Enforcement Report - Week of May 11, 2016

Biologics | Cosmetics | Devices | Drugs | Food | Tobacco | Veterinary

Class II Drugs Event

Event ID:
73642
Product Type:
Drugs

Status:
Ongoing
Recalling Firm:
Akorn, Inc.
1925 W Field Ct Ste 300
Lake Forest IL United States
Recall Initiation Date:
04/07/2016
Center Classification Date:
05/04/2016
Date Terminated:

Voluntary / Mandated:
Voluntary: Firm Initiated
Initial Firm Notification of Consignee or Public:
Letter
Distribution Pattern:
Nationwide

Associated Products

Product Description:
Good Neighbor Pharmacy PEG-Phen Lubricant Eye Drops (Polyethylene Glycol 400 0.4% / Propylene Glycol 0.3%), 15 ml bottle, Distributed by AmerisourceBergen, 1300 Morris Drive, Chesterbrook, PA 19087, NDC 46122-199-05, ALSO labeled as Premier Value Brand PEG-Phen Lubricant Eye Drops (Polyethylene Glycol 400 0.4% / Propylene Glycol 0.3%), 15 ml bottle, Distributed by Chain Drug Consortium, 3301 NW Boca Raton Blvd, Suite 101, Boca Raton, FL 33431, NDC 68016-0404-

Reason for Recall:
Presence of Particulate Matter

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Product Quantity:
10,060 bottles (Good Neighbor Pharmacy: 6,731 bottles/Premier Value Brand: 3,323 bottles)

Code Information:
Good Neighbor Pharmacy Batch Number 4H76A; Exp 07/16 Premier Value Batch Number 4H76B; Exp 07/16

Recall Number:
D-0835-2016

Class II Drugs Event

Event ID:
73909

Product Type:
Drugs

Status:
Ongoing

Recalling Firm:
VistaPharm, Inc.
7265 Ulmerton Rd
Largo FL United States

Recall Initiation Date:
04/18/2016

Center Classification Date:
05/04/2016

Date Terminated:

Voluntary / Mandated:
Voluntary: Firm Initiated

Initial Firm Notification of Consignee or Public:
E-Mail

Distribution Pattern:
Nationwide

Associated Products

Product Description:
Oxycodone Hydrochloride Oral Solution, USP 5 mg/5 mL (1mg/ml) (NDC 66689-401-01), shrink- wrapped in 10 unit dose cups x 5 trays per case (NDC 66689-401-50), Rx only, Manufactured by VistaPharm, Largo, FL 33771

Product Quantity:
8,901 cases

Code Information:

Reason for Recall:
Defective Container: Excess lidding material accumulation between the seal and the cup resulting in the lid not properly adhering and allowing leakage.

Recall Number:
D-0838-2016

Lot # 435200, EXP 01/18

Class III Drugs Event

Event ID:
73647
Product Type:
Drugs

Status:
Ongoing
Recalling Firm:
Hospira Inc.
275 N Field Dr
Lake Forest IL United States
Recall Initiation Date:
03/15/2016
Center Classification Date:
05/04/2016
Date Terminated:

Voluntary / Mandated:
Voluntary: Firm Initiated
Initial Firm Notification of Consignee or Public:
Letter
Distribution Pattern:
Nationwide

Associated Products

Product Description:
Quelicin (Succinylcholine Chloride) Injection, USP 200 mg. (20 mg/mL), 10 mL Multiple-dose vial, packaged in 25 Unit vials per carton, Rx only, HOSPIRA, INC., LAKE FOREST, IL 60045 USA, NDC 0409-6629-02
Product Quantity:
103,600 vials
Code Information:
Lot 52-045-EV, Exp 07/1/2016

Reason for Recall:
Labeling: Incorrect or Missing Lot and/or Exp Date: Potential for the lot number and/or expiration date to be faded or missing from the primary label on the glass vial.

Recall Number:
D-0836-2016

Class III Drugs Event

Event ID:
73683
Product Type:
Drugs

Voluntary / Mandated:
Voluntary: Firm Initiated
Initial Firm Notification of Consignee or Public:

Letter

Status:
Ongoing
Recalling Firm:
Bryant Ranch Prepack Inc.
1919 N Victory Pl
Burbank CA United States
Recall Initiation Date:
03/25/2016
Center Classification Date:
05/04/2016
Date Terminated:

Distribution Pattern:
Nationwide

Associated Products

Product Description:
Venlafaxine 75 mg Tablet, Compare to Effexor 75 mg Tablet, a) 30-count bottle (NDC 636290-3324-2), b) 100-count bottle (NDC 63629-3324-6), Rx Only, Manufactured by Teva Pharmaceuticals USA, Inc. Packaged by Bryant Ranch.
Product Quantity:
21 bottles (910 extended release tablets)
Code Information:
Lot # 94983; Exp 10/17

Reason for Recall:
Labeling: Label Mix-Up: Bryant Ranch received Tevas venlafaxine hydrochloride extended-release tablets for repackaging, but labeled it incorrectly as the immediate release formulation.

Recall Number:
D-0837-2016

Class III Drugs Event

Event ID:
74011
Product Type:
Drugs

Status:
Ongoing
Recalling Firm:
A-S Medication Solutions LLC.
2401 Commerce Dr
Libertyville IL United States
Recall Initiation Date:

Voluntary / Mandated:
Voluntary: Firm Initiated
Initial Firm Notification of Consignee or Public:
Telephone
Distribution Pattern:
Virginia

04/22/2016

Center Classification Date:
05/05/2016

Date Terminated:

Associated Products

Product Description:
Acetaminophen & Codeine Phosphate Tablets, 300 mg/30 mg, 15-count plastic bottle, Rx only, Mfr: Aurolife Pharma LLC, Dayton NJ, Packaged Exclusively by: A-S Medication Solutions LLC, Libertyville, ILL 60048, NDC 54569-8305-0

Product Quantity:
2730 bottles

Code Information:
Lot # 6050129, Exp 05/31/17

Reason for Recall:
Labeling: Not elsewhere classified - count on the label was incorrect.

Recall Number:
D-0839-2016