

Enforcement Report - Week of January 13, 2021

Class II Drugs Event

Event ID:

86850

Product Type:

Drugs

Status:

Ongoing

Date Terminated:**Recall Initiation Date:**

11/23/2020

Voluntary / Mandated:

Voluntary: Firm initiated

Center Classification Date:

01/04/2021

Initial Firm Notification of Consignee or Public:

E-Mail

Recalling Firm:

Ascend Laboratories LLC
339 Jefferson Rd Ste 101
Parsippany NJ United States

Distribution Pattern:

Distributed Nationwide in the USA

Associated Products

Product Description:

Cephalexin for Oral Suspension, USP, 125 mg per 5 mL, packaged as a) 100 ml (when mixed) bottle, NDC 67877-544-88; b) 200 ml (when mixed) bottle NDC 67877-544-68, Rx Only, Manufactured by: Alkem Laboratories, Ltd, Mumbai -400 013 INDIA. Distributed by: Ascend Laboratories, LLC Parsippany, NJ 07054

Product Quantity:

20,232 bottles

Reason for Recall:

Failed Impurity/Degradation Specifications: Unidentified impurities not complying with specifications were observed in various lots of Cephalexin FOS USP 125 mg/5 mL.

Recall Number:

D-0185-2021

Code Information:

Lot#: a) 19144340, 19144341, Exp AUG 2021; b) 20142226, 20142227, Exp MAY 2022

Class II Drugs Event

Event ID:

86990

Product Type:

Drugs

Status:

Ongoing

Date Terminated:**Recall Initiation Date:**

12/17/2020

Voluntary / Mandated:

Voluntary: Firm initiated

Center Classification Date:

01/07/2021

Initial Firm Notification of Consignee or Public:

Letter

Recalling Firm:

SCA Pharmaceuticals
755 Rainbow Rd Ste B
Windsor CT United States

Distribution Pattern:

Product was distributed to hospitals nationwide.

Associated Products

Product Description:

Atropine Sulfate Injection, 0.8 mg/2 mL (0.4 mg/mL), 2 mL Single Dose Syringe, Rx Only, SCA Pharmaceuticals, 755 Rainbow Rd., Windsor, CT, 06095, barcode 70004004006

Product Quantity:

1,930 syringes

Reason for Recall:

Lack of Assurance of Sterility; potential for a defective syringe cap, resulting in a non-integral unit

Recall Number:

D-0186-2021

Code Information:

Lot # 1220023001, BUD 2/5/2021; 1220023126, BUD 2/9/2021 & 1220023606, BUD 2/25/2021.

Product Description:

Buffered Lidocaine HCl, 1%, 5 mL (10mg/mL) with Sodium Bicarbonate Injection for Local Anesthetic Use, 5 mL Single Dose Syringe, Rx Only SCA Pharmaceuticals, 755 Rainbow Rd., Windsor, CT, 06095, barcode 70004072509

Product Quantity:

3,793 syringes

Reason for Recall:

Lack of Assurance of Sterility; potential for a defective syringe cap, resulting in a non-integral unit

Recall Number:

D-0187-2021

Code Information:

Lot # 1220023305, BUD 12/17/2020; 12200223400, BUD 12/19/2020; 1220023536, BUD 12/25/2020; 1220023608, BUD 12/27/2020; 1220023811, BUD 12/26/2020 & 1220023812, BUD 12/26/2020.

Product Description:

ePHEDrine Sulfate, 50 mg/5mL in 0.9% Sodium Chloride Injection, 5 mL Single Dose Syringe, Rx Only, SCA Pharmaceuticals, 755 Rainbow Rd., Windsor, CT, 06095, barcode 70004060509

Product Quantity:

1,879 syringes

Reason for Recall:

Lack of Assurance of Sterility; potential for a defective syringe cap, resulting in a non-integral unit

Recall Number:

D-0188-2021

Code Information:

Lot # 1220023041, BUD 1/20/2021; 1220023188, BUD 1/27/2021 & 1220023397, BUD 2/3/2021.

Product Description:

ePHEDrine Sulfate 50 mg/10mL in 0.9% Sodium Chloride Injection, 10 mL Single Dose Syringe, Rx Only, SCA Pharmaceuticals, 755 Rainbow Rd., Windsor, CT, 06095 barcode 70004060412

Product Quantity:

7,257 syringes

Reason for Recall:

Lack of Assurance of Sterility; potential for a defective syringe cap, resulting in a non-integral unit

Recall Number:

D-0189-2021

Code Information:

Lot # 1220022996, BUD 1/21/2021; 1220023017, BUD 1/20/2021; 1220023021, BUD 1/17/2021; 1220023033, BUD 1/19/2021; 1220023146, BUD 1/26/2021; 1220023189, BUD 1/27/2021 1220023242, BUD 1/25/2021; 1220023321, BUD 2/2/2021; 1220023357 BUD 2/10/2021

Product Description:

Esmolol HCl 100 mg/10 mL (10mg/ mL), 10 mL Single Dose Syringe, Rx Only, SCA Pharmaceuticals, 755 Rainbow Rd., Windsor, CT, 06095, barcode 70004062012

Product Quantity:

952 syringes

Reason for Recall:

Lack of Assurance of Sterility; potential for a defective syringe cap, resulting in a non-integral unit

Recall Number:

D-0190-2021

Code Information:

Lot # 1220023042, BUD 1/21/2021

Product Description:

fentaNYL 100 mcg/50mL Ropivacaine HCl 0.1% in 0.9% Sodium Chloride 50 mL, 50 mL Single Dose Syringe, Rx Only, SCA Pharmaceuticals, 755 Rainbow Rd., Windsor, CT, 06095, barcode 70004026422

Product Quantity:

1,774 syringes

Reason for Recall:

Lack of Assurance of Sterility; potential for a defective syringe cap, resulting in a non-integral unit

Recall Number:

D-0191-2021

Code Information:

Lot # 1220023275, BUD 2/15/2021; 1220023312, BUD 2/15/2021; 1220023433, 2/22/2021; 1220023515, BUD 2/24/2021 & 1220023671, BUD 3/1/2021.

Product Description:

fentaNYL 100 mcg/50mL Bupivacaine HCl 0.125% in 0.9% Sodium Chloride 50 mL, 50 mL Single Dose Syringe, Rx Only, SCA Pharmaceuticals, 755 Rainbow Rd., Windsor, CT, 06095, barcode 70004023122

Product Quantity:

996 syringes

Reason for Recall:

Lack of Assurance of Sterility; potential for a defective syringe cap, resulting in a non-integral unit

Recall Number:

D-0192-2021

Code Information:

Lot # 1220022911, BUD 1/18/2021; 1220023092, BUD 1/25/2021 & 1220023247, BUD 1/27/2021.

Product Description:

fentaNYL 1500 mcg/30 mL (50 mcg/mL), 30 mL Single Dose Syringe, Rx Only, SCA Pharmaceuticals, 755 Rainbow Rd., Windsor, CT, 06095, barcode 70004020016

Product Quantity:

2,834 syringes

Reason for Recall:

Lack of Assurance of Sterility; potential for a defective syringe cap, resulting in a non-integral unit

Recall Number:

D-0193-2021

Code Information:

Lot # 1220022977, BUD 1/20/2021; 1220023122, BUD 1/25/2021; 1220023209, BUD 1/28/2021; 1220023248, BUD 1/27/2021; 1220023319, BUD 2/1/2021; 1220023496, BUD 2/8/2021 & 1220023560, BUD 2/9/2021.

Product Description:

Glycopyrrolate 1 mg/5mL (0.2mg/mL), 5 mL Single Dose Syringe, Rx Only, SCA Pharmaceuticals, 755 Rainbow Rd., Windsor, CT, 06095, barcode 70004063809

Product Quantity:

1,614 syringes

Reason for Recall:

Lack of Assurance of Sterility; potential for a defective syringe cap, resulting in a non-integral unit

Recall Number:

D-0194-2021

Code Information:

Lot # 1220023043, BUD 2/3/2021; 1220023141, BUD 2/9/2021; 1220023429, BUD 2/18/2021 & 1220023470, BUD 2/18/2021.

Product Description:

HYDROMorphone HCl 6 mg/30mL in 0.9% Sodium Chloride Injection (0.2 mg/mL), Rx Only, a) 30 mL Plungerless Single Dose Syringe (barcode 70004030016) and b) 30 mL Single Dose Syringe (barcode 70004030018), SCA Pharmaceuticals, 755 Rainbow Rd., Windsor, CT, 06095

Product Quantity:

3,092 syringes

Reason for Recall:

Lack of Assurance of Sterility; potential for a defective syringe cap, resulting in a non-integral unit

Recall Number:

D-0195-2021

Code Information:

a) Lot # 1220023171, BUD 1/26/2021; 1220023282, BUD 2/1/2021; 1220023446, BUD 2/7/2021; 1220023532, BUD 2/8/2021; 1220023650, BUD 2/11/2021 & 1220023727, BUD 2/14/2021. b) Lot # 1220023241, BUD 1/25/2021; 1220023313, BUD 2/1/2021 & 1220023442, BUD 2/7/2021.

Product Description:

HYDROMorphone HCl 30 mg/30 mL in 0.9% Sodium Chloride Injection (1 mg/mL) a) 30 mL Plungerless Single Dose Syringe (barcode 70004030316) and b) 30 mL Single Dose Syringe (barcode 70004030321), Rx Only, SCA Pharmaceuticals, 755 Rainbow Rd., Windsor, CT, 06095

Product Quantity:

1,056 syringes

Reason for Recall:

Lack of Assurance of Sterility; potential for a defective syringe cap, resulting in a non-integral unit

Recall Number:

D-0196-2021

Code Information:

a) Lot # 1220022964, BUD 1/19/2021; 1220023280, BUD 2/1/2021 & 1220023623, BUD 2/10/2021. b) Lot # 1220023347, BUD 2/17/2021.

Product Description:

Ketamine 100 mg/10mL in 0.9% Sodium Chloride Injection (10 mg/mL), CII, Rx Only, 10 mL Single Dose Syringe, SCA Pharmaceuticals, 755 Rainbow Rd., Windsor, CT, 06095, barcode 70004043012

Product Quantity:

11,075 syringes

Reason for Recall:

Lack of Assurance of Sterility; potential for a defective syringe cap, resulting in a non-integral unit

Recall Number:

D-0197-2021

Code Information:

a) Lot # 1220023076, BUD 1/24/2021 & 1220023549, BUD 2/9/2021. b) Lot # 1220023040, BUD 1/19/2021; 1220023070, BUD 1/21/2021; 1220023105, BUD 1/25/2021; 1220023158, BUD 1/26/2021; 1220023315, BUD 2/1/2021; 1220023342, BUD 2/2/2021; 1220023431, BUD 2/4/2021; 1220023471, BUD 2/3/2021; 1220023481, BUD 2/4/2021 & 1220023509, BUD 2/8/2021.

Product Description:

labetalol HCl 20 mg/4 mL, Injection for Intravenous Use (5mg/mL), Rx Only, 4 mL Single Dose Syringe, SCA Pharmaceuticals, 755 Rainbow Rd., Windsor, CT, 06095, barcode 70004070028

Product Quantity:

9,057 syringes

Reason for Recall:

Lack of Assurance of Sterility; potential for a defective syringe cap, resulting in a non-integral unit

Recall Number:

D-0198-2021

Code Information:

Lot # 1220022969, BUD 3/1/2021; 1220023002, BUD 3/2/2021; 1220023045, BUD 3/2/2021; 1220023081, BUD 3/2/2021; 1220023130, BUD 3/6/2021; 1220023229, BUD 3/9/2021; 1220023287, BUD 3/12/2021 & 1220023335, BUD 3/22/2021.

Product Description:

Lidocaine HCl 1% 10 mL (10mg/ml), Rx Only, 1 mL Single Dose Syringe, SCA Pharma, Inc., 755 Rainbow Rd., Windsor, CT, 06095, barcode 70004072012

Product Quantity:

1,880 syringes

Reason for Recall:

Lack of Assurance of Sterility; potential for a defective syringe cap, resulting in a non-integral unit

Recall Number:

D-0199-2021

Code Information:

Lot # 1220023097, BUD 1/25/2021; 1220023134, BUD 1/25/2021 & 1220023326, BUD 2/1/2021

Product Description:

Lidocaine HCl 2% 5 mL, 20 mg/mL, Rx Only, 5 mL syringe, Rx Only, SCA Pharmaceuticals, 755 Rainbow Rd., Windsor, CT, 06095, barcode 70004072309

Product Quantity:

7,275 syringes

Reason for Recall:

Lack of Assurance of Sterility; potential for a defective syringe cap, resulting in a non-integral unit

Recall Number:

D-0200-2021

Code Information:

Lot # 1220023034, BUD 1/19/2021; 1220023088, BUD 1/24/2021; 1220023112, BUD 1/25/2021; 1220023288, BUD 1/31/2021; 1220023323, BUD 2/2/2021; 1220023539, BUD 2/8/2021 & 1220023613, BUD 2/10/2021.

Product Description:

morphine sulfate 150 mg/30 mL in 0.9% Sodium Chloride Injection, (5 mg/mL), Rx Only, 30 mL Single Dose Syringe, SCA Pharmaceuticals, 755 Rainbow Rd., Windsor, CT, 06095, barcode 70004010316

Product Quantity:

50 syringes

Reason for Recall:

Lack of Assurance of Sterility; potential for a defective syringe cap, resulting in a non-integral unit

Recall Number:

D-0202-2021

Code Information:

Lot # 1220023221, BUD 1/31/2021 & 1220023584, BUD 2/9/2021.

Product Description:

neostigmine methylsulfate 5 mg/5 mL, (1mg/ml), Rx Only, 5 mL Single Dose Syringe, SCA Pharmaceuticals, 755 Rainbow Rd., Windsor, CT, 06095, barcode 70004075009

Product Quantity:

390 syringes

Reason for Recall:

Lack of Assurance of Sterility; potential for a defective syringe cap, resulting in a non-integral unit

Recall Number:

D-0203-2021

Code Information:

Lot # 1220023044, BUD 1/30/2021

Product Description:

PHENYLEphrine HCl 1000 mcg/10 mL in 0.9% Sodium Chloride, (100 mcg/mL) Rx Only, 10 mL Single Dose Syringe, SCA Pharmaceuticals, 755 Rainbow Rd., Windsor, CT, 06095, barcode 70004081012

Product Quantity:

23,029 syringes

Reason for Recall:

Lack of Assurance of Sterility; potential for a defective syringe cap, resulting in a non-integral unit

Recall Number:

D-0204-2021

Code Information:

Lot # 1220022957, BUD 1/20/2021; 1220022993, BUD 1/21/2021; 1220023020, BUD 1/14/2021; 1220023037, BUD 1/19/2021; 1220023038, BUD 1/20/2021; 1220023074, 1/24/2021; 1220023103, BUD 1/24/2021; 1220023160, BUD 1/26/2021; 1220023180, BUD 1/27/2021; 1220023183, BUD 1/27/2021; 1220023216, BUD 1/28/2021; 1220023267, BUD 2/1/2021; 1220023272, BUD 1/3/2021; 1220023344, BUD 2/10/2021; 1220023387, BUD 2/9/2021; 1220023475, BUD 2/4/2021; 1220023479, BUD 2/4/2021; 1220023564, BUD 2/9/2021; 1220023565, BUD 2/9/2021; 1220023587, BUD 2/10/2021 & 1220023624, BUD 2/11/2021.

Product Description:

PHENYLEphrine HCl 800 mcg/10 mL in 0.9% Sodium Chloride (80 mcg/mL), Rx Only, 10 mL Single Dose Syringe, SCA Pharmaceuticals, 755 Rainbow Rd., Windsor, CT, 06095, barcode 70004081612

Product Quantity:

7,890 syringes

Reason for Recall:

Lack of Assurance of Sterility; potential for a defective syringe cap, resulting in a non-integral unit

Recall Number:

D-0205-2021

Code Information:

Lot # 1220023039, BUD 1/21/2021; 1220023080, BUD 1/24/2021; 1220023374, BUD 2/3/2021; 1220023375, BUD 2/2/2021; 1220023490, BUD 2/7/2021; 1220023554, BUD 2/8/2021 & 1220023837, BUD 2/14/2021.

Product Description:

Rocuronium Br 100 mg/10mL (10 mg/mL), Rx Only, 10 mL Single Dose Syringe, SCA Pharmaceuticals, 8821 Knoedl Ct. Little Rock, AR, 72205, barcode 70004085012

Product Quantity:

7,940 syringes

Reason for Recall:

Lack of Assurance of Sterility; potential for a defective syringe cap, resulting in a non-integral unit

Recall Number:

D-0206-2021

Code Information:

Lot # 1220022998, BUD 1/21/2021; 1220023115, BUD 1/25/2021; 1220023163, BUD 1/26/2021; 1220023186, BUD 1/27/2021; 1220023234, BUD 1/31/2021; 1220023393, BUD 2/3/2021; 1220023477, BUD 2/4/2021; 1220023568, BUD 2/9/2021 & 1220023625, BUD 2/11/2021.

Product Description:

Sodium Citrate 4% 3 mL Anticoagulation Solution (40mg/mL), Rx only, 3 mL Single Dose Syringe, SCA Pharmaceuticals, 755 Rainbow Rd., Windsor, CT, 06095, barcode 70004090025

Product Quantity:

5,990 syringes

Reason for Recall:

Lack of Assurance of Sterility; potential for a defective syringe cap, resulting in a non-integral unit

Recall Number:

D-0207-2021

Code Information:

Lot # 1220022961, BUD 1/20/2021; 1220023121, BUD 1/25/2021; 1220023207, BUD 2/12/2021; 1220023363, BUD 2/17/2021 & 1220023526, BUD 2/23/2021.

Product Description:

SUCcinylocholine Chloride 200 mg/10 mL, (20 mg/mL), Rx Only, 10 mL Single Dose Syringe, SCA Pharmaceuticals, 755 Rainbow Rd., Windsor, CT, 06095, barcode 70004090812

Product Quantity:

3,239 syringes

Reason for Recall:

Lack of Assurance of Sterility; potential for a defective syringe cap, resulting in a non-integral unit

Recall Number:

D-0208-2021

Code Information:

Lot # 1220023028, BUD 1/19/2021; 1220023124, BUD 1/25/2021; 1220023162, BUD 1/26/2021 & 1220023210, BUD 1/28/2021.

Product Description:

Morphine Sulfate 30 mg/30 mL in 0.9% Sodium Chloride (1mg/ml), CII, Rx Only, 30 mL Single Dose Syringe, SCA Pharmaceuticals, 755 Rainbow Rd., Windsor, CT, 06095, barcode 70004010016

Product Quantity:

116 syringes

Reason for Recall:

Lack of Assurance of Sterility; potential for a defective syringe cap, resulting in a non-integral unit

Recall Number:

D-0209-2021

Code Information:

Lot # 1220023412, BUD 2/2/2021; 12220023500, BUD 2/3/2021 & 1220023689 BUD 2/11/2021.

Product Description:

PHENYLEphrine HCl 500 mcg/5mL in 0.9% Sodium Chloride (100 mcg/mL), Rx Only, 5 mL Single Dose Syringe, SCA Pharmaceuticals, 755 Rainbow Rd., Windsor, CT, 06095, barcode 70004081011

Product Quantity:

14,580 syringes

Reason for Recall:

Lack of Assurance of Sterility; potential for a defective syringe cap, resulting in a non-integral unit

Recall Number:

D-0210-2021

Code Information:

Lot # 1220022958, BUD 1/20/2021; 1220023013, BUD 1/18/2021; 1220023035, BUD 1/19/2021; 1220023036, BUD 1/21/2021; 1220023059, BUD 1/21/2021; 1220023094, BUD 1/25/2021; 1220023167, BUD 1/26/2021; 1220023208, BUD 1/27/2021; 1220023291, BUD 1/31/2021; 1220023359, BUD 2/2/2021; 1220023401, BUD 2/2/2021 & 1220023473, BUD 2/4/2021.

Product Description:

Rocuronium Br 50 mg/5mL (10 mg/mL), a) 5 mL Single Dose Syringe Red Label(barcode 7000485009) Rx Only, SCA Pharmaceuticals, 755 Rainbow Rd., Windsor, CT, 06095 and b) 5 mL Single Dose Syringe White Label (barcode 70004085028), Rx Only, SCA Pharmaceuticals, 8821 Knoedl Ct, Little Rock, AR 72205

Product Quantity:

13,096 syringes

Reason for Recall:

Lack of Assurance of Sterility; potential for a defective syringe cap, resulting in a non-integral unit

Recall Number:

D-0211-2021

Code Information:

a) Lot # 1220023011, BUD 1/12/2021; 1220023027, BUD 1/19/2021; 1220023151, BUD 1/26/2021; 1220023152, BUD 1/26/2021; 1220023194, BUD 1/26/2021; 1220023228, BUD 1/28/2021; 1220023358, BUD 2/3/2021; 1220023396, BUD 2/3/2021; 1220023398, BUD 2/10/2021; 1220023569, BUD 2/9/2021 & 1220023633, BUD 2/11/2021. b)1220023031, BUD 1/19/2021; 1220023032, BUD 1/24/2021; 1220023161, BUD 1/26/2021 & 1220023224, BUD 1/28/2021.

Product Description:

SUCcinyIcholine Chloride 100 mg/5mL, Rx Only, 5 mL Single Dose Syringe, SCA Pharmaceuticals, 755 Rainbow Rd., WIndsor, CT, 06095, barcode 70004090809

Product Quantity:

5067 syringes

Reason for Recall:

Lack of Assurance of Sterility; potential for a defective syringe cap, resulting in a non-integral unit

Recall Number:

D-0212-2021

Code Information:

Lot # 1220023019, BUD 1/17/2021; 1220023025, BUD 1/18/2021; 1220023026, BUD 1/24/2021 & 1220023264, BUD 2/1/2021.

Product Description:

ePHEDrine 25 mg/5 mL in 0.9% Sodium Chloride Injection, Rx Only, 5 mL Single Dose Syringe, SCA Pharmaceuticals 8521 Knoedl Ct., Little Rock, AR, 72205, barcode 70004060409

Product Quantity:

9416 syringes

Reason for Recall:

Lack of Assurance of Sterility; potential for a defective syringe cap, resulting in a non-integral unit

Recall Number:

D-0213-2021

Code Information:

Lot # 1220023022, BUD 1/17/2021; 1220023023, BUD 1/17/2021; 1220023029, BUD 1/19/2021; 1220023030, BUD 1/20/2021; 1220023117, BUD 1/25/2021; 1220023145, BUD 1/26/2021 & 1220023166, BUD 1/27/2021.

Product Description:

fentaNYL 100 mcg/2mL Injection for IV or IM Use, 2 mL Single Dose Syringe, CII, Rx Only, SCA Pharmaceuticals, 755 Rainbow Rd., Windsor, CT, 06095 barcode 70004020006

Product Quantity:

6710 syringes

Reason for Recall:

Lack of Assurance of Sterility; potential for a defective syringe cap, resulting in a non-integral unit

Recall Number:

D-0214-2021

Code Information:

Lot #1220023109, BUD 1/25/2021; 1220023255, BUD 1/26/2021; 1220023256, BUD 1/26/2021; 1220023257, BUD 1/28/2021; 1220023334, BUD 2/2/2021 & 1220023518, BUD 2/8/2021.

Product Description:

HYDROMorphone HCl 10mg/50mL in 0.9% Sodium Chloride Injection, CII, Rx Only, 50 mL Single Dose Syringe, SCA Pharmaceuticals, 755 Rainbow Rd., Windsor, CT, 06095, barcode 70004030022

Product Quantity:

428 syringes

Reason for Recall:

Lack of Assurance of Sterility; potential for a defective syringe cap, resulting in a non-integral unit

Recall Number:

D-0215-2021

Code Information:

Lot # 1220023220, BUD 1/31/2021; 1220023337, BUD 2/2/2021 & 1220023443, BUD 2/22/2021.

Product Description:

PHENYLephrine HCl 5000 mg/50 mL in Sodium Chloride 0.9% (100 mcg/mL) Rx Only, 5 mL Single Dose Syringe, SCA Pharmaceuticals, 755 Rainbow Rd., Windsor, CT, 06095, barcode 70004081022

Product Quantity:

3152 syringes

Reason for Recall:

Lack of Assurance of Sterility; potential for a defective syringe cap, resulting in a non-integral unit

Recall Number:

D-0216-2021

Code Information:

Lot # 1220023003, BUD 12/22/2020; 1220023057, BUD 12/25/2020; 1220023104, BUD 12/25/2020; 1220023144, BUD 12/27/2020; 1220023168, BUD 12/27/2020; 1220023222, BUD 12/29/2020; 1220023240, BUD 12/28/2020; 1220023284, BUD 1/1/2021; 1220023456, BUD 1/8/2021; 1220023474, BUD 1/4/2021; 1220023530, BUD 1/8/2021 & 1220023542, BUD 1/9/2021.

Product Description:

Ketamine 50 mg/5mL in 0.9% Sodium Chloride Injection (10 mg/mL), CII, Rx Only, 5 mL Single Dose Syringe, SCA Pharmaceuticals, 755 Rainbow Rd., Windsor, CT, 06095, barcode 70004043009

Product Quantity:

9942 syringes

Reason for Recall:

Lack of Assurance of Sterility; potential for a defective syringe cap, resulting in a non-integral unit

Recall Number:

D-0217-2021

Code Information:

Lot # 1220023040, BUD 1/19/2021; 1220023070, BUD 1/21/2021; 1220023105, BUD 1/25/2021; 1220023158, BUD 1/26/2021; 1220023315, BUD 2/1/2021; 1220023342, BUD 2/2/2021; 1220023431, BUD 2/4/2021; 1220023471, BUD 2/3/2021; 1220023481, BUD 2/4/2021 & 1220023509, BUD 2/8/2021.

Class II Drugs Event

Event ID:

87018

Product Type:

Drugs

Status:

Ongoing

Date Terminated:**Recall Initiation Date:**

12/21/2020

Voluntary / Mandated:

Voluntary: Firm initiated

Center Classification Date:

01/07/2021

Initial Firm Notification of Consignee or Public:

Letter

Recalling Firm:

Merck Sharp & Dohme
126 E Lincoln Ave
Rahway NJ United States

Distribution Pattern:

U.S.A. Nationwide

Associated Products

Product Description:

Zerbaxa (ceftolozane and tazobactam) 1.5g per vial for injection, Single-Dose vial, Rx only, Manuf. for: Merck Sharp & Dohme Corp. a subsidiary of Merck & Co., Inc., NDC 67919-030-01

Product Quantity:

106,503 vials

Reason for Recall:

Lack of assurance of sterility: The results of sterility tests of seven batches of product were out of specification. Five of these batches tested positive for *Ralstonia pickettii* and two batches produced turbid results that could not be further identified. While all product distributed to the market has met the registered specifications for release, including for sterility, it was manufactured on the same equipment as the affected batches.

Recall Number:

D-0176-2021

Code Information:

All lots within expiry: SP1488 08-Jun-21; SP1490 11-Jun-21; SP1492 13-Jun-21; SP1493 15-Jun-21; SP1494 21-Jun-21; SP1495 23-Jun-21; SP1496 25-Jun-21; SP1497 27-Jun-21; SP1498 29-Jun-21; SP1509 20-Sep-21; SP1510 26-Sep-21; SP1515 16-Oct-21; SP1517 23-Oct-21; SP1518 25-Oct-21; SP1519 30-Oct-21; SP1520 01-Nov-21; SP1521 06-Nov-21; SP1522 08-Nov-21; SP1523;13-Nov-21; SP1524; 15-Nov-21; SP1525 20-Nov-21; SP1526 27-Nov-21; SP1537 11-Jan-22; SP1564 17-Oct-22; SP1567 16-Oct-22; SP1572 24-Oct-22; SP1573; 28-Oct-22; SP1574 29-Oct-22; SP1584; 14-Nov-22; SP1586; 15-Nov-22; SP1588; 19-Nov-22; SP1593 03-Dec-22; SP1602 18-Dec-22; SP1603; 19-Dec-22; SP1606 08-Jan-23; SP1609 15-Jan-23; SP1610 20-Jan-23; SP1611 22-Jan-23; SP1626 13-Apr-23; SP1629 17-Apr-23; SP1633 21-Apr-23

Class III Drugs Event

Event ID:
86990

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
12/17/2020

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
01/07/2021

Initial Firm Notification of Consignee or Public:
Letter

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

Distribution Pattern:
Product was distributed to hospitals nationwide.

Associated Products

Product Description:

Morphine Sulfate 3 mg/3 mL in 0.9% Sodium Chloride (1mg/mL) CII, Rx Only, 3 ml Single Dose Syringe, SCA Pharmaceuticals, 755 Rainbow Rd., Windsor, CT, 06095, barcode 70004010025

Product Quantity:

751 syringes

Reason for Recall:

Lack of Assurance of Sterility; potential for a defective syringe cap, resulting in a non-integral unit

Recall Number:

D-0201-2021

Code Information:

Lot # 1220023452, BUD 2/7/2021