Enforcement Report - Week of June 1, 2016

Biologics | Cosmetics | Devices | Drugs | Food | Tobacco | Veterinary

Class I Drugs Event

Event ID:
71401
Product Type:
Drugs

Status:
Ongoing
Recalling Firm:
Centro Naturista
14211 Coit Rd Ste H
Dallas TX United States
Recall Initiation Date:
06/03/2015
Center Classification Date:
05/26/2016
Date Terminated:

Voluntary / Mandated:
Voluntary: Firm Initiated
Initial Firm Notification of Consignee or Public:
Press Release
Distribution Pattern:
Nationwide

Associated Products

Product Description:
Smart Lipo Dietary Supplement capsules, 800 mg, packaged in 30-count plastic bottle, Distributed by: SmartLipo365, Arlington, TX 76011

Product Quantity:
Unknown
Code Information:
All lots

Reason for Recall:
Marketed without an approved NDA/ANDA - Product contains undeclared sibutramine, desmethylsibutramine and phenolphthalein.
Recall Number:
D-0877-2016

Product Description:
Smart Lipo Dietary Supplement capsules, 900 mg, packaged in 30-

Reason for Recall:
Marketed without an approved NDA/ANDA - Product contains

count plastic bottle, Distributed by: SmartLipo365, Arlington, TX 76011

Product Quantity:
Unknown
Code Information:
All lots

undeclared sibutramine, desmethylsibutramine and phenolphthalein.
Recall Number:
D-0878-2016

Class I Drugs Event

Event ID:
72269
Product Type:
Drugs

Status:
Ongoing
Recalling Firm:
Lucy's Weight Loss (dba. Waisted With Lucy)
813 Oram St
Arlington TX United States
Recall Initiation Date:
09/23/2015
Center Classification Date:
05/26/2016
Date Terminated:

Voluntary / Mandated:
Voluntary: Firm Initiated
Initial Firm Notification of Consignee or Public:
Press Release
Distribution Pattern:
Nationwide

Associated Products

Product Description:
Pink Bikini Strong Formula capsules, 750 mg, packaged in 30-count plastic bottle, Manufactured and Distributed by: Lucy's Weight Loss System, Arlington, Texas 76010
Product Quantity:
Unknown
Code Information:
All lots

Reason for Recall:
Marketed without an approved NDA/ANDA: Product contains undeclared sibutramine and phenolphthalein.

Recall Number:
D-0879-2016

Product Description:

Reason for Recall:

Shorts on The Beach Strong Formula by Pink Bikini capsules, 750 mg, packaged in 30-count plastic bottle, Manufactured and Distributed by: Lucy's Weight Loss System, Arlington, Texas 76010

Product Quantity:
Unknown

Code Information:
All lots

Reason for Recall:
Marketed without an approved NDA/ANDA: Product contains undeclared sibutramine and phenolphthalein.

Recall Number:
D-0880-2016

Product Description:
Shorts on The Beach Golden Edition by Pink Bikini, 800 mg, packaged in 30-count plastic bottle, Manufactured and Distributed by: Lucy's Weight Loss System, Arlington, Texas 76010

Product Quantity:

Code Information:
All lots

Reason for Recall:
Marketed without an approved NDA/ANDA: Product contains undeclared sibutramine and phenolphthalein.

Recall Number:
D-0881-2016

Class I Drugs Event

Event ID:
72527

Product Type:
Drugs

Status:
Ongoing

Recalling Firm:
Sanofi-Aventis U.S. LLC
55 Corporate Dr
Bridgewater NJ United States

Recall Initiation Date:
10/28/2015

Center Classification Date:
05/25/2016

Date Terminated:

Voluntary / Mandated:
Voluntary: Firm Initiated

Initial Firm Notification of Consignee or Public:
Press Release

Distribution Pattern:
Nationwide

Associated Products

Product Description:
Auvi-Q (epinephrine injection, USP) Auto-Injector, 0.3 mg (a) 2 prefilled auto injectors + 1 trainer (NDC 0025-5833-02) and (b) 1 prefilled auto injector + 1 trainer (NDC 0024-5833-00), Rx Only, Manufactured for Sanofi-Aventis US, LLC Bridgewater, NJ 08807 A Sanofi Company

Reason for Recall:
Defective Delivery System; potential to have inaccurate dosage delivery

Product Quantity:
383,900 prefilled syringes

Recall Number:
D-0872-2016

Code Information:
a) 2081278, 2113841, 2113842, 2144138, exp 10/2015; 2440675, exp 04/2016; 2506456, 2506460, 2546946, 2546947, exp 05/2016; 2620206, 2620207, 2659534, exp 06/2016; 2692111, 2692112, exp 07/2016; 2716517, 2719817, 2734079, 2734080, 2734081, 2778035, 2800128, exp 08/2016; 2800130, 2824828, 2824829, 2857516, 2867928, 2870928, 2867929, 2867930, 2883616, 2883617, exp 09/2016; 2883618, 2883619, 2974267, 2883620, 2945419, 2974269, exp 10/2016; 3026968, 3026969, exp 11/2016; 3026970, 3028227, 3032005, 3037217, 3037218, 3037219, exp 12/2016; b) 2299596, 03/2016

Product Description:
Auvi-Q (epinephrine injection, USP) Auto-Injector, 0.15 mg (a) 2 prefilled auto injectors + 1 trainer (NDC 0024-5831-02) and (b) 1 prefilled auto injector + 1 trainer (NDC 0024-5831-00), Rx Only, Manufactured for Sanofi-Aventis US, LLC Bridgewater, NJ 08807 A Sanofi Company

Reason for Recall:
Defective Delivery System; potential to have inaccurate dosage delivery

Product Quantity:
159,000 prefilled injectors

Recall Number:
D-0873-2016

Code Information:

a) 2144144, exp 10/2015; 2469674, exp 04/2016; 2506492, 2546978, 2546979, exp 05/2016; 2654817, 2654818, exp 06/2016; 2692143, 2692144, exp 07/2016; 2719838, exp 08/2016; 2824845, 2891021, 2857530, exp 09/2016; 2883631, 2883632, exp 10/2016; 2883633, 2945429, 3028243, exp 11/2016; 3037230, 2966680, 2974276, 2974280, exp 12/2016; and
b) 2525474, exp 05/2016

Class I Drugs Event

Event ID:
72782
Product Type:
Drugs

Status:
Ongoing
Recalling Firm:
Lipo Escultura Corp.
888 Wyckoff Ave
Brooklyn NY United States
Recall Initiation Date:
12/03/2015
Center Classification Date:
05/23/2016
Date Terminated:

Voluntary / Mandated:
Voluntary: Firm Initiated
Initial Firm Notification of Consignee or Public:
Press Release
Distribution Pattern:
Nationwide via Internet sales

Associated Products

Product Description:
LIPO ESCULTURA capsules, 250 mg, 60-count bottles, Distributed By: JAT Productos Naturales Corp., BROOKLYN, NY 11238, www.lipoesculturatreatment.com

Reason for Recall:
Marketed Without An Approved NDA/ANDA: Tainted product marketed as a dietary supplement. Product found to be tainted with sibutramine, an appetite suppressant that was withdrawn from the U.S. market in October 2010 for safety reasons, and diclofenac, a prescription non-steroidal anti-inflammatory drug, making this an

unapproved drug.

Product Quantity:
unknown
Code Information:
All lots

Recall Number:
D-0860-2016

Class I Drugs Event

Event ID:
72820
Product Type:
Drugs

Status:
Ongoing
Recalling Firm:
Lucy's Weight Loss (dba. Waisted With Lucy)
813 Oram St
Arlington TX United States
Recall Initiation Date:
12/09/2015
Center Classification Date:
05/26/2016
Date Terminated:

Voluntary / Mandated:
Voluntary: Firm Initiated
Initial Firm Notification of Consignee or Public:
Press Release
Distribution Pattern:
Nationwide

Associated Products

Product Description:
Pink Bikini capsules, (all colors and all strengths), packaged in 30-count bottle, Manufactured and Distributed by: Lucy's Weight Loss System (dba Waisted With Lucy), Arlington, TX 76010
Product Quantity:
Unknown
Code Information:
All lots, all colors and all strengths

Reason for Recall:
Marketed without an approved NDA/ANDA: Product contains undeclared Sibutramine, Phenolphthalein and/or Diclofenac.

Recall Number:
D-0882-2016

Product Description:
Shorts on the Beach capsules, (all

Reason for Recall:
Marketed without an approved

colors and all strengths), packaged in 30-count bottle, Manufactured and Distributed by: Lucy's Weight Loss System (dba Waisted With Lucy), Arlington, TX 76010

Product Quantity:
Unknown

Code Information:
All lots, all colors and all strengths

NDA/ANDA: Product contains undeclared Sibutramine, Phenolphthalein and/or Diclofenac.

Recall Number:
D-0883-2016

Class I Drugs Event

Event ID:
73018

Product Type:
Drugs

Status:
Ongoing

Recalling Firm:
R Thomas Marketing, LLC
3704 White Plains Rd
Bronx NY United States

Recall Initiation Date:
01/09/2016

Center Classification Date:
05/26/2016

Date Terminated:

Voluntary / Mandated:
Voluntary: Firm Initiated

Initial Firm Notification of Consignee or Public:
Press Release

Distribution Pattern:
Nationwide via Internet sales

Associated Products

Product Description:
Black Ant, packaged in Big Box (20 small boxes / 4 capsules per box / 80 capsules total), Distributed by: R Thomas Marketing, LLC, Bronx, NY 10467

Product Quantity:
unknown

Code Information:
all lots

Reason for Recall:
Marketed Without An Approved NDA/ANDA

Recall Number:
D-0884-2016

Product Description:
Black Ant, packaged in Big Box (20 small boxes / 4 capsules per box / 80 capsules total), Distributed by: R Thomas Marketing, LLC, Bronx, NY 10467

Reason for Recall:
Marketed Without An Approved NDA/ANDA

Product Quantity:
unknown

Recall Number:
D-0885-2016

Code Information:
all lots

Product Description:
Real Skill, packaged in 20 small boxes / 4 capsules per box / 80 capsules total, Distributed by: R Thomas Marketing, LLC, Bronx, NY 10467

Reason for Recall:
Marketed Without An Approved NDA/ANDA

Product Quantity:
unknown

Recall Number:
D-0886-2016

Code Information:
all lots

Product Description:
Stree Overlord, packaged in 10 small boxes / 1 capsule per box, Distributed by: R Thomas Marketing, LLC, Bronx, NY 10467

Reason for Recall:
Marketed Without An Approved NDA/ANDA

Product Quantity:
unknown

Recall Number:
D-0887-2016

Code Information:
all lots

Product Description:
Weekend Prince, packaged in 24 individual cards / 2 capsules per card/ 48 capsules total, Distributed by: R Thomas Marketing, LLC, Bronx, NY 10467

Reason for Recall:
Marketed Without An Approved NDA/ANDA

Product Quantity:
unknown

Recall Number:
D-0888-2016

Code Information:
all lots

Product Description:
African Black Ant, packaged in 8 small boxes / 6 capsules per box / 48 capsules total, Distributed by: R Thomas Marketing, LLC, Bronx, NY 10467

Reason for Recall:
Marketed Without An Approved NDA/ANDA

Product Quantity:
unknown

Recall Number:
D-0889-2016

Code Information:
all lots

Product Description:
Bull, packaged in CASE (10 packs / 3 capsules per can / 30 capsules), Distributed by: R Thomas Marketing, LLC, Bronx, NY 10467

Reason for Recall:
Marketed Without An Approved NDA/ANDA

Product Quantity:
unknown

Recall Number:
D-0890-2016

Code Information:
all lots

Product Description:
Bull's Genital, packaged in CASE (10 Cans / 10 capsules per can / 100 capsules),Distributed by: R Thomas Marketing, LLC, Bronx, NY 10467

Reason for Recall:
Marketed Without An Approved NDA/ANDA

Product Quantity:
unknown

Recall Number:
D-0891-2016

Code Information:
all lots

Product Description:
Zhong Hua Niu Bian, packaged in BIG BOX (6 small boxes / 6 capsules per box / 36 capsules), Distributed by: R Thomas Marketing, LLC, Bronx, NY 10467

Reason for Recall:
Marketed Without An Approved NDA/ANDA

Product Quantity:
unknown

Recall Number:
D-0892-2016

Code Information:
all lots

Product Description:
African Superman, packaged in BIG BOX (6 small boxes / 8 capsules per box / 48 capsules), Distributed by: R Thomas Marketing, LLC, Bronx, NY 10467

Reason for Recall:
Marketed Without An Approved NDA/ANDA

Product Quantity:
unknown

Recall Number:
D-0893-2016

Code Information:
all lots

Product Description:
Bigger Longer More Time More Sperms, packaged in BIG BOX (6 small boxes / 6 capsules per small box / 36 capsules), Distributed by: R Thomas Marketing, LLC, Bronx, NY 10467

Reason for Recall:
Marketed Without An Approved NDA/ANDA

Product Quantity:
unknown

Recall Number:
D-0894-2016

Code Information:
all lots

Product Description:
Black Ant King, packaged in BIG BOX (10 capsules / can / 12 cans per box / 120 capsules), Distributed by: R Thomas Marketing, LLC, Bronx, NY 10467

Reason for Recall:
Marketed Without An Approved NDA/ANDA

Product Quantity:
unknown

Recall Number:
D-0895-2016

Code Information:
all lots

Product Description:
Black Storm, packaged in SMALL BOX (6 capsules), Distributed by: R Thomas Marketing, LLC, Bronx, NY 10467

Reason for Recall:
Marketed Without An Approved NDA/ANDA

Product Quantity:
unknown

Recall Number:
D-0896-2016

Code Information:
all lots

Product Description:
Germany Niubian, packaged in BIG BOX (10 small boxes / 24 capsules per box / 240 capsules), Distributed by: R Thomas Marketing, LLC, Bronx, NY 10467

Reason for Recall:
Marketed Without An Approved NDA/ANDA

Product Quantity:
unknown

Recall Number:
D-0897-2016

Code Information:
all lots

Product Description:
Happy Passengers, packaged in BIG BOX (30 small boxes / 1 capsule per box / 30 capsules), Distributed by: R Thomas Marketing, LLC, Bronx, NY 10467

Reason for Recall:
Marketed Without An Approved NDA/ANDA

Product Quantity:
unknown

Recall Number:
D-0898-2016

Code Information:
all lots

Product Description:
Plant Vigra, packaged in BIG BOX / (18 cans / 6 capsules per can / 108 capsules), Distributed by: R Thomas Marketing, LLC, Bronx, NY 10467

Reason for Recall:
Marketed Without An Approved NDA/ANDA

Product Quantity:
unknown

Recall Number:
D-0899-2016

Code Information:
all lots

Product Description:
Hard Ten Days, packaged in BIG BOX (6 small boxes / 6 capsules per box / 36 capsules), Distributed by: R Thomas Marketing, LLC, Bronx, NY 10467

Reason for Recall:
Marketed Without An Approved NDA/ANDA

Product Quantity:
unknown

Recall Number:
D-0900-2016

Code Information:

all lots

Product Description:
Man King, packaged in BIG BOX (8 small boxes / 5 capsules per box / 40 capsules), Distributed by: R Thomas Marketing, LLC, Bronx, NY 10467

Reason for Recall:
Marketed Without An Approved NDA/ANDA

Product Quantity:
unknown

Recall Number:
D-0901-2016

Code Information:
all lots

Product Description:
Mojo Risen, packaged in BIG BOX (24 individual cards / 2 capsules per card/ 48 capsules), Distributed by: R Thomas Marketing, LLC, Bronx, NY 10467

Reason for Recall:
Marketed Without An Approved NDA/ANDA

Product Quantity:
unknown

Recall Number:
D-0902-2016

Code Information:
all lots

Product Description:
Night Man, packaged in SMALL BOX (6 capsules), Distributed by: R Thomas Marketing, LLC, Bronx, NY 10467

Reason for Recall:
Marketed Without An Approved NDA/ANDA

Product Quantity:
unknown

Recall Number:
D-0903-2016

Code Information:
all lots

Product Description:
Tiger King, packaged in BIG BOX (10 small bottles / 10 capsules per bottle / 100 capsules), Distributed by: R Thomas Marketing, LLC, Bronx, NY 10467

Reason for Recall:
Marketed Without An Approved NDA/ANDA

Product Quantity:
unknown

Recall Number:
D-0904-2016

Code Information:
all lots

Product Description:
Samurai-X, packaged in BIG BOX (24 individually wrapped capsules), Distributed by: R Thomas Marketing, LLC, Bronx, NY 10467
Product Quantity:
unknown
Code Information:
all lots

Reason for Recall:
Marketed Without An Approved NDA/ANDA

Recall Number:
D-0905-2016

Product Description:
Super Hard, packaged in BIG BOX (20 small boxes / 6 capsules per box / 120 capsules), Distributed by: R Thomas Marketing, LLC, Bronx, NY 10467
Product Quantity:
unknown
Code Information:
all lots

Reason for Recall:
Marketed Without An Approved NDA/ANDA

Recall Number:
D-0906-2016

Product Description:
Zhen Gong Fu, packaged in BIG BOX (16 small boxes / 2 capsules per box / 32 capsules), Distributed by: R Thomas Marketing, LLC, Bronx, NY 10467
Product Quantity:
unknown
Code Information:
all lots

Reason for Recall:
Marketed Without An Approved NDA/ANDA

Recall Number:
D-0907-2016

Class I Drugs Event

Event ID:
73102
Product Type:
Drugs

Status:
Ongoing

Voluntary / Mandated:
Voluntary: Firm Initiated
Initial Firm Notification of Consignee or Public:
Press Release
Distribution Pattern:
Nationwide

Recalling Firm:
Master Herbs, Inc./Li
1452 W Holt Ave
Pomona CA United States
Recall Initiation Date:
01/15/2016
Center Classification Date:
05/26/2016
Date Terminated:

Associated Products

Product Description:
Licorice Coughing Liquid (guaifenesin), 5%, 3.38 fl. oz. (100 ml), OTC, Manufactured by: Ma Ying Long Pharmaceutical Group Co., LTD, Wuhan, China; Distributed by: Master Herbs (USA) Inc., NDC 68511-0460-01
Product Quantity:
6024 bottles
Code Information:
all lots

Reason for Recall:
Marketed Without An Approved NDA/ANDA: presence of undeclared morphine.

Recall Number:
D-0908-2016

Class I Drugs Event

Event ID:
73118
Product Type:
Drugs

Status:
Ongoing
Recalling Firm:
Baxter Healthcare Corp.
1 Baxter Pkwy
Deerfield IL United States
Recall Initiation Date:
01/21/2016
Center Classification Date:
05/23/2016
Date Terminated:

Voluntary / Mandated:
Voluntary: Firm Initiated
Initial Firm Notification of Consignee or Public:
Letter
Distribution Pattern:
Nationwide and Puerto Rico

Associated Products

Product Description:
0.9% Sodium Chloride Injection USP, MINI-BAG Plus Container, 100 mL VIAFLEX Single Dose Container bags, Rx only, Baxter Healthcare Corporation, Deerfield, IL 60015, Product Code 2B0043, NDC 0338-0553-18.

Reason for Recall:
Presence of Particulate Matter: identified as cardboard.

Product Quantity:
273,520 bags

Recall Number:
D-0862-2016

Code Information:
Lot #: P328997, Exp 01/31/2016

Product Description:
Metronidazole Injection USP, 500 mg per 100 mL (5 mg/mL), 100mL Sterile Single Dose Container bag, Rx only, Baxter USA, Product Code 2B3421, NDC 0338-1055-48.

Reason for Recall:
Presence of Particulate Matter: identified as a cloth fiber.

Product Quantity:
334,560 bags

Recall Number:
D-0863-2016

Code Information:
Lot #: P339135, Exp 08/31/2017

Product Description:
CLINIMIX E 5/15 sulfite-free (5% Amino Acid with Electrolytes in 15% Dextrose with Calcium) Injection, 1000 mL Injection Port Chamber 30% Dextrose Injection with Calcium, 1000 mL Outlet Port Chamber 10% Amino Acid Injection with Electrolytes, 2000 mL CLARITY Dual Chamber Container bag, Rx only, Baxter Healthcare Corporation, Deerfield, IL 60015, Product Code 2B7721, NDC 0338-1123-04.

Reason for Recall:
Presence of Particulate Matter: identified as dried skin.

Product Quantity:
7,436 bags

Recall Number:
D-0864-2016

Code Information:
Lot #: P333930, Exp 05/31/2017

Class I Drugs Event

Event ID:
73297
Product Type:
Drugs

Status:
Ongoing
Recalling Firm:
Pharmakon Pharmaceuticals
14450 Getz Rd
Noblesville IN United States
Recall Initiation Date:
02/11/2016
Center Classification Date:
05/25/2016
Date Terminated:

Voluntary / Mandated:
Voluntary: Firm Initiated
Initial Firm Notification of Consignee or Public:
Telephone
Distribution Pattern:
IN and IL

Associated Products

Product Description:
Morphine Sulfate 0.5 mg/mL, Preservative Free in 0.9% Sodium Chloride, Rx, total volume 1 mL, This is a compounded drug, CII, IV Use, syringe, Pharmakon Pharmaceuticals, NDC 45183-0322-78.
Product Quantity:
75 Syringes
Code Information:
Lot #: E52418EV11C, Exp 03/19/2016

Reason for Recall:
Super-Potent Drug: Out of specification for potency results (high) were obtained for one lot of morphine sulfate Inj.

Recall Number:
D-0871-2016

Class I Drugs Event

Event ID:
73361
Product Type:
Drugs

Voluntary / Mandated:
Voluntary: Firm Initiated
Initial Firm Notification of Consignee or Public:
Two or more of the following: Email, Fax, Letter, Press Release, Telephone, Visit

Status:
Ongoing
Recalling Firm:
Super Herbs
10740 Sw 222nd Dr
Miami FL United States
Recall Initiation Date:
11/23/2015
Center Classification Date:
05/26/2016
Date Terminated:

Distribution Pattern:
9 consignees - only 9 bottles distributed

Associated Products

Product Description:
SUPER HERBS 350 mg, 30 capsules per bottle.

Product Quantity:
9 bottles
Code Information:
All lots

Reason for Recall:
Marketed without an approved NDA/ANDA - presence of undeclared sibutramine, desmethylsibutramine (an active metabolite of sibutramine) and/or phenolphthalein.
Recall Number:
D-0909-2016

Class I Drugs Event

Event ID:
73455
Product Type:
Drugs

Status:
Ongoing
Recalling Firm:
Teva Pharmaceuticals USA
1090 Horsham Rd
North Wales PA United States
Recall Initiation Date:
03/09/2016
Center Classification Date:
05/23/2016
Date Terminated:

Voluntary / Mandated:
Voluntary: Firm Initiated
Initial Firm Notification of Consignee or Public:
Letter
Distribution Pattern:
Nationwide and Puerto Rico

Associated Products

Product Description:
Amikacin Sulfate injection USP,1 gm/4 mL (250 mg/mL) 4mL vial, Rx only, Manufactured in Hungary For: Teva Pharmaceuticals USA, INC. North Wales, PA 19454. Individual Pack NDC 0703-9040-01, Shelf Pack NDC 0703-9040-03

Reason for Recall:
Presence of Particulate Matter: particulate matter identified as glass in one vial.

Product Quantity:
6,291 units

Recall Number:
D-0859-2016

Code Information:
Lot #: 4750915, Exp 9/2017

Class I Drugs Event

Event ID:
73560

Voluntary / Mandated:
Voluntary: Firm Initiated

Product Type:
Drugs

Initial Firm Notification of Consignee or Public:
Two or more of the following: Email, Fax, Letter, Press Release, Telephone, Visit

Status:
Ongoing

Distribution Pattern:
Nationwide

Recalling Firm:
Pacifico National, Inc. dba AmEx Pharmacy
1515 Elizabeth St Ste J
Melbourne FL United States

Recall Initiation Date:
01/20/2015

Center Classification Date:
05/25/2016

Date Terminated:

Associated Products

Product Description:
Avastin (Bevacizumab) 2 mg/0.08 mL syringe, Office Administration Only,

Reason for Recall:
Non-Sterility: Product tested positive for bacterial contamination.

AmEx Pharmacy, 1515 Elizabeth St
Suite J, Melbourne, FL 32901.
Product Quantity:
45 syringes
Code Information:
Lot #: 141224C, Exp. 03/24/2015;
150915B, Exp. 12/14/2015

Recall Number:
D-0869-2016

Product Description:
Avastin (Bevacizumab) 1.25 mg/0.05 mL syringe, Office Administration Only, AmEx Pharmacy, 1515 Elizabeth St Suite J, Melbourne, FL 32901.
Product Quantity:
836 syringes
Code Information:
Lot #: 150116B, Exp. 04/16/2015; 150119R, Exp. 04/19/2015; 150316H, Exp. 06/14/2015

Reason for Recall:
Non-Sterility: Product tested positive for bacterial contamination.

Recall Number:
D-0870-2016

Class I Drugs Event

Event ID:
73653
Product Type:
Drugs

Status:
Ongoing
Recalling Firm:
Hospira Inc.
275 N Field Dr
Lake Forest IL United States
Recall Initiation Date:
03/18/2016
Center Classification Date:
05/23/2016
Date Terminated:

Voluntary / Mandated:
Voluntary: Firm Initiated
Initial Firm Notification of Consignee or Public:
Letter
Distribution Pattern:
Nationwide

Associated Products

Product Description:

Reason for Recall:

8.4% Sodium Bicarbonate Injection, USP 50mEq (1mEq/mL), 4.2 grams (84 mg/mL), 50 mL, Rx only, Hospira Inc, Lake Forest, IL 60045, NDC 0409-6625-02

Product Quantity:
72,000 units

Code Information:
Lot # 56-148-EV, Exp 8/1/2017

Reason for Recall:
Presence of Particulate Matter: particulate matter identified as an insect in one vial.

Recall Number:
D-0865-2016

Class II Drugs Event

Event ID:
73118

Product Type:
Drugs

Status:
Ongoing

Recalling Firm:
Baxter Healthcare Corp.
1 Baxter Pkwy
Deerfield IL United States

Recall Initiation Date:
01/21/2016

Center Classification Date:
05/23/2016

Date Terminated:

Voluntary / Mandated:
Voluntary: Firm Initiated

Initial Firm Notification of Consignee or Public:
Letter

Distribution Pattern:
Nationwide and Puerto Rico

Associated Products

Product Description:
0.9% Sodium Chloride Injection USP, MINI-BAG Plus Container, 100 mL VIAFLEX Single Dose Container bags, Rx only, Baxter Healthcare Corporation, Deerfield, IL 60015, Product Code 2B0043, NDC 0338-0553-18.

Product Quantity:
282,080 bags

Code Information:
Lot #: P337857, Exp 07/31/16

Reason for Recall:
Lack of Assurance of Sterility: potential for leaking containers which lacks the assurance of sterility.

Recall Number:
D-0861-2016

Class II Drugs Event

Event ID:
73491
Product Type:
Drugs

Status:
Ongoing
Recalling Firm:
Akorn, Inc.
1925 W Field Ct Ste 300
Lake Forest IL United States
Recall Initiation Date:
03/23/2016
Center Classification Date:
05/25/2016
Date Terminated:

Voluntary / Mandated:
Voluntary: Firm Initiated
Initial Firm Notification of Consignee or Public:
Letter
Distribution Pattern:
Nationwide and Puerto Rico

Associated Products

Product Description:
ORIS (chlorhexidine gluconate), oral rinse, 0.12%, packaged in 16 fl. oz. (473 mL) PET bottle, Rx only, Manufactured for DENTSPLY Professional, York, PA 17404, UPC D00513003001O
Product Quantity:
33,862 mL
Code Information:
Lot # 628146, Exp 6/16; 629690, Exp 9/16; 348295, Exp 10/17

Reason for Recall:
Failed impurities/degradation specifications: Out-of-specification result (for multiple batches) for an unknown impurity of Chlorhexidine gluconate.

Recall Number:
D-0874-2016

Product Description:
Chlorhexidine gluconate, oral rinse, 0.12% packaged in 16 fl. oz. (473 mL) PET bottle, Rx only, Manufactured by HI-TECH PHARMACAL CO., INC., Amityville, NY 11701, NDC 5083-0720-16

Reason for Recall:
Failed impurities/degradation specifications: Out-of-specification result (for multiple batches) for an unknown impurity of Chlorhexidine gluconate.

Product Quantity:
3,112,657 mL

Recall Number:
D-0875-2016

Code Information:
Lot # 627528, 627763, 627766, 627921, 627924, 627927, 627930, 627933, 627953, 627956, 627959, 628040, Exp 5/16; 628148, 628151, 628230, 628232, 628365, Exp 6/16; 628589 , 628592, 628598, 628802, 628805, 628808, 628811, 628814, Exp 7/16 ; 629059, 629204, 629207, 629232, 629235, 629307, 629310, 629313, 629316, Exp 8/16; 629687, 629693, 629696, 629882, 629888, 630058, Exp 9/16; 630061, 630064, 630221, 630224, 630362, 630365, 630613, Exp 10/16; 630615, 630732, 630735, 630853, 630856, 630859, 631008, Exp 11/16; 631026, 631027, 631169, 631172, 631175, 631655, 631658, Exp 12/16; 631704, 631707, 631861, 631864, 631867, 632059, 632062, 632065, 632068, 632071, 632074, 632211, 632214 Exp 1/17; 632328, 632331, 632334, 632337, 632472, 632475, 632504, 632507, 632697, Exp 2/17; 633090, 633093, 632776, 632781, 632784, 632790, 632793, 632796, 632805, 632808, 632811, 632814, 633072, 633078, 633081, 633084, 633087, Exp 3/17; 633681, 633682, 633099, 633684, 633111, Exp 4/17; 345607, 345618, 345620, Exp 5/17; 346575, 346863, 346571, 346720,3 46573, Exp 7/17

Product Description:
PerioRx (chlorhexidine gluconate), oral rinse, 0.12%, packaged in 16 fl. oz. (473 mL) PET bottle, Rx only, Manufactured for Discus Dental, LLC, Ontario, CA 91761, UPC 4235 020 91701

Reason for Recall:
Failed impurities/degradation specifications: Out-of-specification result (for multiple batches) for an unknown impurity of Chlorhexidine gluconate.

Product Quantity:
294,090 mL

Recall Number:
D-0876-2016

Code Information:
Lot # 627525, Exp 5/16; 628362, Exp 6/16; 628595, Exp 7/16; 629319, Exp 8/16; 629885, Exp 9/16; 630467,Exp10/16; 32218, 632500, Exp 2/17; 633075, 632799, Exp 3/17; 345624, 345679, Exp 5/17; 347420, 347662, Exp 9/17

Class II Drugs Event

Event ID:
73811
Product Type:
Drugs

Status:
Ongoing
Recalling Firm:
Fresenius Kabi USA, LLC
3 Corporate Dr
Lake Zurich IL United States
Recall Initiation Date:
05/04/2016
Center Classification Date:
05/24/2016
Date Terminated:

Voluntary / Mandated:
Voluntary: Firm Initiated
Initial Firm Notification of Consignee or Public:
Letter
Distribution Pattern:
Nationwide and Puerto Rico.

Associated Products

Product Description:
OCTREOTIDE ACETATE INJECTION, 50 mcg (base)/mL (0.05 mg/mL), 1 mL Single Dose Vial, Rx only, Manufactured by Fresenius Kabi USA, LLC, Schaumburg, IL 60173, NDC 63323-365-01.
Product Quantity:
355,150 vials
Code Information:
Lot # 6108322; Exp. 04/16 Lot # 6108824; Exp. 07/16

Reason for Recall:
Failed Impuities/Degradation Specifications

Recall Number:
D-0866-2016

Product Description:
OCTREOTIDE ACETATE INJECTION, 50 mcg (base)/mL (0.05 mg/mL), 1 mL Single Dose Vial, Rx only, Manufactured by Fresenius Kabi USA, LLC, Schaumburg, IL 60173, NDC 63323-365-04

Reason for Recall:
Failed Impuities/Degradation Specifications

Product Quantity:
40,280 vials

Recall Number:
D-0867-2016

Code Information:
Lot # 6108831; Exp. 07/16

Class II Drugs Event

Event ID:
73896

Voluntary / Mandated:
Voluntary: Firm Initiated

Product Type:
Drugs

Initial Firm Notification of Consignee or Public:
E-Mail

Status:
Ongoing

Distribution Pattern:
Nationwide

Recalling Firm:
Lymol Medical
4 Plympton St
Woburn MA United States

Recall Initiation Date:
04/28/2016

Center Classification Date:
05/20/2016

Date Terminated:

Associated Products

Product Description:
Sclerosol Intrapleural Aerosol (sterile talc powder), Intrapleural administration, 4 g Canister, Rx Only, Distributed by: Bryan Corporation, Woburn, MA 01801, USA, NDC 63256-100-30

Reason for Recall:
Defective Delivery System: Defective stem valve causes leakage of the propellant in the spray canister delivering no drug or an inadequate amount of the drug to be delivered.

Product Quantity:
25,007 canisters

Recall Number:
D-0858-2016

Code Information:
Lot #: 4L034, Exp. MAY 2017

Class II Drugs Event

Event ID:
73913
Product Type:
Drugs

Status:
Ongoing
Recalling Firm:
Pfizer Inc.
235 East 42nd Street
New York NY United States
Recall Initiation Date:
04/28/2016
Center Classification Date:
05/20/2016
Date Terminated:

Voluntary / Mandated:
Voluntary: Firm Initiated
Initial Firm Notification of Consignee or Public:
Letter
Distribution Pattern:
Nationwide and Puerto Rico

Associated Products

Product Description:
Zoloft (sertraline HCl) tablets, 100 mg*, 30 count bottles, Rx only, Distributed by Roerig, Division of Pfizer, Inc., NY NY 10017, NDC 0049-4910-30.
Product Quantity:
68, 214 bottles
Code Information:
Lot #: M25569, Exp 08/18

Reason for Recall:
Failed Tablet/Capsule Specifications: thick tablets exceeding specifications were found.

Recall Number:
D-0857-2016

Class II Drugs Event

Event ID:
74180
Product Type:
Drugs

Voluntary / Mandated:
Voluntary: Firm Initiated
Initial Firm Notification of Consignee or Public:
Letter

Status:
Ongoing
Recalling Firm:
Teva North America
425 Privet Rd
Horsham PA United States
Recall Initiation Date:
04/27/2016
Center Classification Date:
05/24/2016
Date Terminated:

Distribution Pattern:
Nationwide

Associated Products

Product Description:
Linezolid Injection, 600 mg/300 mL Single use container bags (NDC 0703-9060-31), packaged in 10 x 300 mL Single Use Container bags per Box Pack (NDC 0703-9060-33), Rx only, Manufactured In Hungary By: Teva Pharmaceutical Works Ltd., Hungary, H-2100 Godollo, Tancsics M. ut 82 Hungary; Manufactured For: Teva Pharmaceuticals USA, Inc., North Wales, PA 19454
Product Quantity:
546 bags
Code Information:
Lot # 2520715, Exp Date: 7/17

Reason for Recall:
Lack of Assurance of Sterility: Due to potential for leaking bags.

Recall Number:
D-0868-2016