Enforcement Report - Week of April 12, 2017

Class I Drugs Event

Event ID:
76284

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
01/24/2017

Voluntary / Mandated:
Voluntary: Firm Initiated

Center Classification Date:
04/05/2017

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Hospira Inc., A Pfizer Company
275 N Field Dr
Lake Forest IL United States

Distribution Pattern:
U.S. Nationwide

Associated Products

Product Description:
Vancomycin Hydrochloride for Injection, USP, 10 grams, Pharmacy Bulk Package - Not For Direct Infusion, For Intravenous Use, packaged in 100 mL glass vial, Hospira, Inc., Lake Forest, IL 60045, NDC 0409-6510-01

Product Quantity:
30,880 vials

Reason for Recall:
Presence of Particulate Matter: A hair was found stuck to the stopper of inside a single vial. The hair came in contact with the reconstituted drug product.

Recall Number:
D-0638-2017

Code Information:
Lot # 591053A, Exp 11/1/2017

Class I Drugs Event

Event ID:
76395

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
02/03/2017

Voluntary / Mandated:
Voluntary: Firm Initiated

Center Classification Date:
04/05/2017

Initial Firm Notification of Consignee or Public:
Letter

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

Distribution Pattern:
U.S. Nationwide

Associated Products

Product Description:
Vancomycin HCl 1.25 g added to 5% Dextrose 250 mL Bag For IV Use Only, Rx Only, SCA Pharmaceuticals, Little Rock, AR 72205, NDC 70004-0922-40

Product Quantity:
50 bags

Reason for Recall:
Presence of particulate matter - this recall is due to a recent Hospira recall of vancomyicn hydrochloride 10gm vials due to presence of particulate matter.

Recall Number:
D-0639-2017

Code Information:
Lot: 20161221@70, Exp 02/04/2017

Product Description:
Vancomycin HCl 1 g added to 0.9% Sodium Chloride 250 mL Bag For IV Use Only, Rx Only, SCA Pharmaceuticals, Little Rock, AR 72205, NDC 70004-0920-59

Product Quantity:
386 bags

Reason for Recall:
Presence of particulate matter - this recall is due to a recent Hospira recall of vancomyicn hydrochloride 10gm vials due to presence of particulate matter.

Recall Number:
D-0640-2017

Code Information:
Lot: 20161228@65, Exp 02/26/2017; Lot: 20161214@76, Exp 02/12/2017

Product Description:
Vancomycin HCl 1.25 g added to 0.9% Sodium Chloride 250 mL Bag For IV Use Only, Rx Only, SCA Pharmaceuticals, Little Rock, AR 72205, NDC 70004-0923-59

Product Quantity:
716 bags

Reason for Recall:
Presence of particulate matter - this recall is due to a recent Hospira recall of vancomyicn hydrochloride 10gm vials due to presence of particulate matter.

Recall Number:
D-0641-2017

Code Information:
Lot: 20161213@23, Exp 2/11/2017; Lot: 20161214@80, Exp 2/12/2017; Lot: 20161215@1, Exp 2/13/2017

Product Description:
Vancomycin HCl 1.5 g added to 0.9% Sodium Chloride 250 mL Bag For IV Use Only Rx Only, SCA Pharmaceuticals, Little Rock, AR 72205, NDC 70004-0924-59

Product Quantity:
490 bags

Reason for Recall:
Presence of particulate matter - this recall is due to a recent Hospira recall of vancomyicn hydrochloride 10gm vials due to presence of particulate matter.

Recall Number:
D-0642-2017

Code Information:
Lot: 20161212@44, Exp 2/10/2017; Lot: 20161230@40, Exp 2/28/2017

Product Description:
Vancomycin HCl 1.5 gram added to 5% Dextrose 500 mL Total Approximate Volume 515 mL For IV Use Only, Rx Only , SCA Pharmaceuticals, Little Rock, AR 72205, NDC 70004-0925-44

Product Quantity:
50 bags

Reason for Recall:
Presence of particulate matter - this recall is due to a recent Hospira recall of vancomyicn hydrochloride 10gm vials due to presence of particulate matter.

Recall Number:
D-0643-2017

Code Information:
Lot: 20161221@74, Exp 2/4/2017

Product Description:
Vancomycin HCl 750 mg added to 250 mL 0.9% Sodium Chloride For IV Use Only, Rx Only, SCA Pharmaceuticals, Little Rock, AR 72205, NDC 70004-0929-40

Product Quantity:
30 bags

Reason for Recall:
Presence of particulate matter - this recall is due to a recent Hospira recall of vancomyicn hydrochloride 10gm vials due to presence of particulate matter.

Recall Number:
D-0644-2017

Code Information:
Lot: 20161222@8, Exp 2/5/2017

Product Description:
Vancomycin HCl 750 mg added to 5% Dextrose 250 mL For IV Use Only, Rx Only, SCA Pharmaceuticals, Little Rock, AR 72205, NDC 70004-0918-40

Product Quantity:
62 bags

Reason for Recall:
Presence of particulate matter - this recall is due to a recent Hospira recall of vancomyicn hydrochloride 10gm vials due to presence of particulate matter.

Recall Number:
D-0645-2017

Code Information:
Lot: 20161219@3, Exp 2/2/2017

Class I Drugs Event

Event ID:
76410

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
02/08/2017

Voluntary / Mandated:
Voluntary: Firm Initiated

Center Classification Date:
04/05/2017

Initial Firm Notification of Consignee or Public:
Two or more of the following: Email, Fax, Letter, Press Release, Telephone, Visit

Recalling Firm:
X-Gen Pharmaceuticals Inc.
300 Daniel Zenker Dr
Horseheads NY United States

Distribution Pattern:
Nationwide in the USA.

Associated Products

Product Description:
Ibuprofen Lysine Injection, 20 mg/2 mL (10 mg/mL), 2 mL Single-Dose Vial (NDC 39822-1030-1), packaged in 3 x 2 mL Single-Dose Vials per carton (NDC 39822-1030-2); Rx only, Distributed by: X-Gen Pharmaceuticals, Inc., Big Flats, NY 14814; Manufactured by: Exela Pharma Sciences, LLC, Lenoir, NC 28645.

Product Quantity:
2593 cartons

Reason for Recall:
Presence of Particulate Matter

Recall Number:
D-0637-2017

Code Information:
PLND1613, Exp 02/18

Class I Drugs Event

Event ID:
76511

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
02/16/2017

Voluntary / Mandated:
Voluntary: Firm Initiated

Center Classification Date:
04/05/2017

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Organic Herbal Supply
8303 Sierra College Blvd Ste 128
Roseville CA United States

Distribution Pattern:
Nationwide through Amazon.com online and direct from firm's website www.xtrahrd.com and www.Zrect.com

Associated Products

Product Description:
XtraHRD Natural Male Enhancement Capsules, Herbal Dietary Supplement, 500 mg capsules, 2, 4 and 10 count boxes, Made in Malaysia, Distributed by Naturally Hard Supplements, Reno, NV 89503, UPC 680474228768

Product Quantity:
100,000 to 150,000 capsules

Reason for Recall:
Marketed without an Approved NDA/ANDA: Product contains N-desmethyl tadalafil an analogue to tadalafil which is an active pharmaceutical ingredient in a FDA approved drug used to treat erectile dysfunction (ED).

Recall Number:
D-0646-2017

Code Information:
All lots

Class II Drugs Event

Event ID:
76726

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
03/13/2017

Voluntary / Mandated:
Voluntary: Firm Initiated

Center Classification Date:
04/05/2017

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Genentech Inc.
1 Dna Way
South San Francisco CA United States

Distribution Pattern:
NJ and IL

Associated Products

Product Description:
Cotellic (cobimetinib) Tablets, 20 mg, 63 count bottle, Rx Only, Made in Switzerland. Distributed by Genentech USA, Inc., South Francisco, CA. 94080, NDC 50242-717-01,UPC 3 50242-717-01.

Product Quantity:
748 bottles

Reason for Recall:
Superpotent Drug: An oversized tablet was found in a bottle.

Recall Number:
D-0648-2017

Code Information:
B1009MC, B1009M9, B1009MA; Exp. 02/18 B1009MT 02/19

Class II Drugs Event

Event ID:
76761

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
03/17/2017

Voluntary / Mandated:
Voluntary: Firm Initiated

Center Classification Date:
03/31/2017

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Shire
300-400 Shire Way
Lexington MA United States

Distribution Pattern:
Nationwide and Kuwait

Associated Products

Product Description:
Kalbitor (ecallantide), 10mg/mL, packaged in 3 vials per Carton, Rx Only, Dynax Corp., Burlington, MA. NDC47783-101-01

Product Quantity:
3, 536 cartons (3 vials per carton)

Reason for Recall:
Presence of Particulate Matter: Glass

Recall Number:
D-0625-2017

Code Information:
Lot #: A1500009, Exp. Jan 31, 2019

Class II Drugs Event

Event ID:
76839

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
03/22/2017

Voluntary / Mandated:
Voluntary: Firm Initiated

Center Classification Date:
03/31/2017

Initial Firm Notification of Consignee or Public:
Telephone

Recalling Firm:
GlaxoSmithKline, LLC
1011 N Arendell Ave
Zebulon NC United States

Distribution Pattern:
Nationwide in the USA and Puerto Rico

Associated Products

Product Description:
Ventolin HFA (albuterol sulfate) Inhalation Aerosol, 90 mcg per actuation, 200 Metered Inhalations, Net Wt. 18 g inhalers, Rx only, GlaxoSmithKline, Research Triangle Park, NC 22709, NDC 0173-0682-20.

Product Quantity:
593,088 inhalers

Reason for Recall:
Defective Delivery System: Elevated number of units with out of specification results for leak rate.

Recall Number:
D-0626-2017

Code Information:
Lot #: 6ZP9848, Exp 03/18; 6ZP0003, 6ZP9944, Exp 04/18.

Class III Drugs Event

Event ID:
76664

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
03/07/2017

Voluntary / Mandated:
Voluntary: Firm Initiated

Center Classification Date:
04/04/2017

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Alvogen, Inc
10 Bloomfield Ave Bldg B Ste 2
Pine Brook NJ United States

Distribution Pattern:
Nationwide

Associated Products

Product Description:
Nifedipine Extended-Release Tablets, 30 mg, 100-count bottles, Rx Only, Manufactured for Alvogen Inc. Pine Brook, NJ 07058 USA, NDC 47781-368-01.

Product Quantity:

Reason for Recall:
Cross Contamination with another product:residual powder found in inlet air duct identified as sorafenib

Recall Number:
D-0627-2017

Code Information:
Lot #: BXH1P22, BXH1P21A, BXH1P21, BXH1P31, BXH1P21B, Exp. 11/2017; BXH6EL1, BXH66A1, BXH6EN1, BXH6EP1, BXH6ER1, Exp. 06/2018; BXH81K1A, BXHBJD1A, Exp. 10/2018

Product Description:
Adalat CC (nifedipine) Extended Release Tablets 30 mg, 100-count bottles, Rx only, Manufactured for Bayer Healthcare Bayer Healthcare Pharmaceuticals Inc. Whippany, NJ 07901 Manufactured in Germany, NDC 50419-701-05

Product Quantity:

Reason for Recall:
Cross Contamination with another product:residual powder found in inlet air duct identified as sorafenib

Recall Number:
D-0628-2017

Code Information:
Lot #: BXH1P21A, Exp. 11/2017

Product Description:
Adalat CC (nifedipine) Extended Release Tablets, 60 mg, 100- count bottles, Rx only Manufactured for Almatica, Almatica Pharma Inc. Pinebrook, NJ 07058 USA, NDC 50419-702-05

Product Quantity:

Reason for Recall:
Cross Contamination with another product:residual powder found in inlet air duct identified as sorafenib

Recall Number:
D-0629-2017

Code Information:
Lot #: BXH1BE1A, BXH1P41A, Exp. 01/2018.

Product Description:
Nifedipine Extended-Release Tablets, 60 mg, 100-count bottles, Rx Only, Manufactured for Alvogen Inc. Pine Brook, NJ 07058 USA, NDC 47781-369-01.

Product Quantity:

Reason for Recall:
Cross Contamination with another product:residual powder found in inlet air duct identified as sorafenib

Recall Number:
D-0630-2017

Code Information:
Lot #: BXH1P41, BXH1BEE1, BXH1BE2, BXH1BE1B, BXH1BE1A, BXH1P41A, Exp. 01/2018; BXH81R1, BXHBD41A, BXH5ZR1, BXH9AL1A, Exp. 06/2018; BXHCUD1A, BXHCUF2A, Exp. 01/2019.

Product Description:
Nifedipine Extended-Release Tablets, 90 mg, 100-count bottles, Rx Only, Manufactured for Alvogen Inc. Pine Brook, NJ 07058 USA, NDC 47781-370-01.

Product Quantity:

Reason for Recall:
Cross Contamination with another product:residual powder found in inlet air duct identified as sorafenib

Recall Number:
D-0631-2017

Code Information:
Lot #: BXH1P51, BXH66D1, BXH1P51A, BXH5ZS1, Exp. 03/2018; BXH1P52, Exp. 05/2018; BXHBKF1A, and BXHB8S1A, Exp. 10/2018.

Product Description:
Adalat CC (nifedipine) Extended-Release Tablets, 90 mg, 100-count bottles, Rx Only, Manufactured for Almatica Pharma Inc. Pine Brook, NJ 07058 USA, NDC 50419-70305

Product Quantity:

Reason for Recall:
Cross Contamination with another product:residual powder found in inlet air duct identified as sorafenib

Recall Number:
D-0632-2017

Code Information:
Lot #: BXH66D1A, Exp. 03/2018

Product Description:
Adalat CC (nifedipine) Extended-Release Tablets, 30 mg, 100-count bottles, Rx Only, Manufactured for Almatica Pharma Inc. Pine Brook, NJ 07058 USA, NDC 5242749401

Product Quantity:

Reason for Recall:
Cross Contamination with another product:residual powder found in inlet air duct identified as sorafenib

Recall Number:
D-0633-2017

Code Information:
Lot #: BXHBJD1A, Exp. 10/2018

Product Description:
Adalat CC (nifedipine) Extended-Release Tablets, 60 mg, 100-count bottles, Rx Only, Manufactured for Almatica Pharma Inc. Pine Brook, NJ 07058 USA, NDC 5242749501

Product Quantity:

Reason for Recall:
Cross Contamination with another product:residual powder found in inlet air duct identified as sorafenib

Recall Number:
D-0634-2017

Code Information:
Lot #: BXCUE1A, Exp. 01/2019

Product Description:
Adalat CC (nifedipine) Extended-Release Tablets, 90 mg, 100-count bottles, Rx Only, Manufactured for Almatica Pharma Inc. Pine Brook, NJ 07058 USA, NDC 5242749601

Product Quantity:

Reason for Recall:
Cross Contamination with another product:residual powder found in inlet air duct identified as sorafenib

Recall Number:
D-0635-2017

Code Information:
Lot #: BXHD7U1A, Exp. 10/2018

Class III Drugs Event

Event ID:
76699

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
03/06/2017

Voluntary / Mandated:
Voluntary: Firm Initiated