Enforcement Report - Week of November 22, 2017

Class II Drugs Event

Event ID:
78035

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
08/31/2017

Voluntary / Mandated:
Voluntary: Firm Initiated

Center Classification Date:
11/13/2017

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Amneal Pharmaceuticals LLC
118 Beaver Trl
Glasgow KY United States

Distribution Pattern:
MS, NC, OH, TX, UT

Associated Products

Product Description:
Fosphenytoin Sodium Injection, USP, 500 mg PE/10 mL (50 mg PE/mL. 10 mL Single Dose Vial, Rx Only. Distributed by: Amneal Biosciences, Bridgewater, NJ 08807. NDC: 70121-1390-7

Product Quantity:
14,000 vials

Reason for Recall:
Presence of Particulate Matter

Recall Number:
D-0076-2018

Code Information:
Lot # AP160016; Exp. 05/18

Class II Drugs Event

Event ID:
78074

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
09/05/2017

Voluntary / Mandated:
Voluntary: Firm Initiated

Center Classification Date:
11/15/2017

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Llorens Pharmaceutical Corp.
Carr. #1 Km 34.3
Caguas PR United States

Distribution Pattern:
Puerto Rico

Associated Products

Product Description:
Urin D/S Tablets Methenamine 81.6 mg, Sodium Biphosphate 40.8 mg, Phenyl Salicylate 36.2 mg, Methylene Blue 10.8 mg, Hyoscyamine Sulfate 0.12 mg, Rx Only, 100-count bottle, Manufactured For: Llorens Pharmaceutical Corp., International Division, Miami, FL 33166. NDC: 54859-701-10

Product Quantity:
19232 bottles

Reason for Recall:
Superpotent Drug: Subpotent Drug. FDA analysis found this product to be Out of Specification for assay which could result in either Subpotent and/or Superpotent tablets.

Recall Number:
D-0081-2018

Code Information:
Lots: 22811601, 22811602, Exp. 05/18; 202U1601 Exp. 11/18

Class II Drugs Event

Event ID:
78402

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
10/25/2017

Voluntary / Mandated:
Voluntary: Firm Initiated

Center Classification Date:
11/14/2017

Initial Firm Notification of Consignee or Public:
Telephone

Recalling Firm:
Fagron, Inc
2400 Pilot Knob Rd
Saint Paul MN United States

Distribution Pattern:
Nationwide in USA

Associated Products

Product Description:
Estriol, For Prescription Compounding, packaged in a) 1 G bottle (NDC: 51552-1392-1), b) 5 G bottle (NDC: 51552-1392-2), c) 25 G bottle (NDC: 51552-1392-3) and d) 100 G bottle (NDC 51552-1392-5), Rx only, Distributed by Fagron, Inc., 2400 Pilot Knob Rd, St. Paul, MN 55120 Tel. 1-(800) 423-6967

Product Quantity:
934 grams

Reason for Recall:
cGMP Deviations: lack of quality assurance at the API manufacturer.

Recall Number:
D-0079-2018

Code Information:
Lot #, Expiration Date: a) 1 G bottle: 16F23-U05-033657, Exp. 5/26/2017. b) 5 G bottle: 16F23-U05-033656, Exp. 5/26/2018; 17C02-U02-035890, Exp. 1/19/2019. c) 25 G bottle: 16F23-U05-033655, Exp. 5/26/2018; 17C02-U02-035887, Exp. 1/19/2019. d) 100 G bottle: 17C02-U02-035888, Exp. 1/19/2019

Class II Drugs Event

Event ID:
78503

Product Type:
Drugs

Status:
Completed

Date Terminated:

Recall Initiation Date:
10/13/2017

Voluntary / Mandated:
Voluntary: Firm Initiated

Center Classification Date:
11/14/2017

Initial Firm Notification of Consignee or Public:
Telephone

Recalling Firm:
PharMEDium Services, LLC.
6100 Global Dr
Memphis TN United States

Distribution Pattern:
CA, IL

Associated Products

Product Description:
Hydromorphone HCl 0.5 mg per mL in 0.9% Sodium Chloride Injection 1 mL, packaged in syringes, Rx Only , PharMEDium Services, LLC. 913 N. Davis Ave Cleveland, MS 38732, NDC 61553-352-40

Product Quantity:
499 syringes

Reason for Recall:
Superpotent drug: out of specification result for potency

Recall Number:
D-0080-2018

Code Information:
Lot#: 172820134M, Exp 01/18

Class III Drugs Event

Event ID:
78118

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
08/29/2017

Voluntary / Mandated:
Voluntary: Firm Initiated

Center Classification Date:
11/10/2017

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Amerisource Health Services
2550 John Glenn Ave Ste A
Columbus OH United States

Distribution Pattern:
Nationwide USA and Puerto Rico

Associated Products

Product Description:
Enalapril Maleate Tablets, USP, 5 mg, 100 Tablets (10 x 10), Rx Only. Packaged and Distributed by: American Health Packaging, Columbus, Ohio 43217. NDC: 68084-390-01

Product Quantity:
93,600 tablets

Reason for Recall:
Failed Stability Specifications

Recall Number:
D-0074-2018

Code Information:
Lot #:167194; Exp. 12/31/2018

Class III Drugs Event

Event ID:
78286

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
10/12/2017

Voluntary / Mandated:
Voluntary: Firm Initiated

Center Classification Date:
11/10/2017

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Genzyme Corporation
11 Forbes Rd
Northborough MA United States

Distribution Pattern:
Nationwide

Associated Products

Product Description:
Clolar (clofarabine) 20 mg/20 mL (1 mg/mL) Injection, for intravenous use, Rx Only, Mfd. by: Teva Pharmachemie Swensweg 5 Haarlem, The Netherlands Mfd. for: Genzyme Corporation, Cambridge, MA 02142, NDC 0024-5860-01.

Product Quantity:
9,343 single dose vials

Reason for Recall:
Labeling: Incorrect or Missing Package Insert.

Recall Number:
D-0075-2018

Code Information:
Lot #: K5006Y01; Exp. 08/31/18 Lot #: K5006Y03; Exp. 08/31/18 Lot #: K6001Y01; Exp. 03/31/19

Class III Drugs Event

Event ID:
78325

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
10/19/2017

Voluntary / Mandated:
Voluntary: Firm Initiated

Center Classification Date:
11/13/2017

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Allergan Sales, LLC
8301 Mars Dr
Waco TX United States

Distribution Pattern:
Nationwide and Barbados, Curacao, Dominican Republic, Guyana, Jamaica, and Trinidad and Tobago.

Associated Products

Product Description:
Combigan (brimonidine tartrate/timolol maleate ophthalmic solution) 0.2%/0.5%, Rx only, packaged in a) 2.5 mL NDC# 0023-9211-03; b) 5 mL (NDC# 0023-9211-05); c) 10 mL (NDC# 0023-9211-10); d) 15 mL (NDC# 0023-9211-15) bottles, Manufactured By: Allergan, Irvine, CA 92612..

Product Quantity:
715,041 bottles

Reason for Recall:
Failed Impurities/Degradation Specifications.

Recall Number:
D-0077-2018

Code Information:
Lot #: a) 94659 Exp. FEB-2019; b) 94715, Exp. JAN-2019; 94757, Exp. FEB-2019, 94715A, Exp. JAN-2019; 95297, Exp. MAR-2019; c) 95223 Exp. MAR-2019; d) 95220 Exp. MAR-2019

Product Description:
Lumigan (bimatoprost ophthalmic solution) 0.01%, 2.5 mL bottle, Rx only, Allergan, Irvine, CA 92612. NDC# 0023-3205-03

Product Quantity:
153,616 bottles

Reason for Recall:
Failed Impurities/Degradation Specifications.

Recall Number:
D-0078-2018

Code Information:
Lot #: 92575 Exp. JUN-2018

Class III Drugs Event

Event ID:
78461

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
10/30/2017

Voluntary / Mandated:
Voluntary: Firm Initiated

Center Classification Date:
11/16/2017

Initial Firm Notification of Consignee or Public:
Letter

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

Distribution Pattern:
Nationwide

Associated Products

Product Description:
Meclizine hydrochloride tablets USP, 12.5 mg, 100 count HDPE bottle, Rx only, Manufactured by: Jubilant Cadista Pharmaceuticals Inc., Salisbury, MD 21801, NDC 59746-122-06

Product Quantity:
744 bottles

Reason for Recall:
Marketed without an approved NDA/ANDA: Bottles were released prior to final approval.

Recall Number:
D-0082-2018

Code Information:
Lot # 17P0430, Exp 05/19