Enforcement Report - Week of July 11, 2018

Class I Drugs Event

Event ID:
80383

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
06/29/2018

Voluntary / Mandated:
Voluntary: Firm Initiated

Center Classification Date:
07/06/2018

Initial Firm Notification of Consignee or Public:

Recalling Firm:
Fagron Compounding Services LLC dba Fagron Sterile Services
8710 E 34th St N
Wichita KS United States

Distribution Pattern:
Nationwide in the USA

Associated Products

Product Description:
Neostigmine Methylsulfate Injection Solution, 5 mg per 5 mL, 1 mg per mL, 5 mL prefilled syringe, 5 syringes per package, Rx only, Fagron Sterile Services, ICB Laboratories, 8710 E 34th St. N., Wichita, KS 67205, NDC 71266-2003-02.

Product Quantity:
840 prefilled syringes

Reason for Recall:
Labeling: Label Error on Declared Strength: syringes of Neostigmine Methylsulfate 1 mg per mL, 5 mg per 5 mL may be incorrectly labeled as Neostigmine Methylsulfate 1 mg per mL, 3 mg per 3 mL.

Recall Number:
D-0910-2018

Code Information:
Lot #: C274-000004690, BUD: 09/21/18.

Product Description:
Neostigmine Methylsulfate Injection Solution, 3 mg per 3 mL, 1 mg per mL, 3 mL prefilled syringe, 5 syringes per package, Rx only, Fagron Sterile Services, ICB Laboratories, 8710 E 34th St. N., Wichita, KS 67205, NDC 71266-2003-01.

Product Quantity:
390 prefilled syringes

Reason for Recall:
Labeling: Label Error on Declared Strength: syringes of Neostigmine Methylsulfate 1 mg per mL, 5 mg per 5 mL may be incorrectly labeled as Neostigmine Methylsulfate 1 mg per mL, 3 mg per 3 mL.

Recall Number:
D-0911-2018

Code Information:
Lot #: C274-000004678, BUD: 09/20/18

Class II Drugs Event

Event ID:
80254

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
06/08/2018

Voluntary / Mandated:
Voluntary: Firm Initiated

Center Classification Date:
06/29/2018

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Ingenus Pharmaceuticals Llc
4190 Millenia Blvd
Orlando FL United States

Distribution Pattern:
Nationwide in the USA

Associated Products

Product Description:
Irinotecan Hydrochloride Injection, USP, 100 mg/5 mL (20 mg/mL), 1 x 5 mL Single Dose Vial, Rx Only, Manufactured for: Ingenius Pharmaceuticals, LLC, Orlando, FL 32839-6408; Manufactured by: Ingenius Pharmaceuticals, GmbH Ticino 6917, Switzerland, NDC 50742-402-05.

Product Quantity:
34964 vials

Reason for Recall:
Superpotent Drug: High out of specification assay value results for potency.

Recall Number:
D-0890-2018

Code Information:
Lot #: 17034-1, 17035-1, 17036-1; Exp. 08/19

Product Description:
Irinotecan Hydrochloride Injection, USP, 40 mg/2 mL (20 mg/mL), 1 x 2 mL Single Dose Vial, Rx Only, Manufactured for: Ingenius Pharmaceuticals, LLC, Orlando, FL 32839-6408; Manufactured by: Ingenius Pharmaceuticals, GmbH Ticino 6917, Switzerland, NDC 50742-401-02.

Product Quantity:
14089 vials

Reason for Recall:
Superpotent Drug: High out of specification assay value results for potency.

Recall Number:
D-0891-2018

Code Information:
Lot #: 17034-2, 17035-2, 17036-2; Exp. 08/19

Class II Drugs Event

Event ID:
80303

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
06/14/2018

Voluntary / Mandated:
Voluntary: Firm Initiated

Center Classification Date:
07/02/2018

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
SCA Pharmaceuticals, LLC
755 Rainbow Rd Ste B
Windsor CT United States

Distribution Pattern:
Product was distributed throughout the United States.

Associated Products

Product Description:
Morphine Sulfate 1 mg/mL (preservative free; sulfite free) 2 mL fill 3 mL syringe, SCA Pharmaceuticals, LLC, Windsor, CT

Product Quantity:
440 syringes

Reason for Recall:
Lack of Assurance of Sterility: SCA is conducting a voluntary recall of certain lots of sterile admixtures due to a potential for leakage.

Recall Number:
D-0894-2018

Code Information:
Lot # 20180323@44, Exp 06/21/2018

Product Description:
Fentanyl (as citrate) 10 mcg/mL in 0.9% Sodium Chloride 250 mL bag, SCA Pharmaceuticals, LLC, Windsor, CT

Product Quantity:
492 bags

Reason for Recall:
Lack of Assurance of Sterility: SCA is conducting a voluntary recall of certain lots of sterile admixtures due to a potential for leakage.

Recall Number:
D-0895-2018

Code Information:
Lot # 20180328@19, 20180328@31, 20180328@39, 20180328@49, 20180328@53, 20180328@58, 20180323@9, 20180327@33, Exp 6/26/2018

Product Description:
Fentanyl (as citrate) 2 mcg/mL + Bupivacaine HCL 0.0625% in 0.9% Sodium Chloride 250 mL bag, SCA Pharmaceuticals, LLC, Windsor, CT

Product Quantity:
179 bags

Reason for Recall:
Lack of Assurance of Sterility: SCA is conducting a voluntary recall of certain lots of sterile admixtures due to a potential for leakage.

Recall Number:
D-0896-2018

Code Information:
Lot # 20180327@27, 20180327@40, 20180328@9, Exp 06/28/2018

Product Description:
Diltiazem HCL 1 mg/mL in 125 mL 0.9% Sodium Chloride 100 mL bag (total volume 125 mL) (125 mg), SCA Pharmaceuticals, LLC, Windsor, CT

Product Quantity:
2,869 bags

Reason for Recall:
Lack of Assurance of Sterility: SCA is conducting a voluntary recall of certain lots of sterile admixtures due to a potential for leakage.

Recall Number:
D-0897-2018

Code Information:
Lot # 1218001315, 1218001316, 1218001349, 1218001416, 1218001510, 1218001682, 1218001683, 1218001684, 1218001721, 1218001763, 1218001764, Exp 07/26/2018-08/27/2018

Product Description:
Norepinephrine Bitartrate 4 mg (16 mcg/mL) in 0.9% Sodium Chloride 250 mL bag, SCA Pharmaceuticals, LLC, Windsor, CT

Product Quantity:
2,268 bags

Reason for Recall:
Lack of Assurance of Sterility: SCA is conducting a voluntary recall of certain lots of sterile admixtures due to a potential for leakage.

Recall Number:
D-0898-2018

Code Information:
Lot # 1218000928, 1218000944, 1218000945, 1218001075, 1218001076, 1218001188, Exp 06/19/2018-07/03/2018

Product Description:
Norepinephrine Bitartrate 8 mg (32 mcg/mL) in 0.9% Sodium Chloride 250 mL bag, SCA Pharmaceuticals, LLC, Windsor, CT

Product Quantity:
1,882 bags

Reason for Recall:
Lack of Assurance of Sterility: SCA is conducting a voluntary recall of certain lots of sterile admixtures due to a potential for leakage.

Recall Number:
D-0899-2018

Code Information:
Lot # 1218000930, 1218000946, 1218001058, 1218001077, 1218001169, 1218001170, 1218001190, 1218001191, 1218001206, 1218001317, Exp 06/18/2018-07/11/2018

Product Description:
Norepinephrine Bitartrate 16 mg (64 mcg/mL) in 0.9% Sodium Chloride 250 mL bag, SCA Pharmaceuticals, LLC, Windsor, CT

Product Quantity:
1,397 bags

Reason for Recall:
Lack of Assurance of Sterility: SCA is conducting a voluntary recall of certain lots of sterile admixtures due to a potential for leakage.

Recall Number:
D-0900-2018

Code Information:
Lot # 1218000677, 1218000947, 1218000982, 1218001018, 1218001029, 1218001059, 1218001060, 1218001078, 1218001079, 1218001171, 1218001172, 1218001192, 1218001193, 1218001207, 1218001209, 1218001210, Exp 06/19/2018-07/03/2018

Product Description:
Phenylephrine HCL 10 mg in 0.9% Sodium Chloride 250 mL Bag (40 mcg/mL), SCA Pharmaceuticals, LLC, Windsor, CT

Product Quantity:
451 bags

Reason for Recall:
Lack of Assurance of Sterility: SCA is conducting a voluntary recall of certain lots of sterile admixtures due to a potential for leakage.

Recall Number:
D-0901-2018

Code Information:
Lot # 20180323@24, Exp 06/21/2018

Product Description:
Phenylephrine HCL 40 mg in 0.9% Sodium Chloride 250 mL Bag (160 mcg/mL), SCA Pharmaceuticals, LLC, Windsor, CT

Product Quantity:
451 bags

Reason for Recall:
Lack of Assurance of Sterility: SCA is conducting a voluntary recall of certain lots of sterile admixtures due to a potential for leakage.

Recall Number:
D-0902-2018

Code Information:
Lot # 20180323@24

Product Description:
Phenylephrine HCL 20 mg in 0.9% Sodium Chloride 250 mL Bag (160 mcg/mL), SCA Pharmaceuticals, LLC, Windsor, CT

Product Quantity:
400 bags

Reason for Recall:
Lack of Assurance of Sterility: SCA is conducting a voluntary recall of certain lots of sterile admixtures due to a potential for leakage.

Recall Number:
D-0903-2018

Code Information:
Lot # 20180323@29, Exp 06/21/2018

Product Description:
Phenylephrine HCL 50 mg in 0.9% Sodium Chloride 250 mL Bag (200 mcg/mL), SCA Pharmaceuticals, LLC, Windsor, CT

Product Quantity:

Reason for Recall:
Lack of Assurance of Sterility: SCA is conducting a voluntary recall of certain lots of sterile admixtures due to a potential for leakage.

Recall Number:
D-0904-2018

Code Information:
Lot # 20180329@2, Exp 06/27/2018

Product Description:
Phenylephrine HCL 80mg in 0.9% Sodium Chloride 250 mL Bag (320 mcg/mL), SCA Pharmaceuticals, LLC, Windsor, CT

Product Quantity:
196 bags

Reason for Recall:
Lack of Assurance of Sterility: SCA is conducting a voluntary recall of certain lots of sterile admixtures due to a potential for leakage.

Recall Number:
D-0905-2018

Code Information:
Lot # 20180328@25, Exp 06/26/2018

Class II Drugs Event

Event ID:
80359

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
06/22/2018

Voluntary / Mandated:
Voluntary: Firm Initiated

Center Classification Date:
07/03/2018

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Eb5 Corporation
538 Sw 4th Ave
Portland OR United States

Distribution Pattern:
Distributed Nation Wide in the USA.

Associated Products

Product Description:
eb5 Skincare that Works. Age Spot Treatment. Skin Lightening Cream with 2% Hydroquinone. 177.4 ml / 6 fl oz carton containing a tube. Manufactured For: EB5 Corporation Portland, OR 97210 Carton Bar Code: 7 41099 00009 9

Product Quantity:
4,632 tubes

Reason for Recall:
Failed Stability Specifications: Out-of-specification for viscosity, pH and specific gravity

Recall Number:
D-0908-2018

Code Information:
Batch B4276A EXP 03/2019

Class III Drugs Event

Event ID:
80203

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
06/08/2018

Voluntary / Mandated:
Voluntary: Firm Initiated

Center Classification Date:
06/29/2018

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Qualgen, LLC
14844 Bristol Park Blvd
Edmond OK United States

Distribution Pattern:
Nationwide in the USA

Associated Products

Product Description:
ESTRADIOL 20mg PELLET, 1-count 3ml amber vial. RX only. Compounded by: Qualgen 14844 Bristol Park Blvd, Edmond OK 73013. NDC 69761-020-01

Product Quantity:
2,940 pellets

Reason for Recall:
Labeling: Incorrect or Missing Lot and/or Exp Date.

Recall Number:
D-0892-2018

Code Information:
lot# C211 Exp. date 10/03/2018; C257 Exp. date 12/14/2018 and lot # D001 exp. date 01/02/19

Product Description:
TESTOSTERONE 200 mg PELLET, 1-count 3ml amber vial. RX only. Compounded by: Qualgen 14844 Bristol Park Blvd, Edmond OK 73013. NDC 69761-120-01

Product Quantity:

Reason for Recall:
Labeling: Incorrect or Missing Lot and/or Exp Date.

Recall Number:
D-0893-2018

Code Information:
lot# D001 EXP: 01/02/2018 CPD: 01/02/2019

Class III Drugs Event

Event ID:
80266

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
06/13/2018

Voluntary / Mandated:
Voluntary: Firm Initiated

Center Classification Date:
07/03/2018

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
LUPIN SOMERSET
400 Campus Dr
Somerset NJ United States

Distribution Pattern:
Nationwide

Associated Products

Product Description:
Equate ClearLAX, Polyethylene Glycol 3350 Powder for Solution, OS Osmotic Laxative, OTC, packaged in a) 119 g bottle (NDC 49035-312-07), b) 238 g bottle (NDC 49035-312-08), Distributed by: Wal-mart Stores, Inc., Bentonville, AR 72716

Product Quantity:
2,229,052 bottles

Reason for Recall:
Labeling: Not Elsewhere Classified - A private label distributor noted unfiled NDC numbers on EQ ClearLax Polyethylene Glycol 3350 NF Powder Solution of various sizes.

Recall Number:
D-0907-2018

Code Information:
a) M16425A, Exp 06/18; M16463A, Exp 7/18; M16516A, Exp 8/19; M16605A, Exp 10/19; M17005A, Exp 1/20; S700119, S700157, Exp 3/20; S700228, Exp 4/20; S700304, Exp 5/20; S700510, Exp 7/20; S700780, Exp 10/20; S701063, S701112, Exp 12/20; S800170, Exp 2/21; S800349, Exp 3/21; S800366, Exp 4/21; S800453, Exp 5/21; b) M16560A, M16561A, M16562A, Exp 9/19; M16607A, Exp 11/19; S700202, Exp 4/20; S700415, Exp 6/20; S700511, Exp 7/20; S700752, Exp 9/20; S700902, Exp 10/20; S701119, Exp 12/20; S800097, Exp 2/21; S800296, S800306, Exp 3/21.