Enforcement Report - Week of October 17, 2018

Class II Drugs Event

Event ID:
80964

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
09/10/2018

Voluntary / Mandated:
Voluntary: Firm Initiated

Center Classification Date:
10/15/2018

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Takeda Development Center Americas, Inc.
1 Takeda Pkwy 4034BB1
Deerfield IL United States

Distribution Pattern:
AR, LA, MS, NC, NJ, OH, PA, SC and Puerto Rico

Associated Products

Product Description:
Actoplus met XR (pioglitazone and metformin HCl, extended-release) tablets, 15 mg/1000 mg, Rx Only, 30 tablet bottle, Distributed by: Takeda Pharmaceuticals America, Inc, Deerfield, IL 60015. NDC: 64764-510-30

Product Quantity:
7,248 bottles

Reason for Recall:
Defective Delivery System: tablets may be missing, in whole or in part, the laser drilled holes on the metformin core of the Actoplus met XR tablets.

Recall Number:
D-0026-2019

Code Information:
Lot, expiry: A26004, exp Apr 2020; A26443 and A26444, exp Sep 2020

Class II Drugs Event

Event ID:
81028

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
09/20/2018

Voluntary / Mandated:
Voluntary: Firm Initiated

Center Classification Date:
10/09/2018

Initial Firm Notification of Consignee or Public:
Letter

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

Distribution Pattern:
Nationwide

Associated Products

Product Description:
Glipizide XL (glipizide) extended-release tablets 5 mg 500-tablet bottle, Rx only Distributed by: Greenstone LLC. Peapack, NJ 07977 --- NDC 59762-0541-2

Product Quantity:
7777 bottles

Reason for Recall:
CGMP Deviations; rejected product was used to manufacture final bulk lot

Recall Number:
D-0010-2019

Code Information:
Lot: T71137 Exp. Feb. 2022

Class II Drugs Event

Event ID:
81126

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
10/03/2018

Voluntary / Mandated:
Voluntary: Firm Initiated

Center Classification Date:
10/11/2018

Initial Firm Notification of Consignee or Public:
Letter

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

Distribution Pattern:
Nationwide in the USA and Puerto Rico

Associated Products

Product Description:
Magnesium Sulfate in Water for Injection (0.325 mEq Mg++/mL) 40 mg/mL, 20 g Total, 500 mL Single-Dose Container bag, Rx only, Hospira, Inc. Lake Forest, IL 60045 USA, NDC 0409-6729-03.

Product Quantity:
94,752 bags

Reason for Recall:
Correct Labeled Product Mispack: confirmed report involving a single unit of properly labeled Heparin in 0.45% Sodium Chloride for Injection (NDC 0409-7651-03, Lot 87903FW) that was found inside a case of Magnesium Sulfate in Water for Injection.

Recall Number:
D-0015-2019

Code Information:
Lot: 87904FW, Exp. 1MAR2020

Class II Drugs Event

Event ID:
81128

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
08/22/2018

Voluntary / Mandated:
Voluntary: Firm Initiated

Center Classification Date:
10/11/2018

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Syntec Pharma Corp
96 Gazza Blvd
Farmingdale NY United States

Distribution Pattern:
Al & TX only

Associated Products

Product Description:
THYROID POWDER USP, Full Strength (Levothyroxine labeled range of 103-125mcg/grain; Liothyroine (correct spelling Liothyronine): labeled range of 24.3-29.7mcg/grain) active pharmaceutical ingredient; 5 KG bag, Rx Compounding only, Manu By: Sichuan Friendly Pharmaceutical Co., Ltd., No. 680 Hongpai Road, Neijiang, sichuan 641000, china; Distributed: Syntec Pharma Corp., 96 Gazza Blvd., Farmingdale NY 11735, CAS No. 50809-32-0

Product Quantity:
2 drums

Reason for Recall:
CGMP Deviations: Recall notice received from supplier that Thyroid Powder has inconsistent levels of the active ingredients levothyroxine and liothyronine.

Recall Number:
D-0013-2019

Code Information:
All lots

Product Description:
THYROID POWDER USP (Levothyroxine labeled range of 34.2-41.8mcg/grain; Liothyroine (correct spelling Liothyronine): labeled range of 8.1-9.9mcg/grain) active pharmaceutical ingredient; 25 KG bag, Rx Compounding only, Manu By: Sichuan Friendly Pharmaceutical Co., Ltd., No. 680 Hongpai Road, Neijiang, sichuan 641000, china; Distributed: Syntec Pharma Corp., 96 Gazza Blvd., Farmingdale NY 11735, CAS No. 50809-32-0

Product Quantity:
486 kg

Reason for Recall:
CGMP Deviations: Recall notice received from supplier that Thyroid Powder has inconsistent levels of the active ingredients levothyroxine and liothyronine.

Recall Number:
D-0014-2019

Code Information:
All lots

Class II Drugs Event

Event ID:
81147

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
08/30/2018

Voluntary / Mandated:
Voluntary: Firm Initiated

Center Classification Date:
10/05/2018

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Alkano Chemicals, Inc
655 N Central Ave Fl 17 Ste 1704a
Glendale CA United States

Distribution Pattern:
Distributed to two compounding firms in Minnesota.

Associated Products

Product Description:
Thyroid powder, 4.5 kg foil bag, 5x1 kg foil bags packed in 25 Kg Fiber Drum, Thyroid Powder 25kg/drum, US Pharmacopoeia, Sichuan Friendly Pharmaceutical Co., LTD, Production Address: No. 680, Hongpai Road, Dongxing District, Neijiang City Sichuan, China Tel:+886 832 2240082/2240298, NDC 7807-0170-11

Product Quantity:
8 kgs

Reason for Recall:
CGMP Deviations: Recall notice received from supplier that Thyroid Powder has inconsistent levels of the active ingredients levothyroxine and liothyronine.

Recall Number:
D-0008-2019

Code Information:
Lot # 170501

Class II Drugs Event

Event ID:
81162

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
10/02/2018

Voluntary / Mandated:
Voluntary: Firm Initiated

Center Classification Date:
10/09/2018

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Jubilant Cadista Pharmaceuticals, Inc.
207 Kiley Dr
Salisbury MD United States

Distribution Pattern:
Product was distributed Nationwide in the USA and Puerto Rico.

Associated Products

Product Description:
Pantoprazole Sodium Delayed-Release Tablets, USP, 40 mg*, 90-count bottle, Rx only, Manufactured by: Jubilant Generics Ltd., Roorkee - 247661, India; Marketed by: Jubilant Cadista Pharmaceuticals Inc., Salisbury, MD 21801; NDC 59746-284-90.

Product Quantity:
158,466 bottles

Reason for Recall:
Discoloration: Presence of dark discoloration or brown spots on the edges of the tablets.

Recall Number:
D-0011-2019

Code Information:
Lot #: PA26038A, Exp 04/19; PA26039A, PA26040A, PA26050A, Exp 05/19; PA26052A, Exp 06/19; PA26073A, Exp 07/19; PA217071A, PA217072A, PA217073B, PA217074B, Exp 06/20; PA217101A, Exp 08/20; and PA218023A, Exp 01/21.

Class III Drugs Event

Event ID:
81044

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
09/18/2018

Voluntary / Mandated:
Voluntary: Firm Initiated

Center Classification Date:
10/11/2018

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Xiromed LLC
180 Florham Park Suite 101
Florham Park NJ United States

Distribution Pattern:
Nationwide in the USA

Associated Products

Product Description:
Altavera Levonorgestrel and Ethinyl Estradiol Tablets, USP 0.15 mg and 0.03 mg, Rx only, 3 tablet dispensers x 28 tablets. Manufactured by Laboratories Leon Farma S.A., Spain, for Xiromed, LLC., Florham Park, NJ 07932. Product of Spain NDC 70700-116-85 (I unit x 28 tablets 70700-116-84)

Product Quantity:
40064 3x28 units

Reason for Recall:
Labeling: Not Elsewhere Classified: mislabeling of the Altavera generic name on the packaging component that may cause confusion.

Recall Number:
D-0016-2019

Code Information:
Lots: LF11838A Expiry May 2020; LF12107A, LF12106A, Expiry June 2020

Class III Drugs Event

Event ID:
81099

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
10/03/2018

Voluntary / Mandated:
Voluntary: Firm Initiated

Center Classification Date:
10/11/2018

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
InvaGen Pharmaceuticals, Inc.
7 Oser Ave
Hauppauge NY United States

Distribution Pattern:
Nationwide with the United States

Associated Products

Product Description:
Amlodipine Besylate USP 10 mg Tablets, 1000-count bottles, Rx Only, Manufactured by: Cipla Ltd., Verna Goa, India, Manufactured for: Cipla USA, Inc. 1560 Sawgrass Corporate Parkway, Suite 130, Sunrise FL 33323 UPC 369097128159, NDC 69097-128-15

Product Quantity:
2880 bottles

Reason for Recall:
Subpotent Drug: One lot of product does not meet the product specification for Assay test at 3 month long term stability condition.

Recall Number:
D-0012-2019

Code Information:
Lot #: GG80218, Exp. 12/2019

Not Yet Classified Drugs Event

Event ID:
81041

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
09/26/2018

Voluntary / Mandated:
Voluntary: Firm Initiated

Center Classification Date:

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
GLAXOSMITHKLINE NEBRASKA
10401 Hwy 6
Lincoln NE United States

Distribution Pattern:
Nationwide USA and Puerto Rico

Associated Products

Product Description:
PREVACID 24HR, Lansoprazole delayed-release capsules, 15 mg, 14 capsules per bottle in a carton containing 1 bottle (NDC: 0067-6286-14), 2 bottles (NDC: 0067-6286-28) or 3 bottles (NDC: 0067-6286-42), Over-the-counter, Distributed By: GSK Consumer Healthcare, Warren, NJ 07059.

Product Quantity:
5,548,673 bottles

Reason for Recall:
Potential microbial contamination.

Recall Number:

Code Information:
1-bottle cartons lots, expiration: GE2743, GE4570, GG0536, 9/30/2018; GE3445, GG4810, 11/30/2018; A38M, 12/31/2018; K63J, 4/30/2018; H24T, 5/31/2018; RS4U, M721601MA, 7/31/2018; 379H, 8/31/2018; A93E, AE2S, 10/31/2018; GB7D, GS5B, M801001MA, M807901MA, M807902MA, 11/30/2019; D88E, 11/30/2020 2-bottle cartons lots, expiration: GJ0440, 1/31/2019; LE6J, 7/31/2018; A93E, 10/31/2018 3-bottle cartons lots, expiration: 17D19N, 8/31/2018; 1GE2743, GE4570, GG0536, 9/30/2018; GA8391, 10/31/2018; GE3445, GA6310, 11/30/2018; GG1094, GH1913, GH8818, M703002EH, M703003EH, M703004EH, M703006EH, M703007EH, M703008EH, M713101EH, M707401MB, M707402MB, M707403MB, M707404MB, M707405MB, M707406MB, M721201MB, M717001MA, M717002MA, 1/31/2018; AF5C, AK2T, AV5T, M713102EH, M713104EH, M716001EH, M716002EH, M716003EH, M716004EH, M716005EH, M721202MB, M721203MB, M721204MB, M717003MA, M717004MA, M717005MA, M717006MA, 4/30/2019; FL8P, FM4K, M720505EH, M720507EH, M720508EH, M720509EH, M721205MB, M721206MB, M721207MB, 5/31/2019; P77N, P77P, PN3Y, R72E, 8/31/2019; 728J, 728K, 728L, 8E6T, A93E, 10/31/2019; H43X, HT4P, M85L, 11/30/2019; T73J, UT9X, UV7Y, 2/29/2019; BR4Y, FN2N, 11/30/2020; MC2P, MJ9F, RC2T, 1/31/2021