Enforcement Report - Week of July 12, 2017

Class II Drugs Event

Event ID:
77392

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
05/26/2017

Voluntary / Mandated:
Voluntary: Firm Initiated

Center Classification Date:
07/02/2017

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

Recalling Firm:
American Pharmaceutical Ingredients LLC
6650 Highland Rd Ste 302
Waterford MI United States

Distribution Pattern:
Nationwide

Associated Products

Product Description:
Methocarbamol, USP, packaged in a) 100 g container (NDC: 58597-8023-6, b) 500 g container (NDC: 58597-8023-7), c) 1,000 g container (NDC: 58597-8023-8). For Prescription Compounding RX Only. Packed under cGMP conditions by American Pharmaceutical Ingredients, LLC 6650 Highland Road, Waterford, MI 48327

Product Quantity:
5,000g (5 kg)

Reason for Recall:
CGMP Deviations: Lack of quality assurance at the API manufacturer.

Recall Number:
D-0937-2017

Code Information:
Lots: MCMR1308029NS, MCMR1308029NS-4202015; Exp. 08/18

Class II Drugs Event

Event ID:
77443

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
06/01/2017

Voluntary / Mandated:
Voluntary: Firm Initiated

Center Classification Date:
07/02/2017

Initial Firm Notification of Consignee or Public:
Telephone

Recalling Firm:
Xttrium Laboratories Inc
415 W Pershing Rd
Chicago IL United States

Distribution Pattern:
Natiowide

Associated Products

Product Description:
Chlorhexidine Gluconate 0.12% Oral Rinse, USP, 1 Pint (473 ml), Rx Only, Distributed by: Xttrium Laboratories, Inc., Mount Prospect, IL 60056, NDC 0116-2001-16

Product Quantity:
36,720 16 oz. glass bottles

Reason for Recall:
CGMP Deviations

Recall Number:
D-0938-2017

Code Information:
1999CHG16MC-Lot number 704-201 (full lot # 704-1999-201), Exp 03/20 1999CHG16MC-Lot number 705-208 (full lot # 705-1999-208), Exp 04/20

Class II Drugs Event

Event ID:
77526

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
06/08/2017

Voluntary / Mandated:
Voluntary: Firm Initiated

Center Classification Date:
07/06/2017

Initial Firm Notification of Consignee or Public:
Press Release

Recalling Firm:
Phillips Co.
311 Chikasaw Street
Millerton OK United States

Distribution Pattern:
Nationwide and United Kingdom

Associated Products

Product Description:
Tetracycline-ABC Brand Topical ointment First Aid Antibiotic, tetracycline (3%), 3 mL in a 5 mL bottle, sold over the counter Phillips Company, Millerton, OK -- NDC 4307410201

Product Quantity:
100-200 bottles

Reason for Recall:
GMP Deviations; FDA inspection found significant manufacturing practices that call into question the safety, identity, strength, quality and purity of unexpired drug products manufactured by the firm.

Recall Number:
D-0947-2017

Code Information:
All lots remaining within expiry.

Product Description:
TetraStem brand Topical Ointment First Aid Antibiotic, tetracycline (3%), 3 mL in a 5 mL bottle, sold over the counter Phillips Company, Millerton, OK -- NDC 04307-301-11

Product Quantity:
200-300 bottles

Reason for Recall:
GMP Deviations; FDA inspection found significant manufacturing practices that call into question the safety, identity, strength, quality and purity of unexpired drug products manufactured by the firm.

Recall Number:
D-0948-2017

Code Information:
All lots remaining within expiry.

Product Description:
Diabecline brand Topical Ointment First Aid Antibiotic, tetracycline (3%), 3 mL in a 5 mL bottle, sold over the counter Phillips Company, Millerton, OK -- NDC 04307-100-11

Product Quantity:
100-200 bottles

Reason for Recall:
GMP Deviations; FDA inspection found significant manufacturing practices that call into question the safety, identity, strength, quality and purity of unexpired drug products manufactured by the firm.

Recall Number:
D-0949-2017

Code Information:
All lots remaining within expiry.

Product Description:
StingMed Insect bites Skin Protectant. Zinc acetate (.1% by volume), 0.3 fl. oz. (3 mL) bottle, Phillips Company, Millerton, OK -- NDC 04307-100-11

Product Quantity:
20-50 bottles/units

Reason for Recall:
GMP Deviations; FDA inspection found significant manufacturing practices that call into question the safety, identity, strength, quality and purity of unexpired drug products manufactured by the firm.

Recall Number:
D-0950-2017

Code Information:
All lots remaining within expiry.

Product Description:
StaphWash+Plus+ Skin Protectant, Zinc acetate (.1% by volume), 0.3 fl. oz. (3 mL) bottle, Phillips Company, Millerton, OK -- NDC 43074-101-01

Product Quantity:
10-30 bottles/units

Reason for Recall:
GMP Deviations; FDA inspection found significant manufacturing practices that call into question the safety, identity, strength, quality and purity of unexpired drug products manufactured by the firm.

Recall Number:
D-0951-2017

Code Information:
All lots remaining within expiry.

Product Description:
VenomX, Zinc acetate (.1% by volume), 0.3 fl. oz. (3 mL) bottles, Skin Protectant Phillips Company, Millerton, OK -- NDC 43074-207-01

Product Quantity:
20-50 bottles/units

Reason for Recall:
GMP Deviations; FDA inspection found significant manufacturing practices that call into question the safety, identity, strength, quality and purity of unexpired drug products manufactured by the firm.

Recall Number:
D-0952-2017

Code Information:
All lots remaining within expiry.

Class II Drugs Event

Event ID:
77545

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
06/16/2017

Voluntary / Mandated:
Voluntary: Firm Initiated

Center Classification Date:
07/03/2017

Initial Firm Notification of Consignee or Public:
Press Release

Recalling Firm:
Alvogen, Inc
10 Bloomfield Ave Bldg B Ste 2
Pine Brook NJ United States

Distribution Pattern:
Nationwide

Associated Products

Product Description:
Clindamycin Injection USP; 300 mg/2 mL (150 mg/mL). 2 mL Single-dose ADD-VANTAGE Vial, Rx Only, Manufactured for Alvogen, Inc., Pine Brook, NJ 07058, NDC 47781-462-69

Product Quantity:
5,100 2 mL vials

Reason for Recall:
Lack of Assurance of Sterility

Recall Number:
D-0939-2017

Code Information:
Lot: 73-154-EV; Exp. 12/31/17

Product Description:
Clindamycin Injection USP; 600 mg/4 mL (150 mg/mL). 4 mL Single-dose ADD-VANTAGE Vial, Rx Only, Manufactured for Alvogen, Inc., Pine Brook, NJ 07058, NDC 47781-463-69

Product Quantity:
72,575 4 mL vials

Reason for Recall:
Lack of Assurance of Sterility

Recall Number:
D-0940-2017

Code Information:
Lots: 68-104-EV; Exp 07/31/18, 73-155-EV; Exp. 12/31/18, 73-156-EV; Exp.12/31/18

Product Description:
Clindamycin Injection USP; 900 mg/6 mL (150 mg/mL). 6 mL Single-dose ADD-VANTAGE Vial, Rx Only, Manufactured for Alvogen, Inc., Pine Brook, NJ 07058, NDC 47781-464-69

Product Quantity:
71,825 6 mL vials

Reason for Recall:
Lack of Assurance of Sterility

Recall Number:
D-0941-2017

Code Information:
Lots: 68-105-EV; Exp. 07/31/18, 68-106-EV; Exp. 07/31/18, and 73-157-EV; Exp. 12/31/18

Class II Drugs Event

Event ID:
77584

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
06/19/2017

Voluntary / Mandated:
Voluntary: Firm Initiated

Center Classification Date:
07/06/2017

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Fagron Compounding Services LLC dba Fagron Sterile Services
8710 E 34th St N
Wichita KS United States

Distribution Pattern:
Nationwide in the USA

Associated Products

Product Description:
Succinylcholine Chloride, 100 mg per 5mL, 20 mg per mL syringe. IV Use Only. JCB Laboratories, 8710 E 34th St., N. Wichita, KS 67226 UPC 7335968405

Product Quantity:
1,056 5mL syringes

Reason for Recall:
Lack Of Assurance Of Sterility: voluntary recall initiated by the commercial supplier

Recall Number:
D-0946-2017

Code Information:
Lot #: C274-000000331, BUD 08/30/2017; C274-000001274, BUD 09/07/2017; C274-000001326, BUD 09/14/2017

Class II Drugs Event

Event ID:
77651

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
06/28/2017

Voluntary / Mandated:
Voluntary: Firm Initiated

Center Classification Date:
07/06/2017

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
GSK Consumer Healthcare
184 Liberty Corner Rd Ste 200
Warren NJ United States

Distribution Pattern:
Nationwide in the USA

Associated Products

Product Description:
parodontax WHITENING (Stannous fluoride) Daily Fluoride Anticavity and Antigingivitis Toothpaste, 0.454% (0.15% w/v fluoride ion), 3.4 OZ (96.4 g) tube, Distributed by: GSK Consumer Healthcare, Warren, NJ 07059, NDC 0135-0601-01.

Product Quantity:
15,708 tubes

Reason for Recall:
Presence of Foreign Substance: possibility of the presence of metal in the product.

Recall Number:
D-0944-2017

Code Information:
G7E101, Exp 04/19

Class III Drugs Event

Event ID:
77374

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
02/15/2017

Voluntary / Mandated:
Voluntary: Firm Initiated

Center Classification Date:
07/02/2017

Initial Firm Notification of Consignee or Public:
Telephone

Recalling Firm:
Pharmedium Services Llc
150 N Field Dr
Lake Forest IL United States

Distribution Pattern:
Nationwide

Associated Products

Product Description:
Ropivacaine HCl 0.2% 400 mL Total Volume in an ON-Q Pump in 0.9% Sodium Chloride Injection in 400 mL, Rx Only, Compounded by PharMEDium Services, LLC, Sugar Land, TX 77478, NDC: 61553-256-09

Product Quantity:
79 I.V. pumps

Reason for Recall:
Labeling: Incorrect or Missing Lot and/or Exp Date

Recall Number:
D-0930-2017

Code Information:
Lot: 170340164s Lot: 170380152s Ex.: 01/1/1900

Product Description:
Ropivacaine HCl 0.2% 500 mL Total Volume in an ON-Q Pump in 0.9% Sodium Chloride Injection in 400 mL, Rx Only, Compounded by PharMEDium Services, LLC, Sugar Land, TX 77478, NDC: 61553-258-03

Product Quantity:
22 I.V. pumps

Reason for Recall:
Labeling: Incorrect or Missing Lot and/or Exp Date

Recall Number:
D-0931-2017

Code Information:
Lot: 170340167s; Exp. 01/01/1900

Product Description:
Ropivacaine HCl 0.2% 500 mL Total Volume in an ON-Q Pump in 0.9% Sodium Chloride Injection in 400 mL, Rx Only, Compounded by PharMEDium Services, LLC, Sugar Land, TX 77478, NDC: 61553-258-25

Product Quantity:
147 I.V. pumps

Reason for Recall:
Labeling: Incorrect or Missing Lot and/or Exp Date

Recall Number:
D-0932-2017

Code Information:
Lot: 170270192s Lot: 170330167s Lot: 170320087s Ex.: 01/01/1900

Product Description:
Ropivacaine HCl 0.2% 750 mL Total Volume in an ON-Q Pump in 0.9% Sodium Chloride Injection in 600 mL, Rx Only, Compounded by PharMEDium Services, LLC, Sugar Land, TX 77478, NDC: 61553-279-33

Product Quantity:
10 I.V. pumps

Reason for Recall:
Labeling: Incorrect or Missing Lot and/or Exp Date

Recall Number:
D-0933-2017

Code Information:
Lot: 170170204s; Exp. 01/01/1900

Product Description:
Ropivacaine HCl 0.2% 550 mL Total Volume in an AutoFuser Pump in 0.9% Sodium Chloride Injection, Rx Only, Compounded by PharMEDium Services, LLC, Sugar Land, TX 77478, NDC: 61553-100-13

Product Quantity:
21 I.V. pumps

Reason for Recall:
Labeling: Incorrect or Missing Lot and/or Exp Date

Recall Number:
D-0934-2017

Code Information:
Lot: 170310113s; Exp. 01/01/1900

Product Description:
Bupivacaine HCl 0.25% 270 mL Total Volume in an ON-Q Pump in 0.9% Sodium Chloride Injection in 270 mL, Rx Only, Compounded by PharMEDium Services, LLC, Sugar Land, TX 77478, NDC: 61553-044-57

Product Quantity:
2 I.V. pumps

Reason for Recall:
Labeling: Incorrect or Missing Lot and/or Exp Date

Recall Number:
D-0935-2017

Code Information:
Lot: 170320107s; Exp. 01/01/1900

Product Description:
Bupivacaine HCl 0.25% 400 mL Total Volume in an ON-Q Pump in 0.9% Sodium Chloride Injection in 400 mL, Rx Only, Compounded by PharMEDium Services, LLC, Sugar Land, TX 77478, NDC: 61553-023-09

Product Quantity:
7 I.V. pumps

Reason for Recall:
Labeling: Incorrect or Missing Lot and/or Exp Date

Recall Number:
D-0936-2017

Code Information:
Lot: 170300146s; Exp. 01/01/1900

Class III Drugs Event

Event ID:
77401

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
06/02/2017

Voluntary / Mandated:
Voluntary: Firm Initiated

Center Classification Date:
07/06/2017

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
G & W Laboratories, Inc.
111 Coolidge St
South Plainfield NJ United States

Distribution Pattern:
Nationwide

Associated Products

Product Description:
G & W Clobetasol Propionate Ointment 0.05%, packaged in a) 15 g tube (NDC 0713-0656-15), b) 30 g tube (NDC 0713-0656-31, c) 45 g tube (NDC 0713-0656-37), d) 60 g tube (NDC 0713-0656-60), Rx Only, Manufactured by G & W Laboratories, Inc. 111 Coolidge Street, South Plainfield, NJ 07080

Product Quantity:
145284 tubes

Reason for Recall:
Failed impurities/degradation specifications: This product is being recalled due to out of specification results for Clobetasol Related Compound A, a known impurity which is a degradation product.

Recall Number:
D-0945-2017

Code Information:
Lot #: a) 1001090, Exp 8/ 17; 1002881, Exp 2/18; b) 1001086, Exp 8/ 17; 1001154, Exp 11/ 17; 1001156, Exp 9/17; 1002882, Exp 2/18, 1004564, Exp 7/18; c) 1001155, Exp 9/17; 1004572, Exp 7/18; d) 1001158, Exp 9/17; 1001159, Exp 10/17; 1002884, Exp 4/18

Class III Drugs Event

Event ID:
77433

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
05/18/2017

Voluntary / Mandated:
Voluntary: Firm Initiated

Center Classification Date:
07/05/2017

Initial Firm Notification of Consignee or Public:

Telephone

Recalling Firm:
Lantheus MI Radipharmaceuticals Inc.
150 Calle Federico Costa Ste 1
San Juan PR United States

Distribution Pattern:
Puerto Rico

Associated Products

Product Description:	**Product Quantity:**
Fludeoxyglucose F 18 Injection, 20mCi/mL to 200 mCi/mL at EOS, 30 mL Multiple-Dose Vial, Rx Only, Manufactured by: Lantheus MI Radiopharmaceuticals, Inc., San Juan, PR --- NDC 11994-015-01	26 doses
Reason for Recall:	**Recall Number:**
Failed Impurities/Degradation Specifications; out of specification result for Acetonitrile residual solvent	D-0942-2017
Code Information:	
Lot: FDG170518-01, exp 5/18/2017	

Class III Drugs Event

Event ID:	**Product Type:**	**Status:**	**Date Terminated:**
77567	Drugs	Ongoing	
Recall Initiation Date:	**Voluntary / Mandated:**	**Center Classification Date:**	**Initial Firm Notification of Consignee or Public:**
06/16/2017	Voluntary: Firm Initiated	07/06/2017	Letter

Recalling Firm:
Sandoz Incorporated
2555 W Midway Blvd
Broomfield CO United States

Distribution Pattern:
Product was distributed throughout the United States

Associated Products

Product Description:	**Product Quantity:**
Amitriptyline HCl Tablets, USP 25 mg, Packaged in a)100-count bottles (NDC 0781-1487-01) and b) 1000-count bottles (NDC 0781-1487-10), Rx only, Manufactured by Sandoz Inc., Princeton, NJ 08540	38,234 bottles
Reason for Recall:	**Recall Number:**
Cross Contamination With Other Product: Imipramine	D-0943-2017
Code Information:	
Lot #: a) GR3831, GS9690, Exp. 08/2019; b) GR3832, Exp. 08/2019.	