

Enforcement Report - Week of October 9, 2019

Class II Drugs Event

Event ID:

83427

Product Type:

Drugs

Status:

Ongoing

Date Terminated:**Recall Initiation Date:**

07/24/2019

Voluntary / Mandated:

Voluntary: Firm initiated

Center Classification Date:

10/01/2019

Initial Firm Notification of Consignee or Public:

Letter

Recalling Firm:

Colonia Care Pharmacy
515 Inman Ave Ste A
Colonia NJ United States

Distribution Pattern:

Patient Specific Prescriptions in NJ

Associated Products

Product Description:

C-ACETYLCYSTEINE OPHTH 10% SOLN, packaged in a) 5 mL and b) 10 mL droptainer bottles, Rx only, Colonia Care Pharmacy, 515 Inman Ave., Suite A, Colonia, N.J. 07067

Product Quantity:

2 droptainer bottles

Reason for Recall:

Lack of Assurance of Sterility: product sterility cannot be guaranteed.

Recall Number:

D-0003-2020

Code Information:

Lot #: a) 070819A, BUD 08/22/19; b) 071619F, BUD 08/30/19

Product Description:

C-ALBUMIN 5% OPHTH SOLUTION, 10 mL droptainer bottles, Rx only, Colonia Care Pharmacy, 515 Inman Ave., Suite A, Colonia, N.J. 07067

Product Quantity:

1 droptainer bottle

Reason for Recall:

Lack of Assurance of Sterility: product sterility cannot be guaranteed.

Recall Number:

D-0004-2020

Code Information:

Lot #: 071819E, BUD 09/01/19

Product Description:

C-ATROPINE SULF OPHTH 0.01%, 5 mL droptainer bottles, Rx only, Colonia Care Pharmacy, 515 Inman Ave., Suite A, Colonia, N.J. 07067

Product Quantity:

12 droptainer bottles

Reason for Recall:

Lack of Assurance of Sterility: product sterility cannot be guaranteed.

Recall Number:

D-0005-2020

Code Information:

Lot #: 070119A, BUD 08/15/19; 072219N, BUD 09/05/19

Product Description:

C-ATROPINE SULF OPTH 0.02%, 5 mL droptainer bottles, Rx only, Colonia Care Pharmacy, 515 Inman Ave., Suite A, Colonia, N.J. 07067

Product Quantity:

1 droptainer bottles

Reason for Recall:

Lack of Assurance of Sterility: product sterility cannot be guaranteed.

Recall Number:

D-0006-2020

Code Information:

Lot #: 071619D, BUD 08/30/19

Product Description:

C-CALCIUM GLUCNATE 1% INJECTION SOLN, 10 mL vial, Rx only, Colonia Care Pharmacy, 515 Inman Ave., Suite A, Colonia, N.J. 07067

Product Quantity:

1 vial

Reason for Recall:

Lack of Assurance of Sterility: product sterility cannot be guaranteed.

Recall Number:

D-0007-2020

Code Information:

Lot #: 071119C, BUD 08/25/19

Product Description:

C-CROMOLYN SOD 20 MG/2 ML INHALATION SOLUTION, 120 mL in 60 nebulizer vials, Rx only, Colonia Care Pharmacy, 515 Inman Ave., Suite A, Colonia, N.J. 07067

Product Quantity:

60 nebulizer vials

Reason for Recall:

Lack of Assurance of Sterility: product sterility cannot be guaranteed.

Recall Number:

D-0008-2020

Code Information:

Lot #: 070219B, BUD 08/06/19

Product Description:

C-DEXAMETHASONE 24MG/ML INJ SOLUTION, packaged in 1 mL single dose vials, Rx only, Colonia Care Pharmacy, 515 Inman Ave., Suite A, Colonia, N.J. 07067

Product Quantity:

37 vials

Reason for Recall:

Lack of Assurance of Sterility: product sterility cannot be guaranteed.

Recall Number:

D-0009-2020

Code Information:

Lot #: 070319G, BUD 08/17/19; 071219P, BUD 08/26/19

Product Description:

C-EDETATE DISODIUM 1.5% OPTH SOLUTION, 10 ML droptainer bottle, Rx only, Colonia Care Pharmacy, 515 Inman Ave., Suite A, Colonia, N.J. 07067

Product Quantity:

1 droptainer vial

Reason for Recall:

Lack of Assurance of Sterility: product sterility cannot be guaranteed.

Recall Number:

D-0010-2020

Code Information:

Lot #: 072219B, BUD 08/05/19

Product Description:

C-GENTAMICIN 30MG/ML INJ SOLUTION SDV, 3 mL vial, Rx only, Colonia Care Pharmacy, 515 Inman Ave., Suite A, Colonia, N.J. 07067

Product Quantity:

1 vial

Reason for Recall:

Lack of Assurance of Sterility: product sterility cannot be guaranteed.

Recall Number:

D-0011-2020

Code Information:

Lot #: 070319J, BUD 08/17/19

Product Description:

C-HYDROXOCOBALAMIN 5 MG/ML INJECTION SOLUTION, 1 mL syringe, Rx only, Colonia Care Pharmacy, 515 Inman Ave., Suite A, Colonia, N.J. 07067

Product Quantity:

30 syringe

Reason for Recall:

Lack of Assurance of Sterility: product sterility cannot be guaranteed.

Recall Number:

D-0012-2020

Code Information:

Lot #: 062619E, BUD 08/10/19

Product Description:

C-HYDROXOCOBALAMIN 25 MG/ML INJECTION SOLUTION, 1 mL syringe, Rx only, Colonia Care Pharmacy, 515 Inman Ave., Suite A, Colonia, N.J. 07067

Product Quantity:

15 syringes

Reason for Recall:

Lack of Assurance of Sterility: product sterility cannot be guaranteed.

Recall Number:

D-0013-2020

Code Information:

Lot #: 070919E, BUD 08/23/19

Product Description:

C-HYDROXYPROGESTERONE CAPRO 250MG/ML INJECTION, 5 mL vial, Rx only, Colonia Care Pharmacy, 515 Inman Ave., Suite A, Colonia, N.J. 07067

Product Quantity:

18 vials

Reason for Recall:

Lack of Assurance of Sterility: product sterility cannot be guaranteed.

Recall Number:

D-0014-2020

Code Information:

Lot #: 041119A, BUD 10/08/19; 051019J, BUD 11/6/19; 070519C, BUD 01/01/20

Product Description:

C-INTERFERON ALFA2B 1MILU/ML OPHTHAL SOLUTION, 3 mL droptainer bottle, Rx only, Colonia Care Pharmacy, 515 Inman Ave., Suite A, Colonia, N.J. 07067

Product Quantity:

1 droptainer bottle

Reason for Recall:

Lack of Assurance of Sterility: product sterility cannot be guaranteed.

Recall Number:

D-0015-2020

Code Information:

Lot #: 070819B, BUD 08/07/19

Product Description:

C-MB12/HB12 5MG/5MG/ML INJ SOLN, 0.9 mL in a 3 mL syringe, Rx only, Colonia Care Pharmacy, 515 Inman Ave., Suite A, Colonia, N.J. 07067

Product Quantity:

6 syringes

Reason for Recall:

Lack of Assurance of Sterility: product sterility cannot be guaranteed.

Recall Number:

D-0016-2020

Code Information:

Lot #: 071819C, BUD 09/01/19

Product Description:

C-MB12 NAC 13MG/48MG/ML INJ SOLN, 0.29 mL in a 0.3 mL syringe, Rx only, Colonia Care Pharmacy, 515 Inman Ave., Suite A, Colonia, N.J. 07067

Product Quantity:

15 syringes

Reason for Recall:

Lack of Assurance of Sterility: product sterility cannot be guaranteed.

Recall Number:

D-0017-2020

Code Information:

Lot #: 070919C, BUD 08/23/19

Product Description:

C-METHYLCOBALAMIN 25MG/ML INJECTION PFS, packaged in 0.3 mL, 0.5 mL, 1 mL, and 3 mL syringes, Rx only, Colonia Care Pharmacy, 515 Inman Ave., Suite A, Colonia, N.J. 07067

Product Quantity:

191 syringes

Reason for Recall:

Lack of Assurance of Sterility: product sterility cannot be guaranteed.

Recall Number:

D-0018-2020

Code Information:

Lot #: 020719A, BUD 08/06/19; 051619E, BUD 11/12/19

Product Description:

C-PAPAV/PHEHTOL/PGE1 10MG/1MG/10MCG/ML, packaged in a) 5 mL and b) 10 mL vials, Rx only, Colonia Care Pharmacy, 515 Inman Ave., Suite A, Colonia, N.J. 07067

Product Quantity:

6 vials

Reason for Recall:

Lack of Assurance of Sterility: product sterility cannot be guaranteed.

Recall Number:

D-0019-2020

Code Information:

Lot #: a) and b) 071119E, BUD 08/25/19

Product Description:

C-PAPAV/PHENTOL/PGE1 10MG/1MG/20MCG/ML, 5 mL vial, Rx only, Colonia Care Pharmacy, 515 Inman Ave., Suite A, Colonia, N.J. 07067

Product Quantity:

1 vial

Reason for Recall:

Lack of Assurance of Sterility: product sterility cannot be guaranteed.

Recall Number:

D-0020-2020

Code Information:

Lot #: 071619J, BUD 08/30/19

Product Description:

C-PAPAV/PHENTOL/PGE1 18MG/0.6MG/5.8MCG/ML, 5 mL vial, Rx only, Colonia Care Pharmacy, 515 Inman Ave., Suite A, Colonia, N.J. 07067

Product Quantity:

2 vials

Reason for Recall:

Lack of Assurance of Sterility: product sterility cannot be guaranteed.

Recall Number:

D-0021-2020

Code Information:

Lot #: 072419C, BUD 09/07/19; 071519D, BUD 08/29/19

Product Description:

C-PAPAV/PHENTOL/PGE1 18MG/0.6MG/5.88MCG/ML, 5 mL vial, Rx only, Colonia Care Pharmacy, 515 Inman Ave., Suite A, Colonia, N.J. 07067

Product Quantity:

1 vial

Reason for Recall:

Lack of Assurance of Sterility: product sterility cannot be guaranteed.

Recall Number:

D-0022-2020

Code Information:

Lot #: 071519E, BUD 08/29/19

Product Description:

C-PAPAV/PHENTOL/PGE1 18MG/0.6MG/11.8MCG/ML, 10 mL vial, Rx only, Colonia Care Pharmacy, 515 Inman Ave., Suite A, Colonia, N.J. 07067

Product Quantity:

1 vial

Reason for Recall:

Lack of Assurance of Sterility: product sterility cannot be guaranteed.

Recall Number:

D-0023-2020

Code Information:

Lot #: 062719E, BUD 08/11/19

Product Description:

C-PAPAV/PHENTOL/PGE1 20MG/2MG/20MCG/ML, packaged in a) 5 mL and b) 10 mL vial, Rx only, Colonia Care Pharmacy, 515 Inman Ave., Suite A, Colonia, N.J. 07067

Product Quantity:

7 vials

Reason for Recall:

Lack of Assurance of Sterility: product sterility cannot be guaranteed.

Recall Number:

D-0024-2020

Code Information:

Lot #: a) and b) 070519A, BUD 08/19/19

Product Description:

C-PAPAV/PHEHTOL/PGE1 30MG/0.5MG/30MCG/ML, 5 mL vial, Rx only, Colonia Care Pharmacy, 515 Inman Ave., Suite A, Colonia, N.J. 07067

Product Quantity:

1 vial

Reason for Recall:

Lack of Assurance of Sterility: product sterility cannot be guaranteed.

Recall Number:

D-0025-2020

Code Information:

Lot #: 072219A, BUD 09/05/19

Product Description:

C-PAPAV/PHEHTOL/PGE1 30MG/1MG/20MCG/ML, 5 mL vial, Rx only, Colonia Care Pharmacy, 515 Inman Ave., Suite A, Colonia, N.J. 07067

Product Quantity:

1 vial

Reason for Recall:

Lack of Assurance of Sterility: product sterility cannot be guaranteed.

Recall Number:

D-0026-2020

Code Information:

Lot #: 071819H, BUD 09/01/19

Product Description:

C-PAPAV/PHEHTOL/PGE1 30MG/1MG/30MCG/ML, 5 mL vial, Rx only, Colonia Care Pharmacy, 515 Inman Ave., Suite A, Colonia, N.J. 07067

Product Quantity:

1 vial

Reason for Recall:

Lack of Assurance of Sterility: product sterility cannot be guaranteed.

Recall Number:

D-0027-2020

Code Information:

Lot #: 062419C, BUD 08/08/19

Product Description:

C-PAPAV/PHEHTOL/PGE1 30MG/1MG/50MCG/ML, 5 mL vial, Rx only, Colonia Care Pharmacy, 515 Inman Ave., Suite A, Colonia, N.J. 07067

Product Quantity:

1 vial

Reason for Recall:

Lack of Assurance of Sterility: product sterility cannot be guaranteed.

Recall Number:

D-0028-2020

Code Information:

Lot #: 062419B, BUD 08/08/19

Product Description:

C-PAPAV/PHEHTOL/PGE1 30MG/2MG/5MCG/ML, 5 mL vial, Rx only, Colonia Care Pharmacy, 515 Inman Ave., Suite A, Colonia, N.J. 07067

Product Quantity:

1 vial

Reason for Recall:

Lack of Assurance of Sterility: product sterility cannot be guaranteed.

Recall Number:

D-0029-2020

Code Information:

Lot #: 072419B, BUD 09/07/19

Product Description:

C-PAPAV/PHEHTOL/PGE1 30MG/2MG/20MCG/ML, 5 mL vial, Rx only, Colonia Care Pharmacy, 515 Inman Ave., Suite A, Colonia, N.J. 07067

Product Quantity:

1 vial

Reason for Recall:

Lack of Assurance of Sterility: product sterility cannot be guaranteed.

Recall Number:

D-0030-2020

Code Information:

Lot #: 070319A, BUD 08/17/19

Product Description:

C-PHENOL/COTTONSEED OIL INJ 5%, 5 mL vial, Rx only, Colonia Care Pharmacy, 515 Inman Ave., Suite A, Colonia, N.J. 07067

Product Quantity:

1 vial

Reason for Recall:

Lack of Assurance of Sterility: product sterility cannot be guaranteed.

Recall Number:

D-0031-2020

Code Information:

Lot #: 070319F, BUD 08/17/19

Product Description:

C-TACROLIMUS 0.03% OPHTHAL SUSPENSION, 5 mL droptainer bottle, Rx only, Colonia Care Pharmacy, 515 Inman Ave., Suite A, Colonia, N.J. 07067

Product Quantity:

1 droptainer bottle

Reason for Recall:

Lack of Assurance of Sterility: product sterility cannot be guaranteed.

Recall Number:

D-0032-2020

Code Information:

Lot #: 071019B, BUD 08/09/19

Product Description:

C-UREA 40% BLADDER INSTILL, 30 mL vial, Rx only, Colonia Care Pharmacy, 515 Inman Ave., Suite A, Colonia, N.J. 07067

Product Quantity:

7 vials

Reason for Recall:

Lack of Assurance of Sterility: product sterility cannot be guaranteed.

Recall Number:

D-0033-2020

Code Information:

Lot #: 062719A, BUD 08/11/19

Product Description:

C-VERAPAMIL 2.5MG/ML INJ SOLN, 10 mL vial, Rx only, Colonia Care Pharmacy, 515 Inman Ave., Suite A, Colonia, N.J. 07067

Product Quantity:

1 vial

Reason for Recall:

Lack of Assurance of Sterility: product sterility cannot be guaranteed.

Recall Number:

D-0034-2020

Code Information:

Lot #: 072319A, BUD 09/06/19

Class II Drugs Event

Event ID:

83789

Status:

Ongoing

Recall Initiation Date:

09/12/2019

Center Classification Date:

10/01/2019

Recalling Firm:

KRS Global Biotechnology, Inc
791 Park of Commerce Blvd Ste 600
Boca Raton FL United States

Distribution Pattern:

Nationwide

Product Type:

Drugs

Date Terminated:**Voluntary / Mandated:**

Voluntary: Firm initiated

Initial Firm Notification of Consignee or Public:

Press Release

Associated Products

Product Description:

Alpha Lipoic Acid (PF) 750 mg/30 mL (25 mg/mL) 30 mL Single Dose Vial for IV Use, Rx Only, KRS Global Biotechnology 791 Park of Commerce Blvd, Boca Raton, FL 33487. NDC 3321674205

Product Quantity:

77 vials

Reason for Recall:

Lack of Assurance of Sterility

Recall Number:

D-0039-2020

Code Information:

All lots remaining within expiry.

Product Description:

Ascorbic Acid (Tapioca Source) (PF) 25 g/50 mL (0.5 g/mL) 50 mL Vial-Single Dose Only-For IV/SC/IM Use, Rx Only, KRS Global Biotechnology 791 Park of Commerce Blvd, Boca Raton, FL 33487 NDC 3321675412

Product Quantity:

2219 vials

Reason for Recall:

Lack of Assurance of Sterility

Recall Number:

D-0040-2020

Code Information:

All lots remaining within expiry.

Product Description:

Ascorbic Acid (Tapioca Source) 25 g/50 mL (0.5 g/mL) 50 mL Vial--For SC/IM Use--Contains Sulfites, Rx Only, KRS Global Biotechnology 791 Park of Commerce Blvd, Boca Raton, FL 33487. NDC 3321675033

Product Quantity:

602 vials

Reason for Recall:

Lack of Assurance of Sterility

Recall Number:

D-0041-2020

Code Information:

All lots remaining within expiry.

Product Description:

Bacteriostatic Water for Injection, 30 mL Vial, Rx Only, KRS Global Biotechnology 791 Park of Commerce Blvd, Boca Raton, FL 33487, NDC 3321674177

Product Quantity:

6568 vials

Reason for Recall:

Lack of Assurance of Sterility

Recall Number:

D-0042-2020

Code Information:

All lots remaining within expiry.

Product Description:

Bimix #3 (Papaverine HCl 30 mg/mL/Phentolamine Mesylate 3 mg/mL) in 5 mL Vial, Rx Only, KRS Global Biotechnology 791 Park of Commerce Blvd, Boca Raton, FL 33487. NDC 3321676500

Product Quantity:

162 vials

Reason for Recall:

Lack of Assurance of Sterility

Recall Number:

D-0043-2020

Code Information:

All lots remaining within expiry.

Product Description:

L-Carnitine 27 mL in a 30 mL Vial, 4,590 mg/27 mL (170 mg/mL) Rx Only, KRS Global Biotechnology 791 Park of Commerce Blvd, Boca Raton, FL 33487. NDC 3321674166

Product Quantity:

10014 vials

Reason for Recall:

Lack of Assurance of Sterility

Recall Number:

D-0044-2020

Code Information:

All lots remaining within expiry.

Product Description:

L-Carnitine 27 mL Fill in a 30 mL Vial, For Dilution Use Only, 2,025 mg/27 mL (75 mg/mL) Rx Only, KRS Global Biotechnology 791 Park of Commerce Blvd, Boca Raton, FL 33487. NDC 3321676396

Product Quantity:

6447 vials

Reason for Recall:

Lack of Assurance of Sterility

Recall Number:

D-0045-2020

Code Information:

All lots remaining within expiry.

Product Description:

ePHEDrine Sulfate in 0.9% Sodium Chloride (PF), 50 mg/5 mL (10 mg/mL) 5 mL Fill in a 6 mL Syringe, Single Dose Syringe. KRS Global Biotechnology 791 Park of Commerce Blvd, Boca Raton, FL 33487. NDC 3321678375

Product Quantity:

3895 syringes

Reason for Recall:

Lack of Assurance of Sterility

Recall Number:

D-0046-2020

Code Information:

All lots remaining within expiry.

Product Description:

ePHEDrine Sulfate in 0.9% Sodium Chloride (PF) 25 mg/5 mL (5 mg/mL) 5 mL Fill in a 6 mL Syringe, Single Dose Syringe, Rx Only, KRS Global Biotechnology 791 Park of Commerce Blvd, Boca Raton, FL 33487. NDC 3321678374

Product Quantity:

12445 syringes

Reason for Recall:

Lack of Assurance of Sterility

Recall Number:

D-0047-2020

Code Information:

All lots remaining within expiry.

Product Description:

ePHEDrine Sulfate in 0.9% Sodium Chloride (PF) 50 mg/10 mL (5 mg/mL) 10 mL Fill in a 12 mL Single Dose Syringe, Rx Only, KRS Global Biotechnology 791 Park of Commerce Blvd, Boca Raton, FL 33487. NDC 3321678373

Product Quantity:

16585 syringes

Reason for Recall:

Lack of Assurance of Sterility

Recall Number:

D-0048-2020

Code Information:

All lots remaining within expiry.

Product Description:

fentaNYL Citrate in 0.9% Sodium Chloride (PF) 1,000 mcg/100 mL (10 mcg/mL) 100 mL Fill in 150 mL IV Bag, Rx Only, KRS Global Biotechnology 791 Park of Commerce Blvd, Boca Raton, FL 33487. NDC 33216282300

Product Quantity:

492 bags

Reason for Recall:

Lack of Assurance of Sterility

Recall Number:

D-0049-2020

Code Information:

All lots remaining within expiry.

Product Description:

fentaNYL Citrate in 0.9% Sodium Chloride (PF), 2,000 mcg/100 mL (20 mcg/mL) 100 mL Fill in 150 mL IV Bag, Rx Only, KRS Global Biotechnology 791 Park of Commerce Blvd, Boca Raton, FL 33487. NDC 33216286300

Product Quantity:

934 bags

Reason for Recall:

Lack of Assurance of Sterility

Recall Number:

D-0050-2020

Code Information:

All lots remaining within expiry.

Product Description:

fentaNYL Citrate in 0.9% Sodium Chloride (PF) 2,500 mcg/100 mL (25 mcg/mL) 100 mL Fill in 150 mL IV Bag, Rx Only, KRS Global Biotechnology 791 Park of Commerce Blvd, Boca Raton, FL 33487 NDC 33216286000

Product Quantity:

1882 bags

Reason for Recall:

Lack of Assurance of Sterility

Recall Number:

D-0051-2020

Code Information:

All lots remaining within expiry.

Product Description:

Fluorescein (PF) Lyophilized-For IV Use, Single Dose Vial, 500 mg/vial, Rx Only, KRS Global Biotechnology 791 Park of Commerce Blvd, Boca Raton, FL 33487. NDC 3321676632

Product Quantity:

1980 vials

Reason for Recall:

Lack of Assurance of Sterility

Recall Number:

D-0052-2020

Code Information:

All lots remaining within expiry.

Product Description:

Glutathione 30 mL Vial-For IM Use-Hypertonic solution, 6,000 mg/30 mL (200 mg/mL) Rx Only, KRS Global Biotechnology 791 Park of Commerce Blvd, Boca Raton, FL 33487. NDC3321674186

Product Quantity:

402 vials

Reason for Recall:

Lack of Assurance of Sterility

Recall Number:

D-0053-2020

Code Information:

All lots remaining within expiry.

Product Description:

GLYCOpyrrolate (PF) 0.6 mg/3 mL (0.2 mg/mL) in 3 mL Single Dose Syringe, Rx Only, KRS Global Biotechnology 791 Park of Commerce Blvd, Boca Raton, FL 33487. NDC3321678316

Product Quantity:

10630 syringes

Reason for Recall:

Lack of Assurance of Sterility

Recall Number:

D-0054-2020

Code Information:

All lots remaining within expiry.

Product Description:

GLYCOpyrrrolate (PF) 1 mg/5 mL (0.2 mg/mL) 5 mL Fill in a 6 mL Single Dose Syringe, Rx Only, KRS Global Biotechnology 791 Park of Commerce Blvd, Boca Raton, FL 33487. NDC03321678317

Product Quantity:

2625 syringes

Reason for Recall:

Lack of Assurance of Sterility

Recall Number:

D-0055-2020

Code Information:

All lots remaining within expiry.

Product Description:

Human Chorionic Gonadotropin 11,000 Units/Vials Lyophilized For SC/IM Use, Rx Only, KRS Global Biotechnology 791 Park of Commerce Blvd, Boca Raton, FL 33487. NDC 3321673974

Product Quantity:

6620 vials

Reason for Recall:

Lack of Assurance of Sterility

Recall Number:

D-0056-2020

Code Information:

All lots remaining within expiry.

Product Description:

Human Chorionic Gonadotropin 20,000 Units/Vials Lyophilized For SC/IM Use, Rx Only, KRS Global Biotechnology 791 Park of Commerce Blvd, Boca Raton, FL 33487. NDC 3321673977

Product Quantity:

1871 vials

Reason for Recall:

Lack of Assurance of Sterility

Recall Number:

D-0057-2020

Code Information:

All lots remaining within expiry.

Product Description:

Human Chorionic Gonadotropin 5,000 Units/Vials Lyophilized For SC/IM Use, Rx Only, KRS Global Biotechnology 791 Park of Commerce Blvd, Boca Raton, FL 33487. NDC03321673964

Product Quantity:

2219 vials

Reason for Recall:

Lack of Assurance of Sterility

Recall Number:

D-0058-2020

Code Information:

All lots remaining within expiry.

Product Description:

Human Chorionic Gonadotropin 6,000 Units/Vials Lyophilized For SC/IM Use, Rx Only, KRS Global Biotechnology 791 Park of Commerce Blvd, Boca Raton, FL 33487. NDC 3321673969

Product Quantity:

2263 vials

Reason for Recall:

Lack of Assurance of Sterility

Recall Number:

D-0059-2020

Code Information:

All lots remaining within expiry.

Product Description:

Hyaluronidase (PF) Ophthalmic Injection 450 Units/3 mL (150 Units/mL) 3 mL Fill in a 5 mL Single Dose Vial, Rx Only, KRS Global Biotechnology 791 Park of Commerce Blvd, Boca Raton, FL 33487. NDC 3321678359

Product Quantity:

928 vials

Reason for Recall:

Lack of Assurance of Sterility

Recall Number:

D-0060-2020

Code Information:

All lots remaining within expiry.

Product Description:

Hydroxocobalamin 10 mL Vial 5 mg/10 mL (0.5 mg/mL) For IM Use, Rx Only, KRS Global Biotechnology 791 Park of Commerce Blvd, Boca Raton, FL 33487. NDC 3321678336

Product Quantity:

1528

Reason for Recall:

Lack of Assurance of Sterility

Recall Number:

D-0061-2020

Code Information:

All lots remaining within expiry.

Product Description:

Hydroxocobalamin 10 mg/20 mL (0.5 mg/mL) 20 mL fill in a 30 mL Vial, Rx Only, KRS Global Biotechnology 791 Park of Commerce Blvd, Boca Raton, FL 33487. NDC 3321678337

Product Quantity:

345 vials

Reason for Recall:

Lack of Assurance of Sterility

Recall Number:

D-0062-2020

Code Information:

All lots remaining within expiry.

Product Description:

Hydroxocobalamin 30 mg/30 mL (1 mg/mL) 30 mL Vial For IM Use, Rx Only, KRS Global Biotechnology 791 Park of Commerce Blvd, Boca Raton, FL 33487. NDC 3321678334

Product Quantity:

345 vials

Reason for Recall:

Lack of Assurance of Sterility

Recall Number:

D-0063-2020

Code Information:

All lots remaining within expiry.

Product Description:

Ketamine in 0.9% Sodium Chloride (PF) 10 mg/mL, 1 mL fill in a 3 mL Syringe, Rx Only, KRS Global Biotechnology 791 Park of Commerce Blvd, Boca Raton, FL 33487. NDC 33216077967

Product Quantity:

1044 syringes

Reason for Recall:

Lack of Assurance of Sterility

Recall Number:

D-0064-2020

Code Information:

All lots remaining within expiry.

Product Description:

Ketamine in 0.9% Sodium Chloride (PF) 50 mg/ 5mL (10 mg/mL) 5 mL fill in a 6 mL Single Dose Syringe, Rx Only, KRS Global Biotechnology 791 Park of Commerce Blvd, Boca Raton, FL 33487. NDC 3321678093

Product Quantity:

11733 syringes

Reason for Recall:

Lack of Assurance of Sterility

Recall Number:

D-0065-2020

Code Information:

All lots remaining within expiry.

Product Description:

Labetalol HCl 5 mg/mL 20 mg/4 mL (5 mg/mL) 4 mL Fill in a 6 mL Single Dose Syringe, Rx only, KRS Global Biotechnology 791 Park of Commerce Blvd, Boca Raton, FL 33487. NDC 3321676419

Product Quantity:

6405 syringes

Reason for Recall:

Lack of Assurance of Sterility

Recall Number:

D-0066-2020

Code Information:

All lots remaining within expiry.

Product Description:

LIDOCaine HCl 0.75%(7.5 mg/mL)/ EPINRPHrine 0.025% (0.25 mg/mL) (PF) (Sulfite Free) in BSS, 1 mL Fill in a 3 mL Single Dose Syringe, Rx only, KRS Global Biotechnology 791 Park of Commerce Blvd, Boca Raton, FL 33487. NDC 3321678395

Product Quantity:

4105 syringes

Reason for Recall:

Lack of Assurance of Sterility

Recall Number:

D-0067-2020

Code Information:

All lots remaining within expiry.

Product Description:

LIDOCaine HCl 1% (PF) 50 mg/5 mL (10 mg/mL), 5 mL Fill in a 6 mL Single Dose Syringe, Rx Only, KRS Global Biotechnology 791 Park of Commerce Blvd, Boca Raton, FL 33487. NDC 3321678424

Product Quantity:

2565 syringes

Reason for Recall:

Lack of Assurance of Sterility

Recall Number:

D-0068-2020

Code Information:

All lots remaining within expiry.

Product Description:

LIDocaine HCl 2% (PF) 100 mg/5 mL (20 mg/mL) 5 mL Fill in a 6 mL Single Dose Syringe, Rx Only, KRS Global Biotechnology 791 Park of Commerce Blvd, Boca Raton, FL 33487NDC 3321678315

Product Quantity:

4450 syringes

Reason for Recall:

Lack of Assurance of Sterility

Recall Number:

D-0069-2020

Code Information:

All lots remaining within expiry.

Product Description:

Lidocaine HCl 30 mg/mL/Hyaluronidase 15 Units/mL (PF) 5 mL Fill in a 6 mL Single Dose Syringe, Rx Only, KRS Global Biotechnology 791 Park of Commerce Blvd, Boca Raton, FL 33487. NDC 3321678368

Product Quantity:

2615 syringes

Reason for Recall:

Lack of Assurance of Sterility

Recall Number:

D-0070-2020

Code Information:

All lots remaining within expiry.

Product Description:

LIDocaine 2% (20 mg/mL)/Bupivacaine 0.375% (3.75 mg/mL)/ Hyaluronidase 3 U/mL (PF) Ophthalmic Injection, 5 mL Fill in a 6 mL Single Dose Syringe, Rx Only, KRS Global Biotechnology 791 Park of Commerce Blvd, Boca Raton, FL 33487. NDC 3321678362

Product Quantity:

2255 syringes

Reason for Recall:

Lack of Assurance of Sterility

Recall Number:

D-0071-2020

Code Information:

All lots remaining within expiry.

Product Description:

Methionine 750 mg / Inositol 1,500 mg / Choline Chloride 1,500 mg / Pyridoxine HCl 1,500 mg / Cyanocobalamin 30 mg Lyophilized, Vial For IM Use, Rx Only KRS Global Biotechnology 791 Park of Commerce Blvd, Boca Raton, FL 33487. NDC 3321675952

Product Quantity:

497 vials

Reason for Recall:

Lack of Assurance of Sterility

Recall Number:

D-0072-2020

Code Information:

All lots remaining within expiry.

Product Description:

Methylcobalamin 30 mL Vial-For SC / IM / IV Use, 30 mg / 30 mL (1 mg / mL) Rx Only, KRS Global Biotechnology 791 Park of Commerce Blvd, Boca Raton, FL 33487. NDC 3321674232

Product Quantity:

1189 vials

Reason for Recall:

Lack of Assurance of Sterility

Recall Number:

D-0073-2020

Code Information:

All lots remaining within expiry.

Product Description:

Magnesium Chloride Hexahydrate 82.5 mg/mL; Calcium Gluconate 30 mg/mL (PF), For IV Use, 10 mL Single Dose vial, Rx Only, KRS Global Biotechnology 791 Park of Commerce Blvd, Boca Raton, FL 33487. NDC 3321678355

Product Quantity:

878 vials

Reason for Recall:

Lack of Assurance of Sterility

Recall Number:

D-0074-2020

Code Information:

All lots remaining within expiry.

Product Description:

Moxifloxacin 0.1% in BSS, Ophthalmic Injection, 0.25 mg / 0.25 mL, 0.25 mL Fill in a 1 mL Single Dose Syringe, Rx Only, KRS Global Biotechnology 791 Park of Commerce Blvd, Boca Raton, FL 33487. NDC 3321678126

Product Quantity:

1290 syringes

Reason for Recall:

Lack of Assurance of Sterility

Recall Number:

D-0075-2020

Code Information:

All lots remaining within expiry.

Product Description:

Moxifloxacin 0.1% in BSS, Ophthalmic Injection, 0.3 mg/0.3 mL, 0.3 mL Fill in a 1 mL Single Dose Syringe, Rx Only, KRS Global Biotechnology 791 Park of Commerce Blvd, Boca Raton, FL 33487. NDC 3321678320

Product Quantity:

9920 syringes

Reason for Recall:

Lack of Assurance of Sterility

Recall Number:

D-0076-2020

Code Information:

All lots remaining within expiry.

Product Description:

NEOstigmine Methylsulfate (PF), 3 mg/3 mL (1 mg/mL), 3 mL Single Dose Syringe, Rx Only, KRS Global Biotechnology 791 Park of Commerce Blvd, Boca Raton, FL 33487. NDC 3321677847

Product Quantity:

7685 syringes

Reason for Recall:

Lack of Assurance of Sterility

Recall Number:

D-0077-2020

Code Information:

All lots remaining within expiry.

Product Description:

NEostigmine Methylsulfate (PF), 5 mg/5 mL (1 mg/mL), 5 mL fill in a 6 mL Single Dose Syringe, Rx Only, KRS Global Biotechnology 791 Park of Commerce Blvd, Boca Raton, FL 33487. NDC 3321678303

Product Quantity:

3410 syringes

Reason for Recall:

Lack of Assurance of Sterility

Recall Number:

D-0078-2020

Code Information:

All lots remaining within expiry.

Product Description:

Nicotinamide Adenine Dinucleotide (PF), Lyophilized-For IV Use-Single Dose Vial, 500 mg/Vial, Rx Only, KRS Global Biotechnology 791 Park of Commerce Blvd, Boca Raton, FL 33487. NDC 3321678103

Product Quantity:

4390 vials

Reason for Recall:

Lack of Assurance of Sterility

Recall Number:

D-0079-2020

Code Information:

All lots remaining within expiry.

Product Description:

NORepinephrine in 0.9% Sodium Chloride (PF), 250 mL IV bag, 4 mg/250 mL (0.016 mg/mL), Rx Only, KRS Global Biotechnology 791 Park of Commerce Blvd, Boca Raton, FL 33487, NDC 3321678032

Product Quantity:

528 bags

Reason for Recall:

Lack of Assurance of Sterility

Recall Number:

D-0080-2020

Code Information:

All lots remaining within expiry.

Product Description:

NORepinephrine in 0.9% Sodium Chloride (PF), 250 mL IV bag, 8 mg/250 mL (0.032 mg/mL), Rx Only, KRS Global Biotechnology 791 Park of Commerce Blvd, Boca Raton, FL 33487. NDC 3321678406

Product Quantity:

1464 bags

Reason for Recall:

Lack of Assurance of Sterility

Recall Number:

D-0081-2020

Code Information:

All lots remaining within expiry.

Product Description:

Norepinephrine added to 5% Dextrose (PF), 250 mL IV bag, 8 mg/250 mL (0.032 mg/mL), Rx Only, KRS Global Biotechnology 791 Park of Commerce Blvd, Boca Raton, FL 33487. NDC 3321678217

Product Quantity:

2760 bags

Reason for Recall:

Lack of Assurance of Sterility

Recall Number:

D-0082-2020

Code Information:

All lots remaining within expiry.

Product Description:

OxyTOCIN in 0.9% Sodium Chloride Solution (PF), 30 Units / 500 mL (0.06 Units / mL) Single Dose IV Bag, Rx Only, KRS Global Biotechnology 791 Park of Commerce Blvd, Boca Raton, FL 33487. NDC 3321676819

Product Quantity:

4497 bags

Reason for Recall:

Lack of Assurance of Sterility

Recall Number:

D-0083-2020

Code Information:

All lots remaining within expiry.

Product Description:

Phenylephrine HCl 1.5% (15 mg/mL) Lidocaine HCl 1% (10 mg/mL) (PF) (Sulfite Free) Ophthalmic Injection, 3 mL Single Dose Syringe, Rx Only, KRS Global Biotechnology 791 Park of Commerce Blvd, Boca Raton, FL 33487. NDC 3321678441

Product Quantity:

825 syringe

Reason for Recall:

Lack of Assurance of Sterility

Recall Number:

D-0084-2020

Code Information:

All lots remaining within expiry.

Product Description:

PHENYLephrine HCl 1.5% (15 mg/mL) LIDOcaine 1% (10 mg/mL) (PF) (Sulfite Free) Ophthalmic Injection, 3 mL fill in a 5 mL Single Dose Syringe, Rx Only, KRS Global Biotechnology 791 Park of Commerce Blvd, Boca Raton, FL 33487. NDC 3321678170

Product Quantity:

3150 vials

Reason for Recall:

Lack of Assurance of Sterility

Recall Number:

D-0085-2020

Code Information:

All lots remaining within expiry.

Product Description:

PHENYLephrine HCl in 0.9% Sodium Chloride (PF), 1 mg / 10 mL (0.1 mg/mL), 10 mL Fill in a 12 mL Single Dose Syringe Injection, Rx Only, KRS Global Biotechnology 791 Park of Commerce Blvd, Boca Raton, FL 33487. NDC 3321677379

Product Quantity:

15260 syringes

Reason for Recall:

Lack of Assurance of Sterility

Recall Number:

D-0086-2020

Code Information:

All lots remaining within expiry.

Product Description:

PHENYeprine HCl in 0.9% Sodium Chloride (PF) (Contains Sulfites), 100 mg / 250 mL (0.4 mg/mL), 250 mL Single-Dose Bag For IV Infusion Use, Rx Only, KRS Global Biotechnology 791 Park of Commerce Blvd, Boca Raton, FL 33487. NDC 3321678039

Product Quantity:

228 bags

Reason for Recall:

Lack of Assurance of Sterility

Recall Number:

D-0087-2020

Code Information:

All lots remaining within expiry.

Product Description:

PHENYephine HCl in 0.9% Sodium Chloride (PF) (Contains Sulfites), 25 mg / 250 mL (0.1 mg/mL), 250 mL Single-Dose Bag For IV Infusion Use, Rx Only, KRS Global Biotechnology 791 Park of Commerce Blvd, Boca Raton, FL 33487. NDC 3321677861

Product Quantity:

708 bags

Reason for Recall:

Lack of Assurance of Sterility

Recall Number:

D-0088-2020

Code Information:

All lots remaining within expiry.

Product Description:

PHENYephine HCl in 0.9% Sodium Chloride (PF) (Contains Sulfites). 30 mg/250 mL (0.12 mg/mL), 250 mL Single-Dose Bag For IV Infusion Use, Rx Only, KRS Global Biotechnology 791 Park of Commerce Blvd, Boca Raton, FL 33487. NDC 3321678401

Product Quantity:

60 bags

Reason for Recall:

Lack of Assurance of Sterility

Recall Number:

D-0089-2020

Code Information:

All lots remaining within expiry.

Product Description:

Polidocanol 5%, 500 mg / 10 mL (50 mg/mL), 10 mL Vial for IV Use, Rx Only, KRS Global Biotechnology 791 Park of Commerce Blvd, Boca Raton, FL 33487. NDC 3321677749

Product Quantity:

317 vials

Reason for Recall:

Lack of Assurance of Sterility

Recall Number:

D-0090-2020

Code Information:

All lots remaining within expiry.

Product Description:

Quadmix #13A (Prostaglandin E1-0.3 mg / Papaverine HCl-200 mg / Phentolamine Mesylate-30 mg / Atropine Sulfate Monohydrate-0.375 mg / Vial) Rx Only, KRS Global Biotechnology 791 Park of Commerce Blvd, Boca Raton, FL 33487. NDC 3321678398

Product Quantity:

91 vials

Reason for Recall:

Lack of Assurance of Sterility

Recall Number:

D-0091-2020

Code Information:

All lots remaining within expiry.

Product Description:

Quadmix # 19 (Prostaglandin E1-0.75 mg / Papaverine HCl-150 mg / Phentolamine Mesylate-15 mg / Atropine Sulfate Monohydrate-1.5 mg/vial), Rx Only, KRS Global Biotechnology 791 Park of Commerce Blvd, Boca Raton, FL 33487. NDC 3321678383

Product Quantity:

95 vials

Reason for Recall:

Lack of Assurance of Sterility

Recall Number:

D-0092-2020

Code Information:

All lots remaining within expiry.

Product Description:

Sermorelin Acetate, 9 mg / GHRP-2, 5.4 mg/vial Lyophilized-for SC Use, Rx Only, KRS Global Biotechnology 791 Park of Commerce Blvd, Boca Raton, FL 33487. NDC 3321674047

Product Quantity:

258 vials

Reason for Recall:

Lack of Assurance of Sterility

Recall Number:

D-0093-2020

Code Information:

All lots remaining within expiry.

Product Description:

Sermorelin Acetate, 3 mg/mL/GHRP6, 1.8 mg/mL/GHRP2, 1.8 mg/mL, 3 mL Injections-CART-Item#: 73752, For SC Use, Rx Only, KRS Global Biotechnology 791 Park of Commerce Blvd, Boca Raton, FL 33487.

Product Quantity:

218 cartridges

Reason for Recall:

Lack of Assurance of Sterility

Recall Number:

D-0094-2020

Code Information:

All lots remaining within expiry.

Product Description:

Sermorelin, 3 mg/GHRP6, 3 mg/GHRP2, 3 mg/Vial, For SC Use, Vial-Lyophilized, Rx Only, KRS Global Biotechnology 791 Park of Commerce Blvd, Boca Raton, FL 33487. NDC 3321673816

Product Quantity:

647 vials

Reason for Recall:

Lack of Assurance of Sterility

Recall Number:

D-0095-2020

Code Information:

All lots remaining within expiry.

Product Description:

Sermorelin 9 mg / GHRP6, 5.4 mg / GHRP2, 5.4 mg, Vial For SC Use-Lyophilized, Rx Only, KRS Global Biotechnology 791 Park of Commerce Blvd, Boca Raton, FL 33487. NDC 3321673589

Product Quantity:

246 vials

Reason for Recall:

Lack of Assurance of Sterility

Recall Number:

D-0096-2020

Code Information:

All lots remaining within expiry.

Product Description:

Sermorelin Acetate 9 mg/ 3 mL (3 mg/mL),Rx Only, KRS Global Biotechnology 791 Park of Commerce Blvd, Boca Raton, FL 33487.

Product Quantity:

152 cartridges

Reason for Recall:

Lack of Assurance of Sterility

Recall Number:

D-0097-2020

Code Information:

All lots remaining within expiry.

Product Description:Sermorelin Acetate 3 mg / Vial, For SC Use-Lyophilized, Rx Only, KRS Global Biotechnology 791 Park of Commerce Blvd, Boca Raton, FL 33487.
NDC 3321601122**Product Quantity:**

64 vials

Reason for Recall:

Lack of Assurance of Sterility

Recall Number:

D-0098-2020

Code Information:

All lots remaining within expiry.

Product Description:Sermorelin Acetate 9 mg / Vial, For SC Use-Lyophilized, Rx Only, KRS Global Biotechnology 791 Park of Commerce Blvd, Boca Raton, FL 33487.
NDC 3321673588**Product Quantity:**

341 vials

Reason for Recall:

Lack of Assurance of Sterility

Recall Number:

D-0099-2020

Code Information:

All lots remaining within expiry.

Product Description:

Sermorelin, 3 mg / GHRP-2, 3 mg / Vial, For SC Use-Lyophilized, Rx Only, KRS Global Biotechnology 791 Park of Commerce Blvd, Boca Raton, FL 33487. NDC 3321674092

Product Quantity:

120 vials

Reason for Recall:

Lack of Assurance of Sterility

Recall Number:

D-0100-2020

Code Information:

All lots remaining within expiry.

Product Description:

Sodium Bicarbonate 8.4%, 4,200 mg / 50 mL 50 mEq / 50 mL (84 mg/mL) (1 mEq/mL), 50 mL Fill in a 60 mL Single Dose Syringe, For IV Use, Rx

Only KRS Global Biotechnology 791 Park of Commerce Blvd, Boca Raton, FL 33487. NDC 3321674199

Product Quantity:

540 syringes

Reason for Recall:

Lack of Assurance of Sterility

Recall Number:

D-0101-2020

Code Information:

All lots remaining within expiry.

Product Description:

Sodium Citrate 40 mg/mL (4%) / Gentamicin 0.32 mg/mL. 30 mL vial for Intra-Catheter Use Only, Rx Only, KRS Global Biotechnology 791 Park of Commerce Blvd, Boca Raton, FL 33487. NDC 3321676603

Product Quantity:

150 vials

Reason for Recall:

Lack of Assurance of Sterility

Recall Number:

D-0102-2020

Code Information:

All lots remaining within expiry.

Product Description:

SUCCinylcholine Chloride (PF), 100 mg / 5 mL (20 mg/mL), 5 mL Fill in a 6 mL Single Dose Syringe, For IV Use-Injection, Rx Only, KRS Global Biotechnology 791 Park of Commerce Blvd, Boca Raton, FL 33487. NDC 3321678418

Product Quantity:

7905 syringes

Reason for Recall:

Lack of Assurance of Sterility

Recall Number:

D-0103-2020

Code Information:

All lots remaining within expiry.

Product Description:

SUCCinylcholine Chloride (PF), 140 mg/7 mL (20 mg/mL), 7 mL Fill in a 12 mL Single Dose Syringe, For IV Use Injection, Rx Only, KRS Global Biotechnology 791 Park of Commerce Blvd, Boca Raton, FL 33487. NDC 3321678417

Product Quantity:

1350 syringes

Reason for Recall:

Lack of Assurance of Sterility

Recall Number:

D-0104-2020

Code Information:

All lots remaining within expiry.

Product Description:

SUCCinylcholine Chloride (PF), 200 mg/10 mL (20 mg/mL), 10 mL Fill in a 12 mL Single Dose Syringe, For IV Use Injection, Rx Only KRS Global Biotechnology 791 Park of Commerce Blvd, Boca Raton, FL 33487. NDC 3321678416

Product Quantity:

3820 syringes

Reason for Recall:

Lack of Assurance of Sterility

Recall Number:

D-0105-2020

Code Information:

All lots remaining within expiry.

Product Description:

Cyclopentolate HCl 1% (5 mg/0.5 mL) / Phenylephrine HCl 2.5% (12.5 mg/0.5 mL) / Tropicamide 1% (5 mg/0.5 mL) / Ketorolac Tromethamine 0.5% (2.5 mg/0.5 mL), Sterile Ophthalmic Topical Solution, 0.5 mL Fill in 3 mL Syringe, Rx Only, KRS Global Biotechnology 791 Park of Commerce Blvd, Boca Raton, FL 33487. NDC 3321677510

Product Quantity:

1815 syringes

Reason for Recall:

Lack of Assurance of Sterility

Recall Number:

D-0106-2020

Code Information:

All lots remaining within expiry.

Product Description:

Cyclopentolate HCl 1% (10 mg/mL) / Phenylephrine HCl 2.5% (25 mg/mL) / Tropicamide 1% (10 mg/mL), Sterile Ophthalmic Topical Solution, 5 mL Fill in a 7 mL Droptainer, Rx Only, KRS Global Biotechnology 791 Park of Commerce Blvd, Boca Raton, FL 33487. NDC 3321678092

Product Quantity:

242 droptainers

Reason for Recall:

Lack of Assurance of Sterility

Recall Number:

D-0107-2020

Code Information:

All lots remaining within expiry.

Product Description:

Cyclopentolate HCl 1% (10 mg/mL) / Phenylephrine HCl 2.5% (25 mg/mL) / Tropicamide 1% (10 mg/mL) / Ketorolac Tromethamine 0.5% (5 mg/mL), 3 mL Droptainer, Sterile Ophthalmic Topical Solution, Rx Only, KRS Global Biotechnology 791 Park of Commerce Blvd, Boca Raton, FL 33487. NDC 3321676225

Product Quantity:

649 droptainers

Reason for Recall:

Lack of Assurance of Sterility

Recall Number:

D-0108-2020

Code Information:

All lots remaining within expiry.

Product Description:

Cyclopentolate HCl 1% (5 mg/0.5 mL) / Phenylephrine HCl 2.5% (12.5 mg/0.5 mL) / Tropicamide 1% (5 mg/0.5 mL), 0.5 mL Fill in a 3 mL Syringe, Sterile Ophthalmic Topical Solution, (Contains Sulfites), Rx Only, KRS Global Biotechnology 791 Park of Commerce Blvd, Boca Raton, FL 33487. NDC 3321677124

Product Quantity:

465 syringes

Reason for Recall:

Lack of Assurance of Sterility

Recall Number:

D-0109-2020

Code Information:

All lots remaining within expiry.

Product Description:

Vitamin 10 B Lyophilized, Vial, For IM Use, Rx Only, KRS Global Biotechnology 791 Park of Commerce Blvd, Boca Raton, FL 33487. NDC3321678338

Product Quantity:

6747 vials

Reason for Recall:

Lack of Assurance of Sterility

Recall Number:

D-0110-2020

Code Information:

All lots remaining within expiry.

Product Description:

Vitamin 10 D Lyophilized, Vial For IM/Slow IV Infusion Use, Rx Only, KRS Global Biotechnology 791 Park of Commerce Blvd, Boca Raton, FL 33487. NDC 3321678341

Product Quantity:

508 vials

Reason for Recall:

Lack of Assurance of Sterility

Recall Number:

D-0111-2020

Code Information:

All lots remaining within expiry.

Product Description:

Vitamin 5 B, 30 mL Vial For IM Use, Rx Only, KRS Global Biotechnology 791 Park of Commerce Blvd, Boca Raton, FL 33487. NDC 3321674253

Product Quantity:

616 vials

Reason for Recall:

Lack of Assurance of Sterility

Recall Number:

D-0112-2020

Code Information:

All lots remaining within expiry.

Product Description:

Vitamin 9 Lyophilized, Vial For IM Use, Rx Only, KRS Global Biotechnology 791 Park of Commerce Blvd, Boca Raton, FL 33487. NDC 3321674147

Product Quantity:

470 vials

Reason for Recall:

Lack of Assurance of Sterility

Recall Number:

D-0113-2020

Code Information:

All lots remaining within expiry.

Product Description:

Vitamin 9A/B Lyophilized, Vial For IM Use, Rx Only, KRS Global Biotechnology 791 Park of Commerce Blvd, Boca Raton, FL 33487. NDC 3321678339

Product Quantity:

6325 vials

Reason for Recall:

Lack of Assurance of Sterility

Recall Number:

D-0114-2020

Code Information:

All lots remaining within expiry.

Product Description:

Vitamin B1/B2/B3/B6/HYDROXOCOBALAMIN 66/1.33/66/66/0.66 mg/mL (PF), For IV Use, 3 mL fill in a 5 mL Single Dose Vial, Rx Only, KRS Global Biotechnology 791 Park of Commerce Blvd, Boca Raton, FL 33487. NDC 3321678335

Product Quantity:

948 vials

Reason for Recall:

Lack of Assurance of Sterility

Recall Number:

D-0115-2020

Code Information:

All lots remaining within expiry.

Product Description:

Cyclopentolate HCl 1% (10 mg/mL) / Phenylephrine HCl 10% (100 mg/mL) / Tropicamide 1% (10 mg/mL) / Ketorolac Tromethamine 0.5% (5 mg/mL), Sterile Ophthalmic Topical Solution, 5 mL Fill in a 7 mL Droptainer, Rx Only, KRS Global Biotechnology 791 Park of Commerce Blvd, Boca Raton, FL 33487. NDC 3321676223

Product Quantity:

242 droptainers

Reason for Recall:

Lack of Assurance of Sterility

Recall Number:

D-0116-2020

Code Information:

All lots remaining within expiry.

Product Description:

L-Asparaginase Lyophilized, 10,000 International Units/Vial, For IV / IM / SC Use, Rx Only, KRS Global Biotechnology 791 Park of Commerce Blvd, Boca Raton, FL 33487. NDC 3321674499

Product Quantity:**Reason for Recall:**

Lack of Assurance of Sterility

Recall Number:

D-0117-2020

Code Information:

All lots remaining within expiry.

Product Description:

Isoproterenol HCL (PF) in D5W, 200 mcg / 50 mL (4 mcg/mL), 50 mL IV Bag, Single Dose Only, Contains Sulfites, For Slow IV use, Rx Only, KRS Global Biotechnology 791 Park of Commerce Blvd, Boca Raton, FL 33487. NDC 3321677610

Product Quantity:**Reason for Recall:**

Lack of Assurance of Sterility

Recall Number:

D-0118-2020

Code Information:

All lots remaining within expiry.

Class II Drugs Event

Event ID:
83840

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
09/19/2019

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
10/02/2019

Initial Firm Notification of Consignee or Public:
Two or more of the following: Email, Fax, Letter, Press Release, Telephone, Visit

Recalling Firm:
Torrent Pharma Inc.
150 Allen Rd Ste 102
Basking Ridge NJ United States

Distribution Pattern:
Nationwide USA and Puerto Rico

Associated Products

<p>Product Description: Losartan Potassium Tablets, USP 50mg, 1000 tablets per bottle, Rx Only, Manufactured for: Torrent Pharma Inc., Basking Ridge, NJ 07920. NDC: 13668-409-10</p> <p>Product Quantity: 8,688 bottles</p> <p>Reason for Recall: CGMP Deviations: FDA lab confirmed presence of an impurity, N-Methylnitrosobutyric acid (NMBA) in the finished product above the interim acceptable daily intake level of 9.82 parts per million.</p> <p>Recall Number: D-0121-2020</p> <p>Code Information: Lot 4DU2E009</p>

<p>Product Description: Losartan Potassium Tablets, USP 100 mg, [90 or 1000] tablets per bottle, Rx Only, Manufactured for: Torrent Pharma Inc., Basking Ridge, NJ 07920. NDC 90 tablets: 13668-115-90; NDC 1000 tablets: 13668-115-10</p> <p>Product Quantity: 39,432 bottles</p> <p>Reason for Recall: CGMP Deviations: FDA lab confirmed presence of an impurity, N-Methylnitrosobutyric acid (NMBA) in the finished product above the interim acceptable daily intake level of 9.82 parts per million.</p> <p>Recall Number: D-0122-2020</p> <p>Code Information: Count, lot, expiry: [90 count] Lot 4DU3E009, exp 12/31/2020; [1000 count] Lot 4DU3D018, exp 02/28/2021</p>

<p>Product Description: Losartan Potassium /Hydrochlorothiazide Tablets, USP 50mg/12.5mg, 90 tablets per bottle, Rx Only, Manufactured for: Torrent Pharma Inc., Basking Ridge, NJ 07920. NDC: 13668-116-90</p> <p>Product Quantity: 17,088 bottles</p> <p>Reason for Recall: CGMP Deviations: FDA lab confirmed presence of an impurity, N-Methylnitrosobutyric acid (NMBA) in the finished product above the interim acceptable daily intake level of 9.82 parts per million.</p> <p>Recall Number: D-0123-2020</p>

Code Information:

Lot BEF7D051

Product Description:

Losartan Potassium/ Hydrochlorothiazide Tablets, USP 100mg/25mg, 90 tablets per bottle, Rx Only, Manufactured for: Torrent Pharma Inc., Basking Ridge, NJ 07920. NDC: 13668-118-90

Product Quantity:

8,688 bottles

Reason for Recall:

CGMP Deviations: FDA lab confirmed presence of an impurity, N-Methylnitrosobutyric acid (NMBA) in the finished product above the interim acceptable daily intake level of 9.82 parts per million.

Recall Number:

D-0124-2020

Code Information:

Lot 4P04D007

Class II Drugs Event

Event ID:

83843

Product Type:

Drugs

Status:

Ongoing

Date Terminated:**Recall Initiation Date:**

09/20/2019

Voluntary / Mandated:

Voluntary: Firm initiated

Center Classification Date:

09/30/2019

Initial Firm Notification of Consignee or Public:

Letter

Recalling Firm:

Akorn, Inc.
1925 W Field Ct Ste 300
Lake Forest IL United States

Distribution Pattern:

Nationwide in the USA and Puerto Rico

Associated Products

Product Description:

Phenylephrine Hydrochloride Ophthalmic Solution, USP, 2.5%, 15 mL bottle, Rx only, Mfd. by: Akorn, Inc., Lake Forest, IL 60045; NDC 17478-201-15.

Product Quantity:

60,176 bottles

Reason for Recall:

Lack of Assurance of Sterility: Out of specification results for container closure test which cannot guarantee the sterility of the product.

Recall Number:

D-1883-2019

Code Information:

Lot #: 031908A, Exp 03/20

Class II Drugs Event

Event ID:

83878

Product Type:

Drugs

Status:

Ongoing

Date Terminated:

Recall Initiation Date:

09/26/2019

Voluntary / Mandated:

Voluntary: Firm initiated

Center Classification Date:

10/02/2019

Initial Firm Notification of Consignee or Public:

Letter

Recalling Firm:

Alkermes, Inc.
852 Winter St
Waltham MA United States

Distribution Pattern:

Nationwide USA and Canada

Associated Products

Product Description:

Vivitrol (naltrexone for extended-release injectable suspension) 380 mg/vial. Each Carton Contains: 1) One vial of 380 mg of Vivitrol, 2) One vial containing 4 mL of diluent, 3) One 5-mL prepackaged syringe, 4) One 20-gauge 1-inch needle, 5) Two 20-gauge 1.5-inch safety needles, 6) Two 20-gauge 2-inch safety needles. Rx Only. Manufactured and marketed by: Alkermes, Inc. Kit NDC: 65757-300-01

Product Quantity:

16,231 kits

Reason for Recall:

Labeling: Not Elsewhere Classified. Drug product kit recalled due to 1 inch needles being placed in the 1 1/2 inch needle cardboard sleeve labelled as administration needles. The product vial is not impacted.

Recall Number:

D-0119-2020

Code Information:

Lot 2019-1002T, 2019-1003T, Exp 05/2021