

Enforcement Report - Week of July 27, 2022

Class I Drugs Event

Event ID:

90627

Product Type:

Drugs

Status:

Ongoing

Date Terminated:
Recall Initiation Date:

05/26/2022

Voluntary / Mandated:

Voluntary: Firm initiated

Center Classification Date:

07/27/2022

Initial Firm Notification of Consignee or Public:

E-Mail

Recalling Firm:

Amazon.com, Inc.
2021 7th Ave
Seattle WA United States

Distribution Pattern:

Nationwide within the U.S.A.

Associated Products

Product Description:

Artri Ajo King Reforzado con Ortiga y Omega 3 tablets, 500 mg, 100-count bottle, Hecho en Mexico por: PLANTAS MEDICINALES DE MEXICO , Melchor Ocampo No. 55 Local D, Delegacion Xochimilco. C.P. 16800, Mexico, D.F., ASIN B092P4615M, UPC 7 501031 111190

Product Quantity:

2,441 bottles

Reason for Recall:

Marketed Without An Approved NDA/ANDA: FDA laboratory analysis found the product to contain undeclared diclofenac.

Recall Number:

D-1295-2022

Code Information:

Lot #: LTARTKNGOMG30220, Exp. Diciembre 2025 (December 2025).

Product Description:

Ortiga mas Ajo Rey Reforzado con Omega 3, 6 y 9, is packaged in a carton containing 30 tablets (500 mg c/u) in a bottle and 60 capsules (400 mg c/u) in a bottle, Hecho en Mexico por: Omega Nutrition , Jorge Washington No. 108 Col. Las Americas, Hidalgo del Parral, Chihuahua. C.P. 33880, ASIN B084L2XM3Z, UPC 3166557819586

Product Quantity:

35,622 cartons

Reason for Recall:

Marketed Without An Approved NDA/ANDA: FDA laboratory analysis found the product to contain undeclared diclofenac.

Recall Number:

D-1296-2022

Code Information:

Lot #: 040 19, Exp. 09 FEB 2025

Product Description:

Artri King Reforzado con Ortiga y Omega 3 tablets, 500 mg, 100-count bottle, Hecho en Mexico por: PLANTAS MEDICINALES DE MEXICO , Melchor Ocampo No. 55 Local D, Delegacion Xochimilco. C.P. 16800, Mexico, D.F., ASIN B084KSV12L, UPC 7 501031 111190

Product Quantity:

15,087 bottles

Reason for Recall:

Marketed Without An Approved NDA/ANDA: FDA laboratory analysis found the product to contain undeclared diclofenac.

Recall Number:

D-1297-2022

Code Information:

Lot #: LTARTKNGOMG30720, Exp. Diciembre 2026 (December 2026)

Class II Drugs Event

Event ID:

90512

Product Type:

Drugs

Status:

Ongoing

Date Terminated:**Recall Initiation Date:**

06/30/2022

Voluntary / Mandated:

Voluntary: Firm initiated

Center Classification Date:

07/18/2022

Initial Firm Notification of Consignee or Public:

Letter

Recalling Firm:

Nephron Sterile Compounding Center LLC
4500 12th Street Ext
West Columbia SC United States

Distribution Pattern:

Nationwide in the USA

Associated Products

Product Description:

Amino Acid Injection 50 g/1000 mL (50 mg/mL) bags, Rx Only, Nephron 503B outsourcing facility, 4500 12th Extension, West Columbia, SC 29172, NDC: 69374-988-10

Product Quantity:

163 bags

Reason for Recall:

Lack of Assurance of Sterility

Recall Number:

D-1245-2022

Code Information:

Lots: AA2012A, Exp. 07/04/2022

Product Description:

Atropine Sulfate Injection, USP 1.2 mg/3 mL (0.4 mg/mL) syringe, packaged in 5 x 3 mL Pre-Filled Syringes per carton, 6 x 5 Syringe Carton per case, Rx Only, Nephron 503B outsourcing facility 4500 12th Street Extension, West Columbia, SC 29172, NDC: 69374-935-03

Product Quantity:

13,340 syringes

Reason for Recall:

Lack of Assurance of Sterility

Recall Number:

D-1246-2022

Code Information:

Lots: AS2001A, Exp. 8/2/2022; AS2002A, Exp. 8/17/2022; AS2003A, Exp. 9/3/2022.

Product Description:

0.125% Bupivacaine HCl Injection, USP, 62.5 mg/50 mL (1.25 mg/mL) syringes, packaged in 5 x 50 mL Pre-Filled Syringes per carton, 6 x 5 Syringe Carton per case, Rx Only, Nephron 503B outsourcing facility, 4500 12th St. Ext., West Columbia, SC 29172, NDC: 69374-970-50

Product Quantity:

6900 syringes

Reason for Recall:

Lack of Assurance of Sterility

Recall Number:

D-1247-2022

Code Information:

Lots: BH2001A, Exp. 7/15/2022; BH2002A, Exp. 8/7/2022; BH2004A, Exp. 8/22/2022; BH2005A, Exp. 9/2/2022; BH2006A, Exp. 9/14/2022; BH2007A, Exp. 9/29/2022; BH2008A, Exp. 10/3/2022; BH2010A, Exp. 10/19/2022

Product Description:

0.9% Buffered Lidocaine HCl (buffered in 8.4% Sodium Bicarbonate), 45 mg/5 mL (9 mg/mL) syringes, packaged in 5 x 5 mL Prefilled Syringes per carton, 6 x 5 Syringe Carton per case, Rx Only, Nephron 503B outsourcing facility, 4500 12th St. Extension, West Columbia, SC 29172, NDC: 69374-947-50

Product Quantity:

1380 syringes

Reason for Recall:

Lack of Assurance of Sterility

Recall Number:

D-1248-2022

Code Information:

Lots: BL2007A, Exp. 7/3/2022

Product Description:

Bupivacaine HCl 150 mg (3.0 mg/mL), Ketorolac Tromethamine 60 mg (1.2 mg/mL), Ketamine HCl 60 mg (1.2 mg/mL) Injection, 50 mL syringes, packaged in 5 x 50 mL Pre-Filled Syringes per carton, 6 x 5 Syringe Carton per case, Rx Only, Nephron 503B outsourcing facility, 4500 12th St. Extension, West Columbia, SC 29172, NDC: 69374-514-50

Product Quantity:

2315 syringes

Reason for Recall:

Lack of Assurance of Sterility

Recall Number:

D-1249-2022

Code Information:

Lots: BP2001A, Exp. 7/6/2022; BP2002A, Exp. 7/27/2022; BP2007A, Exp. 7/3/2022

Product Description:

EPINEPHrine Injection, USP, 0.1 mg/10 mL (10 mcg/mL) syringes, 5 x 10 mL Pre-Filled Syringes per carton, 6 x 5 Syringe Carton per case, Rx Only, Nephron 503B outsourcing facility, 4500 12th Street Extension, West Columbia SC 29172, NDC: 69374-544-10

Product Quantity:

19,060 syringes

Reason for Recall:

Lack of Assurance of Sterility

Recall Number:

D-1250-2022

Code Information:

Lots: EN2001A, Exp. 7/9/2022; EN2003A, Exp. 7/18/2022; EN2004A, Exp. 8/1/2022; EN2012A, Exp. 9/1/2022

Product Description:

EPINEPHrine Injection, USP, 1 mg/10 mL (100 mcg/mL) syringe, packaged in 5 x 10 mL Pre-Filled Syringes per carton, 6 x 5 Syringe Carton per case, Rx Only, Nephron 503B outsourcing facility, 4500 12th St. Extension, West Columbia, SC 29172, NDC: 69374-925-10

Product Quantity:

134,385 syringes

Reason for Recall:

Lack of Assurance of Sterility

Recall Number:

D-1251-2022

Code Information:

Lots: EN2007A, Exp. 7/31/2022; EN2008A, Exp. 8/18/2022; EN2013A, Exp. 9/11/2022; EN2014A, Exp. 10/2/2022

Product Description:

Fentanyl Citrate in 0.9% Sodium Chloride Injection, USP, 2500 mcg/250 mL (10 mcg/mL*) bags, packaged as 10 x 1 IV bag per case, Rx Only, Nephron 503B outsourcing facility, 4500 12th St. Extension, West Columbia, SC 29172, NDC: 69374-523-21

Product Quantity:

9410 bags

Reason for Recall:

Lack of Assurance of Sterility

Recall Number:

D-1252-2022

Code Information:

Lots: FN2001A, Exp. 7/8/2022; FN2001B, Exp. 7/8/2022; FN2002A, Exp. 7/19/2022; FN2002B, Exp. 7/19/2022; FN2003A, Exp. 8/24/2022; FN2003B, Exp. 8/24/2022

Product Description:

Glycopyrrolate Injection, USP, 1 mg/5 mL (0.2 mg/mL) syringes, packaged in 5 x 5 mL Pre-Filled Syringes per carton, 6 x 5 Syringe Carton per case, Rx Only, Nephron 503B outsourcing facility, 4500 12th St. Extension, West Columbia, SC 29172, NDC: 69374-903-05

Product Quantity:

3690 syringes

Reason for Recall:

Lack of Assurance of Sterility

Recall Number:

D-1253-2022

Code Information:

Lots: GL2001A, Exp. 7/15/2022

Product Description:

Glycopyrrolate Injection, USP, 0.6 mg/3 mL (0.2 mg/mL) syringes, packaged in 5 x 3 mL Pre-Filled Syringes per carton, 6 x 5 Syringe Carton per case, Rx Only, Nephron 503B outsourcing facility, 4500 12th St. Extension, West Columbia, SC 29172, NDC: 69374-903-30

Product Quantity:

3450 syringes

Reason for Recall:

Lack of Assurance of Sterility

Recall Number:

D-1254-2022

Code Information:

Lot: GL2004A, Exp. 8/26/2022

Product Description:

HYDROmorphone HCl Injection, USP, 10 mg/50 mL (0.2 mg/mL) syringes, 5 x 50 mL Pre-Filled Syringes per carton, 6 x 5 Syringe Carton per case, Rx Only, Nephron 503B outsourcing facility, 4500 12th Street Extension, West Columbia SC 29172, NDC: 69374-529-50

Product Quantity:

22,805 syringes

Reason for Recall:

Lack of Assurance of Sterility

Recall Number:

D-1255-2022

Code Information:

Lots: HH2002A, Exp. 7/7/2022; HH2004A, Exp. 8/28/2022; HH2005A, Exp. 8/11/2022; HH2007A, Exp. 9/2/2022; HH2009A, Exp. 9/10/2022; HH2011A, Exp. 10/17/2022

Product Description:

HYDRomorphine HCl Injection, USP, 6 mg/30 mL (0.2 mg/mL) syringes, 5 x 30 mL Pre-Filled Syringes per carton, 6 x 5 Syringe Carton per case, Rx Only, Nephron 503B outsourcing facility, 4500 12th St. Extension, West Columbia, SC 29172, NDC: 69374-529-30

Product Quantity:

12,900 syringes

Reason for Recall:

Lack of Assurance of Sterility

Recall Number:

D-1256-2022

Code Information:

Lots: HH2003A, Exp. 7/26/2022; HH2006A, Exp. 8/22/2022

Product Description:

HYDRomorphine HCl Injection, USP 30 mg/30 mL (1 mg/mL) syringe, 5 x 30 mL Pre-Filled Syringes per carton, 6 x 5 Syringe Carton per case, Rx Only, Nephron 503B outsourcing facility, 4500 12th St. Extension, West Columbia, SC 29172, NDC: 69374-559-30

Product Quantity:

18,570 syringes

Reason for Recall:

Lack of Assurance of Sterility

Recall Number:

D-1257-2022

Code Information:

Lots: HN2001A, Exp. 7/23/2022; HN2003A, Exp. 8/19/2022; HN2004A, Exp. 9/9/2022

Product Description:

HYDRomorphine HCl Injection, USP, 50 mg/50 mL (1 mg/mL) syringes, packaged in 5 x 50 mL Pre-Filled Syringes per carton, 6 x 5 Syringe Carton per case, Rx Only, Nephron 503B outsourcing facility, 4500 12th St. Extension, West Columbia, SC 29172, NDC: 69374-559-50

Product Quantity:

3740 syringes

Reason for Recall:

Lack of Assurance of Sterility

Recall Number:

D-1258-2022

Code Information:

Lot: HN2002A, Exp. 7/26/2022

Product Description:

Ketamine HCl Injection, USP, 50 mg/5 mL (10 mg/mL*) syringes, packaged in 5 x 5 mL Pre-Filled Syringes per carton, 6 x 5 Syringe Carton per case, Rx Only, Nephron 503B outsourcing facility, 4500 12th St. Extension, West Columbia, SC 29172, NDC: 69374-982-55

Product Quantity:

91,445 syringes

Reason for Recall:

Lack of Assurance of Sterility

Recall Number:

D-1259-2022

Code Information:

Lots: KH2006A, Exp. 7/20/2022; KH2006B, Exp. 7/20/2022; KH2012B, Exp. 8/23/2022

Product Description:

Ketamine HCl Injection, USP 30 mg/3 mL (10 mg/mL*) syringes, packaged in 5 x 3 mL Pre-Filled Syringes per carton, 6 x 5 Syringe Carton per case, Rx Only, Nephron 503B outsourcing facility, 4500 12th St. Extension, West Columbia, SC 29172, NDC: 69374-982-33

Product Quantity:

30,745 syringes

Reason for Recall:

Lack of Assurance of Sterility

Recall Number:

D-1260-2022

Code Information:

Lots: KH2002A, Exp. 7/5/2022

Product Description:

Ketamine HCl Injection, USP, 50 mg/1 mL (50 mg/mL*) syringe, packaged in 5 x 1 mL Pre-Filled Syringes per carton, 6 x 5 Syringe Carton per case, Rx Only, Nephron 503B outsourcing facility, 4500 12th St. Extension, West Columbia, SC 29172, NDC: 69374-511-01

Product Quantity:

47,905 syringes

Reason for Recall:

Lack of Assurance of Sterility

Recall Number:

D-1261-2022

Code Information:

Lots: KH2009A, Exp. 8/16/2022; KH2011A, Exp. 8/24/2022; KH2013A, Exp. 8/28/2022; KH2014A, Exp. 9/9/2022; KH2018A, Exp. 10/7/2022; KH2020A, Exp. 10/18/2022

Product Description:

Labetalol HCl Injection, USP, 20 mg/4 mL (5 mg/mL) syringe, packaged in 5 x 4 mL Pre-Filled Syringes per carton, 6 x 5 Syringe Carton per case, Rx Only, Nephron 503B outsourcing facility, 4500 12th St. Extension, West Columbia, SC 29172, NDC: 69374-946-04

Product Quantity:

184,370 syringes

Reason for Recall:

Lack of Assurance of Sterility

Recall Number:

D-1262-2022

Code Information:

Lots: LB2002A, Exp. 7/12/2022; LB2004A, Exp. 8/21/2022; LB2006A, Exp. 9/3/2022; LB2008A, Exp. 10/6/2022

Product Description:

Lidocaine HCl Injection, USP 2%, 100 mg/5 mL (20 mg/mL) syringe, packaged in 5 x 5 mL Pre-Filled Syringes per carton, 6 x 5 Syringe Carton per case, Rx Only, Nephron 503B outsourcing facility, 4500 12th St. Extension, West Columbia, SC 29172, NDC: 69374-949-05

Product Quantity:

64,380 syringes

Reason for Recall:

Lack of Assurance of Sterility

Recall Number:

D-1263-2022

Code Information:

Lots: LI2007A, Exp. 9/24/2022

Product Description:

Lidocaine HCl Injection, USP 1%, 50 mg/5 mL (10 mg/mL) syringe, packaged in 5 x 5 mL Pre-Filled Syringes per carton, 6 x 5 Syringe Carton per case, Rx Only, Nephron 503B outsourcing facility, 4500 12th St. Extension, West Columbia, SC 29172, NDC: 69374-985-05

Product Quantity:

37,310 syringes

Reason for Recall:

Lack of Assurance of Sterility

Recall Number:

D-1264-2022

Code Information:

Lots: LI2004A, Exp. 8/6/2022; LI2005A, Exp. 8/31/2022; LI2006A, Exp. 9.21.2022; LI2008A, Exp. 10/11/2022

Product Description:

Morphine Sulfate Injection, USP, 50 mg/50 mL (1 mg/mL) syringe, packaged in 5 x 50 mL Pre-Filled Syringes per carton, 6 x 5 Syringe Carton per case, Rx Only, Nephron 503B outsourcing facility, 4500 12th St. Extension, West Columbia, SC 29172, NDC: 69374-979-50

Product Quantity:

5495 syringes

Reason for Recall:

Lack of Assurance of Sterility

Recall Number:

D-1265-2022

Code Information:

Lots: MS2002A, Exp. 7/2/2022; MS2003A, Exp. 7/30/2022; MS2005A, Exp. 7/31/2022; MS2008A, Exp. 8/23/2022; MS2013A, Exp. 9/9/2022; MS2015A, Exp. 9/26/2022; MS2019A, Exp. 10/14/2022

Product Description:

Morphine Sulfate Injection, USP, 30 mg/30 mL (1 mg/mL) syringe, packaged in 5 x 30 mL Pre-Filled Syringes per carton, 6 x 5 Syringe Carton per case, Rx Only, Nephron 503B outsourcing facility, 4500 12th St. Extension, West Columbia, SC 29172, NDC: 69374-979-30

Product Quantity:

8985 syringes

Reason for Recall:

Lack of Assurance of Sterility

Recall Number:

D-1266-2022

Code Information:

Lots: MS2004A, Exp. 7/30/2022; MS2007A, Exp. 8/23/2022; MS2012A, Exp. 9/6/2022; MS2014A, Exp. 9/10/2022; MS2016A, Exp. 9/29/2022; MS2018A, Exp. 10/12/2022

Product Description:

Morphine Sulfate Injection, USP, 2 mg/2 mL (1 mg/mL) syringe, packaged in 5 x 2 mL Pre-Filled Syringes per carton, 6 x 5 Syringe Carton per case, Rx Only, Nephron 503B outsourcing facility, 4500 12th St. Extension, West Columbia, SC 29172, NDC: 69374-979-02

Product Quantity:

43,385 syringes

Reason for Recall:

Lack of Assurance of Sterility

Recall Number:

D-1267-2022

Code Information:

Lots: MS2001A, Exp. 7/2/2022; MS2006A, Exp. 8/9/2022; MS2009A, Exp. 8/25/2022; MS2011A, Exp. 9/3/2022; MS2017A, Exp. 10/2/2022

Product Description:

Morphine Sulfate Injection, USP, 1 mg/mL syringe, packaged in 5 x 1 mL Pre-Filled Syringes per carton, 6 x 5 Syringe Carton per case, Rx Only, Nephron 503B outsourcing facility, 4500 12th St. Extension, West Columbia, SC 29172, NDC: 69374-979-01

Product Quantity:

4620 syringes

Reason for Recall:

Lack of Assurance of Sterility

Recall Number:

D-1268-2022

Code Information:

Lot: MS2010A, Exp. 8/26/2022

Product Description:

del Nido Cardioplegia Solution 1000 mL (1000 mL) Single-Dose Container IV bag, 4 x 1 IV Bag per case, Rx Only, Nephron 503B outsourcing facility, 4500 12th St. Extension, West Columbia, SC 29172, NDC: 69374-984-10

Product Quantity:

1765 bags

Reason for Recall:

Lack of Assurance of Sterility

Recall Number:

D-1269-2022

Code Information:

Lots: NC2031A, Exp. 7/7/2022; NC2033A, Exp. 7/12/2022; NC2034A, Exp. 7/18/2022; NC2035A, Exp. 7/19/2022

Product Description:

Neostigmine Methylsulfate Injection, USP, 3 mg/3 mL (1 mg/mL) syringe, packaged in 5 x 3 mL Pre-Filled Syringes per carton, 6 x 5 Syringe Carton per case, Rx Only, Nephron 503B outsourcing facility, 4500 12th St. Extension, West Columbia, SC 29172, NDC: 69374-932-03

Product Quantity:

59,520 syringes

Reason for Recall:

Lack of Assurance of Sterility

Recall Number:

D-1270-2022

Code Information:

Lots: NE2002A, Exp. 7/14/2022; NE2003A, Exp. 7/24/2022; NE2006A, Exp. 8/1/2022; NE2007A, Exp. 8/9/2022; NE2008A, Exp. 8/18/2022; NE2009A, Exp. 8/27/2022; NE2012D, Exp. 10/3/2022

Product Description:

Neostigmine Methylsulfate Injection, USP, 4 mg/4 mL (1 mg/mL) syringe, packaged in 5 x 4 mL Pre-Filled Syringes per carton, 6 x 5 Syringe Carton per case, Rx Only, Nephron 503B outsourcing facility, 4500 12th St. Extension, West Columbia, SC 29172, NDC: 69374-942-04

Product Quantity:

10,700 syringes

Reason for Recall:

Lack of Assurance of Sterility

Recall Number:

D-1271-2022

Code Information:

Lots: NE2004A, Exp. 7/26/2022; NE2010A, Exp. 9/5/2022; NE2013A, Exp. 10/20/2022

Product Description:

Neostigmine Methylsulfate Injection, USP, 5 mg/5 mL (1 mg/mL) syringe, packaged in 5 x 5 mL Pre-Filled Syringes per carton, 6 x 5 Syringe Carton per case, Rx Only, Nephron 503B outsourcing facility, 4500 12th St. Extension, West Columbia, SC 29172, NDC: 69374-902-05

Product Quantity:

64,365 syringes

Reason for Recall:

Lack of Assurance of Sterility

Recall Number:

D-1272-2022

Code Information:

Lots: NE2005A, Exp. 7/23/2022; NE2012A, Exp. 10/3/2022; NE2012B, Exp. 10/3/2022; NE2012C, Exp. 10/3/2022

Product Description:

Oxytocin 30 Units/500 mL (0.06 Units/mL) in 0.9% Sodium Chloride Injection, USP IV bag, packaged in 10 x 1 IV Bag per case, Rx Only, Nephron 503B outsourcing facility, 4500 12th St. Extension, West Columbia, SC 29172, NDC: 69374-543-50

Product Quantity:

1810 bags

Reason for Recall:

Lack of Assurance of Sterility

Recall Number:

D-1273-2022

Code Information:

Lots: OX2013C, Exp. 7/9/2022; OX2013E, Exp. 7/9/2022

Product Description:

Phenylephrine HCl Injection, USP, 0.4 mg/10 mL (40 mcg/mL) syringe, packaged in 5 x 10 mL Pre-Filled Syringes per carton, 6 x 5 Syringe Carton per case, Rx Only, Nephron 503B outsourcing facility, 4500 12th St. Extension, West Columbia, SC 29172, NDC: 69374-955-10

Product Quantity:

75,630 syringes

Reason for Recall:

Lack of Assurance of Sterility

Recall Number:

D-1274-2022

Code Information:

Lots: PE2001A, Exp. 7/1/2022; PE2003A, Exp. 7/12/2022; PE2013A, Exp. 8/29/2022; PE2014A, Exp. 10/5/2022

Product Description:

Phenylephrine HCl Injection, USP, 0.8 mg/10 mL (80 mcg/mL) syringe, packaged in 5 x 10 mL Pre-Filled Syringes per carton, 6 x 5 Syringe Carton per case, Rx Only, Nephron 503B outsourcing facility, 4500 12th St. Extension, West Columbia, SC 29172, NDC: 69374-956-10

Product Quantity:

18,930 syringes

Reason for Recall:

Lack of Assurance of Sterility

Recall Number:

D-1275-2022

Code Information:

Lots: PE2018A, Exp. 10/3/2022

Product Description:

Phenylephrine HCl Injection, USP, 1 mg/10 mL (100 mcg/mL) syringe, packaged in 5 x 10 mL Pre-Filled Syringes per carton, 6 x 5 Syringe Carton per case, Rx Only, Nephron 503B outsourcing facility, 4500 12th St. Extension, West Columbia, SC 29172, NDC: 69374-957-10

Product Quantity:

464,265 syringes

Reason for Recall:

Lack of Assurance of Sterility

Recall Number:

D-1276-2022

Code Information:

Lots: PE2004A, Exp. 7/11/2022; PE2008A, Exp. 7/22/2022; PE2008B, Exp. 7/22/2022; PE2008C, Exp. 7/22/2022; PE2009A, Exp. 8/5/2022; PE2009B, Exp. 8/5/2022; PE2009C, Exp. 8/5/2022; PE2011B, Exp. 8/22/2022; PE2017C, Exp. 9/14/2022; PE2019B, Exp. 4/11/2023; PE2019C, Exp. 4/11/2023

Product Description:

Rocuronium Bromide Injection, 50 mg/5 mL (10 mg/mL) syringe, packaged in 5 x 5 mL Pre-Filled Syringes per carton, 6 x 5 Syringe Carton per case, Rx Only, Nephron 503B outsourcing facility, 4500 12th St. Extension, West Columbia, SC 29172, NDC: 69374-924-05

Product Quantity:

6340 syringes

Reason for Recall:

Lack of Assurance of Sterility

Recall Number:

D-1277-2022

Code Information:

Lot: RC2003B, Exp. 8/28/2022

Product Description:

Ropivacaine HCl 123 mg (2.46 mg/mL), Clonidine HCl 0.04 mg (0.0008 mg/mL), Ketorolac Tromethamine 15 mg (0.3 mg/mL) Injection, 50 mL syringe, packaged in 5 x 50 mL Pre-Filled Syringes per carton, 6 x 5 Syringe Carton per case, Rx Only, Nephron 503B outsourcing facility, 4500 12th St. Extension, West Columbia, SC 29172, NDC: 69374-515-50

Product Quantity:

2210 syringes

Reason for Recall:

Lack of Assurance of Sterility

Recall Number:

D-1278-2022

Code Information:

Lots: RP2003A, Exp. 7/20/2022; RP2003B, Exp. 7/20/2022

Product Description:

8.4% Sodium Bicarbonate Injection, USP, 4.2 g/50 mL (84 mg/mL) 1 mEq/mL syringe, packaged in 1 x 50 mL Pre-Filled Syringe per carton, 30 x 1 syringe carton per case, Rx Only Nephron 503B outsourcing facility, 4500 12th St. Extension, West Columbia, SC 29172, NDC: 69374-214-50

Product Quantity:

36,354 syringes

Reason for Recall:

Lack of Assurance of Sterility

Recall Number:

D-1279-2022

Code Information:

Lots: SB2001B, Exp. 1/2/2023; SB2001C, Exp. 1/2/2023; SB2003A, Exp. 2/14/2023; SB2003B, Exp. 2/14/2023; SB2003C, Exp. 2/14/2023; SB2004A, Exp. 3/1/2023; SB2004B, Exp. 3/1/2023; SB2004C, Exp. 3/1/2023; SB2005A, Exp. 3/8/2023; SB2007A, Exp. 3/22/2023; SB2007B, Exp. 3/22/2023; SB2008A, Exp. 3/29/2023; SB2008B, Exp. 3/29/2023; SB2009A, Exp. 4/5/2023; SB2009B, Exp. 4/5/2023

Product Description:

Anticoagulant Sodium Citrate Solution, USP 4%, 200 mg/5 mL (40 mg/mL) syringe, packaged in 5 x 5 mL Pre-Filled Syringes per carton, 6 x 5 Syringe Carton per case, Rx Only, Nephron 503B outsourcing facility, 4500 12th St. Extension, West Columbia, SC 29172, NDC: 69374-906-05

Product Quantity:

85,300 syringes

Reason for Recall:

Lack of Assurance of Sterility

Recall Number:

D-1280-2022

Code Information:

Lots: SC2002A, Exp. 7/9/2022; SC2004A, Exp. 7/17/2022; SC2005A, Exp. 8/2/2022; SC2006A, Exp. 8/16/2022; SC2007A, Exp. 8/27/2022; SC2008A, Exp. 9/7/2022; SC2009A, Exp. 9/14/2022; SC2010A, Exp. 9/20/2022; SC2011A, Exp. 10/10/2022

Product Description:

Succinylcholine Chloride Injection, USP, 200 mg/10 mL (20 mg/mL) syringe, packaged in 5 x 10 mL Pre-Filled Syringes per carton, 6 x 5 Syringe Carton per case, Rx Only, Nephron 503B outsourcing facility, 4500 12th St. Extension, West Columbia, SC 29172, NDC: 69374-919-10

Product Quantity:

18,840 syringes

Reason for Recall:

Lack of Assurance of Sterility

Recall Number:

D-1281-2022

Code Information:

Lot: SU2014A, Exp. 7/2/2022

Class II Drugs Event

Event ID:

90546

Product Type:

Drugs

Status:

Ongoing

Date Terminated:
Recall Initiation Date:

06/28/2022

Voluntary / Mandated:

Voluntary: Firm initiated

Center Classification Date:

07/15/2022

Initial Firm Notification of Consignee or Public:

Letter

Recalling Firm:

Vi-Jon, LLC

1 Swan Dr

Smyrna TN United States

Distribution Pattern:

Nationwide in the USA and Canada

Associated Products

Product Description:

Hydrogen Peroxide Topical Solution USP, 3%, 16 FL OZ (1 PT) 473 mL bottle, packaged as a) Signature Care NDC 21130-871-43 UPC 3 21130-78060 1 Distributed By Better Living Brands LLC P.O. Box 99, Pleasanton, CA 94566-0009; b) Solimo UPC 8 42379 14781 4 Distributed By: Amazon.com Services, Inc. Seattle, WA 98109; c) QC Quality Choice UPC 6 35515 99466 9 Distributed by C.D.M.A., Inc. 43157 W 9 Mile Rd, Novi, MI; d) CVS Health UPC 0 50428 37591 4 Distributed by: CVS Pharmacy, Inc. One CVS Drive, Woonsocket, RI 02895; e) Careone UPC 3 41520 31311 0 Distributed By: Foodhold U.S.A., LLC Landover, MD 20785; f) Market Basket UPC 0 49705 75280 7 Distributed By Demoulas Super Markets, Inc. 875 East Street, Tewksbury, MA 01876; g) Rexall UPC 0 72785 13848 3 Distributed By Old East Main Co. 100 Mission Ridge, Goodlettsville, TN 37072; h) HEB UPC 9 41220 25111 7 Distributed By: HEB San Antonio, TX 78204; i) Core Values UPC 0 79068 00707 8 Distributed by Liberty Procurement Co., Inc. Union, NJ 07083; j) Swan NDC 0869-0871-43 UPC 3 08694 70610 0 Distributed by Vi-Jon One Swan Drive, Smyrna, TN 37167; k) Cariba Care UPC 6 46702 05602 2 Distributed by: Cariba International P.O. Box 1208, Safety Harbor, Florida 34695; l) Kroger UPC 0 11110 79460 4 Distributed By The Kroger Co., Cincinnati, Ohio 45202; m) CVP Health UPC 7 61706 16314 6 Distributed By Salado Sales, Inc. Temple, TX 76503; n) Medline NDC 53329-981-06 UPC 0 80196 74870 2 Made in US with US and foreign components for Medline Industries, Inc., Northfield, IL 60093; o) Exchange Select UPC 6 14299 39968 6 Manufactured For Your Military Exchanges By: Vi-Jon 8515 Page Avenue, St. Louis, MO 63114; p) Premier Value UPC 8 40986 01021 7 Distributed by: Pharmacy Value Alliance LLC 407 East Lancaster Avenue Wayne, PA 19087; q) Publix UPC 0 41415 00973 8 Distributed By Publix Super Markets, Inc. 3300 Publix Corporate Parkway Lakeland, FL 33811; r) Being Well UPC 0 51933 13950 3 Distributed By: Moran Foods, LLC St. Ann, MO 63074; s) Medicare NPN 80016265 UPC 8 39748 00017 7 Manufactured by/Fabrique par: Vi-Jon Inc., Smyrna, TN 37167; t) Swan NPN 80035214 UPC 0 72785 11239 1 Manufactured By: Vi-Jon, Inc. St. Louis, MO 63114; u) Equate NPN 80036214 UPC 6 28915 16613 3 Manufactured By: Vi-Jon, Inc. St. Louis, MO 63114; v) Iris UPC 61504-871-43 UPC 0 41512 12940 7 Distributed By: Amerifoods Trading Co. P.O. Box 512377, Los Angeles, CA 90051-0377; w) Equaline NDC 41163-871-43 UPC 0 41163 25134 2 Distributed by Supervalu Inc. Eden Prairie, MN 55344 USA; x) TopCare health UPC 0 36800 26711 4 Distributed By TopCo Associates LLC Elk Grove Village, IL 60007; y) Best Choice UPC 0 70038 20055 0 Distributed By: Valu Merchandisers, Co. 6000 Kansas Ave. Kansas City, KS 66106; z) Walgreens NDC 0363-0871-43 UPC 3 11917 20771 1 Distributed By: Walgreen Co. 200 Wilmot Rd., Deerfield, IL 60015; aa) Equate NDC 49035-871-43 UPC 6 81131 11871 2 Distributed By: Walmart, Inc., Bentonville, AR 72716

Product Quantity:

3,421,032 bottles

Reason for Recall:

Cross Contamination With Other Products: Product is cross contaminated with low levels of isopropyl alcohol.

Recall Number:

D-1244-2022

Code Information:

Lots: 0555123 Exp. 11/2023 ; 0556347 Exp. 01/2024 ; 0559888 Exp. 03/2024 ; 0546090 Exp. 09/2023 ; 0546364 Exp. 08/2023 ; 0554099 Exp. 11/2023 ; 0535281 Exp. 05/2023 ; 0538263 Exp. 07/2023 ; 0542015 Exp. 07/2023 ; 0550161 Exp. 10/2023 ; 0550164 Exp. 11/2023 ; 0556345 Exp. 01/2024 ; 0557214 Exp. 12/2023 ; 0557366 Exp. 01/2024 ; 0568635 Exp. 05/2024 ; 0556328 Exp. 11/2023 ; 0557465 Exp. 03/2024 ; 0566639 Exp. 03/2024 ; 0566835 Exp. 03/2024 ; 0538261 Exp. 06/2023 ; 0538264 Exp. 07/2023 ; 0541465 Exp. 07/2023 ; 0556809 Exp. 11/2023 ; 0566640 Exp. 03/2024 ; 0556351 Exp. 01/2024 ; 0563077 Exp. 02/2024 ; 0564653 Exp. 03/2024 ; 0565511 Exp. 04/2024 ; 0566646 Exp. 03/2024 ; 0532595 Exp. 04/2023

Class II Drugs Event

Event ID:

90569

Status:

Ongoing

Recall Initiation Date:

07/07/2022

Center Classification Date:

07/21/2022

Recalling Firm:

Apotex Corp.
2400 N Commerce Pkwy Ste 400
Weston FL United States

Distribution Pattern:

USA Nationwide

Product Type:

Drugs

Date Terminated:**Voluntary / Mandated:**

Voluntary: Firm initiated

Initial Firm Notification of Consignee or Public:

Letter

Associated Products

Product Description:

Aripiprazole Tablets, USP 20 mg, packaged in a) 1,000-count bottle (NDC 60505-2676-8, UPC 3 60505 26768 2), b) 30-count bottle (NDC 60505-2676-3, UPC 3 60505 26763 7), Rx only, Manufactured by: Apotex, Inc. Toronto, Ontario Canada M9L 1T9 Manufactured for: Apotex Corp. Weston, Florida 33326

Product Quantity:

2010 bottles

Reason for Recall:

Failed dissolution specifications: OOS for dissolution at the 12-month stability time point.

Recall Number:

D-1285-2022

Code Information:

Lots: a) TD9591 Exp. 04/2023; b) TD9592 Exp. 04/2023

Class II Drugs Event

Event ID:

90608

Status:

Ongoing

Recall Initiation Date:

07/14/2022

Center Classification Date:

07/20/2022

Recalling Firm:

CIPLA
10 Independence Blvd
Warren NJ United States

Distribution Pattern:

Nationwide in the USA

Product Type:

Drugs

Date Terminated:**Voluntary / Mandated:**

Voluntary: Firm initiated

Initial Firm Notification of Consignee or Public:

Letter

Associated Products

Product Description:

Difluprednate Ophthalmic Emulsion, 0.05%, 5ml bottles, Rx only, Mfd. by: Cipla Ltd., India At M/S Indoco Remedies Limited., L-32, 33, 34, Verna

Industrial area, Verna - Goa, 403722, India; Mfd. for: Cipla USA, Inc., 10 Independence Boulevard, Suite 300, Warren, NJ 07059, NDC 69097-341-35.

Product Quantity:

8,136 bottles

Reason for Recall:

Lack of Assurance of Sterility: customer complaint for defective container where breakage of the protective cap exposes tip of eye drop which could compromise sterility.

Recall Number:

D-1283-2022

Code Information:

Batch# DEG4LC2, exp. date 05/2023

Class III Drugs Event

Event ID:

90543

Product Type:

Drugs

Status:

Ongoing

Date Terminated:**Recall Initiation Date:**

06/29/2022

Voluntary / Mandated:

Voluntary: Firm initiated

Center Classification Date:

07/18/2022

Initial Firm Notification of Consignee or Public:

Letter

Recalling Firm:

Glenmark Pharmaceuticals Inc., USA
750 Corporate Dr
Mahwah NJ United States

Distribution Pattern:

USA Nationwide

Associated Products

Product Description:

Aspirin and Extended-Release Dipyridamole Capsules, 25mg/200 mg, 60-count bottle, Rx Only, Manufactured for: Glenmark Pharmaceuticals Inc., USA, Mahwah, NJ 07430, Product of India, NDC 68462-405-60.

Product Quantity:

168936 bottles

Reason for Recall:

Failed Tablet/Capsule Specification : Capsule breakage

Recall Number:

D-1282-2022

Code Information:

Lot#: 17201639, Exp 08/2022; 17201759, Exp 09/2022; 17202067, Exp 10/2022; 17210696, Exp 02/2023; 17210092, Exp 11/2022; 17210145, Exp 12/2022; 17210732, Exp 02/2023; 17211062, Exp 04/2023; 17211441, Exp 05/2023; 17211670, Exp 06/2023; 17211810, Exp 07/2023; 17211862, 17212020, 17212068, Exp 08/2023; 17212438, Exp 10/2023; 17220172, 17220251, Exp 12/2023.