Enforcement Report - Week of November 8, 2017

Class II Drugs Event

Event ID:
78235

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
10/06/2017

Voluntary / Mandated:
Voluntary: Firm Initiated

Center Classification Date:
11/01/2017

Initial Firm Notification of Consignee or Public:
Press Release

Recalling Firm:
Kiriko, LLC.
3522 Ewing Dr
Manvel TX United States

Distribution Pattern:
Nationwide.

Associated Products

Product Description:
A1 Slim, Dietary Supplement Beautifully Slim, capsule, 350 mg, 30-count bottle, A1 Slim LLC Pearland TX 77584, www.A1SLIM.COM, info@a1slim.com Bar-Code A105212014

Product Quantity:
700 bottles

Reason for Recall:
Marketed Without An Approved NDA/ANDA: FDA analysis found this product to contain undeclared sibutramine, phenolphthalein, and n-desmethyl sibutramine, making this an unapproved drug for which safety and efficacy have not been established and therefore, subject to recall.

Recall Number:
D-0058-2018

Code Information:
All lots remaining within expiry.

Class II Drugs Event

Event ID:
78240

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
10/06/2017

Voluntary / Mandated:
Voluntary: Firm Initiated

Center Classification Date:
10/27/2017

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
AVKARE Inc.
615 N 1st St
Pulaski TN United States

Distribution Pattern:
Nationwide in the USA

Associated Products

Product Description:
Duloxetine Delayed-release Capsules USP, 20 mg, 50 Capsules (5 x 10) Unit Dose per carton, unit dose blister UPC 5026828311), Rx only, Manufactured for: AvKARE, Inc., Pulaski, TN 38478, NDC 50268-283-15.

Product Quantity:
274 cartons

Reason for Recall:
Failed Impurities/Degradation Specifications: slightly elevated levels of phthalic acid.

Recall Number:
D-0055-2018

Code Information:
Lot: 18103 Exp. 11/18

Class II Drugs Event

Event ID:
78320

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
10/19/2017

Voluntary / Mandated:
Voluntary: Firm Initiated

Center Classification Date:
11/02/2017

Initial Firm Notification of Consignee or Public:
Letter

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

Distribution Pattern:
Nationwide in the United States

Associated Products

Product Description:
SUCcinylcholine 20 mg per mL, Total Volume 10 mL in single-dose syringe, (SUCcinylcholine 200 mg / 10 ml) Rx Only, SCA Pharmaceuticals 8821 Knoedl Ct Little Rock, AR NDC 70004-0910-29

Product Quantity:
1248 syringes

Reason for Recall:
Lack Of Assurance Of Sterility.

Recall Number:
D-0059-2018

Code Information:
Lot: 20170726@35 BUD: 10/24/2017

Product Description:
HYDROmorphone HCL 1 mg per mL in 0.9% Sodium Chloride 25 mL Fill in 30 mL single-dose syringe (Total Dose Hydromorphone 25 mg/25 mL) Rx Only SCA Pharmaceuticals 8821 Knoedl Ct Little Rock, AR NDC 70004-0303-17

Product Quantity:
128 syringes

Reason for Recall:
Lack Of Assurance Of Sterility.

Recall Number:
D-0060-2018

Code Information:
Lot: 20170808@52 BUD: 11/06/2017

Product Description:
HYDROmorphone HCl 20 mcg / mL BUPIvacaine HCl 0.075% in 0.9% Sodium Chloride 50 mL (HYDROmorphone Total Dose 1000 mcg) Rx Only, SCA Pharmaceuticals 8821 Knoedl Ct Little Rock, AR 72205, NDC 70004-0331-22

Product Quantity:
60 bags

Reason for Recall:
Lack Of Assurance Of Sterility.

Recall Number:
D-0061-2018

Code Information:
Lot: 20170816@65 BUD: 10/30/2017

Product Description:
fentanyl as citrate 2 mcg per mL BUPIvacaine HCl 0.125% (Total FentaNYL Dose 500 mcg/250 mL) in 0.9% Sodium Chloride 250 mL Bag, Rx Only, SCA Pharmaceuticals, 8821 Knoedl Ct, Little Rock, AR 72205. NDC 70004-0231-40

Product Quantity:
116 bags

Reason for Recall:
Lack Of Assurance Of Sterility.

Recall Number:
D-0062-2018

Code Information:
Lot: 20170814@20 BUD: 11/12/2017

Product Description:
fentaNYL as citrate 2 mcg / mL, ROPIVacaine HCl 0.1%, Total Fentanyl Dose (200 mcg per 100 mL) in 0.9% Sodium Chloride single dose CADD Cassette Rx Only, SCA Pharmaceuticals 8821 Knoedl Ct Little Rock, AR 72205, NDC 70004-0264-64

Product Quantity:
20 bags inside rigid translucent plastic cases (CADD)

Reason for Recall:
Lack Of Assurance Of Sterility.

Recall Number:
D-0063-2018

Code Information:
Lot: 20170815@26 BUD: 11/13/2017

Product Description:
morphine sulfate 1 mg per mL in 0.9% Sodium Chloride a) Total Volume 100 mL in Single Dose CADD Cassette (Total morphine Dose 100 mg per 100 mL) (NDC 70004-0100-63) b) Total Volume 50 mL in Single Dose Syringe (Total morphine Dose 50 mg / 50 mL) (NDC 70004-0100-22) Rx Only, SCA Pharmaceuticals 8821 Knoedl Ct Little Rock, AR 72205

Product Quantity:
a) 60 bag inside rigid translucent plastic case (CADD) b) 238 bag

Reason for Recall:
Lack Of Assurance Of Sterility.

Recall Number:
D-0064-2018

Code Information:
Lots: a) 20170905@24 BUD: 12/04/2017 b) 20170901@25 BUD: 11/30/2017

Product Description:
oxyTOCIN 30 units added to Lactated Ringers 500 mL Bag, Rx Only, SCA Pharmaceuticals 8821 Knoedl Ct Little Rock, AR 72205, NDC 70004-0086-44

Product Quantity:
450 bags

Reason for Recall:
Lack Of Assurance Of Sterility.

Recall Number:
D-0065-2018

Code Information:
Lot: 20170912@13 BUD: 10/22/2017

Product Description:
PHENYLephrine HCl 100 mcg per mL In 0.9% Sodium Chloride 10 mL Fill Volume in a Single Dose Syringe (1,000 mcg / 10 ml Total Dose), Rx Only, SCA Pharmaceuticals 8821 Knoedl Ct Little Rock, AR, NDC 70004-0810-12

Product Quantity:
1221 syringes

Reason for Recall:
Lack Of Assurance Of Sterility.

Recall Number:
D-0066-2018

Code Information:
Lot: 20170920@53 BUD: 12/19/2017

Product Description:
Calcium GLUCOnate 2 g added to 0.9% Sodium Chloride 50 mL Bag, Each bag contains 9.3 mEq Ca++ Rx Only, SCA Pharmaceuticals 8821 Knoedl Ct Little Rock, AR 72205, NDC 70004-0510-30

Product Quantity:
76 bags

Reason for Recall:
Lack Of Assurance Of Sterility.

Recall Number:
D-0067-2018

Code Information:
Lot: 20170920@20 BUD: 11/09/2017

Product Description:
ROCuronium Bromide 10 mg per mL, 5 mL Fill in single dose syringe, (50 mg / 5 mL Total Dose) Rx Only SCA Pharmaceuticals 8821 Knoedl Ct Little Rock, AR 72205, NDC 70004-850-09

Product Quantity:
487 syringes

Reason for Recall:
Lack Of Assurance Of Sterility.

Recall Number:
D-0068-2018

Code Information:
Lot: 20171004@4 BUD: 01/09/2018

Class II Drugs Event

Event ID:	Product Type:	Status:	Date Terminated:
78364	Drugs	Ongoing	

Recall Initiation Date:
10/25/2017

Voluntary / Mandated:
Voluntary: Firm Initiated

Center Classification Date:
11/02/2017

Initial Firm Notification of Consignee or Public:
Letter

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

Distribution Pattern:
Nationwide in the USA and Puerto Rico.

Associated Products

Product Description:
Dutasteride and Tamsulosin HCl Capsules, 0.5 mg/ 0.4 mg, packaged in a) 30-count bottle (NDC 0591-3771-30), b) 90-count bottle (NDC 0591-3771-19), Rx only, Manufactured by: Actavis Laboratories FL, Inc. Fort Lauderdale, FL 33314 USA; Distributed by: Actavis Pharma, Inc. Parsippany, NJ 07054 USA.

Product Quantity:
140,993 bottles

Reason for Recall:
Failed dissolution specifications; all lots within expiry are being recalled due to out of specification dissolution results.

Recall Number:
D-0069-2018

Code Information:
Lot Numbers: a) 1089376A, 1089382A, 1095210M, 1117768M, 1117769A, Exp. 11/17; 1128452A, 1128453A, 1137658A, 1154207A, 1156087A, Exp. 03/18; b) 1089379A, 1091533M, 1125206A, Exp. 11/17; 1128456A, 1147665A, 1154208A, 1156088A, Exp. 03/18.

Class III Drugs Event

Event ID:
78232

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
10/13/2017

Voluntary / Mandated:
Voluntary: Firm Initiated

Center Classification Date:
10/30/2017

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Sanofi-Aventis U.S. LLC
55 Corporate Dr
Bridgewater NJ United States

Distribution Pattern:
Nationwide in the USA

Associated Products

Product Description:
Clofarabine injection, 20 mg/20 mL, 20 mL Single-Use Vial, Rx only, Mfd by: Teva Pharmachemle, Swensweg 5, Haarlem, The Netherlands; Mfd for: Winthrop U.S., a business of sanofi-aventis U.S. LLC, Bridgewater, NJ 08807; NDC 0955-1746-01.

Product Quantity:
422 vials

Reason for Recall:
Labeling: Incorrect or Missing Package Insert: authorized generic product was packaged with the incorrect insert for the brand name product Clolar (clofarabine) injection.

Recall Number:
D-0056-2018

Code Information:
Lot #: K5006Y02, Exp 31AUG18

Class III Drugs Event

Event ID:
78359

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
09/25/2017

Voluntary / Mandated:
Voluntary: Firm Initiated

Center Classification Date:
11/01/2017

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Precision Dose Inc.
722 Progressive Ln
South Beloit IL United States

Distribution Pattern:
Nationwide in the USA

Associated Products

Product Description:
Carbamazepine Oral Suspension USP, 100 mg/5 mL, 5 mL Unit Dose Cups (NDC 68094-301-59), packaged in 10-count cups per tray, 3 trays per case containing a total of 5 mL x 30 Unit Dose Cups per case (NDC 68094-301-62), Rx only, Pkg: Precision Dose, Inc., S. Beloit, IL 61080.

Product Quantity:
801 cases

Reason for Recall:
Subpotent Drug: low out of specification results.

Recall Number:
D-0057-2018

Code Information:
Lot number: 500105, Exp 04/30/18