Enforcement Report - Week of September 19, 2018

Class I Drugs Event

Event ID:
80893

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
08/23/2018

Voluntary / Mandated:
Voluntary: Firm Initiated

Center Classification Date:
09/17/2018

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Hellolife
4460 44th St SE Ste C600
Grand Rapids MI United States

Distribution Pattern:
Nationwide USA, Algeria Australia Belgium Brazil Bulgaria Canada Colombia Croatia Cyprus Czech Republic Denmark Dominican Republic Ecuador Estonia French Polynesia Greece Guadeloupe Guam Hong Kong Hungary India Ireland Israel Italy Latvia Lithuania Martinique Mexico Monaco Netherlands New Zealand Norway Peru Poland Portugal Romania Russia Russian Federation Saudi Arabia Senegal Serbia Slovakia Slovakia (Slovak Republic) Slovenia Swaziland Sweden Switzerland Taiwan Turkey United Kingdom

Associated Products

Product Description:
Compulsin, Homeopathic (OTC Medicine), 2 fl oz (59 mL) per bottle, Mftd for: HelloLife, Inc. 4635 40th St SE, Grand Rapids, MI 49512. NDC: 49726-034-02

Product Quantity:
989 bottles

Reason for Recall:
Microbial Contamination of Non Sterile Products; Products contaminated with microoganisms, including but not limited to Staphylococcus saprophyticus and Burkholderia cepacia

Recall Number:
D-1200-2018

Code Information:
Lot: CO/030717B, exp 7/2019

Product Description:
Neuroveen, Homeopathic (OTC Medicine), 2 fl oz (59 mL) per bottle, Mftd for: HelloLife, Inc. 4635 40th St SE, Grand Rapids, MI 49512. NDC: 49726-015-02

Product Quantity:
4,358 bottles

Reason for Recall:
Microbial Contamination of Non Sterile Products; Products contaminated with microoganisms, including but not limited to Staphylococcus saprophyticus and Burkholderia cepacia

Recall Number:
D-1201-2018

Code Information:
Lot: NV/030717D, exp 7/2019

Product Description:
Thyroveev, Homeopathic (OTC Medicine), 2 fl oz (59 mL) per bottle, Mftd for: HelloLife, Inc. 4635 40th St SE, Grand Rapids, MI 49512. NDC: 49726-025-02

Product Quantity:
370 bottles

Reason for Recall:
Microbial Contamination of Non Sterile Products; Products contaminated with microoganisms, including but not limited to Staphylococcus saprophyticus and Burkholderia cepacia

Recall Number:
D-1202-2018

Code Information:
Lot: TV/030717F, exp 7/2019

Product Description:
Respitrol, Homeopathic (OTC Medicine), 2 fl oz (59 mL) per bottle, Mftd for: HelloLife, Inc. 4635 40th St SE, Grand Rapids, MI 49512. NDC: 49726-003-02

Product Quantity:
1,869 bottles

Reason for Recall:
Microbial Contamination of Non Sterile Products; Products contaminated with microoganisms, including but not limited to Staphylococcus saprophyticus and Burkholderia cepacia

Recall Number:
D-1203-2018

Code Information:
Lot: RE/030717E, exp 7/2019

Class I Drugs Event

Event ID:
80915

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
08/27/2018

Voluntary / Mandated:
Voluntary: Firm Initiated

Center Classification Date:
09/12/2018

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
SCA Pharmaceuticals
8821 Knoedl Ct
Little Rock AR United States

Distribution Pattern:
Three hospitals in DC, VA, CT

Associated Products

Product Description:
Furosemide 100 mg added to 0.9% Sodium Chloride 100 mL Injection, 100 mL Single Dose Container bag, Rx Only, SCA Pharmaceuticals, 8821 Knoedl Ct., Little Rock, AR 72205, 877.550.5059, barcode 70004063032.

Product Quantity:
1384 bags

Reason for Recall:
Presence of Precipitate: Customer complaint for visible precipitate in product believed to be the active ingredient furosemide.

Recall Number:
D-1189-2018

Code Information:
Lots: 20180711@18, BUD: 10/3/2018; 20180712@19, 20180712@21, 20180712@24 BUD: 10/4/2018; 20180713@19, BUD: 10/5/2018; 20180727@21, BUD: 10/19/2018; 20180803@20, BUD: 10/26/2018

Class III Drugs Event

Event ID:
80782

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
08/07/2018

Voluntary / Mandated:
Voluntary: Firm Initiated

Center Classification Date:
09/10/2018

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Mylan Pharmaceuticals Inc.
781 Chestnut Ridge Rd
Morgantown WV United States

Distribution Pattern:
Distributed Nationwide in the US

Associated Products

Product Description:
Diltiazem HCl Extended-Release Capsules, USP 120 mg 100-count bottle, Rx only, Mylan Pharmaceuticals Inc. Morgantown, WV 26505. NDC 0378-5220-01

Product Quantity:
11,799 bottles of 100

Reason for Recall:
Failed Impurities/Degradation Specifications: Out of specification test results obtained during routine stability testing for related compound.

Recall Number:
D-1186-2018

Code Information:
Batch code # 3093163, expiration date 04/2019

Product Description:
Diltiazem HCl Extended-Release Capsules, USP 120 mg 500-count bottle, Rx only, Mylan Pharmaceuticals Inc. Morgantown, WV 26505. NDC 0378-5220-05

Product Quantity:
656 500-count bottles

Reason for Recall:
Failed Impurities/Degradation Specifications: Out of specification test results obtained during routine stability testing for related compound.

Recall Number:
D-1187-2018

Code Information:
Batch code # 3093163, expiration date 04/2019

Class III Drugs Event

Event ID:
80834

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
08/14/2018

Voluntary / Mandated:
Voluntary: Firm Initiated

Center Classification Date:
09/12/2018

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
United Therapeutics Corp.
55 Tw Alexander Dr
Durham NC United States

Distribution Pattern:
IL, PA

Associated Products

Product Description:
Tyvaso Inhalation System Patient a) Starter Kit with TYVASO (treprostinil) Inhalation Solution. Treprostinil 1.74 mg/2.9 mL (0.6 mg/mL) (NDC 66302-206-01) b) TD-300/A Replacement Device Kit Material Number RTP3099 RX Only. Manufactured by United Therapeutics Corporation Research Triangle Park, NC 27709

Product Quantity:
2801 devices

Reason for Recall:
Defective Delivery System: Water ingress through the lower water cup sensor of the device.

Recall Number:
D-1188-2018

Code Information:
Lot number a) 2101503, 2101507, 2101523, 2101532, 2101533, EXP 07/31/2019; 2101557, EXP 11/30/2019 b) Lot # 2101504, EXP 4/24/2021; 2101509, 2101522, EXP 5/8/2021; 2101531, EXP 5/15/2021; 2101534, EXP 6/10/2021; 2101543, EXP 6/14/2021; 2101558, EXP 7/26/2021

Class III Drugs Event

Event ID:
80923

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
08/28/2018

Voluntary / Mandated:
Voluntary: Firm Initiated

Center Classification Date:
09/07/2018

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

Associated Products

Product Description:
Argatroban Injection, 250 mg/2.5 mL (100 mg/mL), 2.5 mL Single-use Vial, Rx only, Sterile, Manufactured for: Hospira, Inc, Lake Forest, IL 60045 USA. NDC: 0409-1140-01

Product Quantity:
1,580 vials

Reason for Recall:
Failed Impurities/Degradation Specifications; Out of specification stability testing results at the 18 month time point

Recall Number:
D-1184-2018

Code Information:
Lot: DP602, 10/2018

Class III Drugs Event

Event ID:
80969

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
09/06/2018

Voluntary / Mandated:
Voluntary: Firm Initiated

Center Classification Date:
09/10/2018

Initial Firm Notification of Consignee or Public:
Letter

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

Distribution Pattern:
United States nationwide

Associated Products

Product Description:
Pramipexole dihydrochloride extended release tablets, 0.75 mg, packaged in 30-count bottles, Rx only, Manufactured by: Par Pharmaceutical, Chestnut Ridge, NY 10977, NDC 10370-252-11

Product Quantity:
16,207 (bottles of 30 tablets)

Reason for Recall:
Failed impurities/degradation specifications: Finished product contain a known product impurity about current specification levels.

Recall Number:
D-1185-2018

Code Information:
Lot #: 29906202, Exp 12/18; 29993102, Exp 2/19; 30366102, 30373103, Exp 4/19; 31940601, Exp 3/20.

Not Yet Classified Drugs Event

Event ID:
80850

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
08/21/2018

Voluntary / Mandated:
Voluntary: Firm Initiated

Center Classification Date:

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Accord Healthcare, Inc.
1009 Slater Rd Ste 210B
Durham NC United States

Distribution Pattern:
Nationwide in the USA and Puerto Rico.

Associated Products

Product Description:
Hydrochlorothiazide Tablets USP, 12.5 mg, 100-count bottle, Rx Only, Manufactured for: Accord Healthcare, Inc., Durham, NC 27703; Manufactured by: Intas Pharmaceuticals Limited, Ahmedabad - 382 210, India; NDC 16729-182-01.

Product Quantity:
46,632 bottles

Reason for Recall:
Labeling: Label Mix-Up: customer complaint that a sealed bottle labeled as Hydrochlorothiazide Tablets USP 12.5 mg contained only Spironolactone Tablets USP 25 mg.

Recall Number:

Code Information:
Lot: PW05264, Exp. 11/2019