

# Enforcement Report - Week of April 3, 2024

## Class I Drugs Event

**Event ID:**

94166

**Product Type:**

Drugs

**Status:**

Ongoing

**Date Terminated:**
**Recall Initiation Date:**

03/04/2024

**Voluntary / Mandated:**

Voluntary: Firm initiated

**Center Classification Date:**

03/28/2024

**Initial Firm Notification of Consignee or Public:**

Letter

**Recalling Firm:**

Par Sterile Products LLC  
870 Parkdale Rd  
Rochester MI United States

**Distribution Pattern:**

Nationwide in the USA

## Associated Products

**Product Description:**

Treprostinil Injection, 20 mg/20 mL (1 mg/mL), For Subcutaneous or Intravenous Infusion Only, 20 mL Multiple-Dose Vial, Rx Only, Distributed by: Par Pharmaceutical, Chestnut Ridge, NY 10977. NDC: 42023-206-01

**Product Quantity:**

466 vials

**Reason for Recall:**

Presence of Particulate Matter.

**Recall Number:**

D-0429-2024

**Code Information:**

Lot#: 57014; Exp, 04/30/2024

## Class II Drugs Event

**Event ID:**

93456

**Product Type:**

Drugs

**Status:**

Ongoing

**Date Terminated:**
**Recall Initiation Date:**

11/09/2023

**Voluntary / Mandated:**

Voluntary: Firm initiated

**Center Classification Date:**

03/22/2024

**Initial Firm Notification of Consignee or Public:**

Letter

**Recalling Firm:**

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

**Distribution Pattern:**

Nationwide in the USA

## Associated Products

**Product Description:**

Diltiazem HCl 125 mg in 0.9% Sodium Chloride Injection (Concentration = 1mg/mL), 125 mL Bag, Rx only, SCA Pharmaceuticals, 755 Rainbow Rd., Windsor, CT 06095; NDC 70004-0541-35, Bar Code 70004054135

**Product Quantity:**

381 Bags

**Reason for Recall:**

Lack of Assurance of Sterility

**Recall Number:**

D-0394-2024

**Code Information:**

Lot #: 1223049625, Exp 1/24/24

**Product Description:**

fentaNYL 2,500 mcg/250 mL in 0.9% Sodium Chloride Injection (Concentration = 10 mcg/mL), 250 mL Bag, Rx only, SCA Pharmaceuticals, 755 Rainbow Rd., Windsor, CT 06095, 877.550.5059, NDC 70004-0229-40 BAR code 70004022940

**Product Quantity:**

548 bags

**Reason for Recall:**

Lack of Assurance of Sterility

**Recall Number:**

D-0395-2024

**Code Information:**

Lot #: 1223045757, Exp 12/27/23; 1223049716, Exp 5/25/24

**Product Description:**

fentaNYL 2,500 mcg/50 mL Injection (Concentration = 50 mcg/mL), INTRAVENOUS USE ONLY, 50 mL Bag, Rx only, SCA Pharma, 755 Rainbow Rd., Windsor, CT 06095, NDC 70004-0222-30 BAR code 70004022230

**Product Quantity:**

500 bags

**Reason for Recall:**

Lack of Assurance of Sterility

**Recall Number:**

D-0396-2024

**Code Information:**

Lot #: 1223048351, Exp 11/30/23; 1223048532, Exp 12/07/23

**Product Description:**

fentaNYL 200 mcg/100 mL, Bupivacaine HCl 0.125% in 0.9% Sodium Chloride 100 mL Injection (fentaNYL Concentration = 2 mcg/mL), EPIDURAL USE ONLY, 100 mL Bag, Rx only, SCA Pharmaceuticals, 755 Rainbow Rd., Windsor, CT 06095, NDC 70004-0231-32, Bar Code 70004023132

**Product Quantity:**

242 bags

**Reason for Recall:**

Lack of Assurance of Sterility

**Recall Number:**

D-0397-2024

**Code Information:**

Lot #: 1223048855, Exp 12/6/23

**Product Description:**

fentaNYL 200 mcg/100 mL, Bupivacaine HCl 0.125% in 0.9% Sodium Chloride 100 mL Injection, (fentaNYL Concentration = 2 mcg/mL), EPIDURAL USE ONLY, 100 mL Yellow CADD Cassette, Rx only, SCA Pharmaceuticals, 755 Rainbow Rd., Windsor, CT 06095, NDC 70004-0231-64, Bar Code 70004023164

**Product Quantity:**

613 Cassettes

**Reason for Recall:**

Lack of Assurance of Sterility

**Recall Number:**

D-0398-2024

**Code Information:**

Lot #: 1223049754, Exp 01/12/24; 1223049992, Exp 01/23/24; 1223050066, Exp 01/25/24

**Product Description:**

fentaNYL 100 mcg/50 mL, Bupivacaine HCl 0.125% in 0.9% Sodium Chloride 50 mL Injection (fentaNYL Concentration = 2 mcg/mL), EPIDURAL USE ONLY, 50 mL fill Syringe, Rx only, SCA Pharmaceuticals, 755 Rainbow Rd, Windsor, CT 06095, NDC 70004-0231-22, Bar Code 70004023122

**Product Quantity:**

324 syringes

**Reason for Recall:**

Lack of Assurance of Sterility

**Recall Number:**

D-0399-2024

**Code Information:**

Lot #: 1223049125, Exp 12/04/23

**Product Description:**

fentaNYL 500 mcg/100 mL, Bupivacaine HCl 0.04% in 0.9% Sodium Chloride 100 mL Injection (fentaNYL Concentration = 5 mcg/mL), EPIDURAL USE ONLY, 100 mL Yellow CADD Cassette, Rx only, SCA Pharmaceuticals, 755 Rainbow Rd., Windsor, CT 06095, NDC 70004-0289-64, Bar Code 70004028964

**Product Quantity:**

412 cassettes

**Reason for Recall:**

Lack of Assurance of Sterility

**Recall Number:**

D-0400-2024

**Code Information:**

Lot #: 1223049261, Exp 12/25/23; 1223049724, Exp 01/11/24

**Product Description:**

fentaNYL 500 mcg/100 mL, Bupivacaine HCl 0.075% in 0.9% Sodium Chloride 100 mL Injection (fentaNYL Concentration = 5 mcg/mL), EPIDURAL USE ONLY, 100 mL Yellow CADD Cassette, Rx only, SCA Pharmaceuticals, 755 Rainbow Rd., Windsor, CT 06095, NDC 70004-0251-64, Bar Code 70004025164

**Product Quantity:**

130 cassettes

**Reason for Recall:**

Lack of Assurance of Sterility

**Recall Number:**

D-0401-2024

**Code Information:**

Lot #: 1223048722, Exp 11/29/23; 1223049096, Exp 12/15/23

**Product Description:**

fentaNYL 1,250 mcg/25 mL Injection (Concentration = 50 mcg/mL), 25 mL fill in a 30 mL Single Dose Syringe, RX Only, repackaged by SCA Pharma. SCA Pharmaceuticals, 755 Rainbow Rd. Windsor, CT 06095, NDC 70004-0200-17, Bar code 70004020017

**Product Quantity:**

1,259 syringes

**Reason for Recall:**

Lack of Assurance of Sterility

**Recall Number:**

D-0402-2024

**Code Information:**

Lot #: 1223048522, Exp 12/07/23; 1223049168, Exp 01/04/24; 1223049552, Exp 01/19/24

**Product Description:**

fentaNYL 2,500 mcg/50 mL in 0.9 % Sodium Chloride Injection (Concentration = 50 mcg/mL) 50 mL Single Dose Syringe, Rx Only, SCA Pharmaceuticals, 755 Rainbow Rd. Windsor, CT 06095, NDC 70004-0202-22, Bar code 70004020022,

**Product Quantity:**

500 syringes

**Reason for Recall:**

Lack of Assurance of Sterility

**Recall Number:**

D-0403-2024

**Code Information:**

Lot #: 1223048959, Exp 12/11/23; 1223049009, Exp 12/12/23; 1223049170, Exp 12/20/23; 1223049245, Exp 12/22/23

**Product Description:**

HYDRomorphine HCl 20 mg/100mL in 0.9% Sodium Chloride Injection, 100 mL Grey CADD Cassette (20 mg/100 mL), CII, Rx only, SCA Pharmaceuticals, 755 Rainbow Rd., Windsor, CT 06095, NDC 70004-0300-63, Bar Code 70004030063

**Product Quantity:**

256 cassettes

**Reason for Recall:**

Lack of Assurance of Sterility

**Recall Number:**

D-0404-2024

**Code Information:**

Lot #: 1223049529, Exp 01/03/24

**Product Description:**

HYDRomorphine HCl 6 mg/30 mL in 0.9% Sodium Chloride Injection, (Concentration = 0.2 mg/ml) 30 mL fill 35 mL Plungerless Syringe, Rx only, SCA Pharmaceuticals, 755 Rainbow Rd., Windsor, CT 06095, NDC 70004-0300-16, Bar Code 70004030016

**Product Quantity:**

5,734 syringes

**Reason for Recall:**

Lack of Assurance of Sterility

**Recall Number:**

D-0405-2024

**Code Information:**

Lot #: 1223048530, Exp 11/22/23; 1223048692 Exp 11/29/23; 1223048739 EXP 11/30/23; 1223048826 Exp 12/05/23; 1223048963 Exp 12/08/23; 1223048964 EXP 12/11/23; 1223049111 Exp 12/15/23; 1223049128 Exp12/19/23; 1223049210 EXP 12/21/23; 1223049234 Exp 12/22/23; 1223049257 Exp 12/22/23; 1223049322 Exp 12/27/23; 1223049416 Exp 12/28/23; 1223049528 Exp 01/03/24; 1223049559 Exp 01/04/24; 1223049614 Exp 01/05/24; 1223049632 Exp 01/08/24; 1223049725 Exp 01/11/24; 1223049792 Exp 01/15/24; 1223049793 Exp 01/15/24; 1223049905 Exp 01/19/24; 1223050029 Exp 1/24/24; 1223050061 Exp 01/25/24; 1223050179 Exp 01/29/24

**Product Description:**

HYDRomorphine HCl 6 mg/30 mL in 0.9% Sodium Chloride, (Concentration = 0.2mg/ml) 30 mL Syringe, Rx only, SCA Pharmaceuticals, 755 Rainbow Rd., Windsor, CT 06095, NDC 70004-0300-18, Bar Code 70004030018

**Product Quantity:**

1,425 syringes

**Reason for Recall:**

Lack of Assurance of Sterility

**Recall Number:**

D-0406-2024

**Code Information:**

Lot #: 1223048451 Exp 11/20/23; 1223048923 Exp 12/07/23; 1223049097 Exp 12/15/23; 1223049129 Exp 12/19/23;

**Product Description:**

HYDRomorphone HCl 10 mg/50 mL in 0.9% Sodium Chloride Injection (Concentration = 0.2 mg/ml) 50 mL fill Syringe, Rx only, SCA Pharmaceuticals, 755 Rainbow Rd., Windsor, CT 06095, NDC 70004-0300-22, Bar Code 70004030022

**Product Quantity:**

1,023 syringes

**Reason for Recall:**

Lack of Assurance of Sterility

**Recall Number:**

D-0407-2024

**Code Information:**

Lot#: 1223048801 Exp 12/04/23; 1223049225 Exp 12/21/23; 1223049264 Exp 12/25/23; 1223049291 Exp 12/26/23; 1223049726 exp 01/11/24

**Product Description:**

HYDRomorphone HCl 25 mg/25 mL in 0.9% Sodium Chloride Injection, (Concentration = 1mg/mL), 25 mL fill 30 mL Syringe, Rx only, SCA Pharmaceuticals, 755 Rainbow Rd., Windsor, CT 06095, NDC 70004-0303-17, Bar Code 7004030317

**Product Quantity:**

399 syringes

**Reason for Recall:**

Lack of Assurance of Sterility

**Recall Number:**

D-0408-2024

**Code Information:**

Lot #: 1223048491 Exp 11/21/23

**Product Description:**

HYDRomorphone HCl 30 mg/30mL in 0.9% Sodium Chloride Injection, (Concentration = 1 mg/ml) 30 mL fill 35 mL Plungerless Syringe, Rx only, SCA Pharmaceuticals, 755 Rainbow Rd., Windsor, CT 06095, NDC 70004-0303-16, Bar Code 70004030316

**Product Quantity:**

5392 syringes

**Reason for Recall:**

Lack of Assurance of Sterility

**Recall Number:**

D-0409-2024

**Code Information:**

Lot #: 1223048357 Exp 11/15/23; 1223048461 EXP 11/20/23; 1223048486 EXP 11/21/23; 1223048694 EXP 12/01/23; 1223048865 EXP 12/06/23; 1223048967 EXP 12/11/23; 1223049098 EXP 12/15/23; 1223049133 EXP 12/19/23; 1223049175 EXP 12/20/23; 1223049268 EXP 12/25/23; 1223049457 EXP 01/01/24; 1223049561 EXP 01/04/24; 1223049604 EXP 01/05/24; 1223049648 EXP 01/09/24; 1223049870 EXP 01/17/24; 1223049942 EXP 01/19/24; 1223049973 EXP 01/23/24; 1223050060 EXP 01/25/24;

**Product Description:**

HYDRomorphone HCl 30 mg/30 mL in 0.9% Sodium Chloride Injection, (Concentration = 1mg/mL) 30 mL fill Syringe, Rx only, SCA Pharmaceuticals, 755 Rainbow Rd., Windsor, CT 06095, NDC 70004-0303-21, Bar Code 70004030321

**Product Quantity:**

909 syringes

**Reason for Recall:**

Lack of Assurance of Sterility

**Recall Number:**

D-0410-2024

**Code Information:**

Lot#: 1223048258 Exp 11/10/23; 1223048890 Exp 12/07/23; 1223049134 Exp 12/19/23

**Product Description:**

labetalol HCl 20 mg/4mL Injection, (Concentration=5 mg/mL), 4 mL fill Syringe, Rx Only, SCA Pharma, 755 Rainbow Rd., Windsor, CT 06095, NDC 70004-0700-28, Bar Code 70004070028

**Product Quantity:**

2,458, syringes

**Reason for Recall:**

Lack of Assurance of Sterility

**Recall Number:**

D-0411-2024

**Code Information:**

Lot #: 1223047334 Exp 12/23/23; 1223048170 Exp 02/01/24

**Product Description:**

Midazolam HCl 100 mg/100 mL in 0.9% Sodium Chloride Injection, (Concentration = 1mg/mL) 100 mL Bag, Rx Only, SCA Pharmaceuticals, 755 Rainbow Rd., Windsor, CT 06095, NDC 70004-0411-59, Bar Code 70004041159

**Product Quantity:**

1,508 bags; expanded 1,015 bags

**Reason for Recall:**

Lack of Assurance of Sterility

**Recall Number:**

D-0412-2024

**Code Information:**

Lot#: 1223044958 Exp 11/10/23; 1223045436 Exp 11/30/23; 1223046132 Exp 12/28/23; 1223046385 Exp 01/06/24; 1223048807 Exp 04/17/24; 1223049030 Exp 04/26/24 Expanded Recall lots: 1223049328, Exp 05/10/2024; 1223048948, Exp 04/21/2024; 1223048631, Exp 04/10/2024; 1223050389, Exp 06/21/2024.

**Product Description:**

neostigmine methylsulfate 5 mg/5 mL Injection, (Concentration = 1mg/mL), 5 mL fill 6 mL Syringe, Rx Only, SCA Pharma, 755 Rainbow Rd., Windsor, CT 06095, NDC 70004-0750-09, Bar Code 70004075009

**Product Quantity:**

1,122 syringes

**Reason for Recall:**

Lack of Assurance of Sterility

**Recall Number:**

D-0413-2024

**Code Information:**

Lot #: 1223048138 exp 1/31/24

**Product Description:**

PHENYLephrine HCl 1000 mcg/10 mL in 0.9% Sodium Chloride Injection, (Concentration = 100 mcg/mL), 10 mL fill 12 mL Syringe, Rx Only, SCA Pharmaceuticals, 755 Rainbow Rd. Windsor, CT 06095, NDC 70004-0810-12, Bar Code 70004081012

**Product Quantity:**

33,072 syringes; expanded 9,041 syringes

**Reason for Recall:**

Lack of Assurance of Sterility

**Recall Number:**

D-0414-2024

**Code Information:**

Lot #: 1223045536 Exp 12/06/23; 1223045710 Exp 12/10/23; 1223046574 Exp 01/12/24; 1223047579 Exp 02/21/24; 1223047764 Exp 03/06/24; 1223048363 Exp 03/30/24; 1223048364 Exp 03/30/24; 1223048566 Exp 04/06/24; 1223048573 Exp 04/07/24; 1223048574 Exp 04/07/24; 1223048643 Exp 04/11/24; 1223048697 Exp 04/12/24; 1223048742 Exp 04/13/24 Expanded lots#: 1223048065, Exp 04/06/2024; 1223048395, 1223048397, Exp 03/27/2024; 1223049980, Exp 06/05/2024

**Product Description:**

PHENYLephrine HCl 500 mcg/5 mL in 0.9% Sodium Chloride Injection, (Concentration = 100 mcg/mL), 5 mL fill 12 mL Syringe, Rx Only, SCA Pharmaceuticals, 755 Rainbow Rd. Windsor, CT 06095, NDC 70004-0810-11, Bar Code 70004081011

**Product Quantity:**

7,198 syringes; expanded 1,289 syringes

**Reason for Recall:**

Lack of Assurance of Sterility

**Recall Number:**

D-0415-2024

**Code Information:**

Lot #: 1223045053 Exp 11/15/23; 1223046179 Exp 12/28/23; 1223047477 Exp 02/16/24; 1223047602 Exp 02/22/24; 1223047971 Exp 03/14/24; 1223048269 Exp 03/27/24 Expanded lot#: 1223048181, exp. date 03/22/2024

**Product Description:**

PHENYLEphrine HCl 500 mcg/5 mL in 0.9% Sodium Chloride Injection, (Concentration = 100 mcg/mL), 5 mL fill 12 mL Syringe, Rx Only, SCA Pharmaceuticals, 755 Rainbow Rd. Windsor, CT 06095, NDC 70004-0810-11-K, Bar Code 70004081011. (same finished product as F078140, but with RFID for KitCheck

**Product Quantity:**

1,118 syringes in kits

**Reason for Recall:**

Lack of Assurance of Sterility

**Recall Number:**

D-0416-2024

**Code Information:**

Lot #: 1223048431 exp 04/05/24; 1223049023 exp 04/25/24

**Product Description:**

PHENYLEphrine HCl 5000 mcg/50 mL in 0.9% Sodium Chloride Injection, (Concentration = 100 mcg/mL), 50 mL Syringe, Rx Only, SCA Pharmaceuticals, 755 Rainbow Rd. Windsor, CT 06095, NDC 70004-0810-22, Bar Code 70004081022.

**Product Quantity:**

5,948 syringes, expanded 2,102 syringes

**Reason for Recall:**

Lack of Assurance of Sterility

**Recall Number:**

D-0417-2024

**Code Information:**

Lot #: 1223045282 Exp 11/24/23; 1223045370 Exp 11/26/23; 1223045624 Exp 12/07/23; 1223045723 Exp 12/10/23; 1223045732 Exp 12/10/23; 1223046128 Exp 12/24/23; 1223046133 Exp 12/24/23; 1223047112 Exp 02/02/24; 1223047232 Exp 2/07/24; 1223047398 Exp 02/15/24; 1223047456 Exp 02/16/24; 1223047569 Exp 02/18/24; 1223047694 Exp 02/24/24; 1223047780 Exp 03/07/24; 1223047859 Exp 03/08/24; 1223048119 Exp 03/20/24; 1223048183 Exp 03/22/24; 1223048837 Exp 04/18/24; 1223048838 Exp 04/18/24; 1223048982 Exp 04/24/24; 1223049144 Exp 05/02/24; 1223049145 Exp 05/02/24; 1223049147 Exp 05/02/24; 1223049821 Exp 05/30/24 Expanded Lot #: 1223048037, Exp 03/16/2024; 1223048047, Exp 03/17/2024; 1223049146, 1223049149, Exp 05/02/2024; 1223049373, Exp 05/10/2024; 1223048909, Exp 04/20/2024; 1223048696, Exp 04/12/2024; 1223050181, Exp 06/12/2024

**Product Description:**

PHENYLEphrine HCl 400 mcg/10 mL in 0.9% Sodium Chloride Injection, (Concentration = 40 mcg/mL), 10 mL fill 12 mL Syringe, Rx Only, SCA Pharmaceuticals, 755 Rainbow Rd. Windsor, CT 06095, NDC 70004-0811-12, Bar Code 70004081112.

**Product Quantity:**

10,017 syringes, expanded 2579 syringes

**Reason for Recall:**

Lack of Assurance of Sterility

**Recall Number:**

D-0418-2024

**Code Information:**

Lot #: 1223045040 Exp 11/13/23, 1223046397 Exp 01/06/24, 1223046505 Exp 01/10/24, 1223047254 Exp 02/08/24, 1223047436 Exp 02/15/24, 1223047938 Exp 03/13/24, 1223049150 Exp 05/02/24, 1223049300 Exp 05/09/24, Expanded Lot #: 1223048569, Exp 04/06/2024; 1223049600, Exp 05/19/2024

**Product Description:**

PHENYLEphrine HCl 40 mg in 0.9% Sodium Chloride Injection, (Concentration = 160 mcg/mL), 250 mL Bag, Rx Only, SCA Pharmaceuticals, 755

Rainbow Rd. Windsor, CT 06095, NDC 70004-0825-40, Bar Code 70004082540.

**Product Quantity:**

400 bags

**Reason for Recall:**

Lack of Assurance of Sterility

**Recall Number:**

D-0419-2024

**Code Information:**

Lot #: 1223050005 Exp 01/13/24

**Product Description:**

PHENYLEphrine HCl 800 mcg/10 mL in 0.9% Sodium Chloride Injection, (Concentration = 80mcg/mL) 10 mL fill 12 mL Syringe, Rx Only, SCA Pharmaceuticals, 755 Rainbow Rd., Windsor, CT 06095, NDC 70004-0816-12, Bar Code 700040081612.

**Product Quantity:**

3,671 syringes, expanded 1,911 syringes

**Reason for Recall:**

Lack of Assurance of Sterility

**Recall Number:**

D-0420-2024

**Code Information:**

Lot #: 1223045974 Exp 12/18/23; 1223046535 Exp 01/11/24; 1223049152 Exp 05/02/24 Expanded Lot #: 1223048067, Exp 04/06/2024; 1223048792, Exp 04/17/2024.

**Product Description:**

PHENYLEphrine HCl 800 mcg/10 mL in 0.9% Sodium Chloride Injection, (Concentration = 80mcg/mL) 10 mL fill 12 mL Syringe, Rx Only, SCA Pharmaceuticals, 755 Rainbow Rd., Windsor, CT 06095, NDC 70004-0816-12-K, Bar Code 700040081612. (same finished product as F078140, but with RFID for KitCheck compatibility)

**Product Quantity:**

2,427 syringes

**Reason for Recall:**

Lack of Assurance of Sterility

**Recall Number:**

D-0421-2024

**Code Information:**

Lot #: 1223048610 Exp 04/10/24; 1223048611 Exp 04/10/24; 1223048726 Exp 04/13/24; 1223050163 Exp 06/12/24

**Product Description:**

Sodium Citrate 4% 3 mL, Anticoagulation Solution Injection (Concentration = 40/mg/mL) 3mL fill Syringe, Repackaged by SCA Pharma, 755 Rainbow Rd., Windsor, CT 06095, NDC 70004-0900-25, Bar Code 70004090025

**Product Quantity:**

9,624 syringes

**Reason for Recall:**

Lack of Assurance of Sterility

**Recall Number:**

D-0422-2024

**Code Information:**

Lot #: 1223048444 Exp 11/20/23; 1223049011 Exp 12/12/23; 1223049673 Exp 01/09/24; 1223049771 Exp 01/12/24

**Product Description:**

SUCcinylocholine Chloride 200 mg/10mL Injection (Concentration = 20mg/mL), 10 mL fill 12 mL Syringe, Rx only, Repackaged by SCA Pharma, 755 Rainbow Rd., Windsor, CT 06095, NDC 70004-0908-12, Bar Code 70004090812

**Product Quantity:**

8,755 syringe



**Reason for Recall:**

Lack of Assurance of Sterility

**Recall Number:**

D-0423-2024

**Code Information:**

Lot #: 1223049047 Exp 11/29/23; 1223049221 Exp 12/06/23; 1223049343 Exp 12/12/23; 1223049423 Exp 12/14/23; 1223049451 Exp 12/14/23; 1223049452 Exp 12/14/23; 1223049482 Exp 12/14/23

**Product Description:**

SUCcynilcholine Chloride 100 mg/5mL Injection (Concentration = 20mg/mL), 5 mL fill 6 mL Syringe, Rx only, Repackaged by SCA Pharma, 755 Rainbow Rd., Windsor, CT 06095, NDC 70004-0908-09, Bar Code 70004090809

**Product Quantity:**

5,079 syringe

**Reason for Recall:**

Lack of Assurance of Sterility

**Recall Number:**

D-0424-2024

**Code Information:**

Lot #:1223049085 Exp 11/29/23; 1223049364 Exp 12/12/23

**Product Description:**

VANCOMYCIN 1.25 g added to 0.9% Sodium Chloride 250 mL Injection, 250 mL bag, Rx only, SCA Pharmaceuticals, 755 Rainbow Rd., Windsor, CT 06095, NDC 70004-0923-59, Bar Code 70004092359

**Product Quantity:**

368 bags

**Reason for Recall:**

Lack of Assurance of Sterility

**Recall Number:**

D-0425-2024

**Code Information:**

Lot #: 1223049049 Exp 12/28/23

## Class II Drugs Event

**Event ID:**

93976

**Product Type:**

Drugs

**Status:**

Ongoing

**Date Terminated:****Recall Initiation Date:**

12/26/2023

**Voluntary / Mandated:**

Voluntary: Firm initiated

**Center Classification Date:**

03/27/2024

**Initial Firm Notification of Consignee or Public:**

Letter

**Recalling Firm:**

Amneal Pharmaceuticals of New York, LLC  
50 Horseblock Rd  
Brookhaven NY United States

**Distribution Pattern:**

Product was distributed nationwide.

## Associated Products

**Product Description:**

Divalproex Sodium Extended-release Tablets, USP 250 mg, Rx Only, 100 tablets, Manufactured by: Amneal Pharmaceuticals Pvt. Ltd. Ahmedabad, INDIA, Distributed by: Amneal Pharmaceuticals LLC, Bridgewater, NJ 08807, NDC 65162-755-10, NDC# 65162-755-10

**Product Quantity:**

21,452/100 count bottles

**Reason for Recall:**

Failed dissolution specifications

**Recall Number:**

D-0426-2024

**Code Information:**

Lot # AR210704, exp. date 04/2024 AR210706, exp. date 04/2024 AR210707, exp. date 04/2024 AR210708, exp. date 04/2024 AR210709, exp. date 04/2024

## Class II Drugs Event

**Event ID:**

94183

**Product Type:**

Drugs

**Status:**

Ongoing

**Date Terminated:****Recall Initiation Date:**

03/07/2024

**Voluntary / Mandated:**

Voluntary: Firm initiated

**Center Classification Date:**

03/28/2024

**Initial Firm Notification of Consignee or Public:**

Letter

**Recalling Firm:**Teva Pharmaceuticals USA, Inc  
400 Interpace Pkwy Bldg A  
Parsippany NJ United States**Distribution Pattern:**

USA nationwide.

## Associated Products

**Product Description:**

Tri-Lo-Sprintec (norgestimate and ethinyl estradiol) tablets USP - triphasic regimen, packaged in carton containing 3 Blister Cards, 28 Tablets Each, Rx only, Teva Pharmaceuticals USA, INC, North Wales, PA 19454, NDC 0093-2140-62

**Product Quantity:**

92,676 cartons

**Reason for Recall:**

Failed Dissolution Specifications

**Recall Number:**

D-0428-2024

**Code Information:**

Lot # 100039678, Exp 04/31/2024; 100038111, 100042277, Exp 07/31/2024

## Class II Drugs Event

**Event ID:**

94277

**Product Type:**

Drugs

**Status:**

Ongoing

**Date Terminated:****Recall Initiation Date:**

03/21/2024

**Voluntary / Mandated:**

Voluntary: Firm initiated

**Center Classification Date:**

03/28/2024

**Initial Firm Notification of Consignee or Public:**

Letter

**Recalling Firm:**

Apothecus Pharmaceutical Corp.

485 S Broadway Ste 27

Hicksville NY United States

**Distribution Pattern:**

USA nationwide.

**Associated Products****Product Description:**

VCF Vaginal Contraceptive Film (nonoxynol-9, 28%), package in a carton with 9 single films, Distributed By: Apothecus Pharmaceutical Corp, Ronkonkoma, NY 11779, NDC 52925-112-01

**Product Quantity:**

17,280 paper cartons

**Reason for Recall:**

cGMP Diviations

**Recall Number:**

D-0427-2024

**Code Information:**

Lot # 1G008A/1G00804722, Exp 07/31/25