Enforcement Report - Week of April 10, 2019

Class I Drugs Event

Event ID:
82362

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
03/15/2019

Voluntary / Mandated:
Voluntary: Firm Initiated

Center Classification Date:
03/29/2019

Initial Firm Notification of Consignee or Public:
Press Release

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

Distribution Pattern:
United States and Puerto Rico

Associated Products

Product Description:
8.4% Sodium Bicarbonate Injection, USP 50 mEq (1 mEq/mL) 4.2 grams (84 mg/mL) 50 mL Single-dose fliptop vial, 25 vials per carton, Rx only Hospira, Inc. Lake Forest, IL 60045 USA ---- NDC 0409-6625-02

Product Quantity:
283,400 vials

Reason for Recall:
Presence of Particulate Matter; glass particulates

Recall Number:
D-1073-2019

Code Information:
Lots: 79-238-EV Exp. 1 July 2019; 79-240-EV Exp. 1 July 2019; 80-088-EV Exp. 1 August 2019

Class II Drugs Event

Event ID:
82298

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
03/05/2018

Voluntary / Mandated:
Voluntary: Firm Initiated

Center Classification Date:
04/03/2019

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Johnson Matthey Inc.
2003 Nolte Dr
West Deptford NJ United States

Distribution Pattern:
Nationwide in the US

Associated Products

Product Description:
Morphine Sulfate USP Milled, Active Pharmaceutical Ingredient, Rx only, Johnson Matthey Pharmaceutical Materials, 2003 Nolte Drive, West Deptford, NJ 08066-1742

Product Quantity:
169.976 kg

Reason for Recall:
Microbial Contamination of Non-Sterile Products: Bioburden out of specification results for Morphine Sulfate API.

Recall Number:
D-1077-2019

Code Information:
Lot# B1414-160809, Retest Date AUG 2021

Class II Drugs Event

Event ID:
82477

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
08/23/2018

Voluntary / Mandated:
Voluntary: Firm Initiated

Center Classification Date:
04/02/2019

Initial Firm Notification of Consignee or Public:
Telephone

Recalling Firm:
Pacific Compounding Pharmacy & Consultations Inc
312 Lincoln Ctr
Stockton CA United States

Distribution Pattern:
California

Associated Products

Product Description:
Cefuroxime 10mg/mL INJ 0.5 mg, SDV, Rx only, Pacific Compounding, Stockton, CA

Product Quantity:
41.4 mL

Reason for Recall:
Presence of Particulate Matter: Particulate matter was reported in one lot of Cefuroxime by a physician after use of product.. FDA analysis identified the particulate as coring of the rubber stopper

Recall Number:
D-1076-2019

Code Information:
Lot # 07232018@15 BUD 9/6/18 (frozen)

Class II Drugs Event

Event ID:
82490

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
03/01/2019

Voluntary / Mandated:
Voluntary: Firm Initiated

Center Classification Date:
04/01/2019

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Legacy Pharmaceutical Packaging LLC
13333 Lakefront Dr
Earth City MO United States

Distribution Pattern:
AZ, IN, TN

Associated Products

Product Description:
Losartan Potassium Tablets, USP, 50 mg, 30 tablet bottles, Rx Only, Distributed by: The Kroger Co, Cincinnati, OH 45202, Manufactured for: Torrent Pharma Inc., 150 Allen Road, Suite 102, Basking Ridge, NJ 07920, Packaged by: Legacy Pharmaceutical Packaging LLC, Earth City, MO 63045 NDC 68645-494-54

Product Quantity:
179,544 30-count bottles

Reason for Recall:
CGMP Deviations: presence of an impurity, N-Methylnitrosobutyric acid (NMBA) detected.

Recall Number:
D-1075-2019

Code Information:
Lots: 180190, 180191 (exp 10/2020) and 181597 (exp 02/2021)

Class II Drugs Event

Event ID:
82523

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
03/29/2019

Voluntary / Mandated:
Voluntary: Firm Initiated

Center Classification Date:
04/01/2019

Initial Firm Notification of Consignee or Public:
Letter

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

Distribution Pattern:
Nationwide in the USA.

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:
12,960 bottles

Reason for Recall:
Discoloration: Expansion of an earlier recall due to the presence of dark brown discoloration on the edges of the tablets.

Recall Number:
D-1074-2019

Code Information:
Lot #: PA217060A, Exp 05/2020

Class III Drugs Event

Event ID:
82386

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
03/15/2019

Voluntary / Mandated:
Voluntary: Firm Initiated

Center Classification Date:
03/29/2019

Initial Firm Notification of Consignee or Public:
Letter

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

Distribution Pattern:
Nationwide USA and Guam

Associated Products

Product Description:
Cleocin Phosphate (clindamycin injection), USP, 300 mg/ 2 mL (150 mg/mL), 2 mL-vial, Rx only, Distributed by Pharmacia & Upjohn Co, Division of Pfizer, Inc, New York, NY 10017, NDC 0009-6582-02

Product Quantity:
67 cartons (25 vials per carton)

Reason for Recall:
Failed Impurities/Degradation Specifications: High out-of-specification (OOS) results were demonstrated for several specified impurities at the 24-month time point

Recall Number:
D-1067-2019

Code Information:
Lot #: T97469, Exp. 7/2019, W28574, Exp.09/2019

Product Description:
Cleocin Phosphate, clindamycin injection, USP, 600 mg/ 4 mL (150 mg/mL), 4 mL vial, Rx only, Distributed by Pharmacia & Upjohn Co, Division of Pfizer, Inc, New York, NY 10017, NDC 0009-3124-01

Product Quantity:
820 cartons (25 vials per carton)

Reason for Recall:
Failed Impurities/Degradation Specifications: High out-of-specification (OOS) results were demonstrated for several specified impurities at the 24-month time point

Recall Number:
D-1068-2019

Code Information:
Lot#: T78191, Exp.04/2019, T97494, Exp.07/2019

Product Description:
Cleocin Phosphate, clindamycin injection, USP, 900 mg/ 6 mL (150 mg/mL), 6 mL vial, Rx only, Distributed by Pharmacia & Upjohn Co, Division of Pfizer, Inc, New York, NY 10017. NDC 0009-3447-01

Product Quantity:
500 cartons (25 vials per carton)

Reason for Recall:
Failed Impurities/Degradation Specifications: High out-of-specification (OOS) results were demonstrated for several specified impurities at the 24-month time point

Recall Number:
D-1069-2019

Code Information:
Lot #: T78193, Exp.04/2019

Product Description:
Clindamycin Injection, USP, 300 mg/ 2 mL (150 mg/mL), 2 mL vials, Rx only, Distributed by: Alvogen, Inc., Pine Brook, NJ 07058 USA.,NDC 47781-619-94

Product Quantity:
701 cartons (25 vials per carton)

Reason for Recall:
Failed Impurities/Degradation Specifications: High out-of-specification (OOS) results were demonstrated for several specified impurities at the 24-month time point

Recall Number:
D-1070-2019

Code Information:
Lot: T97472 (exp 07/2019), T97473 (exp 04/2019), W28573 (exp 09/2019), W31814 (exp 10/2019)

Product Description:
Clindamycin Injection, USP, 600 mg/ 4 mL (150 mg/mL), 4 mL vials, Rx only, Distributed by: Alvogen, Inc., Pine Brook, NJ 07058 USA, NDC 47781-620-94

Product Quantity:
8,878 cartons (25 vials per carton)

Reason for Recall:
Failed Impurities/Degradation Specifications: High out-of-specification (OOS) results were demonstrated for several specified impurities at the 24-month time point

Recall Number:
D-1071-2019

Code Information:
Lot #: T97496, Exp.04/2019, T97497, Exp.07/2019, W28564(exp 09/2019), W31812, Exp. 10/2019.

Product Description:
Clindamycin Injection, USP, 900 mg/6 mL (150 mg/mL), 6 mL vial, Rx only, Distributed by: Alvogen, Inc., Pine Brook, NJ 07058 USA. NDC 47781-621-94

Product Quantity:
8,320 cartons (25 vials per carton)

Reason for Recall:
Failed Impurities/Degradation Specifications: High out-of-specification (OOS) results were demonstrated for several specified impurities at the 24-month time point

Recall Number:
D-1072-2019

Code Information:
Lot #: T96398, Exp.07/2019, T97492, Exp.04/2019, W28567, Exp. 09/2019, W31813, Exp.10/2019