Enforcement Report - Week of May 15, 2019

Class I Drugs Event

Event ID:
82669

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
04/19/2019

Voluntary / Mandated:
Voluntary: Firm Initiated

Center Classification Date:
05/13/2019

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 in the USA

Associated Products

Product Description:
FENTANYL Transdermal System, 12 mcg/h, five (12 mcg/h) systems per carton, Rx only, Distributed by: Alvogen, Inc., Pine Brook, NJ 07058; Manufactured by: 3M Drug Delivery Systems, St. Paul, MN 55107, NDC 47781-423-47.

Product Quantity:
119,608 cartons

Reason for Recall:
Product Mix-Up: Customer complaint that their carton labeled as Fentanyl Transdermal Systems, 12 mcg/h contained five patches labeled and containing 50 mcg/h.

Recall Number:
D-1277-2019

Code Information:
Lot#: 180060, Exp 05/2020; 180073, Exp 06/2020.

Class II Drugs Event

Event ID:
82714

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
04/25/2019

Voluntary / Mandated:
Voluntary: Firm Initiated

Center Classification Date:
05/07/2019

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Zydus Pharmaceuticals USA Inc
73 Route 31 N
Pennington NJ United States

Distribution Pattern:
Nationwide

Associated Products

Product Description:
Acyclovir Tablets, USP, 400 mg, 100 count bottles, Rx Only Manufactured by: Cadila Healthcare Ltd., India Distributed by: Zydus Pharmaceuticals (USA) Inc. Pennington, NJ USA 08534 NDC 68382-791-01

Product Quantity:

Reason for Recall:
Labeling; Label Mix-up; report received of one bottle labeled as Acyclovir Tablets USP 400 mg actually contained Carvedilol Tablets 6.25 mg

Recall Number:
D-1272-2019

Code Information:
Z804517, Nov 30, 2020

Product Description:
Carvedilol Tablets, USP, 6.25 mg, 500 count bottles, Rx Only Manufactured by: Cadila Healthcare Ltd., India Distributed by: Zydus Pharmaceuticals (USA) Inc. Pennington, NJ USA 08534 NDC 68352-093-05

Product Quantity:
3900

Reason for Recall:
Labeling; Label Mix-up; report received of one bottle labeled as Acyclovir Tablets USP 400 mg actually contained Carvedilol Tablets 6.25 mg

Recall Number:
D-1273-2019

Code Information:
Z804517, exp Nov 30, 2020

Not Yet Classified Drugs Event

Event ID:
82680

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
04/30/2019

Voluntary / Mandated:
Voluntary: Firm Initiated

Center Classification Date:

Initial Firm Notification of Consignee or Public:
Letter

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

Distribution Pattern:
nationwide

Associated Products

Product Description:
Mycophenolate Mofetil for Injection, USP Rx Only 500 mg, 4 Single Dose Vials, Distributed by: Par Pharmaceutical Chestnut Ridge, NY 10977 NDC 342023-172-044

Product Quantity:
4506 packs

Reason for Recall:
Presence of Particulate Matter; glass fragment observed in one vial of reconstituted product

Recall Number:

Code Information:
AD812, exp 9/2020