Enforcement Report - Week of April 8, 2020

Class I Drugs Event

Event ID:
85231

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
03/16/2020

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
04/06/2020

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Dr. Reddy's Laboratories, Inc.
107 College Rd E
Princeton NJ United States

Distribution Pattern:
Nationwide within the United States

Associated Products

Product Description:
Phytonadione Injectable Emulsion, USP, 10 mg/mL 1 mL ampule (NDC 43598-405-11) packaged in 25 x 1 mL Single-Dose Ampules per carton (NDC 43598-405-16); Rx Only, Distributor: Dr. Reddy's Laboratories Inc., Princeton, NJ 08540.

Product Quantity:
10943 cartons

Reason for Recall:
Defective Container: Recall is due to breaking and shattering of ampules upon opening

Recall Number:
D-1094-2020

Code Information:
Lot #: ACB902, ACB903, Exp. Date 03/2021; ACB904, Exp. Date 04/2021, ACB905, Exp. Date 06/2021

Class I Drugs Event

Event ID:
85232

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
03/16/2020

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
04/04/2020

Initial Firm Notification of Consignee or Public:
Press Release

Recalling Firm:
Y-O Management LLC, dba Natural Remedy Store
713 Sw Military Dr
San Antonio TX United States

Distribution Pattern:
Distributed in GA and TX

Associated Products

Product Description:
Natural Remedies Active Male 500 mg Male Pleasure Formula Dietary Supplement Manufactured For: Natural Remedies San Antonio, TX, USA 1(877)543-3501

Product Quantity:
19156 packets estimated distributed

Reason for Recall:
Marketed without an Approved NDA/ANDA: FDA analysis found this product to contain undeclared Tadalafil, an FDA approved drug for the treatment of erectile dysfunction

Recall Number:
D-1080-2020

Code Information:
All lots remaining within expiry.

Class II Drugs Event

Event ID:
85217

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
03/13/2020

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
04/01/2020

Initial Firm Notification of Consignee or Public:
Telephone

Recalling Firm:
Medical Center Pharmacy, Inc.
2401 N Ocoee St
Cleveland TN United States

Distribution Pattern:
Specific prescriptions to patients in TN

Associated Products

Product Description:
C-*Albumin Eye Drop 10% S, packaged in 10 mL bottles, Rx only, Medical Center Pharmacy, 2401 Ocoee Street, Cleveland, TN 37311, NDC 44206-0251-05.

Product Quantity:
2 bottles

Reason for Recall:
Lack of Assurance of Sterility: due to concerns with production processes which cannot assure sterility of products intended to be sterile.

Recall Number:
D-1073-2020

Code Information:
Lot: 03042020@28 BUD: 03/18/2020; 03032020@3 BUD: 03/17/2020

Product Description:
C-*Vancomycin Opthal 14 mg drops, 5 mL bottle, Rx only, Medical Center Pharmacy, 2401 Ocoee Street, Cleveland, TN 37311, NDC 67457-0340-01.

Product Quantity:
1 bottle

Reason for Recall:
Lack of Assurance of Sterility: due to concerns with production processes which cannot assure sterility of products intended to be sterile.

Recall Number:
D-1074-2020

Code Information:
Lot: 03042020@7 BUD: 03/18/2020

Product Description:
*Morphine 2 mg/mL Cassette, 100 mL CADD Cassette, Rx only, Medical Center Pharmacy, 2401 N. Ocoee Street, Cleveland, TN 37311, NDC 00409-1134-03.

Product Quantity:
1 cassette

Reason for Recall:
Lack of Assurance of Sterility: due to concerns with production processes which cannot assure sterility of products intended to be sterile.

Recall Number:
D-1075-2020

Code Information:
Lot: 03032020@34 BUD: 03/17/2020

Product Description:
C-*Gentamicin/Bacitracin Bladder Irrigation in N.S., 250 mL bags, Rx only, Medical Center Pharmacy, 2401 Ocoee Street, Cleveland, TN 37311, NDC 63323-0010-02.

Product Quantity:
2 bags

Reason for Recall:
Lack of Assurance of Sterility: due to concerns with production processes which cannot assure sterility of products intended to be sterile.

Recall Number:
D-1076-2020

Code Information:
Lot: 03022020@3 BUD: 03/16/2020

Product Description:
*Mitomycin 0.04% Ophth DR eye drops, 5 mL bottle, Rx only, Medical Center Pharmacy, 2401 N. Ocoee Street, Cleveland, TN 37311, NDC 67457-0518-05.

Product Quantity:
2 bottles

Reason for Recall:
Lack of Assurance of Sterility: due to concerns with production processes which cannot assure sterility of products intended to be sterile.

Recall Number:
D-1077-2020

Code Information:
Lot: 03022020@5 BUD: 03/16/2020

Class II Drugs Event

Event ID:
85234

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
03/16/2020

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
03/31/2020

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
The Medicine Shoppe Pharmacy
3524 B Tamiami Trl
Port Charlotte FL United States

Distribution Pattern:
Florida

Associated Products

Product Description:
Gentamicin 80mg/60 mL Irrigation, containers, The Medicine Shoppe, 3524 B Tamiami Trail Port Charlotte, FL 33952

Product Quantity:
4 bottles

Reason for Recall:
Lack of Assurance of Sterility

Recall Number:
D-1072-2020

Code Information:
7016542, discard after 01/12/2021

Class II Drugs Event

Event ID:
85333

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
03/30/2020

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
03/30/2020

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Par Pharmaceutical Inc.
1 Ram Ridge Rd
Chestnut Ridge NY United States

Distribution Pattern:
Product was distributed within the United States.

Associated Products

Product Description:
Glycopyrrolate Tablets, USP 1 mg, 100-count bottle, Rx only, Dist. by: Par Pharmaceutical, Chestnut Ridge, NY, 10977, U.S.A, Mfg. by: Par Formulations Private Limited, 1/58, Pudupakkam, Kelambakkam - 603 103., Made in India NDC# 49884-0065-01

Product Quantity:
29,352 bottles

Reason for Recall:
Failed Impurities/Degradation Specification: Presence of unknown impurity observed.

Recall Number:
D-1071-2020

Code Information:
Lot # 32809101, Exp 3/2021

Class II Drugs Event

Event ID:
85355

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
04/01/2020

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
04/02/2020

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Lupin Pharmaceuticals Inc.
Harborplace Tower 111 S Calvert St Fl 21st
Baltimore MD United States

Distribution Pattern:
U.S.A. Nationwide

Associated Products

Product Description:
Lisinopril Tablets USP, 30 mg, 100-count bottle, Rx only, Manufactured for: Lupin Pharmaceuticals, Inc., Baltimore, Maryland 21202, NDC 68180-982-01

Product Quantity:
25,944 bottles

Reason for Recall:
Presence of Foreign Tablet/ Capsule: Product complaint received indicating mix-up of one lisinopril 5mg tablet inside of a 30 mg, 100-count bottle of Lisinopril Tablets.

Recall Number:
D-1079-2020

Code Information:
Lot #: Q900580, Exp 9/2021

Not Yet Classified Drugs Event

Event ID:
85239

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
03/25/2020

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Akorn Inc
1925 W Field Ct Ste 300
Lake Forest IL United States

Distribution Pattern:
Distributed Nationwide in the USA

Associated Products

Product Description:
Fentanyl Citrate Injection, USP, 100 mcg/2 mL (50 mcg/mL), 10 Ampules per carton, (2 mL each), Rx only, Manufactured by: Akorn, Inc., Lake Forest, IL 60045, NDC 17478-030-02

Product Quantity:
15,170 ampules

Reason for Recall:
Failed impurities/degradation specification: Out-of-Specification result for total impurity at 4.1% (Limit: NMT 3.0%) during retained sample testing.

Recall Number:

Code Information:
Lot 081887A, EXP 08/2021