Enforcement Report - Week of March 14, 2018

Class I Drugs Event

Event ID:
79327

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
02/14/2018

Voluntary / Mandated:
Voluntary: Firm Initiated

Center Classification Date:
03/13/2018

Initial Firm Notification of Consignee or Public:
Press Release

Recalling Firm:
Bella All Natural
304 E 11th St
Los Angeles CA United States

Distribution Pattern:
Product was distributed in California to online customers and retail stores.

Associated Products

Product Description:
Bella Capsules, 600mg, 30-count bottles, Manufactured for: Bella All Natural 304 E 11th Street, Los Angeles, CA 90015

Product Quantity:
32 bottles

Reason for Recall:
Marketed Without An Approved NDA/ANDA: This product contains undeclared sibutramine. The presence of sibutramine, a previously approved controlled substance that was withdrawn from the U.S. market in October 2010 due to safety concerns, in this tainted product renders it an unapproved drug for which safety and efficacy have not been established and therefore subject to recall.

Recall Number:
D-0593-2018

Code Information:
Lot #: MFD:10.15.2017, Exp.10/14/2019.

Class II Drugs Event

Event ID:
79238

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
02/20/2018

Voluntary / Mandated:
Voluntary: Firm Initiated

Center Classification Date:
03/02/2018

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Hospira Inc. A Pfizer Company
1776 Centennial Dr
Mcpherson KS United States

Distribution Pattern:
Nationwide in the USA and Puerto Rico.

Associated Products

Product Description:
Labetalol Hydrochloride Injection, USP, 100 mg/ 20 mL (5 mg/mL), 20 mL Multidose Vial, Rx only, labeled as a) Hospira, Inc., Lake Forest, IL 60045, NDC 0409-2267-20; and b) NOVAPLUS, Manufactured by Hospira, Inc., Lake Forest, IL 60045, NDC 0409-2267-25.

Product Quantity:
a) 137,975 vials; b) 40,143 vials

Reason for Recall:
Defective Container: Cracked glass at the rim surface of glass vials, covered by the stopper and crimp seal.

Recall Number:
D-0576-2018

Code Information:
Lots: a) 74370DD, Exp 1FEB2019; 75035DD, 75115DD, Exp 1MAR2019; b) 74230DD, Exp 1FEB2019

Class II Drugs Event

Event ID:
79252

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
02/23/2018

Voluntary / Mandated:
Voluntary: Firm Initiated

Center Classification Date:
03/12/2018

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Bayer HealthCare Pharmaceuticals, Inc.
100 Bayer Blvd
Whippany NJ United States

Distribution Pattern:
Arkansas only

Associated Products

Product Description:
Coppertone Kids Sunscreen Spray (avobenzone 3%, Homosalate 10%, Octisalate 5%, Octocrylene 4%, Oxybenzone 5%) 8.3 oz. bottle, Dist. by: Bayer Healthcare LLC Whippany, NJ 07981, UPC 41100573636.

Product Quantity:
528 units

Reason for Recall:
Labeling: Label mix-up

Recall Number:
D-0590-2018

Code Information:
Lot#: 7N04CS, 7N05CS, Exp. 11/2019

Class II Drugs Event

Event ID:
79304

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
02/19/2018

Voluntary / Mandated:
Voluntary: Firm Initiated

Center Classification Date:
03/07/2018

Initial Firm Notification of Consignee or Public:
Telephone

Recalling Firm:
Kalchem International, Inc.
224 S Main St Ste B
Lindsay OK United States

Distribution Pattern:
TX

Associated Products

Product Description:
Vardenafil HCl, USP (trihydrate), 500 GM Part # 330-05, Rx only, For Manufacturing, Repackaging and Processing for Rx and Research Only, Kalchem International, Inc. 224 South Main Street Lindsay, OK 73052 888-298-9905, NDC 60592-330-05

Product Quantity:
500 gram jar

Reason for Recall:
cGMP Deviations: Lack of stability data and controls to support the manufacturers assigned retest or expiration date in firm's container/closure system.

Recall Number:
D-0582-2018

Code Information:
Lot #: 070717-1

Class II Drugs Event

Event ID:
79331

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
02/15/2018

Voluntary / Mandated:
Voluntary: Firm Initiated

Center Classification Date:
03/06/2018

Initial Firm Notification of Consignee or Public:
E-Mail

Recalling Firm:
Apollo Care
3801 Mojave Ct Ste 101
Columbia MO United States

Distribution Pattern:
Medical Facility in MO

Associated Products

Product Description:
Vancomycin 1g added to 250mL of 0.9% Sodium Chloride IV bag, Rx only, APOLLOcare, 3801 Mojave Ct., Suite 101, Columbia, MO 65202, NDC 71170-254-25.

Product Quantity:
360 bags

Reason for Recall:
Stability Data Does Not Support Expiry: 90-day beyond use date (BUD) for the affected product is not supported.

Recall Number:
D-0579-2018

Code Information:
Lot: AC-015558, Exp 03/07/2018

Product Description:
Vancomycin 1.25g added to 250mL of 0.9% Sodium Chloride IV bag, Rx only, APOLLOcare, 3801 Mojave Ct., Suite 101, Columbia, MO 65202, NDC 71170-264-25.

Product Quantity:
312 bags

Reason for Recall:
Stability Data Does Not Support Expiry: 90-day beyond use date (BUD) for the affected product is not supported.

Recall Number:
D-0580-2018

Code Information:
Lot: AC-015560, Exp 03/14/2018

Class II Drugs Event

Event ID:
79361

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
01/10/2018

Voluntary / Mandated:
Voluntary: Firm Initiated

Center Classification Date:
03/09/2018

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Spirit Pharmaceuticals, LLC
2004 Orville Dr N Ste 2
Ronkonkoma NY United States

Distribution Pattern:
NY

Associated Products

Product Description:
Ibuprofen Tablets USP, 200 mg, 100-count bottles, OTC, Distributed By: Spirit Pharmaceuticals, LLC Ronkonkoma, NY 11779, NDC 68210-0800-1

Product Quantity:
144 bottles

Reason for Recall:
CGMP deviations: Ibuprofen is being recalled in response to previous recall

Recall Number:
D-0583-2018

Code Information:
Lot#: HJ6138

Class III Drugs Event

Event ID:
79278

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
02/21/2018

Voluntary / Mandated:
Voluntary: Firm Initiated

Center Classification Date:
03/05/2018

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

Associated Products

Product Description:
Atropine Sulfate Ophthalmic 1% Solution, USP, 5mL per bottle, Sterile, Rx Only, Manufactured by: Akorn, Inc., Lake Forest, IL 60045. NDC: 17478-215-05

Product Quantity:
31,812 bottles

Reason for Recall:
Failed Stability Specification: OOS low viscosity results discovered during retain testing.

Recall Number:
D-0577-2018

Code Information:
Lot: 011037A

Class III Drugs Event

Event ID:
79290

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
02/23/2018

Voluntary / Mandated:
Voluntary: Firm Initiated

Center Classification Date:
03/09/2018

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
AstraZeneca Pharmaceuticals LP
1800 Concord Pike
Wilmington DE United States

Distribution Pattern:
Nationwide

Associated Products

Product Description:
Lynparza (olaparib) capsules 50 mg, 112 count bottles, Rx only, Manufactured for: Astra Zeneca Pharmaceuticals LP Wilmington, DE 19850 by: Patheon Pharmaceuticals, Inc. Cincinnati OH 45237 Product of Switzerland NDC 0310-0657-58

Product Quantity:
18056 bottles

Reason for Recall:
Failed Impurities/Degradation Specifications; elevated levels of quality attribute Form L (polymorph).

Recall Number:
D-0585-2018

Code Information:
HN0406 02/2018 JH0341 03/2018 JH0342 03/2018 JH0147 03/2018 JC0391 04/2018 JK0147 04/2018 JL0184 04/2018 JC0402 05/2018

Class III Drugs Event

Event ID:
79338

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
01/24/2018

Voluntary / Mandated:
Voluntary: Firm Initiated

Center Classification Date:
03/09/2018

Initial Firm Notification of Consignee or Public:
Telephone

Recalling Firm:
Oxygen Development Llc
1525 S Congress Ave
Palm Springs FL United States

Distribution Pattern:
Canada

Associated Products

Product Description:
Life Brand Clear Action Acne Treatment Concealer Stick (Salicylic acid), 1.9g, Imported for: Shoppers Drug Mart Pharmaprix Toronto, M2J4W8, UPC 057800062653

Product Quantity:
12216 sticks

Reason for Recall:
Superpotent drug: failed assay throughout the stick after 6 months stability.

Recall Number:
D-0584-2018

Code Information:
Lot #: 060E

Class III Drugs Event

Event ID:
79365

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
02/28/2018

Voluntary / Mandated:
Voluntary: Firm Initiated

Center Classification Date:
03/06/2018

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Osmotica Pharmaceutical Corp
895 Sawyer Rd
Marietta GA United States

Distribution Pattern:
Nationwide in the USA

Associated Products

Product Description:
Methylphenidate Hydrochloride Extended-release Tablets, USP, 36 mg, 100-count bottle, Rx only, Trigen Laboratories, LLC Bridgewater, NJ 08807. NDC 13811-708-10

Product Quantity:
19,664 100-bottles

Reason for Recall:
Subpotent Drug:100-count product bottle labeled as Methylphenidate HCL ER Tablets 36 mg found to contain 1 27 mg Methylphenidate HCL ER Tablet.

Recall Number:
D-0581-2018

Code Information:
Lots: 170231B, 170232A, 170233A, 170234A

Not Yet Classified Drugs Event

Event ID:
79367

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
02/26/2018

Voluntary / Mandated:
Voluntary: Firm Initiated

Center Classification Date:

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Mckesson Packaging Services
7101 Weddington Rd Nw
Concord NC United States

Distribution Pattern:
Nationwide

Associated Products

Product Description:
RANITIDINE Tablets, USP 150 mg UD 100 tablets (10x10), RX Only, Manufactured by: Amneal Pharmaceuticals, Hauppauge, NY 11788, NDC 63739-489-10

Product Quantity:
17,192 cartons

Reason for Recall:
Failed Stability Specifications

Recall Number:

Code Information:
Lots: 0113064 Exp. 03/2018, 0114628 Exp. 08/2018, 0115189 Exp. 08/2018, 0115462 Exp. 09/2018