package contains 3 whole fish measuring 11 1/4 to 11 1/2 inches in length. Recall # F-382-9

CODE
Packed: 21.12.2008
RECALLING FIRM/MANUFACTURER
Recalling Firm: San Link, Inc, Brooklyn, NY, by press release on February 24, 2009 and by letter dated February 23, 2009.
Manufacturer: Nivel Ltd. Moscow, Russia. Firm initiated recall is complete.
REASON
The processed fish was found to be uneviscerated based on sampling and analysis by New York State Department of Agriculture & Markets.
VOLUME OF PRODUCT IN COMMERCE
56 cases
DISTRIBUTION
NY, NJ, PA, CT, RI, MA, MD

PRODUCT
MISTICAL ONE brand PEANUT PUNCH - JAMAICAN ALL NATURAL DRINK - ALL NATURAL - NO PRESERVATIVES - 16 fl. oz. 473 ml --- The product is packaged in a plastic bottle. The ingredient statement reads: Vitamin D milk, Water, Sugar, Peanut Butter, Sea Moss, Molasses, Vanilla Extract. Recall # F-383-9
CODE
Code MAR 03 2009
RECALLING FIRM/MANUFACTURER
Mystical One LLC, Jamaica NY, by press release on February 27, 2009. Firm initiated recall is complete.
REASON
The product was found to be contaminated with *Listeria monocytogenes* based on sampling & analysis by New York State Department of Agriculture & Markets.
VOLUME OF PRODUCT IN COMMERCE
Unknown
DISTRIBUTION
NYC

PRODUCT
1) Meijer brand Cheese & Peanut Butter Sandwich Crackers, 8ct- 1.38oz/11oz, Case UPC 4125056235, Individual UPC 4125056236. Recall # F-394-9;

2) Meijer brand Toasty Peanut Butter Sandwich Crackers, 8ct- 1.38 oz/11oz., Case UPC 4125056239, Individual UPC 4125056240. Recall # F-395-9
CODE
All lots
RECALLING FIRM/MANUFACTURER
Recalling Firm: Meijer Distribution, Inc, Grand Rapids, MI, by press release on January 19, 2009.
Manufacturer: Kellogg's Snacks, Cary, NC. Firm initiated recall is complete.
REASON
The product was manufactured using peanut butter recalled by Peanut Corporation of America because it has the potential to be contaminated with *Salmonella*.
VOLUME OF PRODUCT IN COMMERCE
Unknown
DISTRIBUTION
IL, IN, KY, MI, and OH

RECALLS AND FIELD CORRECTIONS: FOODS - CLASS II

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PRODUCT

1) HYDROXYCUT - Lose Weight Fast - DIETARY SUPPLEMENT -RAPID RELEASE CAPLETS - Distributed under the Iovate and/or MuscleTech brand names in the following sizes and UPC codes: -- HYDROXYCUT 30 RAPID RELEASE CAPLETS, UPC 631656600452 (US); -- HYDROXYCUT 36 count CAPLETS "with CARDS", UPC 631656890129 (US); -- HYDROXYCUT 58 count CAPLETS, UPC 631656873214 (US); -- HYDROXYCUT 60 GNC, UPC 631656833621 (US); -- HYDROXYCUT 60 RAPID RELEASE CAPLETS (with or without + 1 FREE Hydroxycut Drink Packet Inside (Sachet WB), UPC 631656600582 (US); -- HYDROXYCUT 60 RAPID RELEASE CAPLETS, UPC 631656500585; -- HYDROXYCUT 70 count CAPLETS, UPC 631656813418 (US); -- HYDROXYCUT 72 RAPID RELEASE CAPLETS (with and without + FREE Hydroxycut Drink Packet Inside (Sachet WB), UPC 631656600476 (US); -- HYDROXYCUT 100 RAPID RELEASE CAPLETS, UPC 631656600483 (US); -- HYDROXYCUT 140 count CAPLETS, UPC 631656893649 (US); -- HYDROXYCUT 150 RAPID RELEASE CAPLETS, UPC 631656600506 (US); -- HYDROXYCUT 170 RAPID RELEASE CAPLETS, UPC 631656601251 (US); -- HYDROXYCUT 210 RAPID RELEASE CAPLETS, UPC 631656843262 (US); -- HYDROXYCUT 300 count CAPLETS, UPC 631656600988 (US); -- HYDROXYCUT 100 count - 6 month supply (7 bottles+ 4 free) Kit , UPC 631656000658; -- HYDROXYCUT 2 x 60 count Club Pack Kit, UPC 631656600896 (US); -- HYDROXYCUT 160 count Caplets, UPC 631656282245 (US) *Discontinued*; -- HYDROXYCUT 70 count Caplets, UPC 631656808612 (US) *Discontinued*; -- HYDROXYCUT 100 count Caplets, UPC 631656808117 (US) *Discontinued*; -- HYDROXYCUT 140 count Caplets, UPC 631656818642 (US) *Discontinued*; -- HYDROXYCUT 80 count Caplets, UPC 631656882414 (US) *Discontinued*; -- HYDROXYCUT 210 count caplets, UPC 631656828665 (US) *Discontinued*; -- HYDROXYCUT 100 count - 1 month supply (1 bottle+1 free) Kit, UPC 631656000672 *Discontinued* -- HYDROXYCUT 58 cap 12-pack Target Kit (US), UPC 631656874693 *Discontinued*; -- HYDROXYCUT 100 count - 3 month supply (4 bottles+2 free) Kit, UPC 631656000665 *Discontinued*; -- HYDROXYCUT 280 count -3 Pak Kit, UPC 631656001501 *Discontinued*; -- HYDROXYCUT 280 count -6 Pak Kit, USPC *Discontinued*. Recall # F-347-9;

2) Caffeine-Free HYDROXYCUT Weight-Loss Formula - RAPID RELEASE CAPLETS - DIETARY SUPPLEMENT - Distributed under the Iovate and/or MuscleTech brand names in the following sizes and UPC codes: -- Caffeine-Free HYDROXYCUT Weight-Loss Formula 36 count Caplets, UPC 631656899122 (US); -- Caffeine-Free HYDROXYCUT Weight-Loss Formula 58 count Caplets, UPC 631656801231 (US); -- Caffeine-Free HYDROXYCUT Weight-Loss Formula 60 RAPID RELEASE CAPLETS or 60 CAPLETS, UPC 631656600544 (US); -- Caffeine-Free HYDROXYCUT Weight-Loss Formula 72 CAPLETS or 72 RAPID RELEASE CAPLETS, UPC 631656600551 (US); -- Caffeine-Free HYDROXYCUT Weight-Loss Formula 100 RAPID RELEASE CAPLETS, UPC 631656600568 (US); -- Caffeine-Free HYDROXYCUT Weight-Loss Formula 100 count Caplets, UPC 631656801217 (US); -- Caffeine-Free HYDROXYCUT Weight-Loss Formula 140 count Caplets, UPC 631656801224 (US); -- Caffeine-Free HYDROXYCUT Weight-Loss Formula 330 count Caplets, UPC 631656821246 (US). Recall # F-348-9;

3) HYDROXYCUT HARDCORE - LIQUID CAPSULES - DIETARY SUPPLEMENT - Distributed under the Iovate and/or MuscleTech brand names in the following sizes and

UPC codes: -- HYDROXYCUT HARDCORE, 30 Liquid Capsules, UPC 631656001778 (US); -- HYDROXYCUT HARDCORE, 30 Liquid Capsules, UPC 631656601848 (US Trial); -- HYDROXYCUT HARDCORE, 120 Liquid Capsules, UPC 631656600650 (US); -- HYDROXYCUT HARDCORE, POWERFUL NEW FORMULA, 120 Liquid Capsules, UPC 631656601749 (US); -- HYDROXYCUT HARDCORE, 210 Liquid Capsules, UPC 631656600834 (US); -- HYDROXYCUT HARDCORE, NEW FORMULA, 210 Liquid Capsules, UPC 631656601756 (US); -- HYDROXYCUT HARDCORE, 252 Liquid Capsules, UPC 631656601435 (US); -- HYDROXYCUT HARDCORE (US), POWERFUL NEW FORMULA, 252 Liquid Capsules, UPC 631656601763; -- HYDROXYCUT HARDCORE Shredded Stack Kit 120 count, UPC 631656660623. Recall # F-349-9;

4) HYDROXYCUT MAX - EXTREME-STRENGTH WEIGHT LOSS FOR WOMEN - Dietary Supplement - Distributed under the Iovate and/or MuscleTech brand names in the following sizes and UPC codes: -- HYDROXYCUT Max!, 120 RAPID-RELEASE LIQUID-CAPS (with and without bonus + hydroxy Max Sachet WB), UPC 631656601466 (US); -- HYDROXYCUT Max!, 210 RAPID-RELEASE LIQUID-CAPS (with and without Bonus + 1 Hydroxycut Max Sachet WB), UPC 631656601633 (US). Recall # F-350-9;

5) HYDROXYCUT Max! AQUA SHED - RAPID WATER-SHEDDING FORMULA FOR WOMEN - 60 RAPID RELEASE LIQUID-CAPS - Dietary Supplement - UPC 631656601855 (US) - Distributed under the Iovate and/or MuscleTech brand names. Recall # F-351-9;

6) HYDROXYCUT CARB CONTROL - Dietary Supplement - Distributed under the Iovate and/or MuscleTech brand names in the following sizes and UPC codes: -- HYDROXYCUT Carb Control 58 count Caps, UPC 631656800036 (US); -- HYDROXYCUT Carb Control 100 count Caps, UPC 631656800029 (US); -- HYDROXYCUT Carb Control 140 count Caps, UPC 631656800012 (US). Recall # F-352-9;

7) HYDROXYCUT 24 - Dietary Supplement - 96 caps/ blister pack, UPC 631656600933 (US) - Distributed under the Iovate and/or MuscleTech brand names. Recall # F-353-9;

8) HYDROXYCUT NATURAL - Dietary Supplement - 100 count, UPC 631656600889 (US) - Distributed under the Iovate and/or MuscleTech brand names. Recall # F-354-9;

9) HYDROXYCUT - Lose Weight Fast - REGULAR DRINK PACKET- Dietary Supplement - Distributed under the Iovate and/or MuscleTech brand names in the following sizes, flavors, and UPC codes: -- HYDROXYCUT Weight Loss Drink Mix, 21 PACKETS, Wild Berry, UPC 631656860191 (US); -- HYDROXYCUT Weight Loss Drink Mix, 21 PACKETS, Country Lemonade, UPC 631656860313 (US); -- HYDROXYCUT Sachet Twin Pack Kit, UPC 631656002362 (US). Recall # F-355-9;

10) Caffeine-Free HYDROXYCUT - Lose Weight Fast - Drink Mix, 21 PACKETS x 3.6g Sachet - Net Weight 76 g - Raspberry Ice, UPC 631656760095 (US) - Distributed under the Iovate and/or MuscleTech brand names. Recall # F-356-9;

11) HYDROXYCUT HARDCORE DRINK PACKET - IGNITION STIX - Dietary Supplement - Distributed under the Iovate and/or MuscleTech brand names in the following sizes, flavors, and codes: -- HYDROXYCUT HARDCORE IGNITION STIX Drink Mix 2.7 g Sachet, BLUE RASPBERRY, UPC 631656701326 (US); --

HYDROXYCUT HARDCORE IGNITION STIX Drink Mix 2.6 g Sachet - FRUIT PUNCH, UPC 631656701319 (US); -- HYDROXYCUT HARDCORE IGNITION STIX Drink Mix, 40 STIX (40 pk x 2 g Sachet), Net Wt. 108 g, BLUE RASPBERRY, UPC 631656760125 (US); -- HYDROXYCUT HARDCORE IGNITION STIX Drink Mix, 40 STIX (40 pk x 2 g Sachet), Net Wt. 104 g - FRUIT PUNCH, UPC 631656760118 (US). Recall # F-357-9;

12) HYDROXYCUT Max! EXTREME-STRENGTH WEIGHT LOSS FOR WOMEN DRINK PACKETS - Distributed under the following flavors and codes: -- HYDROXYCUT Max! Drink Mix, 40 PACKETS x 2.4g Sachet - Wild Berry, UPC 631656860375 (US); -- HYDROXYCUT Max! Drink Mix, 40 PACKETS x 2.7g Sachet, Net Wt. 108 g - Lemonade, UPC 631656860382 (US). Recall # F-358-9;

13) HYDROXYCUT LIQUID SHOT - Lose Weight Fast - Dietary Supplement - Distributed under the Iovate and/or MuscleTech brand names in the following sizes, flavors, and codes: -- HYDROXYCUT, Lose Weight Fast, Single Shot 2 oz., Wild Berry, UPC 31656800159 (US); -- HYDROXYCUT, Lose Weight Fast, Liquid Shot 2 x 2 oz. Pack, Wild Berry, UPC 631656860207(US); -- HYDROXYCUT, Instant Weight Loss Shot 12 x 2 oz ., Wild Berry, UPC 631656860498 (US); -- HYDROXYCUT Instant Weight Loss Shot 12 x 2 oz., Wild Berry, UPC 631656860498 (US Kit). Recall # F-359-9;

14) HYDROXYCUT HARDCORE RTD (READY TO DRINK) - Dietary Supplement - Distributed under the Iovate and/or MuscleTech brand names in the following sizes, flavors, and codes: -- HYDROXYCUT HARDCORE RTD, 4 x 8 fl. oz. (946 mL), GRAPE EXPLOSION (GRAPE INFUSION), UPC 631656860436 (US); -- HYDROXYCUT HARDCORE RTD, 4 x 8 fl. oz. (946 mL), TRIPLE WILDBERRY, UPC 631656860399 (US); -- HYDROXYCUT HARDCORE RTD, 12-Pack, GRAPE INFUSION, UPC 631656860665 (US); -- HYDROXYCUT HARDCORE RTD, 12-pack, TRIPLE WILDBERRY, UPC 631656860568 (US); -- HYDROXYCUT HARDCORE RTD, 3 x 4-pack, GRAPE INFUSION, UPC 631656860467 (US); -- HYDROXYCUT HARDCORE RTD, 3 x 4-pack, TRIPLE WILDBERRY, UPC 631656860443 (US); -- HYDROXYCUT HARDCORE 8 fl. oz., GRAPE EXPLOSION, UPC 631656800265; -- HYDROXYCUT HARDCORE 8 fl. oz. TRIPLE WILDBERRY, UPC 631656800210. Recall # F-360-9

CODE

All lots, sizes, and codes

RECALLING FIRM/MANUFACTURER

Recalling Firm: Lovate Health Sciences, Inc, Oakville, Canada, by letter and press release on May 1, 2009 and May 7, 2009. Firm initiated recall is ongoing.

REASON

Some Hydroxycut products are associated with a number of serious liver-related illnesses and other health problems. FDA received 23 reports of adverse events associated with use of some Hydroxycut products. As a precaution, the company has decided to recall various Hydroxycut products.

VOLUME OF PRODUCT IN COMMERCE

Approximately 21,067,752 units

DISTRIBUTION

Nationwide and Canada

PRODUCT

Marinated Sun Dried Tomatoes -- Net Wt. 8 oz. 228g DR. Wt. 5 oz. --Ingredients: sun dried tomatoes, canola oil, vinegar, oregano - UPC 0 8419 84430 4 --- Nutrition Facts

Information: Serving Size: 3 pcs (15 g) --- Serving Per Container Varies. Recall # F-375-9

CODE

All production codes

RECALLING FIRM/MANUFACTURER

Chloe Foods Corporation, Brooklyn, NY, by press release on March 6, 2009. Firm initiated recall is complete.

REASON

The product contained undeclared sulfites (634.9 ppm) based on sampling and analysis by New York State Department of Agriculture & Markets.

VOLUME OF PRODUCT IN COMMERCE

18 cases (12 – 8 oz. containers per case)

DISTRIBUTION

NY

PRODUCT

1) La Negrita Flan; 4 oz foil pouch containing powder to make dessert flan. Asa Alimmenots, Lima Peru. Recall # F-385-9;

2) Emulsion Scott, Eceite de Higado de Bacalao con Sabor A Cereza; Vitaminas A D. UPC 7 896015, 500108. Recall # F-391-9

CODE

All lots

RECALLING FIRM/MANUFACTURER

Recalling Firm: Fabi-Saa Inc. Newark, NJ, by letter on February 23, 2009.
Manufacturer: Kraft Foods Global, Inc, Bogota, Colombia. Firm initiated recall is ongoing.

REASON

Labeling: products are labeled in Spanish with no English ingredient listing.

VOLUME OF PRODUCT IN COMMERCE

203 cases

DISTRIBUTION

NJ, NY, PA, and CT

RECALLS AND FIELD CORRECTIONS: FOODS - CLASS III

PRODUCT

1) Royal Maicena; 7 oz. corn meal product in 7 oz. sealed flexible pouch. UPC 861005 403028. Recall # F-384-9;

2) LaFavorita Achiote, 500 gram plastic bottle of vegetable oil and achiote seasoning. Recall # F-386-9;

3) Maizabrosa, Harina de Maiz Predocida 16 oz. flexible bag of powdered corn flour; UPC 861029 300006. Recall # F-387-9;

4) Mulgatol Naranja; '7 oz. tube of children's vitamins. Recall # F-388-9;

5) Salsa de Aji Oriental, Aji Picante; UPC 7 861007 92017. Recall # F-389-9;

6) Salsa China de Soya Oriental Sillau; 9 oz glass bottle. UPC 7 861007 900082. Recall # F-390-9;

7) Soyavnea Cereal 100% Natural, 400 gr plastic bag Una Exquisita manera de nutrirse. UPC 7 861025 300277. Recall # F-392-9;

8) Tang Drink Mix (limon, maracuya, naranja and Lulo/Naranjilla) 7 oz. sealed foil pouches. Maracuya UPC 7 702054 08537; Limon UPC 7 702054 0857417; Lulo/Naranjilla: UPC 7 702054 085394; Naranja: UPC 7 702054 085363. Recall # F-393-9

CODE
All Lots
RECALLING FIRM/MANUFACTURER
Recalling Firm: Fabi-Saa Inc. Newark, NJ, by letter on February 23, 2009.
Manufacturer: Kraft Foods Global, Inc, Bogota, Colombia. Firm initiated recall is ongoing.
REASON
Labeling: products are labeled in Spanish with no English ingredient listing.
VOLUME OF PRODUCT IN COMMERCE
203 cases
DISTRIBUTION
NJ, NY, PA, and CT

RECALLS AND FIELD CORRECTIONS: DRUGS - CLASS I

PRODUCT
ETHEX Dextroamphetamine Sulfate Tablets, USP, 5 mg, CII, packaged in 100-ct. bottles, RX, NDC 58177-311-04. Recall # D-810
CODE
Lot #77946, Exp. 11/2009; Lot #81141, Exp. 1/2010; and Lot #81142, Exp. 5/2010
RECALLING FIRM/MANUFACTURER
Recalling Firm: Ethex Corporation, Bridgeton MO, by press release and letters dated October 15, 2008.
Manufacturer: KV Pharmaceutical Co Westport, Saint Louis, MO. Firm initiated recall is ongoing.
REASON
Some of the tablets are oversized.
VOLUME OF PRODUCT IN COMMERCE
39,230/100-ct. bottles
DISTRIBUTION
Nationwide

PRODUCT
Propafenone Hydrochloride Tablets, 225 mg, 100 Tablet bottles, NDC 0591-0583-01. Recall # D-1212-2009
CODE
Lot Number 112680A, exp 7/31/10
RECALLING FIRM/MANUFACTURER
Watson Laboratories, Inc, Corona, CA, by letter on March 10, 2009 and by letter and press release on March 23, 2009. Firm initiated recall is ongoing.
REASON
Some tablets may contain slightly higher levels of the active ingredient than specified.
VOLUME OF PRODUCT IN COMMERCE
6,278 bottles

DISTRIBUTION
Nationwide

PRODUCT
a) Digoxin Tablets, USP, 0.125 mg, Rx only; 100 tablets, NDC 57664-437-88 and 1000 tablets, NDC 57664-437-18. Recall # D-1213-2009;

b) Digoxin Tablets, USP, 0.25 mg, Rx only; 100 tablets, NDC 57664-441-88 and 1000 tablets, NDC 57664-441-18. Recall # D-1214-2009
CODE
All lot numbers beginning with 61 through 82; expiry 9/30/09-9/30/11
RECALLING FIRM/MANUFACTURER
Caraco Pharmaceutical Laboratories, Ltd, Detroit, MI, by press release, telephone and letter dated March 31, 2009 and by follow-up letter dated April 7, 2009. Firm initiated recall is ongoing.
REASON
Some of the tablets are oversized, and some undersized, which will result in the patient not receiving the expected dose.
VOLUME OF PRODUCT IN COMMERCE
639,994 bottles
DISTRIBUTION
Nationwide

RECALLS AND FIELD CORRECTIONS: DRUGS - CLASS II

PRODUCT
Fabrazyme (agalsidase beta), 5 mg, packaged in mL vials, for Intravenous Infusion Only, Rx only, NDC 58468-0041-1. Recall # D-809-2009
CODE
Lots: A8049A01 August, 2010 A8049A02 August, 2011 A8049H01 A8049H02 A8049H03 A8049H04 A8049H05 A8049H06 A8049H07 A8049H08 A8049H09 A8049NA A8049NB A8049NC A8052A01 September, 2010 A8052A02 A8060H01 October, 2011 A8060H02 A8060H04 A8060H05 A8060NA
RECALLING FIRM/MANUFACTURER
Genzyme Corporation, Cambridge, MA, by letters dated February 4, 2009. Firm initiated recall is ongoing.
REASON
Product does not meet specification for release-low fill volume, assay below specification.
VOLUME OF PRODUCT IN COMMERCE
18,295 vials
DISTRIBUTION
Nationwide, Canada, Austria, Denmark, Estonia, Lithuania, United Kingdom, Ireland, Japan, Hungary, Norway, Netherlands, Spain, Italy, Saudi Arabia

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PRODUCT
a) Clonazepam Tablets, USP, 0.5 mg, CIV, 1000 tablet bottles, Rx only, NDC 57664-273-18. Recall # D-811-2009;

b) Metoprolol Tartrate Tablets, USP, 25 mg, Rx only; a) 100 tablet bottles: NDC 57664-506-08, and b) 1000 tablet bottles: NDC 57664-506-18. Recall # D-812-2009;

c) Metoprolol Tartrate Tablets, USP, 50 mg, 1000 tablet bottles. Rx only, NDC 57664-477-18. Recall # D-813-2009

CODE

a) Lot 81529A, exp 11/2009;
b) a) Lot 80658A, exp 2/2011; and 81739A, exp 7/2011; b) Lot 82695A, exp 11/2011;
c) Lot 80959A, exp 3/2011

RECALLING FIRM/MANUFACTURER

Caraco Pharmaceutical Laboratories, Ltd, Detroit, MI, by letter dated April 17, 2009. Firm initiated recall is ongoing.

REASON

Some of the tablets are oversized or undersized, which will result in the patient not receiving the expected dose.

VOLUME OF PRODUCT IN COMMERCE

86,523 bottles

DISTRIBUTION

Nationwide

PRODUCT

1) SIMVASTATIN, 80MG TAB, Mfg RED, Rx only, NDC 55110268-30. Recall # D-814-2009;

2) Quinapril, 20MG TAB, Mfg. API, Rx only, NDC 62037-0533-90. Recall # D-815-2009;

3) NABI-HB, Hepatitis B IMM GLOB, QTY 5ML. Vial, Mfg. NAB, Rx only. Recall # D-816-2009;

4) PROMETHAZINE, Generic Phenergan, 6.25MG/5ML Liquid, Qty. 10ML, Mfg. MGP, Rx only, NDC 50432-0508-04. Recall # D-817-2009;

5) Borofair, Otic Solution, 2% Drop, 60ML. Mfg. MAJ, Rx only, NDC 00904-3524-03. Recall # D-818-2009;

6) Nabumetone, 500MG TAB, Mfg. TEV, Rx only, NDC 00093-1015-01. Recall # D-819-2009;

7) HYOSCYAMINE ER, GENERIC LEVBID, 0.375MG TAB, Mfg ETH, Rx only, NDC 58177-0237-04. Recall # D-820-2009;

8) Desipramine HCl, 25MG, TAB, Mfg. SNZ, Rx only. Recall # D-821-2009;

9) Teveten, Eprosartan Mesylate, 600MG, TAB, Mfg. KOS, Rx only, NDC 60598-0101-01. Recall # D-822-2009;

10) Ethiodol, Ethiodized Oil, 475MG/ML, Injection, 10ML, Mfg. SAV, Rx only. Recall # D-823-2009;

11) Diltiazem, Sub: Cardizem, 120MG TAB, Mfg. MYL, Rx only, NDC 00378-0525-01. Recall # D-824-2009;

12) Candin, Candida Albicans, Skin Test, Mfg. AMD, Rx only. Recall # D-825-2009;

13) Arimmidex, Anastrozole, 1MG TABLET, Mfg. A/Z, Rx only, NDC 00310-0201-30. Recall # D-826-2009;

14) Vitaplex, B-Complex Vitamin TAB, Mfg. A/P, NDC 52152-0076-02. Recall # D-827-2009;

15) Orajel Baby, Benocaine, 7.5% Gel, Mfg. D-P, NDC 01031-0033-13. Recall # D-828-2009;

16) Neutra-Phos-K, PKT, Potassium Phosphate SF, Powder Concentrate, Mfg. ZGP. Recall # D-829-2009;

17) Allegra, Fexofenadine HCL, 180MG, TAB, Mfg. AVE, Rx only, NDC 00088-1109-47. Recall # D-830-2009;

18) Perphen/Amitrip, 2MG/25MG TAB, Mfg. MYL, Rx only, NDC 00378-0442-01. Recall # D-831-2009;

19) Cerefolin-NAC, TAB, Mfg. Pan, Rx only, NDC 00525-0510-90. Recall # D-832-2009;

20) Xeloda, Capecitabine, 150MG TAB, Mfg. ROC, Rx only. Recall # D-833-2009;

21) Ketoprofen ER, 200Mg CAP, Mfg. MYL, Rx only, NDC 00378-8200-01. Recall # D-834-2009;

22) Nexium, Esomeprazole MG, 40MG CAP, Mfg. A/Z, Rx only, NDC 00186-5040-31. Recall # D-835-2009;

23) Altace, Ramipril, 1.25MG CAP, Mfg. MNR, Rx only. Recall # D-836-2009;

24) Oxaprozin, Sub Daypro, 600MG TAB, Mfg. A-C, Rx only, NDC 60605-0175-00. Recall # D-837-2009;

25) Triple Antibiot Oint, Neomy/Bacitr/Poly-b OINT, and Mfg. G&W. Recall #D-838-2009;

26) Visqid A/A, Urinary Antiseptic, TAB, Mfg. VPH, Rx only, NDC 68013-0015-01. Recall # D-839-2009;

27) Xalatan 0.005%, Latanoprost Ohth, 125MCG,/2.5ML Drop, Qty 2.5ML, Mfg. CAR, Rx only. Recall # D-840-2009;

28) Xopenex, Levalbuterol HCL, 1.25MG/0.5ML Vial, 0.5ML, Mfg. SEP, Rx only, NDC 63402-0515-30. Recall # D-841-2009;

29) Trandolapril, 1MG TAB, Mfg. AWP, Rx only, NDC 65862-0164-01. Recall # D-842-2009;

30) Singulair Chew, Montelukast Sodium, 4MG, TAB, Mfg. MSD, Rx only, NDC 00006-0711-31. Recall # D-843-2009;

31) Cardene SR, Nicardipine SR, 30MG, CAP, Mfg. PDL, Rx only, NDC 37286-0001-44. Recall # D-844-2009;

32) Furosemide, sub. Lasix, 80MG TAB, Mfg. ROX, Rx only, NDC 00054-4301-25. Recall # D-845-2009;

33) Effexor XR, Venlafaxine HCl, ER, 75MG CAP, Mfg. WYE, Rx only, NDC 00008-0033-21. Recall # D-846-2009;

34) Trandolapril, 4MG TAB, Mfg. TEV, Rx only, NDC 0003-7327-01. Recall # D-847-2009;

35) Trimethobenzamide, 300MG CAP, Mfg. A/P, Rx only, NDC 52152-0185-02. Recall # D-848-2009;

36) Citalopram HBr, 20MG TAB, Mfg. RED, Rx only, NDC 55111-0343-01. Recall # D-849-2009;

37) Elmiron, Pentosan Polysulfate, 100MG CAP, Mfg. IVX, Rx only, NDC17314-9311-01. Recall # D-850-2009;

38) Niferex-150 Forte, CAP, Mfg. TRC, Rx only, NDC 64011-0164-26. Recall # D-851-2009;

39) Methotrexate Sodium, 2.5MG TAB, Mfg. ROX, Rx only, NDC 00054-4550-15. Recall # D-852-2009;

40) Hyoscyamine, Sublingual, 0.125MG TAB, Mfg. MAJ, Rx only, NDC 00904-5120-60. Recall # D-853-2009;

41) Naproxen Sod, TAB, 550MG, Mfg. W-W, Rx only, NDC 00163-9908-05. Recall # D-854-2009;

42) Casodex, Bicalutamide, 50MG, Mfg. A/Z, Rx only, NDC 00310-0705-10. Recall # D-855-2009;

43) Guanfacine HCl, 1MG TAB, Mfg. MAJ, Rx only, NDC 00904-5579-60. Recall # D-856-2009;

44) Aloxi, Palonosetron HCl, 0.25Mg/5ML Vial, Mfg. MGI, Rx only. Recall # D-857-2009;

45) Fosamax, Alendronate Sodium, 5MG TAB, Mfg. MSD, Rx only, NDC 00006-0925-31. Recall # D-858-2009;

46) Lamisil AT, Terbinafine HCL, 1% Cream, Mfg. NVT, NDC 00067-3998-42. Recall # D-859-2009;

47) Indomethacin, 50MG CAP, Mfg. MYL, Rx only, NDC 00378-0147-01. Recall # D-860-2009;

48) Ketorolac, 1MG TABLET, Mfg. PLV, Rx only, NDC 50111-0608-01. Recall # D-861-2009;

49) Aminophylline, 200MG TAB, Mfg W-W, Rx only, NDC 00143-1025-01. Recall # D-862-2009;

50) Mexiletine HCl, 200MG CAP, Mfg. TEV, Rx only, NDC 00093-8740-01. Recall # D-863-2009;

51) Levothyroxine, sub: Synthroid, 0.05MG TAB, Mfg. LAN, Rx only, NDC 00527-1342-01. Recall # D-864-2009;

52) Venlafaxine, 37.5MG TABLET, Mfg. TEV, Rx only, NDC 00093-7300-01. Recall # D-865-2009;

53) Reyataz, ATAZANAVIR SULFATE, 150MG CAP, Mfg. BRI, Rx only, NDC 00003-3624-12. Recall # D-866-2009;

54) Pindolol, sub: VISKEN, 10MG TAB, Mfg. MYL, Rx only, NDC 00378-0127-01. Recall # D-867-2009;

55) Procardia, NIFEDIPINE, 10MG CAP, Mfg. PFZ, Rx only, NDC 0069-2600-66. Recall # D-868-2009;

56) Glyburide, sub: DIABETA, 1.25MG TAB, Mfg. TEV, Rx only, NDC 00093-9477-53. Recall # D-869-2009;

57) Bumetanide, 2MG TAB, Mfg. TEV, Rx only, NDC 00093-4234-01. Recall # D-870-2009;

58) Theophylline ER, EXTENDED-RELEASE, 300MG TAB, Mfg. INU, Rx only, NDC 00258-3581-01. Recall # D-871-2009;

59) Lidocaine HCl, 2% JELLY, 5ML, Mfg. AKA, Rx only. Recall # D-872-2009;

60) Perdiem, SENNOSIDES, 15MG TAB, Mfg NVT, NDC 00067-0696-60. Recall # D-873-2009;

61) Levothyroxine, sub: SYNTHROID, 25MCG TAB, Mfg. LAN, NDC 00527-1341-01. Recall # D-874-2009;

62) Lipitor, ATORVASTATIN CALCIUM, 10MG TAB, Mfg. PFZ, Rx only, NDC 00071-0155-23. Recall # D-875-2009;

63) Macrodantin, NITROFURANTOIN MACR. 25MG CAP, Mfg. P&G, Rx only, NDC 00149-0007-05. Recall # D-876-2009;

64) Quinapril HCl, sub: ACCUPRIL, 5MG TAB, Mfg. API, Rx only, NDC 62037-0531-90. Recall # D-877-2009;

65) Naproxen SOD, 550 MG TAB, Mfg. TEV, Rx only, NDC 00093-0537-01. Recall # D-878-2009;

66) Cardizem CD, DILTIAZEM HCL, 300MG CAP, Mfg. DJP, Rx only, NDC 64455-0790-42. Recall # D-879-2009;

67) Glyset, MIGLITOL, 25MG TAB, Mfg. PFZ, Rx only, NDC 00009-5012-01. Recall # D-880-2009;

68) Cenestin, SYN CONJ. ESTROG, A, 0.625MG TAB, Mfg. DMD, Rx only, NDC 51285-0442-02. Recall # D-881-2009;

69) Colchicine, 0.6MG TAB, Mfg. W-W, Rx only, NDC 00143-1201-01. Recall # D-882-2009;

70) Cardizem CD, DILTIAZEM HCL, 360 MG CAP, Mfg. API, Rx only, NDC 64455-0799-42. Recall # D-883-2009;

71) Bupropion HCl, 100MG TAB, Mfg. TEV, Rx only, NDC 00093-0290-01. Recall # D-884-2009;

72) Bacid, LACTOBAC, ACIDOPH. + CAPLET, Mfg. H-C, NDC 36373-6105-04. Recall # D-885-2009;

73) Urocit-K, POTASSIUM CITRATE, 5MEQ TAB, Mfg. MIS, Rx only. Recall # D-886-2009;

74) Docusate Sod, 50MG/5ML LIQ, Qty 10ML, Mfg. QLT, NDC 00603-0746-58. Recall # D-887-2009;

75) Caltrate 600, CALCIUM CARBONATE, 600MG TAB, Mfg. U-R, NDC 00005-5510-19. Recall # D-888-2009;

76) Timolol Maleate 0.5%, OPTH SOLUTION, 5ML, Mfg. ALC, Rx only. Recall # D-889-2009;

77) Timolol 10MG, TABLET, 10MG TAB, Mfg. MYL, Rx only, NDC 00378-0221-01. D-890-2009;

78) Pilocarpine, 0.5%, OPHTH DROPS, 15ML, Mfg. B&L, Rx only, NDC 24208-0806-15. Recall # D-891-2009;

79) Nitroglycerin, TRANSDERMAL SYSTEM, 0.6MG/HR PATCH, Mfg. MYL, Rx only. Recall # D-892-2009;

80) Itraconazole, CAP 100MG, Mfg. SDZ, Rx only, NDC 00185-0550-30. Recall # D-893-2009;

81) Hyoscyamine ER, 0.375MG CAP, Mfg. ETH, Rx only, NDC 50177-0017-04. Recall # D-894-2009;

82) Oxcarbazepine, 300MG TAB, Mfg. SUN, Rx only, NDC 62756-0184-88. Recall # D-895-2009;

83) Citalopram, 20MG TAB, Mfg. A-C, Rx only, NDC 60505-2519-01. Recall # D-896-2009;

84) Dexamethasone, OPTH SOLN, 0.1% DROP, 5ML, Mfg. B&L, Rx only, NDC 24208-0720-02. Recall # D-897-2009;

85) Vivactil, PROTRIPTYLINE HCL, 5MG TAB, Mfg. DMD, Rx only. Recall # D-898-2009;

86) Propranolol HCl, 60MG TAB, Mfg. PLV, Rx only, NDC 50111-0470-01. Recall # D-899-2009;

87) Pravastatin, 40MG TAB, Mfg. RED, Rx only, NDC 55111-0231-90. Recall # D-900-2009;

88) Nasalcrom, CROMOLYN SODIUM, 40MG/ML, NASAL SPRAY, 13ML. WWP, Rx only, NDC 00009-7709-01. Recall # D-901-2009;

89) Solu-Cortef, HYDROCORT SOD SUC, 250MG/2ML VIA, Mfg. PFZ, Rx only. Recall # D-902-2009;

90) Metoprolol TAR, 50MG TAB, Mfg. WAT, Rx only, NDC 08591-0462-01. Recall # D-903-2009;

91) Levobunolol, OPTH SOLN, 0.25% DROP, Mfg. B&L, Rx only, NDC 24208-0545-05. Recall # D-904-2009;

92) Opcon-A, OPHTH DROP, 15ML, Mfg. B&L, NDC 01011-9020-90. Recall # D-905-2009;

93) Geneye, TETRAHYDROZOLINE HCl, 0.05%, DROP 15ML, Mfg. GDL, NDC 00182-1692-33. Recall # D-906-2009;

94) Xopenex, LEVALBUTEROL HCL, 0.31MG/3ML SOL, Mfg. SEP, Rx only. Recall # D-907-2009;

95) Bayer Aspirin, 325MG TAB, Mfg. BAY, NDC 31284-3101-12. Recall # D-908-2009;

96) Aspirin, 81MG CHEW TAB, Mfg. GDD, NDC 00113-0467-68. Recall # D-909-2009;

97) Refresh Celluvisc, PRESERVATIVE FREE, 1% DROPS, Mfg. ALL. Recall # D-910-2009;

98) Eye Wash Solution, 118ML, Mfg. Lot 802018A, Exp. 01/01/10, Mfg. HTP. Recall # D-911-2009;

99) Benzonatate, 100MG CAP, Mfg. INW, Rx only, NDC 00258-3654-05. Recall # D-912-2009;

100) Nitroglycerin, EXTENDED-RELEASE, 6.5MG CAP, Mfg. OLT, Rx only, NDC 00603-4783-21. Recall # D-913-2009;

101) Strong Iodine, (Lugol's Solution), DANGER POISON, Qty 15ML, MFG HUM, NDC 30396-2775-16. Recall # D-914-2009;

102) Promethazine, 6.25MG/5ML SYRUP 5ML, Mfg. OLI, Rx only, NDC 00603-1584-58. Recall # D-915-2009;

103) Sulfacetamide/Pred, SULFA/PREDNISOLONE, 10%/0 23% DROP, 5ML, Mfg. B&L, Rx only, NDC 24208-0317-05. Recall # D-916-2009;

104) Phenylephrine, generic Preparation H, 0.25% SUPP, Mfg. GDD. Recall # D-917-2009;

105) Famvir, FAMCICLOVIR, 500MG TAB, Mfg. NVT, Rx only, NDC 00078-0368-15. Recall # D-918-2009;

106) Restasis, 0.4ML, CYCLOSPORINE, 0.05%, OPHTH DROPS, Mfg. ALL, Rx only. Recall # D-919-2009;

107) Ferric Subsulfate, Monsel's Solution, TOPICAL SOLUTION, Qty 15ML, Mfg. SCM, Rx only, NDC 00000-0013-05, Recall # D-920-2009;

108) Terbutaline, sub: BRETHINE, 5MG TAB, Mfg. GLO, Rx only, NDC 00115-2622-01. Recall # D-921-2009;

109) Hyoscyamine, 0.125MG TAB, Mfg. ETH, Rx only. Recall # D-922-2009;

110) Cyclosporine, 100MG CAP, Mfg. PLV, Rx only. Recall # D-923-2009;

111) Ketoprofen, 50MG CAP, Mfg. TEV, NDC 00093-3193-01, Rx only. Recall # D-924-2009;

112) Carbidopa/Levodopa, sub: SINEMET, 10/100MG TAB, Mfg. P-G, Rx only, NDC 00228-2538-10. Recall # D-925-2009;

113) Pamelor, NORTRIPTYLINE HCl, 10MG CAP, Mfg. MAL, Rx only, NDC 00406-9910-03. Recall # D-926-2009;

114) Cyclosporine, 100MG CAP, Mfg. PLV, Rx only. Recall # D-927-2009;

115) Estratest HS, E-ESTROGEN/M-TEST, 0.625/1.25MG TAB, Mfg. SLV, Rx only, NDC 00032-1023-01. Recall # D-928-2009;

116) Vitamin B-6, Pyridoxine HCl, 50MG TAB, Mfg. N-B, NDC 74312-0011-60. Recall # D-929-2009

CODE

1) Mfg. Lot C80399, Exp.04/23/09;
2) Mfg. Lot 83212A, Exp. 03/01/09;

3) Mfg. Lot 906128, Exp. 07/01/10;
4) Mfg. Lot 29146A, Exp. 04/23/09;
5) Mfg. Lot 217871, Exp. 08/01/09;
6) Mfg. Lot 03N015, Exp. 04/28/09;
7) Mfg. Lot 89771, Exp. 04/25/09;
8) Mfg. Lot 171252, Exp. 04/29/09;
9) Mfg. Lot 7025274, Exp. 04/25/09;
10) Mfg. Lot RJ8, Exp 01/01/10;
11) Mfg. Lot 3003934, Exp. 04/25/09;
12) Mfg. Lot CA038, Exp. 11/30/09;
13) Mfg. Lot PC0089, Exp. 04/25/09;
14) Mfg. Lot 80001A2, Exp. 04/22/09;
15) Mfg. Lot 9J445, Exp. 09/01/12
16) Mfg. Lot 158557A, Exp 07/01/10;
17) Mfg. Lot 1116394, Exp. 04/21/09;
18) Mfg. Lot 3000595, Exp. 04/22/09;
19) Mfg. lot 1107003, Exp. 04/18/09;
20) Mfg. Lot U600150, Exp. 04/22/09;
21) Mfg. Lot 1S0365, Exp. 02/01/09;
22) Mfg. Lot U2932, Exp. 04/18/09;
23) Mfg. Lot 51139, Exp. 04/22/09;
24) Mfg. Lot HN8146, Exp. 04/18/09;
25) Mfg. Lot 026008001, Exp. 010/01/10;
26) Mfg. Lot 07022, Exp. 04/21/09;
27) Mfg. Lot KB53952, Exp. 02/01/11;
28) Mfg. Lot 58B037A, Exp. 08/01/09;
29) Mfg. Lot TN0107001, Exp. 04/14/09;
30) Mfg. Lot X3449, Exp. 04/15/09;
31) Mfg. Lot U1024A, Exp 04/16/09;
32) Mfg. Lot 7574538, Ex. 04/11/09;
33) Mfg. Lot C41328, Exp. 04/14/09;
34) Mfg. Lot T23019, Exp. 04/15/09;
35) Mfg. Lot 70916A1, Exp. 04/16/09;
36) Mfg. Lot C73542, Exp. 04/11/09;
37) Mfg. Lot 161615A, Exp. 04/14/09;
38) Mfg. Lot B0949, Exp. 04/16/09;
39) Mfg. Lot 757161A, Exp. 04/11/09;
40) Mfg. Lot 70757A2, Exp. 04/14/09;
41) Mfg. Lot ND432A, Exp. 04/15/09;
42) Mfg. Lot 160785, Exp. 04/16/09;
43) Mfg. Lot 80042A1, Exp. 04/14/09;
44) Mfg. Lot 27004036, Exp. 02/01/10;
45) Mfg. Lot W1110, Exp. 04/15/09;
46) Mfg Lot 10038571, Exp. 05/01/09;
47) Mfg. Lot 3001166, Exp 04/14/09;
48) Mfg. Lot 6087002A, Exp. 04/15/09;
49) Mfg. Lot 63687A, Exp. 04/15/09
50) Mfg. Lot 35301442A, Exp. 04/17/09;
51) Mfg. Lot 018707, Exp 03/04/09;
52) Mfg. Lot 02V017, Exp 03/10/09;
53) Mfg. Lot 7K3008B, Exp 03/10/09;

54) Mfg. Lot 3S1428, Exp 03/04/09;
55) Mfg. Lot 67P401A, Exp 02/01/09;
56) Mfg. Lot 3059778, Exp 02/01/09;
57) 57) Mfg. Lot TE79043, Exp 03/14/09;
58) Mfg. Lot 4C027, Exp 03/07/09;
59) Mfg. Lot 7L99A, Exp. 10/01/09;
60) Mfg. Lot 22343302, Exp 03/14/09;
61) Mfg. Lot 019807, Exp 03/04/09;
62) Mfg. Lot 14697V, Exp 03/10/09;
63) Mfg. Lot 419684, Exp 03/06/09;
64) Mfg. Lot 82802A, Exp 02/01/09;
65) Mfg. Lot 35301378A, Exp 03/12/09;
66) Mfg. Lot 1100785, Exp 03/14/09;
67) Mfg. Lot 54012TK, Exp 03/06/09;
68) Mfg. Lot 305203, Exp 03/10/09;
69) Mfg. Lot 63557A, Exp 03/12/09;
70) Mfg. Lot 1111806, Exp. 03/13/09;
71) Mfg. Lot 35301521A, Exp 03/07/09;
72) Mfg. Lot 25413, Exp 03/10/09;
73) 73) Mfg. Lot 7D030, Exp 03/12/09;
74) Mfg. Lot 5001B, Exp 03/13/09;
75) Mfg. Lot C07813, Exp 01/01/09;
76) Mfg. Lot 134111F, Exp. 12/01/09;
77) Mfg. Lot 1S0242, Exp 03/19/09;
78) Mfg. Lot 2277031, Exp. 09/01/10;
79) Mfg. Lot 6S0104, Exp. 06/01/09;
80) Mfg. Lot MK070957, Exp. 03/19/09;
81) Mfg. Lot 82728, Exp 03/17/09;
82) Mfg. Lot JK72029A, Exp 03/18/09;
83) Mfg. Lot HN9350, Exp 03/19/09;
84) Mfg. Lot 247071, Exp. 03/19/09;
85) Mfg. Lot 7017002A, Exp 03/18/09;
86) Mfg. Lot 14140607A, Exp 03/18/09;
87) Mfg. Lot C73468, Exp 03/20/09;
88) Mfg. Lot 137341, Exp. 12/01/08;
89) Mfg. Lot DAKKA, Exp. 10/01/12;
90) Mfg. Lot 46201E07, Exp 03/19/09;
91) Mfg. Lot 217771, Exp. 08/01/09;
92) Mfg. Lot GJ7029, Exp. 09/01/10;
93) Mfg. Lot 703010, Exp. 09/01/09;
94) Mfg. Lot S7K034, Exp. 04/01/09;
95) Mfg. Lot 254637L, Exp 03/18/09;
96) Mfg. Lot 7l80314, Exp 03/17/09;
97) Mfg. Lot E50320, Exp. 09/01/09;
98) Mfg. Lot 802018A, Exp. 01/01/10;
99) Mfg. Lot P13856, Exp 03/24/09;
100) Mfg. Lot HO13S, Exp 03/21/09;
101) Mfg. Lot 526104, Exp 03/21/09;
102) Exp. 03/25/09, Mfg. Lot L083K07A;
103) Mfg. Lot 237671, Exp. 03/20/09;
104) Mfg. Lot 7KT0151, Exp. 10/01/09;

105) Mfg. Lot F0297, Exp 03/25/09;
106) Mfg. Lot 51793, Exp. 08/01/09;
107) Mfg. Lot WW0066, Exp 03/21/09;
108) Mfg. Lot 7072121, Exp 03/24/09;
109) Mfg. Lot 89648, Exp 03/25/09;
110) Mfg. Lot 37050701, Exp. 06/01/09;
111) Mfg. Lot 28066, Exp 03/25/09;
112) Mfg. Lot 005A82, Exp 03/25/09;
113) Mfg. Lot C6f02492, Exp 03/20/09;
114) Mfg. Lot 37050701, Exp. 06/01/09;
115) Mfg. Lot 500105, Exp 03/25/09;
116) Mfg. Lot 15736923, Exp 03/26/09

RECALLING FIRM/MANUFACTURER
Advantage Dose LLC, Shreveport, LA, by telephone, electronic mail, and letter beginning November 26, 2008. Firm initiated recall is ongoing.

REASON
Not in conformance with cGMP.

VOLUME OF PRODUCT IN COMMERCE
2,635,663 unit doses

DISTRIBUTION
Nationwide

PRODUCT
Sulfazine EC, 500 mg (Sulfasalazine Delayed-Release tablets, USP 500 mg), 300 tablets, Rx only. Recall # D-1100-2009

CODE
Lot C0200108A, exp 01/10

RECALLING FIRM/MANUFACTURER
Recalling Firm: Vintage Pharmaceuticals LLC DBA Qualitest Pharmaceuticals, Huntsville, AL, by letter on May 6, 2009.
Manufacturer: Vintage Pharmaceuticals Inc, Charlotte, NC. Firm initiated recall is ongoing.

REASON
Out of Specification for dissolution test, at 12 month stability time point.

VOLUME OF PRODUCT IN COMMERCE
884,700 tablets

DISTRIBUTION
AL

PRODUCT
1) Xalatan 0.005%, Latanoprost Ophth, 125 MCG/2.5ML Drop, 2.5 ML, Mfg. CAR, Rx Only. Recall # D-1101-2009;

2) Niacin TR, Timed Release, 500 MG TAB, Mfg. NVC, NDC 79854-0100-78, OTC. Recall # D-1102-2009;

3) Flecainide Acetate, 50 MG TAB, Mfg MYL, NDC 00378-8505-01, Rx Only. Recall # D-1103-2009;

4) Ketorolac (Toradol) 10 MG TAB, Mfg. ETH, NDC 58177-0301-04, Rx Only. Recall # D-1104-2009;

5) Glucosamine Sulfate, 500 MG TAB, Mfg. MER, NDC 00394-0250-09, OTC. Recall # D-1105-2009;

6) Paxil CR, Paroxetine CR, 12.5 MG TAB, Mfg. GSK, NDC 00029-3206-13, Rx Only. Recall # D-1106-2009;

7) Starlix, Nateglinide, 120 MG TAB, Mfg NVT, NDC 00078-0352-05, Rx Only. Recall # D-1107-2009;

8) Lactobicillus Acidophilus (Bacid), CAP, Mfg NVC, NDC 79854-0109-10, OTC. Recall # D-1108-2009;

9) Aspirin, Enteric-coated, 325 MG TAB, Mfg RUG, NDC 00536-3313-01, OTC. Recall # D-1109-2009;

10) Quinapril HCl, 40 MG TAB, Mfg. GRN, NDC 59762-5022-01, Rx Only. Recall # D-1110-2009;

11) Duradryl SR, Chlorpheniramine/P-Ephr/Methsc, 8/20/2.5 MG TAB, Mfg. BRK, NDC 51991-0592-01, Rx Only. Recall # D-1111-2009;

12) Januvia, Sitagliptin Phos, 100 MG TAB, Mfg. MSD, NDC 00006-0277-31, Rx Only. Recall # D-1112-2009;

13) Quinapril, 10 MG TAB, Mfg. A-C, NDC 60505-0173-01, Rx Only. Recall # D-1113-2009;

14) Skelaxin, Metaxalone, 800 MG TAB, Mfg. KPI, NDC 60793-0136-01, Rx Only. Recall # D-1114-2009;

15) Avapro, Irbesartan, 75 MG TAB, Mfg. BRI, NDC 00087-2771-32, Rx Only. Recall # D-1115-2009;

16) Crestor, Rosuvastatin, 5 MG TABLET, Mfg. A/Z, NDC 00310-0755-90, Rx Only. Recall # D-1116-2009;

17) Accolate, Zafirlukast, 30 MG TAB, Mfg. IPR, NDC 00310-0402-60, Rx Only. Recall # D-1117-2009;

18) Sulfazine, Sulfasalazine, 500 MG TABLET, Mfg. QLT, NDC 00603-5801-21, Rx Only. Recall # D-1118-2009;

19) Levothyroxine Tab, Sub: Synthroid, 88 MCG (0.088MG), Mfg. LAN, NDC 00527-1344-01, Rx Only. Recall # D-1119-2009;

20) Budeprion XL, Bupropion HCL XL, 150 MG ER TAB, Mfg. TEV, NDC 00093-5350-56, Rx Only. Recall # D-1120-2009;

21) Keppra, Levetiracetam, 500 MG TAB, Mfg UCB, NDC 50474-0595-40, Rx Only. Recall # D-1121-2009;

22) Metformin ER, (Extended-Release), 500 MG TAB, Mfg. C-P, NDC 62756-0142-01, Rx Only. Recall # D-1122-2009;

23) Minoxidil, Sub: Loniten, 10 MG TAB, Mfg WAT, NDC 00591-5643-01, Rx Only. Recall # D-1123-2009;

24) Slo-Niacin, Controlled Release, 250 MG TAB, Mfg UPS, NDC 00245-0062-11, OTC. Recall # D-1124-2009;

25) Lanoxin, Digoxin Tab, 0.25MG (250 MCG), Mfg. GSK, NDC 00173-0249-55, Rx Only. Recall # D-1125-2009;

26) Glyburide Micro, 3 MG TAB, Mfg W-W, NDC 00143-9919-01, Adv Dose, Rx Only. Recall # D-1126-2009;

27) Calcitriol, Sub: Rocaltrol, 0.25MCG CAP, Mfg. ROX, NDC 00054-0007-25, Rx Only. Recall # D-1127-2009;

28) Ferrous Sulfate, 325 MG TAB, Mfg. RUG, NDC 00536-5890-01, OTC. Recall # D-1128-2009;

29) Hydroxyzine HCl, sub Atarax TAB, 25MG TAB, Mfg. 10702-0011-01, Rx Only. Recall # D-1129-2009;

30) Levothyroxine Sod Tab, 112 MCG (0.112MG), Mfg. MYL, NDC00378-1811-01, Rx Only. Recall # D-1130-2009;

31) Senna Gen, Senna Laxative, 8.6 MG TABLET, Mfg. GDL, OTC. Recall # D-1131-2009;

32) Jantoven, Warfarin, 4 MG TAB, Mfg. UPS, Rx Only. Recall # D-1132-2009;

33) Ofloxacin Otic Solution, 0.% Drop, 5 ML, Mfg. B&L, NDC 24208-0410-05, Rx Only. Recall # D-1133-2009;

34) Disopyramide ER, Extended-Release, 150 MG CAP, Mfg ETH, NDC 58177-0002-04, Rx Only. Recall # D-1134-2009;

35) Neo-Synephrine, Phenylephrine, 0.5% Nasal Spray, 15 ML, Mfg. BAY, OTC, Recall # D-1135-2009;

36) Neomy-Polym/Dex Ophth, Neo/Polymx/Dexameth Susp, Drop 5 ML, Mfg FAL, Rx Only. Recall # D-1136-2009;

37) Altace, Ramipril, 10 MG CAP, Mfg KPI, Rx Only. Recall # D-1137-2009;

38) Metamucil S/F Orange, Psyllium Husk, 5.85 GM Powder Packet, Mfg. P&G, OTC. Recall # D-1138-2009;

39) Dopamine Injection, 80 MG/ML Vial, Mfg. A-R, Advantage Dose, Rx Only. Recall # D-1139-2009;

40) Lactinex Chew Tab (Refrigerate) Tablet, Mfg. BDM, NDC 00011-2368-50, OTC. Recall # D-1140-2009;

41) Levsin, Hyoscyamine, 0.5MG/ML AMP, 1 ML, Mfg. SWZ, 30430, Rx Only. Recall # D-1141-2009;

42) Foltx, B-12/FA/B-6, 2/2.5/25 MG TAB, Mfg PAN, NDC 00525-0906-90, Rx Only. Recall # D-1142-2009;

43) Xalatan 0.005%, Latanoprost Ophth Drops, 2.5 ML, Mfg. CAR, NDC 00013-8903-01, Rx Only. Recall # D-1143-2009;

44) Niferex-150 CAP, Mfg. TRC, NDC 64011-0163-26, OTC. Recall # D-1144-2009;

45) Isosorbide Monoitr, Sub: Imdur ER, 60 MG ER-TAB, Mfg. K-U, NDC 62175-0119-37, Rx Only. Recall # D-1145-2009;

46) Nitroglycerin, Transdermal, 0.2MG/HR Patch, Mfg. HLC, Rx Only. Recall # D-1146-2009;

47) Folcaps (B-12/FolicAcid/B-6), 0.5/2.2/25MG TAB, Mfg. MLT, Rx Only. Recall # D-1147-2009;

48) Inderal LA, Propranolol HCl, 60 MG CAP, Mfg. AKP, 54590, Rx Only. Recall # D-1148-2009;

49) Orapred Equiv to Prednisolone, 15 MG/5ML SOL, Qty 5 ML, Mfg. LYN, NDC 59630-0710-08, Rx Only. Recall # D-1149-2009;

50) Xenaderm Oint, Mfg. HEA, Rx Only. Recall # D-1150-2009;

51) Gleevec, Imatinib Mesylate, 100 MG TAB, Mfg. NVT, Rx Only. Recall # D-1151-2009;

52) Hydrochlorothiazide, 12.5 MG CAP, Mfg. MYL, Rx Only. Recall # D-1152-2009;

53) Bupropion SR, 100 MG Tablet, Mfg. WAT, NDC 00591-0858-60, Rx Only. Recall # D-1153-2009;

54) Propylthiouracil, 50 MG TAB, Mfg. ACT, NDC 00228-2348-10, Rx Only. Recall # D-1154-2009;

55) Avodart, Dustasteride, 0.5 MG CAPSULE, Mfg. GSK, NDC 00173-0712-15, Rx Only. Recall # D-1155-2009;

56) Wellburtrin XL, Bupropion ER, 150 MG TABLET, Mfg. BPC, NDC 00173-0730-01, Rx Only. Recall # D-1156-2009;

58) Lamictal, Lamotrigine, 150 MG TAB, Mfg. SKB, NDC 00173-0643-60, Rx Only Recall # D-1158-2009

59) Tricor Fenofibrate, 145 MG TAB, Mfg. F-L, NDC 00074-6123-90, Rx Only. Recall # D-1159-2009;

60) Niaspan E-R, Niacin E-R, 500 MG TAB, Mfg. ABB, NDC 00074-3074-90, Rx Only. Recall # D-1160-2009;

61) Flecainide, Sub: Tambocor, 100 MG TAB, Mfg. R/P, NDC 63301-0795-01, Rx Only. Recall # D-1161-2009;

62) Warfarin Sodium, 7.5 MG Tab, Mfg. BAR, NDC 00555-0834-02, Rx Only. Recall # D-1162-2009;

63) Glipizide XL, Extended-Release, 2.5 MG Tablet, Mfg. GRN, NDC 59762-5031-01, Rx Only. Recall # D-1163-2009;

64) Cilostazol, 50 MG Tab, Mfg. A-C, NDC 60505-2321-01, Rx Only. Recall # D-1164-2009;

65) Meclizine HCL, 25 MG TAB, Mfg RUG, NDC 00536-3990-01, Rx Only. Recall # D-1165-2009;

66) Nardil, Phenelzine Sulfate, 15 MG TAB, Mfg. PFZ, NDC 00071-0350-60, Rx Only. Recall # D-1166-2009;

67)Misoprostol, Sub: Cytotec, 200 MCG TAB, Mfg. GRN, NDC 59762-5008-02, Rx Only. Recall # D-1167-2009;

68) Fludrocortisone, 0.1 MG Tab, Mfg. BAR, NDC 00555-0997-02, Rx Only. Recall # D-1168-2009;

69) Tylenol PM E/S, APAP/Diphenhydramine, 500/25 MG TAB, Mfg. MCN, NDC 00045-0482-24, OTC. Recall # D-1169-2009;

70) Alum/Mag/Simethicone, Sub: Maalox Plus Susp, 225/220/25MG/5ML, Mfg. GDL, NDC 00182-6004-39, OTC. Recall # D-1170-2009;

71) Bupropion HCl, Sub: Wellbutrin SR, 100 MG Tab, Mfg. SDZ, NDC 00185-0410-01, Rx Only. Recall # D-1171-2009;

72) Fosinopril, 10 MG Tab, Mfg. SDZ, NDC 00185-0041-09, Rx Only. Recall # D-1172-2009;

73) Q-Gel Ultra, Co-Enzyme Q10+Vit E, 60 MG/150 IU CAP, Mfg. G-T , NDC 14654-0989-05, OTC. Recall # D-1173-2009;

74) Anaspaz, 1-Hyoscyamine Sulf, 0.125 MG TAB, Mfg. ASH, NDC 00255-0295-15, Rx Only. Recall # D-1174-2009;

75) Lovaza, Omega-3 Acid Eth Est Capsule, Mfg. CPS, NDC 65726-0425-14, Rx Only. Recall # D-1175-2009;

76) Vitamin D Cap, Ergocalciferol, 50,000 U (1.25MG), Mfg. BAN, NDC 50111-0990-01, Rx Only. Recall # D-1176-2009;

77) Bethanechol CHL, 10 MG TAB, Mfg. WCK, NDC. Recall # D-1177-2009;

78) Glucotrol XL, Glipizide ER, 5 MG TAB, Mfg PFZ, NDC 00049-1550-66, Rx Only. Recall # D-1178-2009;

79) Aggrenox, ASA/ E-R Dipyridamole, 25/200 MG Cap, Mfg. BOE, NDC 00597-0001-60, Rx Only. Recall # D-1179-2009;

80) Pentasa, Mesalamine CR, 250 MG CAP, Mfg. SHI, NDC 54092-0189-81, Rx Only. Recall # D-1180-2009;

81) Zerit, Stavudine 20 MG Cap, Mfg. BRI, NDC 00003-1965-01, Rx Only. Recall # D-1181-2009;

82) Verapamil, Sub: Calan, 40 MG TAB, Mfg. WAT, NDC 00591-0404-01, Rx Only. Recall # D-1182-2009;

83) Glucotrol XL, Glipizide ER, 10 MG TAB, Mfg. PFZ, NDC 00049-1560-66, Rx Only. Recall # D-1183-2009;

84) Avandia, Rosiglitazone, 4 MG Tablet, Mfg. GSK, NDC 00029-3159-13, Rx Only. Recall # D-1184-2009;

85) Covaryx HS, Est. Estrog/Me-Testost, 0.625/1.25MG Tab, Mfg. CTX, NDC 11528-0020-01, Rx Only. Recall # D-1185-2009;

86) Sulfasalazine EC, Sub: Azulfidine EN, 500 MG Tab, Mfg. QLT, NDC 00603-5803-21, Rx Only. Recall # D-1186-2009;

87) LaMICTal, Lamotrigine, 100 MG TAB, Mfg. GSK, NDC 00173-0642-55, Rx Only. Recall # D-1187-2009;

88) Mexiletine HCL, 250 MG CAP, Mfg. TEV, NDC 00093-8741-01, Rx Only. Recall # D-1188-2009;

89) Risperidone, 0.25MG TAB, Mfg. PAT, NDC 50458-0590-60, Rx Only. Recall # D-1189-2009;

90) Vit K Inj, 10 MG/ML Amp, 10 ML, Mfg. HOS, NDC 00409-9158-01, Rx Only. Recall # D-1190-2009;

91) Topamax, Topiramate, 25 MG Tablet, Mfg. JOM, NDC 00045-0639-65, Rx Only. Recall # D-1191-2009;

92) Cetirizine HCl, Sub: Zyrtec, 5MG Tab, Mfg. MYL, NDC 00378-3655-01, OTC. Recall # D-1192-2009;

93) Strattera, Atomoxetine HCl, 40 MG Cap, Mfg. LIL, NDC 00002-3229-30, Rx Only. Recall # D-1193-2009;

94) Vitamin E, 400 IUNITS CAP, Mfg. NVC, NDC 79854-0900-20, OTC. Recall # D-1194-2009;

95) Ranexa ER, Ranolazine ER, 500 MG TAB, Mfg. CTP, NDC 67159-0112-03, Rx Only. Recall # D-1195-2009;

96) Acetaminophen Suppository, 600 MG, Mfg. CPL, NDC 45802-0730-32, OTC. Recall # D-1196-2009;

97) Risperidone, 2MG TAB, Mfg. PAT, NDC 50458-0593-60, Rx Only. Recall # D-1197-2009;

98) Floranex, Lactobacillus Tab, Mfg. RIS, NDC 64980-0129-50, OTC. Recall # D-1198-2009;

99) Flomax, Tamsulosin HCL, 0.4MG CAP, Mfg. ASP, NDC 00597-0058-01, Rx Only. Recall # D-1199-2009;

100) Mucinex, Guaifenesin, 100MG/5ML Expectorant, Qty 5ML, Mfg. ADA, NDC 63824-0273-64, OTC. Recall # D-1200-2009;

101) Risperidone, 0.5MG Tab, Mfg. PAT, NDC 50458-0591-60, Rx Only. Recall # D-1201-2009;

102) Actos, Pioglitazone HCL, 15MG Tablet, Mfg TPA, NDC 64764-0151-05, Rx Only. Recall # D-1202-2009;

103) PhosLo, Calcium Acetate, 667 MG GELCAP, Mfg. FRE, NDC 49230-0640-21, Rx Only. Recall # D-1203-2009;

104) Medroxyprogesterone, 5MG Tab, Mfg. GRN, NDC 59762-3741-01, Rx Only. Recall # D-1204-2009;

105) Trazodone, 150 MG Tablet, Mfg A-C, NDC 60505-2655-01, Rx Only. Recall # D-1205-2009;

106) Acetaminophen, 650 MG Supp, Mfg. CPL, NDC 45802-0730-33, OTC. Recall # D-1206-2009;

107) Aspirin, 325 MG Tab, Mfg. GDL, NDC 00182-0444-10, OTC. Recall # D-1207-2009;

108) Fish Oil, Omega 3, 1000 MG, Mfg. N-B, NDC 74312-0038-48, OTC. Recall # D-1208-2009;

109) Miralax, Polyethylene Glycol, 17 GMS Powder, Mfg. SPH, NDC 04110-0820-71, OTC. Recall # D-1209-2009;

110) Vitamin E, 200 IU Cap, Mfg. NVC, NDC 79854-0900-10, OTC. Recall # D-1210-2009;

111) Bidil, Iso Dn/Hydralazine, 20/37, 5 MG Tab, Mfg. NIT, NDC 12948-0001-12, Rx Only. Recall # D-1211-2009

CODE

1) Mfg. Lot KG53985, Exp. 07/31/11;
2) Mfg. Lot 8AB31, Exp 11/12/09;
3) Mfg. Lot 070953, Exp 11/12/09;
4) Mfg. Lot X85111, Exp 11/11/09;
5) Mfg. Lot 56011, Exp 11/12/09;
6) Mfg. Lot 28P06, Exp 11/12/09;
7) Mfg. Lot F0398, Exp 11/12/09;
8) Mfg. Lot 8HA79, Exp 11/11/09;
9) Mfg. Lot 12428U, Exp 11/12/09;
10) Mfg. Lot 12428U, Exp 11/12/09;
11) Mfg. Lot 8AAN, Exp 11/12/09;
12) Mfg. Lot X4873, Exp 11/11/09;
13) Mfg. Lot HX6621, Exp 11/12/09;
14) Mfg. Lot ES808139A, Exp 11/12/09;
15) Mfg. Lot 8G2088A, Exp 11/11/09;
16) Mfg. Lot 108243, Exp 11/11/09;
17) Mfg. Lot 108127, Exp 11/12/09;
18) Mfg. Lot C0280408A, Exp 11/12/09;
19) Mfg. Lot 019308, Exp 11/12/09;
20) Mfg. Lot 20080428A, Exp 11/11/09;
21) Mfg. Lot 48210, Exp 11/12/09;
22) Mfg. Lot JK81576A, Exp 11/12/09;
23) Mfg. Lot 96498A, Exp 11/12/09;
24) Mfg. Log 250575, Exp 11/11/09;
25) Mfg. Lot A38578, Exp 11/12/09;
26) Mfg. Lot GB018A, Exp 11/12/09;
27) Mfg. Lot 837445A, Exp 11/11/09;
28) Mfg. Lot 08K625, Exp 11/11/09;
29) Mfg. Lot 10120, Exp. 11/12/09;
30) Mfg. Lot 3004566, Exp 11/12/09;
31) Mfg. Lot 89A107U, Exp 11/12/09;
32) Mfg. Lot 255418, Exp 11/12/09;
33) Mfg. Lot 337251, Exp 08/31/10;
34) Mfg. Lot 92682, Exp 11/12/09;
35) Mfg. Lot 269748F, Exp 06/30/10;
36) Mfg. Lot 143319F, Exp 07/31/10;
37) Mfg. Lot 51231, Exp 11/12/09;
38) Mfg. Lot 8112ARD1, Exp 03/31/11;
39) Mfg. Lot 8096, Exp 02/28/10;
40) Mfg. Lot 8217097, Exp 11/13/09;
41) Mfg. Lot 31018, Exp 03/31/10;
42) Mfg. Lot 0408005, Exp 11/12/09;

43) Mfg. Lot KE53972, Exp 05/31/11;
44) Mfg. Lot 96954, Exp 11/12/09;
45) Mfg. Lot 8735301, Exp 11/13/09;
46) Mfg. Lot 998037, Exp 05/31/11;
47) Mfg. Lot 400464, Exp 11/12/09;
48) Mfg. Lot C14052, Exp 08/31/09;
49) Mfg. Lot RS0801, Exp 11/13/09;
50) Mfg. Lot ACBL, Exp 09/30/09;
51) Mfg. Lot F0008, Exp 11/12/09;
52) Mfg. Lot 370654, Exp 11/12/09;
53) Mfg. Lot 8ZP9120, Exp 11/12/09;
54) Mfg. Lot 746F81, Exp 11/14/09;
55) Mfg. Lot 132785, Exp 11/14/09;
56) Mfg. Lot P08E004, Exp 09/30/09;
57) Mfg. Lot 857750A, Exp 11/13/09;
58) Mfg. Lot 8ZP5285, Exp 11/13/09;
59) Mfg. Lot 688282E21, Exp 11/14/09;
60) Mfg. Lot 673562E21, Exp 11/14/09;
61) Mfg. Lot 1925914, Exp 11/14/09;
62) Mfg. Lot307398, Exp 11/13/09;
63) Mfg. Lot 15278V, Exp 11/13/09;
64) Mfg. Lot HU7063, Exp 11/14/09;
65) Mfg. Lot 08J515, Exp 11/14/09;
66) Mfg. Lot 8238902, Exp 11/13/09;
67) Mfg. Lot C070802, Exp 04/30/09;
68) Mfg. Lot 307396, Exp 11/13/09;
69) Mfg. Lot SDA031, Exp 11/14/09;
70) Mfg. Lot FAP002, Exp. 11/14/09;
71) Tab, Mfg. Lot MLP80276, Exp 11/13/09;
72) Mfg. Lot 174264, Exp 11/13/09;
73) Mfg. Lot 20517030, Exp 11/13/09;
74) Mfg. Lot 7876711, Exp 11/14/09;
75) Mfg Lot 794661W, Exp 11/14/09;
76) Mfg. Lot DG11530, Exp 11/13/09;
77) Mfg. Lot 307392, Exp 11/13/09;
78) Mfg. Lot 03468U, Exp. 11/13/09;
79) Mfg. Lot 807698, Exp 11/14/09;
80) Mfg. Lot 8D4634, Exp 11/14/09;
81) Mfg. Lot 6L4305B, Exp 11/13/09;
82) Mfg. Lot 40401B08A, Exp 11/13/09;
83) Mfg. Lot 11058V, Exp 11/13/09;
84) Mfg. Lot 7ZP7616, Exp 11/14/09;
85) Mfg. Lot MC020F071, Exp 06/30/09;
86) Mfg. Lot C1010608A, Exp 11/13/09;
87) Mfg. Lot 8ZP5279, Exp 11/13/09;
88) Mfg. Lot 35302307A, Exp 11/13/09;
89) Mfg. Lot 8HG765, Exp 11/14/09;
90) Mfg. Lot 6144EV, Exp 07/01/09;
91) Mfg. Lot 8JH961, Exp 11/14/09;
92) Mfg. Lot 3005900, Exp 11/14/09;
93) Mfg. Lot A508913A, Exp 11/14/09;

94) Mfg. Lot 8AB09, Exp 11/14/09;
95) Mfg. Lot 822349, Exp 11/14/09;
96) Mfg. Lot 8FT0199, Exp 07/31/11;
97) Mfg. Lot 8HG822, Exp 11/14/09;
98) Mfg. Lot 716845, Exp 11/14/09;
99) Mfg. Lot G0800481, Exp 11/14/09;
100) Mfg. Lot 809027, Exp 11/14/09;
101) Mfg. Lot 8HG771, Exp 11/14/09;
102) Mfg. Lot A13723, Exp 11/14/09;
103) Mfg. Lot 1308096, Exp 11/14/09;
104) Mfg. Lot C080315, Exp 11/14/09 ;
105) Mfg. Lot 308145, Exp 11/14/09;
106) Mfg. Lot 8FT0168, Exp 06/30/11;
107 Mfg. Lot P52810, Exp 11/14/09;
108) Mfg. Lot 23918606, Exp 11/14/09;
109) Mfg. Lot 8A08BH, Exp 11/14/09;
110) Mfg. Lot 7LB33, Exp 11/14/09;
111) Mfg. Lot 7650701, Exp 09/30/09

RECALLING FIRM/MANUFACTURER
Advantage Dose LLC, Shreveport, LA, by telephone, electronic mail, and letter beginning November 26, 2008. Firm initiated recall is ongoing.

REASON
Non-conformance with current Good Manufacturing Practices.

VOLUME OF PRODUCT IN COMMERCE
Unknown

DISTRIBUTION
AR, GA, IL, LA, MS, MO, OK, and TX

RECALLS AND FIELD CORRECTIONS: BIOLOGICS - CLASS II

_____

PRODUCT
a) Red Blood Cells. Recall # B-0423-09;
b) Platelets. Recall # B-0424-09

CODE
a) and b) Units: 0619749; 2044422

RECALLING FIRM/MANUFACTURER
Avera McKennan Hospital & University Health Center, Sioux Falls, SD, by letter dated September 2, 2006. Firm initiated recall is complete.

REASON
Blood products, collected from a donor who resided in a HIV Group O risk area, were distributed.

VOLUME OF PRODUCT IN COMMERCE
4 units

DISTRIBUTION
SD

_____

PRODUCT
Platelets. Recall # B- 0876-09

CODE
Unit: F58291

RECALLING FIRM/MANUFACTURER

Michigan Community Blood Centers, Grand Rapids, MI, by fax on September 3, 2008. Firm initiated recall is complete.

REASON

Blood product, collected in a manner that may have compromised the sterility of the collection system, was distributed.

VOLUME OF PRODUCT IN COMMERCE

1 unit

DISTRIBUTION

MI

PRODUCT

a) Red Blood Cells. Recall # B-1009-09;
b) Platelets. Recall # B-1010-09

CODE

a) and b) Unit: 1682545

RECALLING FIRM/MANUFACTURER

Blood Bank of Hawaii, Honolulu, HI, by letter dated November 17, 2008. 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

HI

PRODUCT

Human Cornea. Recall # B-1011-09

CODE

Unit: 082359ODCN

RECALLING FIRM/MANUFACTURER

SightLife, Seattle, WA, by e-mail, facsimile, and telephone on December 14, 2008. Firm initiated recall is complete.

REASON

Human corneal tissue, had not been approved for distribution and was found to be positive for antibodies to hepatitis B core antigen (anti-HBc), was distributed.

VOLUME OF PRODUCT IN COMMERCE

1 unit

DISTRIBUTION

Japan

PRODUCT

a) Red Blood Cells Leukocytes Reduced. Recall # B-1033-09;
b) Plasma Frozen within 24 hours (FP24). Recall # B-1034-09

CODE

a) and b) Unit: 53FN29563

RECALLING FIRM/MANUFACTURER

American National Red Cross-Greater Chesapeake & Potomac Region, Baltimore, MD, by telephone on December 1, 2008 and follow-up letter dated December 10, 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

MD, DC

PRODUCT

a) Plasma Frozen within 24 hours (FP24). Recall # B-1047-09;
b) Red Blood Cells Leukocytes Reduced. Recall # B-1048-09;

CODE

a) and b) Unit: W115908251396

RECALLING FIRM/MANUFACTURER

Central California Blood Center, Fresno, CA, by e-mail and fax on February 26, 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

2 units

DISTRIBUTION

CA

PRODUCT

a) Platelets, Pheresis, Leukocytes Reduced, Irradiated. Recall # B-1050-09;
b) Platelets, Pheresis Leukocytes Reduced. Recall # B-1051-09

CODE

a) Units: 18P82002, 18P80813PT2, 18P80813PT3, 18P80813PT1, 18P73403, 18P74092PT2, 18P74092PT1, 18P81627, 18P82453, 18P82453PT2, 18P83113, 18P83113PT2, 18P83113PT3 and 18P70718;

b) Units: 18P81620PT1, 18P81620PT2, 18P81095PT1, 18P81095PT2, 18P81095PT3, 18P71514PT1, 18P71514PT2, 18P77033PT2, 18P77033PT1, 18P77339PT1, 187339PT2, 18P83183PT1, 18P83183PT2 and 18P80449

RECALLING FIRM/MANUFACTURER

American National Red Cross Great Lakes Region, Lansing, MI, by telephone calls between September 25, 2008 and October 2, 2008 and follow up letters dated between October 10, 2008 and October 13, 2008. Firm initiated recall is complete.

REASON

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

VOLUME OF PRODUCT IN COMMERCE

28 units

DISTRIBUTION

MI

PRODUCT

a) Fresh Frozen Plasma. Recall # B-1058-09;
b) Red Blood Cells Leukocytes Reduced. Recall # B-1059-09;
c) Platelets Leukocytes Reduced. Recall # B-1060-09

CODE

a), b), and c) Unit: 16KP00115

RECALLING FIRM/MANUFACTURER

American Red Cross Blood Services, Central Ohio Region, Columbus, OH, by telephone on July 16, 2007 and follow up letter dated July 24, 2007. Firm initiated recall is complete.

REASON

Blood products, collected from a donor who reported residing in a HIV Group O risk area, were distributed.

VOLUME OF PRODUCT IN COMMERCE

3 units

DISTRIBUTION

GA, OH

PRODUCT

a) Plasma. Recall # B-1061-09;
b) Red Blood Cells Leukocytes Reduced. Recall # B-1062-09;
c) Recovered Plasma. Recall # B-1063-09

CODE

a) W047009022339;
b) W047009170365; W047009022339; W047009022340; W047009170352;
c) Unit: W047009170335

RECALLING FIRM/MANUFACTURER

New York Blood Center, Inc, New Brunswick, NJ, by telephone on February 10, 2009 and letter dated February 23, 2009. Firm initiated recall is complete.

REASON

Blood products, incorrectly tested for HCV by NAT, were distributed.

VOLUME OF PRODUCT IN COMMERCE

6 units

DISTRIBUTION

NY and United Kingdom

PRODUCT

a) Red Blood Cells Leukocytes Reduced. Recall # B-1100-09;
b) Plasma Frozen. Recall # B-1101-09

CODE

a) and b) Unit: 027LW75094

RECALLING FIRM/MANUFACTURER

ARC Greater Alleghenies, Johnstown, PA, by telephone and follow-up letters dated September 25, 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

PA, VA

PRODUCT

a) Platelets Leukocytes Reduced. Recall # B-1102-09;
b) Red Blood Cells Leukocytes Reduced. Recall # B-1103-09

CODE

a) Unit: 13FC77394;
b) Units: 13FC77394; 13FP42478; 13GQ98107

RECALLING FIRM/MANUFACTURER

American Red Cross Southeastern Michigan Region, Detroit, MI, by telephone on December 14, 2008 and follow up letters dated December 29, 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

4 units

DISTRIBUTION

MI

PRODUCT

a) Red Blood Cells Leukocytes Reduced. Recall # B-1105-09;
b) Plasma Frozen. Recall # B-1106-09

CODE

a) and b) 06LE35977

RECALLING FIRM/MANUFACTURER

The American National Red Cross, Pomona, CA, by telephone on November 29, 2008 and follow-up letters dated December 2, 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

CA

PRODUCT

Red Blood Cells Leukocytes Reduced. Recall # B-1107-09

CODE

Unit: 36FN21347

RECALLING FIRM/MANUFACTURER

The American National Red Cross, Columbia, SC, by fax on December 31, 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

SC

PRODUCT

Red Blood Cells Leukocytes Reduced. Recall # B-1110-09

CODE

Unit: 38FK56703

RECALLING FIRM/MANUFACTURER

American National Red Cross, Indiana-Ohio Region, Fort Wayne, IN, by fax on December 18, 2007 and by telephone on April 7, 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
IN

PRODUCT
Source Plasma. Recall # B-1113-09
CODE
Units: TT0147700, TT0148107, TT0148550, TT0148872, TT0149664
RECALLING FIRM/MANUFACTURER
DCI Biologicals, Temple Terrace LLC, Temple Terrace, FL, by facsimile on December 26, 2008. Firm initiated recall is complete.
REASON
Blood products, not properly quarantined after the receipt of post donation information related to a recent tattoo, were distributed.
VOLUME OF PRODUCT IN COMMERCE
5 units
DISTRIBUTION
CA

PRODUCT
Red Blood Cells Leukocytes Reduced. Recall # B-1117-09
CODE
Units: W117008131867; W117008111050
RECALLING FIRM/MANUFACTURER
Blood Centers of the Pacific, San Francisco, CA, by telephone and follow-up letter on December 12, 2008. Firm initiated recall is complete.
REASON
Blood products, collected from a donor who reported travel to a malarial endemic area, were distributed.
VOLUME OF PRODUCT IN COMMERCE
2 units
DISTRIBUTION
CA

PRODUCT
a) Red Blood Cells Leukocytes Reduced. Recall # B-1118-09;
b) Platelets Pooled Leukocytes Reduced. Recall # B-1119-09
CODE
a) Unit: 5686621;
b) Unit: 9997490
RECALLING FIRM/MANUFACTURER
Florida’s Blood Centers, Inc, Orlando, FL, by letter dated January 21, 2009. Firm initiated recall is complete.
REASON

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

VOLUME OF PRODUCT IN COMMERCE

2 units

DISTRIBUTION

FL

PRODUCT

Red Blood Cells Leukocytes Reduced. Recall # B-1132-09

CODE

Units: 3279497; 3268762; 3230551; 3068186; 2897077; 2886924

RECALLING FIRM/MANUFACTURER

Florida’s Blood Centers, Inc, Orlando, FL, by letter on January 9, 2009. Firm initiated recall is complete.

REASON

Blood products, which were collected from a donor who was a resident of a malarial endemic area, were distributed.

VOLUME OF PRODUCT IN COMMERCE

6 units

DISTRIBUTION

FL

PRODUCT

Red Blood Cells Leukocytes Reduced. Recall # B-1135-09

CODE

Unit: 7299484

RECALLING FIRM/MANUFACTURER

Florida’s Blood Centers, Inc, Orlando, FL, by letter on January 23, 2009. Firm initiated recall is complete.

REASON

Blood product, collected from a donor who traveled to a malarial endemic area, was distributed.

VOLUME OF PRODUCT IN COMMERCE

1 unit

DISTRIBUTION

FL

PRODUCT

Red Blood Cells Leukocytes Reduced. Recall # B-1137-09

CODE

Units: 12FZ74980; 12FJ01237

RECALLING FIRM/MANUFACTURER

Recalling Firm: American Red Cross Carolinas Blood Services Region, Charlotte, NC, by telephone and letter on March 29, 2008.

Manufacturer: American Red Cross Blood Services Carolinas Region, Winston Salem, 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 Leukocytes Reduced. Recall # B-1139-09
CODE
Units: W036708101039, W036708101875, W036708102175
RECALLING FIRM/MANUFACTURER
Central Illinois Community Blood Center, Springfield, IL, by facsimile on September 29, 2008, October 8, 2008 and October 9, 2008. Firm initiated recall is complete.
REASON
Blood products, lacking assurance of having been maintained at an acceptable temperature during irradiation, were distributed.
VOLUME OF PRODUCT IN COMMERCE
3 units
DISTRIBUTION
IL

_____

PRODUCT
Platelets Pheresis Leukocytes Reduced. Recall # B-1140-09
CODE
Units: W286908003726; W286908003966
RECALLING FIRM/MANUFACTURER
Lifesource, Glenview, IL, by telephone on October 9, 2008. Firm initiated recall is complete.
REASON
Blood products, with insufficient plasma volume to support the platelet yield, were distributed.
VOLUME OF PRODUCT IN COMMERCE
2 units
DISTRIBUTION
IL

_____

PRODUCT
a) Platelets Pheresis Leukocytes Reduced Irradiated. Recall # B-1143-09;
b) Platelets Pheresis Leukocytes Reduced. Recall # B-1144-09
CODE
a) Unit: G86197 – Part 1;
b) Units: G86197 – Part 2 and W036708101725 Part 2
RECALLING FIRM/MANUFACTURER
Central Illinois Community Blood Center, Springfield, IL, by telephone on October 8, 2008 and by facsimile on November 18, 2008. Firm initiated recall is complete.
REASON
Blood products, lacking appropriate quality control testing, were distributed.
VOLUME OF PRODUCT IN COMMERCE
3 units
DISTRIBUTION
IL

_____

PRODUCT
Red Blood Cells Leukocytes Reduced. Recall # B-1145-09

CODE
Unit: W044208312088
RECALLING FIRM/MANUFACTURER
San Diego Blood Bank, San Diego, CA, by telephone on November 14, 2008 and by letter dated February 3, 2009. Firm initiated recall is complete.
REASON
Blood product, which was labeled as leukoreduced, but may not have been leukoreduced by filtration, was distributed.
VOLUME OF PRODUCT IN COMMERCE
1 unit
DISTRIBUTION
CA

RECALLS AND FIELD CORRECTIONS: BIOLOGICS - CLASS III

PRODUCT
Source Plasma. Recall # B-0712-09
CODE
Unit: TQ050567
RECALLING FIRM/MANUFACTURER
IBBI dba Knoxville Plasma Corp, Knoxville, TN, by fax on January 29, 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
NC

PRODUCT
Source Plasma. Recall # B-0866-09
CODE
Units: KP117524; KP117322; KZ068269; KP115090; KZ059340; KZ058957; KZ058525; KZ058196; KZ057667; KZ056477; KZ056251; KZ048506; KZ048358; KZ048052; KZ047265; KP111626; KZ049056
RECALLING FIRM/MANUFACTURER
Plasma Biological Services Inc, Memphis, TN, by fax on February 2, 2009 and letter dated February 2, 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
17 units
DISTRIBUTION
CA, MO, Ireland, Austria

PRODUCT
Red Blood Cells Leukocytes Reduced Irradiated. Recall # B-1049-09
CODE
Units: W067108016441, W 067108016442

RECALLING FIRM/MANUFACTURER
The Blood Center, New Orleans, LA, by telephone on August 7, 2008. Firm initiated recall is complete.
REASON
Blood products, held out of controlled storage for an undocumented length of time, were distributed.
VOLUME OF PRODUCT IN COMMERCE
2 units
DISTRIBUTION
LA

PRODUCT
Source Plasma. Recall # B-1094-09
CODE
Unit: AQ030655
RECALLING FIRM/MANUFACTURER
Plasma Biological Services, Asheville, NC, by fax on September 20, 2007. 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
Source Plasma. Recall # B-1095-09
CODE
Unit: AQ030453
RECALLING FIRM/MANUFACTURER
Plasma Biological Services, Asheville, NC, by fax on October 2, 2007. 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
Source Plasma. Recall # B-1096-09
CODE
Unit: AQ030501
RECALLING FIRM/MANUFACTURER
Plasma Biological Services, Asheville, NC, by fax on September 28, 2007. 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
Source Plasma. Recall # B-1097-09
CODE
Unit: AQ030503
RECALLING FIRM/MANUFACTURER
Plasma Biological Services, Asheville, NC, by fax on October 2, 2007. 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
Source Plasma. Recall # B-1098-09
CODE
Unit: AQ030486
RECALLING FIRM/MANUFACTURER
Plasma Biological Services, Asheville, NC, by fax on October 2, 2007. 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
Source Plasma. Recall # B-1099-09
CODE
Unit: AQ030455
RECALLING FIRM/MANUFACTURER
Plasma Biological Services, Asheville, NC, by fax on October 2, 2007. 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-1104-09
CODE
Units: 13FC77394; 13FP42478; 13GQ98107
RECALLING FIRM/MANUFACTURER
American Red Cross Southeastern Michigan Region, Detroit, MI, by telephone on December 14, 2008 and follow up letters dated December 29, 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
3 units
DISTRIBUTION
CA

PRODUCT
Recovered Plasma. Recall # B-1108-09
CODE
Unit: 36FN21347
RECALLING FIRM/MANUFACTURER
The American National Red Cross, Columbia, SC, electronically on December 31, 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

PRODUCT
Recovered Plasma. Recall # B-1109-09
CODE
Unit: 38FK56703
RECALLING FIRM/MANUFACTURER
American National Red Cross, Indiana-Ohio Region, Fort Wayne, IN, electronically on December 18, 2007. 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
Source Plasma. Recall # B-1115-09
CODE
Unit: AQ030657
RECALLING FIRM/MANUFACTURER

Plasma Biological Services, Asheville, NC, by fax on October 2, 2007. 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

Source Plasma. Recall # B-1116-09

CODE

Unit: AQ030414

RECALLING FIRM/MANUFACTURER

Plasma Biological Services, Asheville, NC, by fax on September 28, 2007. 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

a) Red Blood Cells Leukocytes Reduced. Recall # B-1133-09;
b) Fresh Frozen Plasma. Recall # B-1134-09

CODE

a) and b) Unit: KJ31109

RECALLING FIRM/MANUFACTURER

Rex Hospital, Inc, Raleigh, NC, by letter on February 16, 2006. Firm initiated recall is complete.

REASON

Blood products, collected from a donor whose body temperature was greater than 99.5 C, were distributed.

VOLUME OF PRODUCT IN COMMERCE

2 units

DISTRIBUTION

NC

PRODUCT

Recovered Plasma. Recall # B-1136-09

CODE

Units: 12FZ74980; 12FJ01237

RECALLING FIRM/MANUFACTURER

Recalling Firm: American Red Cross Carolinas Blood Services Region, Charlotte, NC, by telephone and letter on March 29, 2008.
Manufacturer: American Red Cross Blood Services Carolinas Region, Winston Salem, 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

CA

PRODUCT

Platelets Pheresis Leukocytes Reduced Irradiated. Recall # B-1138-09

CODE

Unit: W036708102070

RECALLING FIRM/MANUFACTURER

Central Illinois Community Blood Center, Springfield, IL, by facsimile on September 29, 2008, October 8, 2008 and October 9, 2008. Firm initiated recall is complete.

REASON

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

VOLUME OF PRODUCT IN COMMERCE

1 unit

DISTRIBUTION

IL

PRODUCT

Red Blood Cells Leukocytes Reduced. Recall # B-1141-09

CODE

Unit: W036708101101

RECALLING FIRM/MANUFACTURER

Central Illinois Community Blood Center, Springfield, IL, by facsimile on September 25, 2008. Firm initiated recall is complete.

REASON

Blood product, manufactured from a Whole Blood unit with an extended collection time, was distributed.

VOLUME OF PRODUCT IN COMMERCE

1 unit

DISTRIBUTION

IL

RECALLS AND FIELD CORRECTIONS: DEVICES - CLASS II

PRODUCT

Remstar Pro M-Series CPAP and Heated Humidifier System. Catalog Numbers: 1049109, 1049110, 1049111, and AC1049109. Recall # Z-1260-2009

CODE

Unknown

RECALLING FIRM/MANUFACTURER

Respironics, Monroeville, PA, by letter dated February 5, 2009. Firm initiated recall is ongoing.

REASON

Malfunction of the J3 connection between the Heater Plate Main printed circuit assembly (PCA) and the heater plate may have an intermittent connection which may lead to excessive heat build-up on the humidifier PCA.

VOLUME OF PRODUCT IN COMMERCE
449,585 units
DISTRIBUTION
OR, OH, KY, TX, MO, AZ, IN and NV and countries of United Arab Emirates, Bosnia, Belgium, Bulgaria, Bahrain, Canada, Czech Republic, Denmark, Egypt, Spain, Finland, Greece, Croatia, Hungary, Ireland, Israel, Jordan, Kuwait, Lebanon, Latvia, Macedonia, Netherlands, Norway, Oman, Poland, Portugal, Romania, Qatar, Russia, Slovenia, Turkey, Serbia and South Africa

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PRODUCT
Cook Medical Tao Brush I.U.M.C. Endometrial Cytology/Histology Sampler (Tao Brush), 9.0Fr/26 cm, 3.5 cm, sterile, Cook Ob/Gyn, Spencer, IN; REF J-ES-090500-BL. Used to obtain endometrial samples for both cytology and histology. Intended for one-time use. Recall # Z-1416-2009
CODE
Lots UF1793872 through UF1793877, UF1811910 through UF1811913, UF1811916, UF1811917, UF1811917S, UF1811918, UF1811919, UF1816687 and UF1816688
RECALLING FIRM/MANUFACTURER
Cook OB/Gyn, Inc, Spencer, IN, by letter dated April 2, 2009. Firm initiated recall is ongoing.
REASON
There is an ink on the brush which has not been tested for use with the Tao Brush.
VOLUME OF PRODUCT IN COMMERCE
15,396 units
DISTRIBUTION
Nationwide

PRODUCT
1) STERRAD 50 Sterilization System Product Code 10050 The STERRAD Sterilization System is a low-temperature general-purpose sterilizer used to sterilize heat and moisture sensitive reusable medical devices. Recall # Z-1419-2009;

2) STERRAD NX Sterilization System Product Code 10033 The STERRAD Sterilization System is a low-temperature general-purpose sterilizer used to sterilize heat and moisture sensitive reusable medical devices. Recall # Z-1420-2009
CODE
All serial numbers
RECALLING FIRM/MANUFACTURER
Advanced Sterilization Products, Irvine, CA, by letters dated March 9, 2009. Firm initiated recall is ongoing.
REASON
ASP has identified a secondary, lower-occurring cause of oil mist within certain STERRAD NX Systems and STERRAD 50 Systems due to potentially defective oil fill plugs.
VOLUME OF PRODUCT IN COMMERCE
4,222 units
DISTRIBUTION
Nationwide, Germany, Italy, France, UK, Switzerland, Benelex, Uruguay, Venezuela, Argentina, Chile, Columbia, Ecuador, Belgium, Puerto Rico, Hong Kong, Indonesia, Mexico, Philippines, Austria, China, Greece, Ireland, Israel, Japan, Korea, Malaysia, Singapore, Thailand, Taiwan, Turkey, Middle East, Peru, Canada, Czech Republic,

Portugal, South Africa, Spain, Sweden, Hungary, Poland, Brazil, Russia, Egypt, India, and Slovenia

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PRODUCT

1) Mavig Portegra 2 which is an accessory to the Siemens angiographic, fluoroscopic and radiographic imaging systems. Component material number 7721165 Upper Body radiation shield, fixed. Used with the following systems 1) Artis Zee floor Model number 10094135; 2) Artis Zee ceiling Model number 10094137; 3) Artis Zee biplane Model number 10094141; 4) Artis Zee floor MN Model number 10094142; 5) Multistar D Model number 3772501; 6) Axiom Iconos R200 Model number 5902775; 7) Axiom Artis FC Model number 5904433; 8) Axiom Artis MP Model number 5904466; 9) Axiom Artis BC Model number 5904649; 10) Axiom Artis BA Model number 5904656; 11) Axiom Artis TA Model number 7007755; 12) Axiom Artis dTA Model number 7008605;
13) Axiom Artis dFC Model number 7412807; 14) Axiom Artis dTC Model number 7413078; 15) Axiom Artis dMP Model number 7555365; 16) Axiom Artis dFA Model number 7555373;17) Axiom Artis dFC Model number 7727717; 18) Axiom Artis TC Model number 7728350; 19) Axiom Artis dBC Model number 7728392; 20) Somatom Definition AS Model number 8098027. Recall # Z-1437-2009;

2) Mavig Portegra 2 which is an accessory to the Siemens angiographic, fluoroscopic and radiographic imaging systems. Component material number 4787714 Upper Body radiation shield, Artis floor. Used with the following systems 1) Artis Zee floor Model number 10094135; 2) Artis Zee ceiling Model number 10094137; 3) Artis Zee biplane Model number 10094141; 4) Artis Zee floor MN Model number 10094142; 5) Multistar D Model number 3772501; 6) Axiom Iconos R200 Model number 5902775; 7) Axiom Artis FC Model number 5904433; 8) Axiom Artis MP Model number 5904466; 9) Axiom Artis BC Model number 5904649; 10) Axiom Artis BA Model number 5904656; 11) Axiom Artis TA Model number 7007755; 12) Axiom Artis dTA Model number 7008605; 13) Axiom Artis dFC Model number 7412807; 14) Axiom Artis dTC Model number 7413078; 15) Axiom Artis dMP Model number 7555365; 16) Axiom Artis dFA Model number 7555373; 17) Axiom Artis dFC Model number 7727717; 18) Axiom Artis TC Model number 7728350; 19) Axiom Artis dBC Model number 7728392; 20) Somatom Definition AS Model number 8098027. Recall # Z-1438-2009;

3) Mavig Portegra 2 which is an accessory to the Siemens angiographic, fluoroscopic and radiographic imaging systems. Component material number 7559375 Upper Body radiation shield, Artis T. Used with the following systems: 1) Artis Zee floor Model number 10094135; 2) Artis Zee ceiling Model number 10094137; 3) Artis Zee biplane Model number 10094141; 4) Artis Zee floor MN Model number 10094142; 5) Multistar D Model number 3772501; 6) Axiom Iconos R200 Model number 5902775; 7) Axiom Artis FC Model number 5904433; 8) Axiom Artis MP Model number 5904466; 9) Axiom Artis BC Model number 5904649; 10) Axiom Artis BA Model number 5904656; 11) Axiom Artis TA Model number 7007755; 12) Axiom Artis dTA Model number 7008605; 13) Axiom Artis dFC Model number 7412807; 14) Axiom Artis dTC Model number 7413078; 15) Axiom Artis dMP Model number 7555365; 16) Axiom Artis dFA Model number 7555373; 17) Axiom Artis dFC Model number 7727717; 18) Axiom Artis TC Model number 7728350; 19) Axiom Artis dBC Model number 7728392; 20) Somatom Definition AS Model number 8098027. Recall # Z-1439-2009;

4) Mavig Portegra 2 which is an accessory to the Siemens angiographic, fluoroscopic and radiographic imaging systems. Component material number 10281150 Surgery

lamp, 230V. Used with the following systems 1) Artis Zee floor Model number 10094135; 2) Artis Zee ceiling Model number 10094137; 3) Artis Zee biplane Model number 10094141; 4) Artis Zee floor MN Model number 10094142; 5) Multistar D Model number 3772501; 6) Axiom Iconos R200 Model number 5902775; 7) Axiom Artis FC Model number 5904433; 8) Axiom Artis MP Model number 5904466; 9) Axiom Artis BC Model number 5904649; 10) Axiom Artis BA Model number 5904656; 11) Axiom Artis TA Model number 7007755; 12) Axiom Artis dTA Model number 7008605; 13) Axiom Artis dFC Model number 7412807; 14) Axiom Artis dTC Model number 7413078; 15) Axiom Artis dMP Model number 7555365; 16) Axiom Artis dFA Model number 7555373; 17) Axiom Artis dFC Model number 7727717; 18) Axiom Artis TC Model number 7728350; 19) Axiom Artis dBC Model number 7728392; 20) Somatom Definition AS Model number 8098027. Recall # Z-1440-2009;

5) Mavig Portegra 2 which is an accessory to the Siemens angiographic, fluoroscopic and radiographic imaging systems. Component material number 10281151 Surgery lamp, 115V. Used with the following systems 1) Artis Zee floor Model number 10094135; 2) Artis Zee ceiling Model number 10094137; 3) Artis Zee biplane Model number 10094141; 4) Artis Zee floor MN Model number 10094142; 5) Multistar D Model number 3772501; 6) Axiom Iconos R200 Model number 5902775; 7) Axiom Artis FC Model number 5904433; 8) Axiom Artis MP Model number 5904466; 9) Axiom Artis BC Model number 5904649; 10) Axiom Artis BA Model number 5904656; 11) Axiom Artis TA Model number 7007755; 12) Axiom Artis dTA Model number 7008605; 13) Axiom Artis dFC Model number 7412807; 14) Axiom Artis dTC Model number 7413078; 15) Axiom Artis dMP Model number 7555365; 16) Axiom Artis dFA Model number 7555373; 17) Axiom Artis dFC Model number 7727717; 18) Axiom Artis TC Model number 7728350; 19) Axiom Artis dBC Model number 7728392; 20) Somatom Definition AS Model number 8098027. Recall # Z-1441-2009;

6) Mavig Portegra 2 which is an accessory to the Siemens angiographic, fluoroscopic and radiographic imaging systems. Component material number 10281152 3-bulb surgery lamp, 230V. Used with the following systems: 1) Artis Zee floor Model number 10094135; 2) Artis Zee ceiling Model number 10094137; 3) Artis Zee biplane Model number 10094141; 4) Artis Zee floor MN Model number 10094142; 5) Multistar D Model number 3772501; 6) Axiom Iconos R200 Model number 5902775; 7) Axiom Artis FC Model number 5904433; 8) Axiom Artis MP Model number 5904466; 9) Axiom Artis BC Model number 5904649; 10) Axiom Artis BA Model number 5904656; 11) Axiom Artis TA Model number 7007755; 12) Axiom Artis dTA Model number 7008605; 13) Axiom Artis dFC Model number 7412807; 14) Axiom Artis dTC Model number 7413078; 15) Axiom Artis dMP Model number 7555365; 16) Axiom Artis dFA Model number 7555373; 17) Axiom Artis dFC Model number 7727717; 18) Axiom Artis TC Model number 7728350; 19) Axiom Artis dBC Model number 7728392; 20) Somatom Definition AS Model number 8098027. Recall # Z-1442-2009;

7) Mavig Portegra 2 which is an accessory to the Siemens angiographic, fluoroscopic and radiographic imaging systems. Component material number 10281153 3-bulb surgery lamp, 115V. Used with the following systems 1) Artis Zee floor Model number 10094135; 2) Artis Zee ceiling Model number 10094137; 3) Artis Zee biplane Model number 10094141; 4) Artis Zee floor MN Model number 10094142; 5) Multistar D Model number 3772501; 6) Axiom Iconos R200 Model number 5902775; 7) Axiom Artis FC Model number 5904433; 8) Axiom Artis MP Model number 5904466; 9) Axiom Artis BC Model number 5904649; 10) Axiom Artis BA Model number 5904656; 11) Axiom Artis TA

Model number 7007755; 12) Axiom Artis dTA Model number 7008605; 13) Axiom Artis dFC Model number 7412807; 14) Axiom Artis dTC Model number 7413078; 15) Axiom Artis dMP Model number 7555365; 16) Axiom Artis dFA Model number 7555373; 17) Axiom Artis dFC Model number 7727717; 18) Axiom Artis TC Model number 7728350; 19) Axiom Artis dBC Model number 7728392; 20) Somatom Definition AS Model number 8098027. Recall # Z-1443-2009

CODE

1) (1) Serial numbers: 135102, 135109, 135117, 135120, 135122, 135125, and 135143; 2) Serial numbers: 146103, 146104, 146107, 146113, 146116, 146119, 146122, 146123, 146136, 146137, and 146138; 3) Serial numbers: 153101, 153102, 153106, 153107, 153110, 153112, 153113, 153119, 153120, 153122, 153124, 153125, 153128, 153130, 153135, 153141, and 153153; 4) Serial number: 140100; 5) Serial number: 1175 and 1667; 6) Serial number 2145; 7) Serial numbers: 10073, 10305, 10477, and 10488; 8) Serial numbers: 20313, 20321, 20338, and 20348; 9) Serial number: 14112; 10) Serial numbers: 28012, 28033, and 28067; 11) Serial numbers: 32042, 32048, and 32106; 12) Serial numbers: 55070, 55217, 55218, 55219, 55220, 55223, 55228, 55230, 55231, 55232, 55233, 55238, 55241, 55243, 55246, 55249, 55250, 55254, 55256, 55259, 55260, 55262, 55263, 55269, 55273, 55274, 55276, 55277, 55279, 55282, 55284, 55285, 55286, 55287, 55288, 55289, 5292, 55294, 55298, 55299, 55304, 55305, 55306, 55307, 55308, 55310, 55312, 55316, 55318, 55320, 55322, 55325, 55338, 55342, 55343, 55355, 55356, 55358, 55359, 55362, 55365, 55368, 55369, 55374, 55375, 55376, 55377, 55378, 55382, 55384, 55388, 55392, 55394, 55395, 55396, 55399, 55400, 55401, 55404, 55405, 55407, 55408, 55409, 55410, 55411, 55414, 55415, 55416, 55423, 55425, 55426, 55435, 55436, 55438, 55439, 55441, 55443, 55455, 55461, 55462, 55466, 55468, 55470, 55473, and 55513; 13) Serial numbers: 35511, 35516, 35525, 35528, 35529, 35535, 35536, 35538, 35540, 35545, 35556, 35560, 35566, 35571, 35580, 35581, 35599, 35600, 35601, 35603, 35610, 35613, 35623, 35627, 35629, 35634, 35649, 35652, 35655, 35659, 35663, 35664, 35665, 35666, 35672, 35678, 35684, 35690, 35698, 35704, 35707, 35727, 35728, 35730, 35736, 35739, 35741, 35743, 35744, 35745, 35750, 35762, 35768, 35776, 35778, 35782, 35783, 35784, 35787, 35788, 35793, 35802, 35810, 35821, 35828, 35831, 35834, 35836, 35937, and 37713; 14) Serial numbers: 46036, 46071, 46097, 46111, 46112, 46115, 46117, 46118, 46120, 46122, 46125, 46129, 46133, 46134, 46138, 46139, 46143, 46144, 46145, 46146, 46147, 46153, 46156, 46158, 46162, 46163, 46168, 46170, 46171, 46172, 46174, 46178, 46179, 46180, 46186, 46189, 46190, 46194, 46196, 46198, 46201, 46202, 46203, 46205, 46208, 46209, 46210, 46213, 46215, 46216, 46218, 46219, 46220, 46221, 46223, 46224, 46225, 46226, 46229, 46231, 46233, 46236, 46241, and 46245; 15) Serial numbers: 57054, 57073, 57076, 57077, 57089, 57111, 57116, 57144, 57155, 57156, 57171, and 57189; 16) Serial numbers: 50074, 50079, 50081, 50087, 50093, 50101, 50105, 50120, 50132, 50139, 50142, and 50161; 17) Serial numbers: 40031, 40050, 40061, 40067, and 40071; 18) Serial number: 30005; 19) Serial numbers: 44152, 44157, 44163, 44165, 44171, 44174, 44189, 44190, 44193, 44195, 44198, 44201, 44206, 44215, 44218, 44223, 44224, 44227, 44229, 44242, 44243, 44251, 44254, 44255, 44262, 44263, 44265, 44267, 44268, 44271, 44275, 44277, 44278, 44280, 44282, 44289, 44290, 44292, and 44304; 20) Serial numbers: 64064, 64065, 64067, 64068, 64071, 64074, 64077, 64078, 64081, 64082, 64085, 64087, 64091, 64097, 64103, 64104, 64105, 64111, 64112, 64113, 64114, 64115, 64117, 64118, 64122, 64123, 64138, 64140, 64142, 64145, 64154, 64164, 64166, 64168, 64169, 64170, 64171, 64172, 64177, 64178, 64179, 64180, 64181, 64190, 64194, 64199, 64202, 64212, 64214, 64228, 64231, 64232, 64235,

64236, 64239, 64241, 64243, 64244, 64245, 64246, 64247, 64248, 64253, 64258, and 64259;

2) (1) Serial numbers: 135102, 135109, 135117, 135120, 135122, 135125, and 135143; 2) Serial numbers: 146103, 146104, 146107, 146113, 146116, 146119, 146122, 146123, 146136, 146137, and 146138; 3) Serial numbers: 153101, 153102, 153106, 153107, 153110, 153112, 153113, 153119, 153120, 153122, 153124, 153125, 153128, 153130, 153135, 153141, and 153153; 4) Serial number: 140100; 5) Serial number: 1175 and 1667; 6) Serial number 2145; 7) Serial numbers: 10073, 10305, 10477, and 10488; 8)Serial numbers: 20313, 20321, 20338, and 20348; 9) Serial number: 14112; 10) Serial numbers: 28012, 28033, and 28067; 11) Serial numbers: 32042, 32048, and 32106; 12) Serial numbers: 55070, 55217, 55218, 55219, 55220, 55223, 55228, 55230, 55231, 55232, 55233, 55238, 55241, 55243, 55246, 55249, 55250, 55254, 55256, 55259, 55260, 55262, 55263, 55269, 55273, 55274, 55276, 55277, 55279, 55282, 55284, 55285, 55286, 55287, 55288, 55289, 5292, 55294, 55298, 55299, 55304, 55305, 55306, 55307, 55308, 55310, 55312, 55316, 55318, 55320, 55322, 55325, 55338, 55342, 55343, 55355, 55356, 55358, 55359, 55362, 55365, 55368, 55369, 55374, 55375, 55376, 55377, 55378, 55382, 55384, 55388, 55392, 55394, 55395, 55396, 55399, 55400, 55401, 55404, 55405, 55407, 55408, 55409, 55410, 55411, 55414, 55415, 55416, 55423, 55425, 55426, 55435, 55436, 55438, 55439, 55441, 55443, 55455, 55461, 55462, 55466, 55468, 55470, 55473, and 55513; 13) Serial numbers: 35511, 35516, 35525, 35528, 35529, 35535, 35536, 35538, 35540, 35545, 35556, 35560, 35566, 35571, 35580, 35581, 35599, 35600, 35601, 35603, 35610, 35613, 35623, 35627, 35629, 35634, 35649, 35652, 35655, 35659, 35663, 35664, 35665, 35666, 35672, 35678, 35684, 35690, 35698, 35704, 35707, 35727, 35728, 35730, 35736, 35739, 35741, 35743, 35744, 35745, 35750, 35762, 35768, 35776, 35778, 35782, 35783, 35784, 35787, 35788, 35793, 35802, 35810, 35821, 35828, 35831, 35834, 35836, 35937, and 37713; 14) Serial numbers: 46036, 46071, 46097, 46111, 46112, 46115, 46117, 46118, 46120, 46122, 46125, 46129, 46133, 46134, 46138, 46139, 46143, 46144, 46145, 46146, 46147, 46153, 46156, 46158, 46162, 46163, 46168, 46170, 46171, 46172, 46174, 46178, 46179, 46180, 46186, 46189, 46190, 46194, 46196, 46198, 46201, 46202, 46203, 46205, 46208, 46209, 46210, 46213, 46215, 46216, 46218, 46219, 46220, 46221, 46223, 46224, 46225, 46226, 46229, 46231, 46233, 46236, 46241, and 46245; 15) Serial numbers: 57054, 57073, 57076, 57077, 57089, 57111, 57116, 57144, 57155, 57156, 57171, and 57189; 16) Serial numbers: 50074, 50079, 50081, 50087, 50093, 50101, 50105, 50120, 50132, 50139, 50142, and 50161; 17) Serial numbers: 40031, 40050, 40061, 40067, and 40071; 18) Serial number: 30005; 19) Serial numbers: 44152, 44157, 44163, 44165, 44171, 44174, 44189, 44190, 44193, 44195, 44198, 44201, 44206, 44215, 44218, 44223, 44224, 44227, 44229, 44242, 44243, 44251, 44254, 44255, 44262, 44263, 44265, 44267, 44268, 44271, 44275, 44277, 44278, 44280, 44282, 44289, 44290, 44292, and 44304; 20) Serial numbers: 64064, 64065, 64067, 64068, 64071, 64074, 64077, 64078, 64081, 64082, 64085, 64087, 64091, 64097, 64103, 64104, 64105, 64111, 64112, 64113, 64114, 64115, 64117, 64118, 64122, 64123, 64138, 64140, 64142, 64145, 64154, 64164, 64166, 64168, 64169, 64170, 64171, 64172, 64177, 64178, 64179, 64180, 64181, 64190, 64194, 64199, 64202, 64212, 64214, 64228, 64231, 64232, 64235, 64236, 64239, 64241, 64243, 64244, 64245, 64246, 64247, 64248, 64253, 64258, and 64259;

3) (1)Serial numbers: 135102, 135109, 135117, 135120, 135122, 135125, and 135143; 2) Serial numbers: 146103, 146104, 146107, 146113, 146116, 146119, 146122,

146123, 146136, 146137, and 146138; 3) Serial numbers: 153101, 153102, 153106, 153107, 153110, 153112, 153113, 153119, 153120, 153122, 153124, 153125, 153128, 153130, 153135, 153141, and 153153; 4) Serial number: 140100; 5) Serial number: 1175 and 1667; 6) Serial number 2145; 7) Serial numbers: 10073, 10305, 10477, and 10488; 8) Serial numbers: 20313, 20321, 20338, and 20348; 9) Serial number: 14112; 10) Serial numbers: 28012, 28033, and 28067; 11) Serial numbers: 32042, 32048, and 32106; 12) Serial numbers: 55070, 55217, 55218, 55219, 55220, 55223, 55228, 55230, 55231, 55232, 55233, 55238, 55241, 55243, 55246, 55249, 55250, 55254, 55256, 55259, 55260, 55262, 55263, 55269, 55273, 55274, 55276, 55277, 55279, 55282, 55284, 55285, 55286, 55287, 55288, 55289, 5292, 55294, 55298, 55299, 55304, 55305, 55306, 55307, 55308, 55310, 55312, 55316, 55318, 55320, 55322, 55325, 55338, 55342, 55343, 55355, 55356, 55358, 55359, 55362, 55365, 55368, 55369, 55374, 55375, 55376, 55377, 55378, 55382, 55384, 55388, 55392, 55394, 55395, 55396, 55399, 55400, 55401, 55404, 55405, 55407, 55408, 55409, 55410, 55411, 55414, 55415, 55416, 55423, 55425, 55426, 55435, 55436, 55438, 55439, 55441, 55443, 55455, 55461, 55462, 55466, 55468, 55470, 55473, and 55513; 13) Serial numbers: 35511, 35516, 35525, 35528, 35529, 35535, 35536, 35538, 35540, 35545, 35556, 35560, 35566, 35571, 35580, 35581, 35599, 35600, 35601, 35603, 35610, 35613, 35623, 35627, 35629, 35634, 35649, 35652, 35655, 35659, 35663, 35664, 35665, 35666, 35672, 35678, 35684, 35690, 35698, 35704, 35707, 35727, 35728, 35730, 35736, 35739, 35741, 35743, 35744, 35745, 35750, 35762, 35768, 35776, 35778, 35782, 35783, 35784, 35787, 35788, 35793, 35802, 35810, 35821, 35828, 35831, 35834, 35836, 35937, and 37713; 14) Serial numbers: 46036, 46071, 46097, 46111, 46112, 46115, 46117, 46118, 46120, 46122, 46125, 46129, 46133, 46134, 46138, 46139, 46143, 46144, 46145, 46146, 46147, 46153, 46156, 46158, 46162, 46163, 46168, 46170, 46171, 46172, 46174, 46178, 46179, 46180, 46186, 46189, 46190, 46194, 46196, 46198, 46201, 46202, 46203, 46205, 46208, 46209, 46210, 46213, 46215, 46216, 46218, 46219, 46220, 46221, 46223, 46224, 46225, 46226, 46229, 46231, 46233, 46236, 46241, and 46245; 15) Serial numbers: 57054, 57073, 57076, 57077, 57089, 57111, 57116, 57144, 57155, 57156, 57171, and 57189; 16) Serial numbers: 50074, 50079, 50081, 50087, 50093, 50101, 50105, 50120, 50132, 50139, 50142, and 50161; 17) Serial numbers: 40031, 40050, 40061, 40067, and 40071; 18) Serial number: 30005; 19) Serial numbers: 44152, 44157, 44163, 44165, 44171, 44174, 44189, 44190, 44193, 44195, 44198, 44201, 44206, 44215, 44218, 44223, 44224, 44227, 44229, 44242, 44243, 44251, 44254, 44255, 44262, 44263, 44265, 44267, 44268, 44271, 44275, 44277, 44278, 44280, 44282, 44289, 44290, 44292, and 44304; 20) Serial numbers: 64064, 64065, 64067, 64068, 64071, 64074, 64077, 64078, 64081, 64082, 64085, 64087, 64091, 64097, 64103, 64104, 64105, 64111, 64112, 64113, 64114, 64115, 64117, 64118, 64122, 64123, 64138, 64140, 64142, 64145, 64154, 64164, 64166, 64168, 64169, 64170, 64171, 64172, 64177, 64178, 64179, 64180, 64181, 64190, 64194, 64199, 64202, 64212, 64214, 64228, 64231, 64232, 64235, 64236, 64239, 64241, 64243, 64244, 64245, 64246, 64247, 64248, 64253, 64258, and 64259;

4) (1) Serial numbers: 135102, 135109, 135117, 135120, 135122, 135125, and 135143; 2) Serial numbers: 146103, 146104, 146107, 146113, 146116, 146119, 146122, 146123, 146136, 146137, and 146138; 3) Serial numbers: 153101, 153102, 153106, 153107, 153110, 153112, 153113, 153119, 153120, 153122, 153124, 153125, 153128, 153130, 153135, 153141, and 153153; 4) Serial number: 140100; 5) Serial number: 1175 and 1667; 6) Serial number 2145; 7) Serial numbers: 10073, 10305, 10477, and 10488; 8) Serial numbers: 20313, 20321, 20338, and 20348; 9) Serial number: 14112;

10) Serial numbers: 28012, 28033, and 28067; 11) Serial numbers: 32042, 32048, and 32106; 12) Serial numbers: 55070, 55217, 55218, 55219, 55220, 55223, 55228, 55230, 55231, 55232, 55233, 55238, 55241, 55243, 55246, 55249, 55250, 55254, 55256, 55259, 55260, 55262, 55263, 55269, 55273, 55274, 55276, 55277, 55279, 55282, 55284, 55285, 55286, 55287, 55288, 55289, 5292, 55294, 55298, 55299, 55304, 55305, 55306, 55307, 55308, 55310, 55312, 55316, 55318, 55320, 55322, 55325, 55338, 55342, 55343, 55355, 55356, 55358, 55359, 55362, 55365, 55368, 55369, 55374, 55375, 55376, 55377, 55378, 55382, 55384, 55388, 55392, 55394, 55395, 55396, 55399, 55400, 55401, 55404, 55405, 55407, 55408, 55409, 55410, 55411, 55414, 55415, 55416, 55423, 55425, 55426, 55435, 55436, 55438, 55439, 55441, 55443, 55455, 55461, 55462, 55466, 55468, 55470, 55473, and 55513; 13) Serial numbers: 35511, 35516, 35525, 35528, 35529, 35535, 35536, 35538, 35540, 35545, 35556, 35560, 35566, 35571, 35580, 35581, 35599, 35600, 35601, 35603, 35610, 35613, 35623, 35627, 35629, 35634, 35649, 35652, 35655, 35659, 35663, 35664, 35665, 35666, 35672, 35678, 35684, 35690, 35698, 35704, 35707, 35727, 35728, 35730, 35736, 35739, 35741, 35743, 35744, 35745, 35750, 35762, 35768, 35776, 35778, 35782, 35783, 35784, 35787, 35788, 35793, 35802, 35810, 35821, 35828, 35831, 35834, 35836, 35937, and 37713; 14) Serial numbers: 46036, 46071, 46097, 46111, 46112, 46115, 46117, 46118, 46120, 46122, 46125, 46129, 46133, 46134, 46138, 46139, 46143, 46144, 46145, 46146, 46147, 46153, 46156, 46158, 46162, 46163, 46168, 46170, 46171, 46172, 46174, 46178, 46179, 46180, 46186, 46189, 46190, 46194, 46196, 46198, 46201, 46202, 46203, 46205, 46208, 46209, 46210, 46213, 46215, 46216, 46218, 46219, 46220, 46221, 46223, 46224, 46225, 46226, 46229, 46231, 46233, 46236, 46241, and 46245; 15) Serial numbers: 57054, 57073, 57076, 57077, 57089, 57111, 57116, 57144, 57155, 57156, 57171, and 57189; 16) Serial numbers: 50074, 50079, 50081, 50087, 50093, 50101, 50105, 50120, 50132, 50139, 50142, and 50161; 17) Serial numbers: 40031, 40050, 40061, 40067, and 40071; 18) Serial number: 30005; 19) Serial numbers: 44152, 44157, 44163, 44165, 44171, 44174, 44189, 44190, 44193, 44195, 44198, 44201, 44206, 44215, 44218, 44223, 44224, 44227, 44229, 44242, 44243, 44251, 44254, 44255, 44262, 44263, 44265, 44267, 44268, 44271, 44275, 44277, 44278, 44280, 44282, 44289, 44290, 44292, and 44304; 20) Serial numbers: 64064, 64065, 64067, 64068, 64071, 64074, 64077, 64078, 64081, 64082, 64085, 64087, 64091, 64097, 64103, 64104, 64105, 64111, 64112, 64113, 64114, 64115, 64117, 64118, 64122, 64123, 64138, 64140, 64142, 64145, 64154, 64164, 64166, 64168, 64169, 64170, 64171, 64172, 64177, 64178, 64179, 64180, 64181, 64190, 64194, 64199, 64202, 64212, 64214, 64228, 64231, 64232, 64235, 64236, 64239, 64241, 64243, 64244, 64245, 64246, 64247, 64248, 64253, 64258, and 64259;

5) (1) Serial numbers: 135102, 135109, 135117, 135120, 135122, 135125, and 135143; 2) Serial numbers: 146103, 146104, 146107, 146113, 146116, 146119, 146122, 146123, 146136, 146137, and 146138; 3) Serial numbers: 153101, 153102, 153106, 153107, 153110, 153112, 153113, 153119, 153120, 153122, 153124, 153125, 153128, 153130, 153135, 153141, and 153153; 4) Serial number: 140100; 5) Serial number: 1175 and 1667; 6) Serial number 2145; 7) Serial numbers: 10073, 10305, 10477, and 10488; 8) Serial numbers: 20313, 20321, 20338, and 20348; 9) Serial number: 14112; 10) Serial numbers: 28012, 28033, and 28067; 11) Serial numbers: 32042, 32048, and 32106; 12) Serial numbers: 55070, 55217, 55218, 55219, 55220, 55223, 55228, 55230, 55231, 55232, 55233, 55238, 55241, 55243, 55246, 55249, 55250, 55254, 55256, 55259, 55260, 55262, 55263, 55269, 55273, 55274, 55276, 55277, 55279, 55282, 55284, 55285, 55286, 55287, 55288, 55289, 5292, 55294, 55298, 55299, 55304, 55305,

55306, 55307, 55308, 55310, 55312, 55316, 55318, 55320, 55322, 55325, 55338, 55342, 55343, 55355, 55356, 55358, 55359, 55362, 55365, 55368, 55369, 55374, 55375, 55376, 55377, 55378, 55382, 55384, 55388, 55392, 55394, 55395, 55396, 55399, 55400, 55401, 55404, 55405, 55407, 55408, 55409, 55410, 55411, 55414, 55415, 55416, 55423, 55425, 55426, 55435, 55436, 55438, 55439, 55441, 55443, 55455, 55461, 55462, 55466, 55468, 55470, 55473, and 55513; 13) Serial numbers: 35511, 35516, 35525, 35528, 35529, 35535, 35536, 35538, 35540, 35545, 35556, 35560, 35566, 35571, 35580, 35581, 35599, 35600, 35601, 35603, 35610, 35613, 35623, 35627, 35629, 35634, 35649, 35652, 35655, 35659, 35663, 35664, 35665, 35666, 35672, 35678, 35684, 35690, 35698, 35704, 35707, 35727, 35728, 35730, 35736, 35739, 35741, 35743, 35744, 35745, 35750, 35762, 35768, 35776, 35778, 35782, 35783, 35784, 35787, 35788, 35793, 35802, 35810, 35821, 35828, 35831, 35834, 35836, 35937, and 37713; 14) Serial numbers: 46036, 46071, 46097, 46111, 46112, 46115, 46117, 46118, 46120, 46122, 46125, 46129, 46133, 46134, 46138, 46139, 46143, 46144, 46145, 46146, 46147, 46153, 46156, 46158, 46162, 46163, 46168, 46170, 46171, 46172, 46174, 46178, 46179, 46180, 46186, 46189, 46190, 46194, 46196, 46198, 46201, 46202, 46203, 46205, 46208, 46209, 46210, 46213, 46215, 46216, 46218, 46219, 46220, 46221, 46223, 46224, 46225, 46226, 46229, 46231, 46233, 46236, 46241, and 46245; 15) Serial numbers: 57054, 57073, 57076, 57077, 57089, 57111, 57116, 57144, 57155, 57156, 57171, and 57189; 16) Serial numbers: 50074, 50079, 50081, 50087, 50093, 50101, 50105, 50120, 50132, 50139, 50142, and 50161; 17) Serial numbers: 40031, 40050, 40061, 40067, and 40071; 18) Serial number: 30005; 19) Serial numbers: 44152, 44157, 44163, 44165, 44171, 44174, 44189, 44190, 44193, 44195, 44198, 44201, 44206, 44215, 44218, 44223, 44224, 44227, 44229, 44242, 44243, 44251, 44254, 44255, 44262, 44263, 44265, 44267, 44268, 44271, 44275, 44277, 44278, 44280, 44282, 44289, 44290, 44292, and 44304; 20) Serial numbers: 64064, 64065, 64067, 64068, 64071, 64074, 64077, 64078, 64081, 64082, 64085, 64087, 64091, 64097, 64103, 64104, 64105, 64111, 64112, 64113, 64114, 64115, 64117, 64118, 64122, 64123, 64138, 64140, 64142, 64145, 64154, 64164, 64166, 64168, 64169, 64170, 64171, 64172, 64177, 64178, 64179, 64180, 64181, 64190, 64194, 64199, 64202, 64212, 64214, 64228, 64231, 64232, 64235, 64236, 64239, 64241, 64243, 64244, 64245, 64246, 64247, 64248, 64253, 64258, and 64259;

6) (1) Serial numbers: 135102, 135109, 135117, 135120, 135122, 135125, and 135143; 2) Serial numbers: 146103, 146104, 146107, 146113, 146116, 146119, 146122, 146123, 146136, 146137, and 146138; 3) Serial numbers: 153101, 153102, 153106, 153107, 153110, 153112, 153113, 153119, 153120, 153122, 153124, 153125, 153128, 153130, 153135, 153141, and 153153; 4) Serial number: 140100; 5) Serial number: 1175 and 1667; 6) Serial number 2145; 7) Serial numbers: 10073, 10305, 10477, and 10488; 8) Serial numbers: 20313, 20321, 20338, and 20348; 9) Serial number: 14112; 10) Serial numbers: 28012, 28033, and 28067; 11) Serial numbers: 32042, 32048, and 32106; 12) Serial numbers: 55070, 55217, 55218, 55219, 55220, 55223, 55228, 55230, 55231, 55232, 55233, 55238, 55241, 55243, 55246, 55249, 55250, 55254, 55256, 55259, 55260, 55262, 55263, 55269, 55273, 55274, 55276, 55277, 55279, 55282, 55284, 55285, 55286, 55287, 55288, 55289, 5292, 55294, 55298, 55299, 55304, 55305, 55306, 55307, 55308, 55310, 55312, 55316, 55318, 55320, 55322, 55325, 55338, 55342, 55343, 55355, 55356, 55358, 55359, 55362, 55365, 55368, 55369, 55374, 55375, 55376, 55377, 55378, 55382, 55384, 55388, 55392, 55394, 55395, 55396, 55399, 55400, 55401, 55404, 55405, 55407, 55408, 55409, 55410, 55411, 55414, 55415, 55416, 55423, 55425, 55426, 55435, 55436, 55438, 55439, 55441, 55443,

55455, 55461, 55462, 55466, 55468, 55470, 55473, and 55513; 13) Serial numbers: 35511, 35516, 35525, 35528, 35529, 35535, 35536, 35538, 35540, 35545, 35556, 35560, 35566, 35571, 35580, 35581, 35599, 35600, 35601, 35603, 35610, 35613, 35623, 35627, 35629, 35634, 35649, 35652, 35655, 35659, 35663, 35664, 35665, 35666, 35672, 35678, 35684, 35690, 35698, 35704, 35707, 35727, 35728, 35730, 35736, 35739, 35741, 35743, 35744, 35745, 35750, 35762, 35768, 35776, 35778, 35782, 35783, 35784, 35787, 35788, 35793, 35802, 35810, 35821, 35828, 35831, 35834, 35836, 35937, and 37713; 14) Serial numbers: 46036, 46071, 46097, 46111, 46112, 46115, 46117, 46118, 46120, 46122, 46125, 46129, 46133, 46134, 46138, 46139, 46143, 46144, 46145, 46146, 46147, 46153, 46156, 46158, 46162, 46163, 46168, 46170, 46171, 46172, 46174, 46178, 46179, 46180, 46186, 46189, 46190, 46194, 46196, 46198, 46201, 46202, 46203, 46205, 46208, 46209, 46210, 46213, 46215, 46216, 46218, 46219, 46220, 46221, 46223, 46224, 46225, 46226, 46229, 46231, 46233, 46236, 46241, and 46245; 15) Serial numbers: 57054, 57073, 57076, 57077, 57089, 57111, 57116, 57144, 57155, 57156, 57171, and 57189; 16) Serial numbers: 50074, 50079, 50081, 50087, 50093, 50101, 50105, 50120, 50132, 50139, 50142, and 50161; 17) Serial numbers: 40031, 40050, 40061, 40067, and 40071; 18) Serial number: 30005; 19) Serial numbers: 44152, 44157, 44163, 44165, 44171, 44174, 44189, 44190, 44193, 44195, 44198, 44201, 44206, 44215, 44218, 44223, 44224, 44227, 44229, 44242, 44243, 44251, 44254, 44255, 44262, 44263, 44265, 44267, 44268, 44271, 44275, 44277, 44278, 44280, 44282, 44289, 44290, 44292, and 44304; 20) Serial numbers: 64064, 64065, 64067, 64068, 64071, 64074, 64077, 64078, 64081, 64082, 64085, 64087, 64091, 64097, 64103, 64104, 64105, 64111, 64112, 64113, 64114, 64115, 64117, 64118, 64122, 64123, 64138, 64140, 64142, 64145, 64154, 64164, 64166, 64168, 64169, 64170, 64171, 64172, 64177, 64178, 64179, 64180, 64181, 64190, 64194, 64199, 64202, 64212, 64214, 64228, 64231, 64232, 64235, 64236, 64239, 64241, 64243, 64244, 64245, 64246, 64247, 64248, 64253, 64258, and 64259;

7) (1) Serial numbers: 135102, 135109, 135117, 135120, 135122, 135125, and 135143; 2) Serial numbers: 146103, 146104, 146107, 146113, 146116, 146119, 146122, 146123, 146136, 146137, and 146138; 3) Serial numbers: 153101, 153102, 153106, 153107, 153110, 153112, 153113, 153119, 153120, 153122, 153124, 153125, 153128, 153130, 153135, 153141, and 153153; 4) Serial number: 140100; 5) Serial number: 1175 and 1667; 6) Serial number 2145; 7) Serial numbers: 10073, 10305, 10477, and 10488; 8) Serial numbers: 20313, 20321, 20338, and 20348; 9) Serial number: 14112; 10) Serial numbers: 28012, 28033, and 28067; 11) Serial numbers: 32042, 32048, and 32106; 12) Serial numbers: 55070, 55217, 55218, 55219, 55220, 55223, 55228, 55230, 55231, 55232, 55233, 55238, 55241, 55243, 55246, 55249, 55250, 55254, 55256, 55259, 55260, 55262, 55263, 55269, 55273, 55274, 55276, 55277, 55279, 55282, 55284, 55285, 55286, 55287, 55288, 55289, 5292, 55294, 55298, 55299, 55304, 55305, 55306, 55307, 55308, 55310, 55312, 55316, 55318, 55320, 55322, 55325, 55338, 55342, 55343, 55355, 55356, 55358, 55359, 55362, 55365, 55368, 55369, 55374, 55375, 55376, 55377, 55378, 55382, 55384, 55388, 55392, 55394, 55395, 55396, 55399, 55400, 55401, 55404, 55405, 55407, 55408, 55409, 55410, 55411, 55414, 55415, 55416, 55423, 55425, 55426, 55435, 55436, 55438, 55439, 55441, 55443, 55455, 55461, 55462, 55466, 55468, 55470, 55473, and 55513; 13) Serial numbers: 35511, 35516, 35525, 35528, 35529, 35535, 35536, 35538, 35540, 35545, 35556, 35560, 35566, 35571, 35580, 35581, 35599, 35600, 35601, 35603, 35610, 35613, 35623, 35627, 35629, 35634, 35649, 35652, 35655, 35659, 35663, 35664, 35665, 35666, 35672, 35678, 35684, 35690, 35698, 35704, 35707, 35727, 35728, 35730,

35736, 35739, 35741, 35743, 35744, 35745, 35750, 35762, 35768, 35776, 35778, 35782, 35783, 35784, 35787, 35788, 35793, 35802, 35810, 35821, 35828, 35831, 35834, 35836, 35937, and 37713; 14) Serial numbers: 46036, 46071, 46097, 46111, 46112, 46115, 46117, 46118, 46120, 46122, 46125, 46129, 46133, 46134, 46138, 46139, 46143, 46144, 46145, 46146, 46147, 46153, 46156, 46158, 46162, 46163, 46168, 46170, 46171, 46172, 46174, 46178, 46179, 46180, 46186, 46189, 46190, 46194, 46196, 46198, 46201, 46202, 46203, 46205, 46208, 46209, 46210, 46213, 46215, 46216, 46218, 46219, 46220, 46221, 46223, 46224, 46225, 46226, 46229, 46231, 46233, 46236, 46241, and 46245; 15) Serial numbers: 57054, 57073, 57076, 57077, 57089, 57111, 57116, 57144, 57155, 57156, 57171, and 57189; 16) Serial numbers: 50074, 50079, 50081, 50087, 50093, 50101, 50105, 50120, 50132, 50139, 50142, and 50161; 17) Serial numbers: 40031, 40050, 40061, 40067, and 40071; 18) Serial number: 30005; 19) Serial numbers: 44152, 44157, 44163, 44165, 44171, 44174, 44189, 44190, 44193, 44195, 44198, 44201, 44206, 44215, 44218, 44223, 44224, 44227, 44229, 44242, 44243, 44251, 44254, 44255, 44262, 44263, 44265, 44267, 44268, 44271, 44275, 44277, 44278, 44280, 44282, 44289, 44290, 44292, and 44304; 20) Serial numbers: 64064, 64065, 64067, 64068, 64071, 64074, 64077, 64078, 64081, 64082, 64085, 64087, 64091, 64097, 64103, 64104, 64105, 64111, 64112, 64113, 64114, 64115, 64117, 64118, 64122, 64123, 64138, 64140, 64142, 64145, 64154, 64164, 64166, 64168, 64169, 64170, 64171, 64172, 64177, 64178, 64179, 64180, 64181, 64190, 64194, 64199, 64202, 64212, 64214, 64228, 64231, 64232, 64235, 64236, 64239, 64241, 64243, 64244, 64245, 64246, 64247, 64248, 64253, 64258, and 64259

RECALLING FIRM/MANUFACTURER

Recalling Firm: Siemens Medical Solutions USA, Inc, Malvern, PA, by visit beginning May 1, 2009.

Manufacturer: Siemens AG, Medical Solution, Forchheim, Germany. Firm initiated recall is ongoing.

REASON

Improper installation of accessory support arm, which could potentially result in the loosening of the arm over time causing it to fall.

VOLUME OF PRODUCT IN COMMERCE

427 units

DISTRIBUTION

Nationwide

PRODUCT

1) Esteem Blue with Neu Thera Surgeons Glove; a sterile, single use powder-free synthetic polyisoprene surgical glove, latex-free, used as an underglove when double-gloving; 1 pair of gloves per sterile pouch, 200 pairs per case; REF2D73PB55 - size 5-1/2; Made in Thailand. To be worn as an under glove by operating room personnel to protect a surgical wound from contamination in environments within the hospital and other healthcare facilities. The gloves are appropriate for using during invasive as well as non-invasive medical procedures requiring sterility. The Esteem Blue with Neu Thera surgeons glove is worn as an under glove, in conjunction with a primary surgical glove where the primary surgical glove comes into direct contact with the surgical wound. Recall # Z-1445-2009;

2) Esteem Blue with Neu Thera Surgeons Glove; a sterile, single use powder-free synthetic polyisoprene surgical glove, latex-free, used as an underglove when double-gloving; 1 pair of gloves per sterile pouch, 200 pairs per case; REF2D73PB60 - size 6;

Made in Thailand. To be worn as an under glove by operating room personnel to protect a surgical wound from contamination in environments within the hospital and other healthcare facilities. The gloves are appropriate for using during invasive as well as non-invasive medical procedures requiring sterility. The Esteem Blue with Neu Thera surgeons glove is worn as an under glove, in conjunction with a primary surgical glove where the primary surgical glove comes into direct contact with the surgical wound. Recall # Z-1446-2009;

3) Esteem Blue with Neu Thera Surgeons Glove; a sterile, single use powder-free synthetic polyisoprene surgical glove, latex-free, used as an underglove when double-gloving; 1 pair of gloves per sterile pouch, 200 pairs per case; REF2D73PB65 - size 6-1/2; Made in Thailand. To be worn as an under glove by operating room personnel to protect a surgical wound from contamination in environments within the hospital and other healthcare facilities. The gloves are appropriate for using during invasive as well as non-invasive medical procedures requiring sterility. The Esteem Blue with Neu Thera surgeons glove is worn as an under glove, in conjunction with a primary surgical glove where the primary surgical glove comes into direct contact with the surgical wound. Recall # Z-1447-2009;

4) Esteem Blue with Neu Thera Surgeons Glove; a sterile, single use powder-free synthetic polyisoprene surgical glove, latex-free, used as an underglove when double-gloving; 1 pair of gloves per sterile pouch, 200 pairs per case; REF2D73PB70 - size 7; Made in Thailand. To be worn as an under glove by operating room personnel to protect a surgical wound from contamination in environments within the hospital and other healthcare facilities. The gloves are appropriate for using during invasive as well as non-invasive medical procedures requiring sterility. The Esteem Blue with Neu Thera surgeons glove is worn as an under glove, in conjunction with a primary surgical glove where the primary surgical glove comes into direct contact with the surgical wound. Recall # Z-1448-2009;

5) Esteem Blue with Neu Thera Surgeons Glove; a sterile, single use powder-free synthetic polyisoprene surgical glove, latex-free, used as an underglove when double-gloving; 1 pair of gloves per sterile pouch, 200 pairs per case; REF2D73PB75 - size 7-1/2; Made in Thailand. To be worn as an under glove by operating room personnel to protect a surgical wound from contamination in environments within the hospital and other healthcare facilities. The gloves are appropriate for using during invasive as well as non-invasive medical procedures requiring sterility. The Esteem Blue with Neu Thera surgeons glove is worn as an under glove, in conjunction with a primary surgical glove where the primary surgical glove comes into direct contact with the surgical wound. Recall # Z-1449-2009;

6) Esteem Blue with Neu Thera Surgeons Glove; a sterile, single use powder-free synthetic polyisoprene surgical glove, latex-free, used as an underglove when double-gloving; 1 pair of gloves per sterile pouch, 200 pairs per case; REF2D73PB80 - size 8; Catalog #SOP69CAFCD and #SOP69CAFCE; Made in Thailand. One pair of size 8 gloves was included as a component of the following Presource Custom Sterile Surgery Packs: Catalog #SOP69CAFCD - Clovis Dr Simonian Arthroscopy Pack; Catalog #SOP69CAFCE - Clovis Dr Simonian Arthroscopy Pack. The affected glove pouch was located outside of the sterile pack. To be worn as an under glove by operating room personnel to protect a surgical wound from contamination in environments within the hospital and other healthcare facilities. The gloves are appropriate for using during

invasive as well as non-invasive medical procedures requiring sterility. The Esteem Blue with Neu Thera surgeons glove is worn as an under glove, in conjunction with a primary surgical glove where the primary surgical glove comes into direct contact with the surgical wound. Recall # Z-1450-2009;

7) Esteem Blue with Neu Thera Surgeons Glove; a sterile, single use powder-free synthetic polyisoprene surgical glove, latex-free, used as an underglove when double-gloving; 1 pair of gloves per sterile pouch, 200 pairs per case; REF2D73PB85 - size 8-1/2; Made in Thailand. To be worn as an under glove by operating room personnel to protect a surgical wound from contamination in environments within the hospital and other healthcare facilities. The gloves are appropriate for using during invasive as well as non-invasive medical procedures requiring sterility. The Esteem Blue with Neu Thera surgeons glove is worn as an under glove, in conjunction with a primary surgical glove where the primary surgical glove comes into direct contact with the surgical wound. Recall # Z-1451-2009;

8) Esteem Blue with Neu Thera Surgeons Glove; a sterile, single use powder-free synthetic polyisoprene surgical glove, latex-free, used as an underglove when double-gloving; 1 pair of gloves per sterile pouch, 200 pairs per case; REF2D73PB90 - size 9; Made in Thailand. To be worn as an under glove by operating room personnel to protect a surgical wound from contamination in environments within the hospital and other healthcare facilities. The gloves are appropriate for using during invasive as well as non-invasive medical procedures requiring sterility. The Esteem Blue with Neu Thera surgeons glove is worn as an under glove, in conjunction with a primary surgical glove where the primary surgical glove comes into direct contact with the surgical wound. Recall # Z-1452-2009

CODE

1) through 5) Lot numbers TS0409472 through TS09020495;
6) Lot numbers TS0409472 through TS09020495; lots 101333, 996891, 998327; lots 104472, 106543, and 108755;
7) and 8) Lot numbers TS0409472 through TS09020495

RECALLING FIRM/MANUFACTURER

Recalling Firm: Cardinal Health, Mc Gaw Park, IL, by letters dated April 24, 2009. Manufacturer: Cardinal Health 222, Rayong, Thailand. Firm initiated recall is ongoing.

REASON

Increase in the number of customer complaints due to cuff tears.

VOLUME OF PRODUCT IN COMMERCE

29,697 cases

DISTRIBUTION

Nationwide, Australia, Austria, Belgium, France, Germany, Japan, New Zealand, Switzerland, Spain, UK, Netherlands, Norway, Sweden, and Turkey

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PRODUCT

1) Bard E LUMINEXX Biliary Stent, Size: 5mm x 120mm, Product Number: ZBL05120. Recall # Z-1453-2009;

2) Bard E LUMINEXX Biliary Stent, Size: 6mm x 40mm, Product Number: ZBL06040. Recall # Z-1454-2009;

3) Bard E LUMINEXX, Biliary Stent Size: 6mm x 80mm, Product Number: ZBL06080. Recall # Z-1455-2009;

4) Bard E LUMINEXX Biliary Stent, Size: 12mm x 40mm, Product Number: ZBL12040. Recall # Z-1456-2009;

5) Bard E LUMINEXX Biliary Stent, Size: 14mm x 60mm, Product Number: ZBL14060. Recall # Z-1457-2009;

6) Bard E LUMINEXX Biliary Stent,Size: 6mm x 20mm, Product Number: ZBM06020. Bard E LUMINEXX Biliary Stent, Size: 14mm x 60mm, Product Number: ZBL14060. Recall # Z-1458-2009;

7) Bard E LUMINEXX Biliary Stent, Size: 6mm x 30mm, Product Number: ZBM06030. Bard E LUMINEXX Biliary Stent, Size: 14mm x 60mm, Product Number: ZBL14060. Recall # Z-1459-2009;

8) Bard E LUMINEXX Biliary Stent, Size: 6mm x 40mm, Product Number: ZBM06040. Recall # Z-1460-2009;

9) Bard E LUMINEXX Biliary Stent, Size: 6mm x 60mm, Product Number: ZBM06060. Recall # Z-1461-2009;

10) Bard E LUMINEXX Biliary Stent, Size: 6mm x 80mm, Product Number: ZBM06080. Recall # Z-1462-2009;

11) Bard E LUMINEXX Biliary Stent, Size: 12mm x 40mm, Product Number: ZBM12040. Recall # Z-1463-2009;

12) Bard E LUMINEXX Biliary Stent, Size: 12mm x 60mm, Product Number: ZBM12060. Recall # Z-1464-2009;

13) Bard E LUMINEXX Biliary Stent, Size: 12mm x 80mm Product Number: ZBM12080. Recall # Z-1465-2009;

14) Bard E LUMINEXX Biliary Stent, Size: 14mm x 30mm, Product Number: ZBM14030. Recall # Z-1466-2009;

15) Bard E LUMINEXX Biliary Stent, Size: 14mm x 40mm, Product Number: ZBM14040. Recall # Z-1467-2009;

16) Bard E LUMINEXX Biliary Stent, Size 14mm x 60mm, Product Number: ZBM14060. Recall # Z-1468-2009;

17) Bard E LUMINEXX Biliary Stent, Size: 14mm x 80mm, Product Number: ZBM14080. Recall # Z-1469-2009

CODE

1) Lot Number: ANSJ0893;
2) Lot Number: ANSG2329;
3) Lot Number: ANSG2333;
4) Lot Number: ANSH0164;
5) Lot Number: ANSH0165;
6) Lot Number: ANSH0293;

7) Lot Number: ANSG2286;
8) Lot Numbers: ANSH0294 and ANSI0239;
9) Lot Numbers: ANSI0241 and ANSI0978;
10) Lot Number: ANSI0242;
11) Lot Numbers: ANSI0303, ANSI0203, ANSI2432, ANSI2433 and ANSH0220;
12) Lot Numbers: ANSI 0307, ANSI0308, ANSI0310 and ANSI12591;
13) Lot Numbers: ANSH0792 and ANSI0311;
14) Lot Number: ANSG3189;
15) Lot Numbers: ANSI0316, ANSI0968 and ANSI0969;
16) Lot Number: ANSI2596;
17) Lot Number: ANSK0628

RECALLING FIRM/MANUFACTURER

Recalling Firm: Bard Peripheral Vascular, Inc, Tempe, AZ, by letter dated December 22, 2008.

Manufacturer: Angiomed GmbH & Co. Medizintechnik KG, Karlsruhe, Germany. Firm initiated recall is ongoing.

REASON

This action is being taken because a label for an indicated use was applied to product sizes that are not approved for that use. The incorrect indication for use label stated "Now Approved for Vascular Use".

VOLUME OF PRODUCT IN COMMERCE

94 units

DISTRIBUTION

Nationwide

PRODUCT

Boston Scientific Wiseguide Guide Catheter, Sterilized. Wiseguide catheters are intended for use in general intravascular and coronary applications. They provide a pathway through which medical instruments, such as balloon dilatation catheters, guide wires or other therapeutic devices may be introduced. Model Numbers: 8F WG FR3.5, 8F WG FR4, 8F WG FR5, 8F WG FR6, 8F WG FL3, 8F WG FL3.5, 8F WG FL4, 8F WG FL4.5, 8F WG FL5, 8F WG FL6, 8F WG AL1.5 ST, 8F WG AL2 ST, 8F WG AL.75 ST, 8F WG AL1 ST SH, 8F WG AL2 ST SH, 8F WG AL.75 ST SH, 8F WG RC3.5 SC SH, 8F WG IM 110cm, 8F WG AL.75 SH, 8F WG AL4 SH, 8F WG RCB SH, 8F WG IM SH, 8F WG FL3.5 ST SH, 8F WG FL4 ST SH, 8F WG FL4.5 ST SH, 8F WG FL5 ST SH, 8F WG MP1 SH, 8F WG MP HS SH, 8F WG FL4P, 8F WG AR1, 8F WG AR2, 8F WG AL1, 8F WG AL2, 8F WG AL3, 8F WG AL.75, 8F WG AL4, 8F WG VR2, 8F WG RCB, 8F WG VL4 HT, 8F WG VR2 SH, 8F WG LCB, 8F WG VL3 HT SH, 8F WG IM, 8F WG FCL3.5 SH, 8F WG FCL4 SH, 8F WG FCL3.5, 8F WG FCL4, 8F WG FCR4 SH, 8F WG FCR3.5, 8F WG FCR4, 8F WG FL3.5 ST, 8F WG FL4 ST, 8F WG Q3.5, 8F WG Q4, 8F WG Q4.5, 8F WG Q3.5 SH, 8F WG Q4 SH, 8F WG Q4.5 SH, 8F WG FL4.5 ST, 8F WG FL5 ST, 8F WG FR4 90cm, 8F WG MP1, 8F WG RCB 90cm, 8F WG MP2, 8F WG MP HS, 8F WG FR3, 8F WG FR3 SH, 8F WG IM 90cm, 8F WG IM 90cm SH, 8F WG RC4 SC, 8F WG RC4 SC SH, 8F WG RC3.5 SC, 8F WG FR3.5 SH, 8F WG FR4 SH, 8F WG FR5 SH, 8F WG ART3, 8F WG ART3 SH, 8F WG ART3.5, 8F WG ART3.5 SH, 8F WG ART4, 8F WG FR6 SH, 8F WG ART4 SH, 8F WG FL3 SH, 8F WG FR4.5, 8F WG FR4.5 SH, 8F WG FL3.5 SH, 8F WG FL4 SH, 8F WG FL4.5 SH, 8F WG FL5 SH, 8F WG FL6 SH, 8F WG FL4A SH, 8F WG CLS3, 8F WG CLS3.5, 8F WG CLS4, 8F WG CLS4.5, 8F WG CLS3 SH, 8F WG CLS3.5 SH, 8F WG CLS4 SH, 8F WG CLS4.5 SH, 8F WG IMC

90cm, 8F WG AR1 SH, 8F WG AR2 SH, 8F WG AL1 SH, 8F WG AL2 SH, 8F WG AL3 SH, 8F WG VL3, 8F WG VL3.5, 8F WG VL4, 8F WG VL4.5, 8F WG VL3 SH, 8F WG VL3.5 SH, 8F WG VL4 SH, 8F WG VL4.5 SH, 8F WG VL5 SH, 8F WG VL6 SH, 8F WG AL1.5, 8F WG AL1.5 SH, 8F WG FR3.5 ST, 8F WG FR4 ST, 8F WG FR3.5 ST SH, 8F WG FR4 ST SH, 7F WISEGUIDE FR3.5, 7F WISEGUIDE FR4, 7F WISEGUIDE FR5, 7F WISEGUIDE FR6, 7F WISEGUIDE FL3, 7F WISEGUIDE FL3.5, 7F WISEGUIDE FL4, 7F WISEGUIDE FL4.5, 7F WISEGUIDE FL5, 7F WISEGUIDE FL6, 7F WISEGUIDE AL1 ST, 7F WISEGUIDE AL.75 ST, 7F WISEGUIDE AL1 ST SH, 7F WISEGUIDE AL.75 ST SH, 7F WISEGUIDE RC3.5 SC SH, 7F WISEGUIDE IM 85cm, 7F WISEGUIDE IM 110cm, 7F WISEGUIDE AL.75 SH, 7F WISEGUIDE AL4 SH, 7F WISEGUIDE RCB SH, 7F WISEGUIDE LCB SH, 7F WISEGUIDE IM SH, 7F WISEGUIDE MP EL G SH, 7F WISEGUIDE FL3.5 ST SH, 7F WISEGUIDE FL4 ST SH, 7F WISEGUIDE FL4.5 ST SH, 7F WISEGUIDE FL5 ST SH, 7F WISEGUIDE MP1 SH, 7F WISEGUIDE MP2 SH, 7F WISEGUIDE MP HS SH, 7F WISEGUIDE AR1, 7F WISEGUIDE AR2, 7F WISEGUIDE AL1, 7F WISEGUIDE AL2, 7F WISEGUIDE AL3, 7F WISEGUIDE AL.75, 7F WISEGUIDE AL4, 7F WISEGUIDE VL2.5, 7F WISEGUIDE RCB, 7F WISEGUIDE VL3 HT, 7F WISEGUIDE LCB, 7F WISEGUIDE IM, 7F WISEGUIDE FCL3.5 SH, 7F WISEGUIDE FCL4 SH, 7F WISEGUIDE MP EL G, 7F WISEGUIDE FCL4.5 SH, 7F WISEGUIDE FCL3.5, 7F WISEGUIDE FCL4, 7F WISEGUIDE FCL5, 7F WISEGUIDE FCR5 SH, 7F WISEGUIDE FL3.5 ST, 7F WISEGUIDE FCR4, 7F WISEGUIDE FCR5, 7F WISEGUIDE FL4 ST, 7F WISEGUIDE Q3.5, 7F WISEGUIDE Q4, 7F WISEGUIDE Q4.5, 7F WISEGUIDE Q5, 7F WISEGUIDE Q3.5 SH, 7F WISEGUIDE Q4 SH, 7F WISEGUIDE Q4.5 SH, 7F WISEGUIDE FL4.5 ST, 7F WISEGUIDE FL5 ST, 7F WISEGUIDE MP1, 7F WISEGUIDE MP2, 7F WISEGUIDE MP HS, 7F WISEGUIDE FR3, 7F WISEGUIDE FR3 SH, 7F WISEGUIDE IM 90cm, 7F WISEGUIDE IM 90cm SH, 7F WISEGUIDE RC4 SC, 7F WISEGUIDE RC4 SC SH, 7F WISEGUIDE RC3.5 SC, 7F WISEGUIDE FR3.5 SH, 7F WISEGUIDE FR4 SH, 7F WISEGUIDE FR5 SH, 7F WISEGUIDE ART3, 7F WISEGUIDE ART3 SH, 7F WISEGUIDE ART3.5, 7F WISEGUIDE ART3.5 SH, 7F WISEGUIDE FR6 SH, 7F WISEGUIDE ART4, 7F WISEGUIDE ART4 SH, 7F WISEGUIDE ART4.5, 7F WISEGUIDE ART4.5 SH, WISEGUIDE FL3 SH, 7F WISEGUIDE FR4.5, 7F WISEGUIDE FR4.5 SH, 7F WISEGUIDE FL3.5 SH, 7F WISEGUIDE FL4 SH, 7F WISEGUIDE FL5 SH, 7F WISEGUIDE FL6 SH, 7F WISEGUIDE CLS3, 7F WISEGUIDE CLS3.5, 7F WISEGUIDE CLS4, 7F WISEGUIDE CLS4.5, 7F WISEGUIDE CLS3 SH, 7F WISEGUIDE CLS3.5 SH, 7F WISEGUIDE IMC 90cm, 7F WISEGUIDE AR1 SH, 7F WISEGUIDE AR2 SH, 7F WISEGUIDE AL1 SH, 7F WISEGUIDE AL2 SH, 7F WISEGUIDE AL3 SH, 7F WISEGUIDE VL3, 7F WISEGUIDE VL3.5, 7F WISEGUIDE VL4, 7F WISEGUIDE VL4.5, 7F WISEGUIDE VL5, 7F WISEGUIDE VL6, 7F WISEGUIDE VL3 SH, 7F WISEGUIDE VL3.5 SH, 7F WISEGUIDE VL4 SH, 7F WISEGUIDE AL1.5, 7F WISEGUIDE AL1.5 SH, 7F WISEGUIDE FR3.5 ST, 7F WISEGUIDE FR4 ST, 7F WISEGUIDE FR4 ST SH, 6F WISEGUIDE FR3.5, 6F WISEGUIDE FR4, 6F WISEGUIDE FR5, 6F WISEGUIDE FR6, 6F WISEGUIDE FL3, 6F WISEGUIDE FL3.5, 6F WISEGUIDE FL4, 6F WISEGUIDE FL4.5, 6F WISEGUIDE FL5, 6F WISEGUIDE FL6, 6F WISEGUIDE IM 85cm, 6F WISEGUIDE RCB SH, 6F WISEGUIDE LCB SH, 6F WISEGUIDE IM SH, 6F WISEGUIDE MP1 SH, 6F WISEGUIDE MP HS SH, 6F WISEGUIDE AR1, 6F WISEGUIDE AR2, 6F WISEGUIDE AL1, 6F WISEGUIDE AL2, 6F WISEGUIDE AL3, 6F WISEGUIDE AL.75, 6F WISEGUIDE AL4, 6F WISEGUIDE VR1, 6F WISEGUIDE VR2, 6F WISEGUIDE RCB, 6F WISEGUIDE VL3.5 HT, 6F WISEGUIDE VL4 HT, 6F WISEGUIDE LCB 6F WISEGUIDE IM, 6F WISEGUIDE FCL3.5, 6F WISEGUIDE FCL4, 6F WISEGUIDE FCL4.5, 6F WISEGUIDE FCR3.5, 6F WISEGUIDE FL4 ST, 6F WISEGUIDE Q3.5, 6F

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CODE

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RECALLING FIRM/MANUFACTURER

Recalling Firm: Boston Scientific Corporation, Maple Grove, MN, by letter dated March 11, 2009.

Manufacturer: Pacific Device De Mexico S A De C V, Tijuana B C Mex, Mexico. Firm initiated recall is ongoing.

REASON

Boston Scientific has initiated a recall of the Wiseguide Guide Catheter. They have received reports of difficulties in connecting the product hubs with the Y-Adaptors and toughy borst connectors. If there is difficulty making such connection, there is a potential for prolongation or delay of the procedure in order to exchange the catheter or connector.

VOLUME OF PRODUCT IN COMMERCE

34,036 units

DISTRIBUTION

Nationwide and United Arab Emirates, Dutch Antilles, Argentina, Austria, Belgium, Brazil, Canada, Switzerland, Chile, Colombia, Czech Republic, Germany, Algeria, Egypt, Spain, Finland, France, Great Britain, India, Indonesia, Ireland, Iraq, Italy, Jamaica, Japan, Kuwait, Sri Lanka, Libya, Netherlands, Norway, Poland, Puerto Rico, Qatar, Saudi Arabia, Sweden, Singapore, Syria, Turkey and South Africa

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PRODUCT

1) ReSolve Halo - Open Back Halo Ring, Model Number: 505300D The ReSolve Halo Ring is a fixation device used to immobilize a patient with a cervical spine injury. Recall # Z-1507-2009;

2) ReSolve Halo - Open Back Halo Ring, Model Number: 505400D The ReSolve Halo Ring is a fixation device used to immobilize a patient with a cervical spine injury. Recall # Z-1508-2009;

3) ReSolve Halo - Open Back Halo Ring, Model Number: 510400D The ReSolve Halo Ring is a fixation device used to immobilize a patient with a cervical spine injury. Recall # Recall # Z-1509-2009

CODE

1) Lot Number: 08032014;

2) Lot Numbers: 08033120, 08040201, 08050204, 08051414, 08060514, 08070706, 08080710, 08091521, 08093027, and 08102723;

3) Lot Number: 08052718

RECALLING FIRM/MANUFACTURER

Ossur Engineering, Inc, Albion, MI, by telephone beginning on November 10, 2008 and by letter beginning on November 12, 2008. Firm initiated recall is complete.

REASON

Ossur initiated the recall after their investigation of some complaints found that in some instances the ceramic pins are difficult to screw through the halo ring

VOLUME OF PRODUCT IN COMMERCE

92 rings

DISTRIBUTION

CA, GA, FL, MD, MI, MO, & WA and countries of Australia, Cyprus, Germany, Italy, Kuwait, Saudi Arabia, Singapore, South Africa, Spain, United Arab Emirates, and the United Kingdom

RECALLS AND FIELD CORRECTIONS: DEVICES - CLASS III

PRODUCT

1) i-STAT EG7+ Cartridge; pH, PCO, PO, Na , K, iCa, Hct. Test include: Electrode Measurement Blood-Gases (Pco2, PO2) and Blood Ph, Electrode, Ion Specific,

Potassium, Electrode, Ion Specific, Calcium, Electrode, ion Specific, Sodium and Hematocrit. Catalog number 220300. Intended use is to quantify measurement of sodium, potassium, ionized calcium, oxygen, carbon dioxide, pH and Hematocrit in blood.
Z-1540-2009;

2) i-STAT G3+ Cartridge; pH, PCO, PO. HCO2, TCO2, BE sO2; Test includes: PCO2 for calculated HCO3 and PO2 for calculated oxygen saturated/sO2. Catalog Number 220100. The iSTAT G3+ Cartridge is intended to be used to quantitatively measure oxygen, carbon dioxide, and pH. Recall # Z-1541-2009

CODE

1) Lot number P08274A, Box numbers: 0822, 0823, 0824, 0831, 0832, 0833, 0834, 0841, 0842, 0843, 0844, 0851, 0852, 0853, 0854, 0861, 0862, 0863, 0864, 0871, 0872, 0873, and 0874;

2) Lot P08321C, Abbott List number 06F03-01 (USA and Canada), Abbott List Number (rest of world) 06F03-02; Box numbers 1491 and 1534

RECALLING FIRM/MANUFACTURER

Abbott Point of Care, Inc, East Windsor, NJ, by letters on February 23, 2009 and letters dated May 2009. Firm initiated recall is ongoing.

REASON

Equipment problem: i-STAT cartridges were not properly sealed as the packaging system jammed, causing compromised seals.

VOLUME OF PRODUCT IN COMMERCE

26,200 cartridges or 23 boxes of EG7+ cartridge; 28,400 cartridges or 1136 boxes of G3+ cartridges

DISTRIBUTION

Nationwide, Austria, China, India, Saudi Arabia, South Africa, and Taiwan

RECALLS AND FIELD CORRECTIONS: VETERINARY - CLASS I

PRODUCT

Fifty pound bags of "45/120 Grower T40 Medicated" White label attached to bag reads "45/120 Grower T40 Medicated For Growing Swine For increased rate of weight gain and improved efficiency. ACTIVE DRUG INGREDIENT Tylosis....40 g/ton" Brown bag says PROFITABLE NUTRITION PAYBACK SWINE." Recall # V-135-2009

CODE

Lot number: M419380 dated 11/25/08

RECALLING FIRM/MANUFACTURER

CHS Nutrition, Hermiston, OR, by letter dated January 28, 2009 and press release dated January 29, 2009. Firm initiated recall is complete.

REASON

The feed contains levels of selenium which may be toxic when consumed. May cause illness or death.

VOLUME OF PRODUCT IN COMMERCE

410/50 lb bags

DISTRIBUTION

WA, OR

END OF ENFORCEMENT REPORT FOR JUNE 24, 2009

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RSS Feed for FDA Enforcement Report
(http://www.fda.gov/AboutFDA/ContactFDA/StayInformed/RSSFeeds/EnforcementReports/rss.xml)
What Is RSS? (http://www.fda.gov/AboutFDA/ContactFDA/StayInformed/RSSFeeds/ucm144575.htm)