Enforcement Report - Week of January 3, 2018

Class II Drugs Event

Event ID:
78657

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
09/05/2017

Voluntary / Mandated:
Voluntary: Firm Initiated

Center Classification Date:
12/26/2017

Initial Firm Notification of Consignee or Public:
Press Release

Recalling Firm:
Simple Diagnostics, Inc.
11555 Heron Bay Blvd Ste 200
Coral Springs FL United States

Distribution Pattern:
Product was distributed throughout the United States

Associated Products

Product Description:
Alcohol Prep Pads (Isopropyl Alcohol USP 70% v/v), 100 Individual Pads, Sterile, Distributed by Simple Diagnostics, Winston Park, NY NDC 98302-0001-05

Product Quantity:
150,250 alcohol pads

Reason for Recall:
Lack of Assurance of Sterility and cGMP Deviations

Recall Number:
D-0134-2018

Code Information:
Lot # SD2070420925 Exp. Date 09/2019, and Lot # SD2070421201 and Lot # SD2070420601, Exp. Date 12/2019

Class II Drugs Event

Event ID:
78678

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
08/10/2017

Voluntary / Mandated:
Voluntary: Firm Initiated

Center Classification Date:
12/28/2017

Initial Firm Notification of Consignee or Public:
E-Mail

Recalling Firm:
SSM Health Care St. Louis DBA SSM St. Clare Health Center
1015 Bowles Ave
Fenton MO United States

Distribution Pattern:
SSM Health entities in the state of MO only

Associated Products

Product Description:
Fentanyl 10 mcg in 0.9% Sodium Chloride 1 mL, 1 mL Vial, Concentration: 10 mcg/mL, This is a compounded injectable drug; Rx only; Hospital/office use only. SSM St. Clare Outsourcing Facility, Fenton, MO. --- NDC: 88890-9010-81

Product Quantity:

Reason for Recall:
Lack of sterility assurance: Microbial growth detected during a routine simulation of the manufacturing process. No batches of distributed product have been identified as actually containing microorganisms.

Recall Number:
D-0136-2018

Code Information:
Lot: 170614-006, exp 9/12/2017

Product Description:
Amiodarone 900 mg in dextrose 5% 500 mL, 500 mL bag, Concentration: 1.8 mg/mL, This is a compounded injectable drug; Rx only; Hospital/office use only. SSM St. Clare Outsourcing Facility, Fenton, MO. --- NDC: 88890-0333-01

Product Quantity:

Reason for Recall:
Lack of sterility assurance: Microbial growth detected during a routine simulation of the manufacturing process. No batches of distributed product have been identified as actually containing microorganisms.

Recall Number:
D-0137-2018

Code Information:
Lot: 170711-005, 10/09/2017

Product Description:
Fentanyl 2 mcg/mL and ropivacaine 0.2% in 0.9% Sodium Chloride 150 mL, 150 mL bag, This is a compounded injectable drug; Rx only; Hospital/office use only. SSM St. Clare Outsourcing Facility, Fenton, MO. --- NDC: 88883-4272-01

Product Quantity:

Reason for Recall:
Lack of sterility assurance: Microbial growth detected during a routine simulation of the manufacturing process. No batches of distributed product have been identified as actually containing microorganisms.

Recall Number:
D-0138-2018

Code Information:
Lot, exp: 170621-008, 09/19/2017; 170703-002, 10/01/2017; 170711-031, 10/09/2017

Product Description:
HYDROmorphone 10 mg in 0.9% Sodium Chloride 50 mL PCA, 50 mL Cartridge, Concentration: 0.2 mg/mL., This is a compounded injectable drug; Rx only; Hospital/office use only. SSM St. Clare Outsourcing Facility, Fenton, MO. --- NDC: 88883-0600-01

Product Quantity:

Reason for Recall:
Lack of sterility assurance: Microbial growth detected during a routine simulation of the manufacturing process. No batches of distributed product have been identified as actually containing microorganisms.

Recall Number:
D-0139-2018

Code Information:
Lot, exp: 170615-004, 9/13/2017; 170720-009, 10/18/2017

Product Description:
Morphine 50 mg in 0.9% Sodium Chloride 5 mL PCA, 50 mL Cartridge, Concentration: 1 mg/mL, This is a compounded injectable drug; Rx only; Hospital/office use only. SSM St. Clare Outsourcing Facility, Fenton, MO. --- NDC: 88887-6795-01

Product Quantity:

Reason for Recall:
Lack of sterility assurance: Microbial growth detected during a routine simulation of the manufacturing process. No batches of distributed product have been identified as actually containing microorganisms.

Recall Number:
D-0140-2018

Code Information:
Lot, exp: 170627-012, 9/25/2017; 170629-019, 9/27/2017

Product Description:
Neostigmine Methylsulfate 5 mg/5 mL, 5 mL Syringe, Concentration: 1 mg/mL. This is a compounded injectable drug; Rx only; Hospital/office use only. SSM St. Clare Outsourcing Facility, Fenton, MO --- NDC: 88890-0329-01

Product Quantity:

Reason for Recall:
Lack of sterility assurance: Microbial growth detected during a routine simulation of the manufacturing process. No batches of distributed product have been identified as actually containing microorganisms.

Recall Number:
D-0141-2018

Code Information:
Lot: 170705-002, 10/03/2017

Product Description:
Norepinephrine 8 mg in dextrose 5% 250 mL, 250mL IV Bag, Concentration: 0.032 mg/mL, This is a compounded injectable drug; Rx only; Hospital/office use only. SSM St. Clare Outsourcing Facility, , Fenton, MO --- NDC: 88890-0334-01

Product Quantity:

Reason for Recall:
Lack of sterility assurance: Microbial growth detected during a routine simulation of the manufacturing process. No batches of distributed product have been identified as actually containing microorganisms.

Recall Number:
D-0142-2018

Code Information:
Lot, exp: 170614-007, 9/12/2017; 170628-001, 9/26/2017; 170703-017, 10/1/2017; 170706-009, 10/4/2017; 170719-007, 10/17/2017

Product Description:
Oxytocin 30 units in 0.9% Sodium Chloride 500 mL, 500 mL IV Bag, Concentration: 0.06 units/mL. This is a compounded injectable drug; Rx only; Hospital/office use only. SSM St. Clare Outsourcing Facility, Fenton, MO --- NDC: 88890-0903-01

Product Quantity:

Reason for Recall:
Lack of sterility assurance: Microbial growth detected during a routine simulation of the manufacturing process. No batches of distributed product have been identified as actually containing microorganisms.

Recall Number:
D-0143-2018

Code Information:
Lot, exp: 170619-011, 9/17/2017; 170707-007, 10/5/2017; 170713-009, 10/11/2017

Product Description:
Phenylephrine 1000 mcg in 0.9% Sodium Chloride 10 mL, 10 mL syringe, Concentration: 100 mcg/mL. This is a compounded injectable drug; Rx only; Hospital/office use only. SSM St. Clare Outsourcing Facility, Fenton, MO --- NDC: 88890-0104-01

Product Quantity:

Reason for Recall:
Lack of sterility assurance: Microbial growth detected during a routine simulation of the manufacturing process. No batches of distributed product have been identified as actually containing microorganisms.

Recall Number:
D-0144-2018

Code Information:
Lot, exp: 170622-007, 9/20/2017; 170710-007, 10/8/2017

Product Description:
Succinylcholine chloride 100 mg in 5 mL syringe, Concentration: 20 mg/mL. This is a compounded injectable drug; Rx only; Hospital/office use only. SSM St. Clare Outsourcing Facility, Fenton, MO --- NDC: 88890-7536-01

Product Quantity:

Reason for Recall:
Lack of sterility assurance: Microbial growth detected during a routine simulation of the manufacturing process. No batches of distributed product have been identified as actually containing microorganisms.

Recall Number:
D-0145-2018

Code Information:
Lot, exp: 170620-005, 9/18/2017; 170626-003, 9/24/2017

Class III Drugs Event

Event ID:
78505

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
11/10/2017

Voluntary / Mandated:
Voluntary: Firm Initiated

Center Classification Date:
12/28/2017

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Bayer HealthCare Pharmaceuticals, Inc.
100 Bayer Blvd
Whippany NJ United States

Distribution Pattern:
Natonwide

Associated Products

Product Description:
Bayer Chewable Low Dose Aspirin 81 mg Orange Flavored 36 tablets, Made in Spain, Distributed by: Bayer Healthcare LLC Morristown, NJ 07962 NDC 0280-2160-36 UPC 3128431310577

Product Quantity:
104,128 HDPE bottles

Reason for Recall:
Failed Stability Specifications

Recall Number:
D-0135-2018

Code Information:
Lot # NAA3T0X; Exp. 07/18

Class III Drugs Event

Event ID:
78694

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
09/26/2017

Voluntary / Mandated:
Voluntary: Firm Initiated

Center Classification Date:
12/22/2017

Initial Firm Notification of Consignee or Public:
Telephone

Recalling Firm:
Pharmedium Services, LLC
150 N Field Dr Ste 350
Lake Forest IL United States

Distribution Pattern:
Nationwide.

Associated Products

Product Description:
morphine Sulfate in 0.9% Sodium Chloride Injection 2 mL Total Volume 1 mg per mL (2 mg per 2 mL), For IV Use, Rx Only, Compounded by: PharMEDium Services LLC. 913 N Davis Ave Cleveland, MS 38732, NDC# 61553-259-28

Product Quantity:
Unknown

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

Recall Number:
D-0130-2018

Code Information:
Lot: 172360026C; Exp. 11/23/2017

Product Description:
morphine Sulfate in 0.9% Sodium Chloride Injection 1 mL Total Volume 2 mg per mL , For IV Use, Rx Only, Compounded by: PharMEDium Services LLC. 913 N Davis Ave Cleveland, MS 38732, NDC# 61553-455-78

Product Quantity:
Unknown

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

Recall Number:
D-0131-2018

Code Information:
Lot:172410028C; Exp. 11/28/2017 Lot: 172470030C; Exp. 12/04/2017

Product Description:
HYDROmorphone HCl in 0.9% Sodium Chloride Injection, 1 mL Total Volume 1 mg per mL, For IV Use Only, Rx Only, Compounded by: PharMEDium Services LLC. 913 N Davis Ave Cleveland, MS 38732, NDC# 61553-165-78

Product Quantity:
Unknown

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

Recall Number:
D-0132-2018

Code Information:
Lot: 172410025C; Exp. 11/27/2017

Class III Drugs Event

Event ID:
78773

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
12/12/2017

Voluntary / Mandated:
Voluntary: Firm Initiated

Center Classification Date:
12/26/2017

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Keryx Biopharmaceuticals, Inc.
1 Marina Park Dr Fl 12
Boston MA United States

Distribution Pattern:
Distributed nationwide in the USA

Associated Products

Product Description:
Auryxia (ferric citrate) tablets, 210 mg , 200-count bottles, RX ONLY, Manufactured for and distributed by: Keryx Biopharmaceticals, Inc. One Marina Park Drive, 12th Floor, Boston, MA 02210 USA. NDC 59922-631-01

Product Quantity:
2,488 200-bottles

Reason for Recall:
Presence of Foreign Substance: Reports have been received of damaged StripPax packets containing silica gel desiccant potentially allowing the silica gel granules to make contact with Auryxia tablets in the bottle.

Recall Number:
D-0133-2018

Code Information:
Lot # AH3842