Enforcement Report - Week of December 27, 2017

Class I Drugs Event

Event ID:
77503

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
06/09/2017

Voluntary / Mandated:
Voluntary: Firm Initiated

Center Classification Date:
12/20/2017

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Advanced Pharma Inc.
9265 Kirby Dr
Houston TX United States

Distribution Pattern:
Nationwide in the USA to hospitals and medical facilities.

Associated Products

Product Description:
NitroGlycerin 1 mg/10 mL in 5% Dextrose Inj, USP QS 10mL (100 mcg per mL), 10 mL Sterile single dose syringe, packaged in 5 x 5 (TWENTY FIVE) syringes per box, Rx only, Advanced Pharma, 9265 Kirby Dr., Houston, TX 77054, NDC 15082-818-61.

Product Quantity:
550 syringes

Reason for Recall:
Subpotent Drug: found to be below the specification for labeled assay.

Recall Number:
D-0113-2018

Code Information:
Lot: 4/17/17 0857 81861S, BUD 08/15/2017

Product Description:
NitroGlycerin (1 mg/5 mL) 1 mg in 5% Dextrose Inj, USP QS 5 mL (200 mcg per mL), 5 mL Sterile single dose syringe, packaged in 8 x 5 (FORTY) syringes per box, Rx only, Advanced Pharma, 9265 Kirby Dr., Houston, TX 77054, NDC 15082-863-67.

Product Quantity:
320 syringes

Reason for Recall:
Subpotent Drug: found to be below the specification for labeled assay.

Recall Number:
D-0114-2018

Code Information:
Lot: 4/10/17 1441 257-86367S, BUD 6/9/17; 4/17/17 0950 86367S, BUD¿6/16/2017; 4/20/17 1505 257-86367S, BUD 6/19/2017; 4/24/17 0115 15-863 67S, BUD ¿6/23/2017; 4/26/17 0301 387-86367S, BUD 6/25/2017

Product Description:
NitroGlycerin (2 mg/10 mL in 5% Dextrose Inj, USP QS 10mL (200 mcg per mL), 10 mL Sterile single dose syringe, packaged in 5 x 5 (TWENTY FIVE) syringes per box, Rx only, Advanced Pharma, 9265 Kirby Dr., Houston, TX 77054, NDC 15082-863-61.

Product Quantity:
50 syringes

Reason for Recall:
Subpotent Drug: found to be below the specification for labeled assay.

Recall Number:
D-0115-2018

Code Information:
Lot: 4/19/17 1445 248-86361S, BUD¿6/18/2017

Class I Drugs Event

Event ID:
77817

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
07/24/2017

Voluntary / Mandated:
Voluntary: Firm Initiated

Center Classification Date:
12/20/2017

Initial Firm Notification of Consignee or Public:
Press Release

Recalling Firm:
EZWeightLossTX LLC
3333 S Padre Island Dr Suite 102
Corpus Christi TX United States

Distribution Pattern:
Nationwide

Associated Products

Product Description:
LaBri's Body Health Atomic 60 Capsules Exclusively distributed worldwide by LaBri's Body Health.

Product Quantity:
4958 bottles

Reason for Recall:
Marketed Without An Approved NDA/ANDA: Tainted Product Marketed As a Dietary Supplements: products found to be tainted with sibutramine making these unapproved drugs.

Recall Number:
D-0121-2018

Code Information:
All lots remaining within expiry.

Product Description:
LaBri's Body Health XPLODE 30 capsules Exclusively distribute worldwide by LaBri's Body Health.

Product Quantity:
1424 bottles

Reason for Recall:
Marketed Without An Approved NDA/ANDA: Tainted Product Marketed As a Dietary Supplements: products found to be tainted with sibutramine making these unapproved drugs.

Recall Number:
D-0122-2018

Code Information:
All lots remaining within expiry.

Class I Drugs Event

Event ID:
77859

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
08/01/2017

Voluntary / Mandated:
Voluntary: Firm Initiated

Center Classification Date:
12/21/2017

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

Recalling Firm:
The Ampt Life, LLC
5134 Navajo Dr
Frisco TX United States

Distribution Pattern:
Nationwide in the USA

Associated Products

Product Description:
NATURAL HERBAL COFFEE AMPT, sold in 25g packages (UPC 6942630905), 10-count packages per box (UPC 6942630912); Manufactured For: The Ampt Life, LLC.

Product Quantity:
1380 packets

Reason for Recall:
Marketed Without An Approved NDA/ANDA: FDA analysis found the product to contain undeclared sildenafil and tadalafil and undeclared milk. The presence of sildenafil and tadalafil makes AMPT Natural Herbal Coffee an unapproved drug for which safety and efficacy have not been established and, therefore, subject to recall. Additionally, this product has been found to contain undeclared milk, milk is recognized as one of the foods reported to have caused deaths due to anaphylactic shock in persons with underlying hypersensitivities.

Recall Number:
D-0126-2018

Code Information:
All lots

Class I Drugs Event

Event ID:
77898

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
08/03/2017

Voluntary / Mandated:
Voluntary: Firm Initiated

Center Classification Date:
12/20/2017

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Amneal Pharmaceuticals of New York, LLC
50 Horseblock Rd
Brookhaven NY United States

Distribution Pattern:
Nationwide

Associated Products

Product Description:
Lorazepam Oral Concentrate, USP, 2 mg/mL, 30 mL bottle, Rx only, Manufactured by: Amneal Pharmaceuticals Branchburg, NJ 08876. Distributed by: Amneal Pharmaceuticals, Glasgow, KY 42141. NDC 65162-687-84

Product Quantity:
136376 bottles

Reason for Recall:
Defective Delivery System: the dropper measurement markings may be reversed, shifted or missing.

Recall Number:
D-0120-2018

Code Information:
Lot 06876016A, 06876017A, 06876018A, Exp 08/2018; 06876019A, 06876020A, 06876021A, 06876022A, Exp 09/2018; 06876023A, Exp 11/2018; 06876024A, 06876025A, Exp 12/2018; 06877001A, 06877002A, Exp 02/2019; 06877003A, Exp 03/2019.

Class I Drugs Event

Event ID:
78000

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
08/30/2017

Voluntary / Mandated:
Voluntary: Firm Initiated

Center Classification Date:
12/20/2017

Initial Firm Notification of Consignee or Public:
Press Release

Recalling Firm:
Pfizer Inc.
235 E 42nd St
New York NY United States

Distribution Pattern:
Nationwide USA and Puerto Rico

Associated Products

Product Description:
Vancomycin Hydrochloride for Injection, USP. 750 mg. Sterile Powder. Rx Only. Hospira, Inc., Lake Forest, IL 60045 USA. NDC: 0409-6531-02

Product Quantity:
102,500 vials

Reason for Recall:
Presence of Particulate Matter: glass particulate found in vial

Recall Number:
D-0123-2018

Code Information:
Lot: 632153A; Exp. 03/18

Class II Drugs Event

Event ID:
77503

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
06/09/2017

Voluntary / Mandated:
Voluntary: Firm Initiated

Center Classification Date:
12/20/2017

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Advanced Pharma Inc.
9265 Kirby Dr
Houston TX United States

Distribution Pattern:
Nationwide in the USA to hospitals and medical facilities.

Associated Products

Product Description:
NitroGlycerin 1 mg/10 mL in 5% Dextrose Inj, USP QS 10mL (100 mcg per mL), 10 mL Sterile single dose syringe, packaged in 5 x 5 (TWENTY FIVE) syringes per box, Rx only, Advanced Pharma, 9265 Kirby Dr., Houston, TX 77054, NDC 15082-818-61.

Product Quantity:
4800 syringes

Reason for Recall:
Stability Data Does Not Support Expiry: lots do not have stability that supports the use of the container system.

Recall Number:
D-0116-2018

Code Information:
Lot: 3/3/17 1830 81861S, BUD 07/01/17; 3/27/17 0658 81861S, BUD 7/25/17

Product Description:
NitroGlycerin 100 mcg/mL QS 5% Dextrose Inj, USP (2 mg per 20 mL) 20 mL Sterile single dose syringe, packaged in 10 x 5 (FIFTY) syringes per box, Rx only, Advanced Pharma, 9265 Kirby Dr., Houston, TX 77054, NDC 15082-818-62.

Product Quantity:
50 syringes

Reason for Recall:
Stability Data Does Not Support Expiry: lots do not have stability that supports the use of the container system.

Recall Number:
D-0117-2018

Code Information:
Lot: 5/31/17 0202 5-81862S, BUD 7/30/17

Product Description:
NitroGlycerin (1 mg/5 mL) 1 mg in 5% Dextrose Inj, USP QS 5 mL (200 mcg per mL), 5 mL Sterile single dose syringe, packaged in 8 x 5 (FORTY) syringes per box, Rx only, Advanced Pharma, 9265 Kirby Dr., Houston, TX 77054, NDC 15082-863-67.

Product Quantity:
680 syringes

Reason for Recall:
Stability Data Does Not Support Expiry: lots do not have stability that supports the use of the container system.

Recall Number:
D-0118-2018

Code Information:
Lot: 4/26/17 0730 20-86367S, BUD 6/25/17; 4/24/17 0106 241-86367S, BUD 6/23/17; 5/1/17 1500 45-86367S, BUD 6/30/17; 5/9/17 1103 241-86367S, BUD 7/8/17; 5/9/17 1104 257-86367S, BUD 7/8/17; 5/12/17 0839 15-86367S, BUD 7/11/17; 5/19/17 0109 15-86367S, BUD 7/18/17; 5/22/17 0828 387-86367S, BUD 7/21/17; 5/23/17 0721 257-86367S, BUD 7/22/17; 5/24/17 0200 241-86367S, BUD 7/23/17; 5/24/17 0203 20-86367S, BUD 7/23/17; 5/26/17 0315 15-86367S, BUD 7/25/17; 5/31/17 1217 20-86367S, BUD 7/30/17

Product Description:
NitroGlycerin (2 mg/10 mL in 5% Dextrose Inj, USP QS 10mL (200 mcg per mL), 10 mL Sterile single dose syringe, packaged in 5 x 5 (TWENTY FIVE) syringes per box, Rx only, Advanced Pharma, 9265 Kirby Dr., Houston, TX 77054, NDC 15082-863-61.

Product Quantity:
550 syringes

Reason for Recall:
Stability Data Does Not Support Expiry: lots do not have stability that supports the use of the container system.

Recall Number:
D-0119-2018

Code Information:
Lot: 4/20/17 0307 265-86361S, BUD 6/19/17; 4/26/17 0732 265-86361S, BUD 6/25/17; 4/28/17 0215 265-86361S, BUD 6/27/17; 5/2/17 0310 248-86361S, BUD 7/1/17; 5/4/17 1422 248-86361S, BUD 7/3/17; 5/12/17 0841 248-86361S, BUD 7/11/17; 5/18/17 0206 250-86361S, BUD 7/17/17

Class II Drugs Event

Event ID:
77979

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
08/10/2017

Voluntary / Mandated:
Voluntary: Firm Initiated

Center Classification Date:
12/21/2017

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Premier Pharmacy Labs Inc
8265 Commercial Way
Weeki Wachee FL United States

Distribution Pattern:
Michigan, Maryland, Minnesota, North Carolina, Ohio, Florida

Associated Products

Product Description:
Neostigmine Methylsulfate (single dose syringe) 1 mg per mL 5 mg per 5 mL Injectable Hospital/Office Use Only Compounded by: Premier Pharmacy Labs., Inc. 8265 Commercial Way Weeki Wachee, FL 34613, NDC# 69623-234-15

Product Quantity:
1610 syringes

Reason for Recall:
Stability Date Doesn't Support Expiry: labeling error indicating a beyond use date that exceeds current stability data.

Recall Number:
D-0129-2018

Code Information:
Lot # NEO071317MMDSA BUD: 01/19/2018 Lot # NEO071317MMDSC BUD: 01/19/2018 Lot # NEO071317MMDSF BUD: 01/19/2018

Class II Drugs Event

Event ID:
78520

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
11/08/2017

Voluntary / Mandated:
Voluntary: Firm Initiated

Center Classification Date:
12/21/2017

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
L. Perrigo Company
515 Eastern Ave
Allegan MI United States

Distribution Pattern:
Nationwide

Associated Products

Product Description:
Maximum Strength Zephrex-D, Pseudoephedrine HCl, 30 mg, Nasal Decongestant. 24 softgel tablets per paper carton, Distributed by Perrigo, Allegan, MI 49010, NDC 70085-151-01

Product Quantity:
19,944 Cartons (24 tablets each)

Reason for Recall:
Microbial Contamination of Non-Sterile Products

Recall Number:
D-0128-2018

Code Information:
Lot # AF4273A; Exp. 02/18

Class II Drugs Event

Event ID:
78590

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
11/20/2017

Voluntary / Mandated:
Voluntary: Firm Initiated

Center Classification Date:
12/20/2017

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Teva Pharmaceuticals USA
1090 Horsham Rd
North Wales PA United States

Distribution Pattern:
Nationwide in the USA and Puerto Rico

Associated Products

Product Description:
Amethyst (Levonorgestrel and Ethinyl Estradiol Tablets USP, 90mcg/20mcg), 28 tablet dispenser (blister foil unit), Rx only, Manufactured by: Warner Chilcott Company, LLC Fajardo, Puerto Rico 00738: Distributed by: Actavis Pharma, Inc. Parsippany, NJ 07054 USA, NDC-52544-295-28

Product Quantity:
5,374 blister cards/28 tablets

Reason for Recall:
Labeling: Incorrect Instructions. "TABLETS IN WEEK 4 ARE INACTIVE" printed on the blister foil and package insert, however,all tablets are active.

Recall Number:
D-0125-2018

Code Information:
Lot # 544637A

Class II Drugs Event

Event ID:
78767

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
12/15/2017

Voluntary / Mandated:
Voluntary: Firm Initiated

Center Classification Date:
12/20/2017

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
B. Braun Medical Inc
2525 McGaw Ave
Irvine CA United States

Distribution Pattern:
Product was distributed nationwide.

Associated Products

Product Description:
0.25% Acetic Acid Irrigation USP, 500 mL Plastic Irrigation Container (PIC), B. Braun Medical Inc. Irvine CA 92614-5895 USA, NDC 0264-2304-10

Product Quantity:
2,576 containers

Reason for Recall:
Presence of Particulate Matter: identified as polyethylene, which is consistent with the material used to manufacture the contain cap

Recall Number:
D-0112-2018

Code Information:
Lot #: J7N965, Exp. 10/31/2020

Class III Drugs Event

Event ID:
78446

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
11/06/2017

Voluntary / Mandated:
Voluntary: Firm Initiated

Center Classification Date:
12/21/2017

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Claris Lifesciences Inc
1445 US Highway 130
North Brunswick NJ United States

Distribution Pattern:
Nationwide

Associated Products

Product Description:
Ciprofloxacin in Dextrose (5%) Injection, USP 200 mg in 100 mL 5% Dextrose, Rx Only, (2 mg/mL), 100 mL Flexible Bag, Manufactured for: Claris LifeScience Inc. North Brunswick NJ 08902 by Claris Injectables Ltd. Gujarat, India UPC 336000008242 NDC 36000-008-249

Product Quantity:

Reason for Recall:
Superpotent

Recall Number:
D-0127-2018

Code Information:
A060192 01/2018; A060305 02/2018; A061038 08/2018; A0A0068 12/2018; A0A0404 04/2019

Class III Drugs Event

Event ID:
78504

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
11/11/2017

Voluntary / Mandated:
Voluntary: Firm Initiated

Center Classification Date:
12/20/2017

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Renaissance Lakewood, LLC
1200 Paco Way
Lakewood NJ United States

Distribution Pattern:
Nationwide

Associated Products

Product Description:
Fluconazole Injection, USP, 2 mg/mL, a) 50 mL (NDC 336000-261-10) and b) 100 mL (NDC 33600-002-10), Rx Only, Manufactured for: Claris LifeSciences, Inc. North Brunswick, NJ 08902 By: Claris Injectables Ltd., Gujarat, India

Product Quantity:
24,569 bags

Reason for Recall:
Superpotent

Recall Number:
D-0124-2018

Code Information:
a) A060174 01/13/2018, A060257 02/28/2018, A060692 05/31/2018, A061165 09/30/2018, A0A0143 01/31/2019, A0A0347 03/31/2019, and A0A0424 04/30/2019 ; b) A060027 12/31/2017

Class III Drugs Event

Event ID:
78764

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
12/18/2017

Voluntary / Mandated:
Voluntary: Firm Initiated

Center Classification Date:
12/20/2017

Initial Firm Notification of Consignee or Public:
Letter