Enforcement Report - Week of March 28, 2018

Class II Drugs Event

Event ID:
79403

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
12/20/2017

Voluntary / Mandated:
Voluntary: Firm Initiated

Center Classification Date:
03/20/2018

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Fresenius Medical Care Renal Therapies Group, LLC
920 Winter St
Waltham MA United States

Distribution Pattern:
Product was distributed throughout the United States to patients and clinics.

Associated Products

Product Description:
DELFLEX Peritoneal Dialysis Solution, 2.5% Low Mg/Low Ca Single Bag, packaged in a) 3L (4 pack, NDC 49230-209-30), b) 2 L(6 pack NDC 49230-209-23), Rx only, Fresenius Medical Care NA, Waltham, MA 02451.

Product Quantity:
3,734 cases

Reason for Recall:
Lack of Assurance of Sterility: Leakage of the peritoneal dialysis (PD) solution bag.

Recall Number:
D-0604-2018

Code Information:
Lot #: a) 17KU03006, 7KU03007; b) 17KU03004, 17KU03005, Exp.08/2019

Class III Drugs Event

Event ID:
79457

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
03/05/2018

Voluntary / Mandated:
Voluntary: Firm Initiated

Center Classification Date:
03/26/2018

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Pine Pharmaceuticals, LLC
100 Colvin Woods Pkwy Ste 300
Tonawanda NY United States

Distribution Pattern:
NY only

Associated Products

Product Description:
Brilliant Blue G for Intraocular Injection 0.5mL vial 0.25 mg/mL Compounded by: Pine Pharmaceuticals 355 Riverwalk Pkwy Tonawanda, NY 14150. NDC 69194-0358-01

Product Quantity:
136 units

Reason for Recall:
Labeling: Label Mix-Up: Brilliant Blue G was labeled with an inaccurate auxiliary label which contained active/inactive ingredient information for incorrect product.

Recall Number:
D-0607-2018

Code Information:
Lot#: 18098@1, Exp. 7/16/2018

Not Yet Classified Drugs Event

Event ID:
79466

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
03/09/2018

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:
Nationwide in the USA and Puerto Rico

Associated Products

Product Description:
Triamcinolone Acetonide Lotion, USP 0.1%, 60 mL bottle, Rx Only, Marketed by: VersaPharm Incorporated, Marietta, GA 30062; Manufactured by: Ei LLC, Kannapolis, NC 28083, NDC 61748-220-60.

Product Quantity:
4,128 bottles

Reason for Recall:
Failed Impurities/Degradation Specifications: High out of specification results for an impurity.

Recall Number:

Code Information:
Lot# 2062900, Exp 05/18

Not Yet Classified Drugs Event

Event ID:
79542

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
03/19/2018

Voluntary / Mandated:
Voluntary: Firm Initiated

Center Classification Date:

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Teva Pharmaceuticals USA
1090 Horsham Rd
North Wales PA United States

Distribution Pattern:
Distributed within the United States and Puerto Rico.

Associated Products

Product Description:
Estradiol Vaginal Inserts, USP 10 mcg, packaged in a) 8 inserts/carton (NDC 0093-3223-08) and b) 18 inserts/carton (NDC 0093-3223-97), Rx only, Teva Women's Health, Inc. Subsidiary of Teva Pharmaceuticals USA, North Wales, PA 19454.

Product Quantity:
640,486 vaginal inserts

Reason for Recall:
Defective Container: This recall is being initiated due to product complaints regarding difficulty in dispensing the tablet from the applicator.

Recall Number:

Code Information:
Lot #: a) 33812545A, 33812546A, 33812774A, Exp. 12/2018; 33812775A, Exp. 01/2019; 33812776A, 33812777A, Exp. 05/2019; 33813786A, 33813868A, Exp. 7/2019; 33813974A, 33814058A, Exp. 09/2019; 33814113A, Exp. 01/2019; b) 33812547A, 33813361A,33813676A, Exp. 1/2019