

Enforcement Report - Week of September 6, 2023

Class II Drugs Event

Event ID:

92898

Product Type:

Drugs

Status:

Ongoing

Date Terminated:**Recall Initiation Date:**

08/17/2023

Voluntary / Mandated:

Voluntary: Firm initiated

Center Classification Date:

08/28/2023

Initial Firm Notification of Consignee or Public:

Letter

Recalling Firm:

Central Admixture Pharmacy Services, Inc.
2200 S 43rd Ave
Phoenix AZ United States

Distribution Pattern:

Nationwide in the USA

Associated Products

Product Description:

CARDIOPLEGIA SOLUTION, 20 mEq K, Maintenance 4:1, Low Potassium, Total Volume = 810 mL, EVA Bag, Rx only, Central Admixture Pharmacy Services, Inc., 2200 South 43rd Avenue, Phoenix, AZ 85043, NDC: 72196-0103-1

Product Quantity:

304 bags

Reason for Recall:

Lack of Assurance of Sterility:Lack of validation data for sanitization cycles

Recall Number:

D-1107-2023

Code Information:

Lot# 36-262315, Exp 8/21/2023; 36-262514, Exp 8/25/2023; 36-262993, Exp 8/28/2023.

Product Description:

CARDIOPLEGIA SOLUTION, 60 mEq K, Induction 4:1, HIGH POTASSIUM, Total Volume = 830 mL, EVA Bag, RX only, Central Admixture Pharmacy Services, Inc., 2200 South 43rd Avenue, Pheonix, AZ 85043, NDC: 72196-0100-1

Product Quantity:

184

Reason for Recall:

Lack of Assurance of Sterility:Lack of validation data for sanitization cycles

Recall Number:

D-1108-2023

Code Information:

Lot# 36-262513, Exp 8/25/2023; 36-262880, Exp 8/27/2023

Product Description:

CARDIOPLEGIA SOLUTION, HIGH K, Induction 4:1, Plasmalyte/Tromethamine, High Potassium, EVA Bags, total volume = 500 mL, Rx Only, Central Admixture Pharmacy Services, Inc., 2200 South 43rd Avenue, Pheonix, AZ 85043, NDC: 72196-0111-1

Product Quantity:

84 bags

Reason for Recall:

Lack of Assurance of Sterility:Lack of validation data for sanitization cycles

Recall Number:

D-1109-2023

Code Information:

Lot# 36-262515, Exp 8/25/2023.

Product Description:

CARDIOPLEGIA SOLUTION, 24 mEq K, Maintenance 8:1, Low Potassium, Total volume = 500 mL, EVA Bag, Rx only, Central Admixture Pharmacy Services, Inc., 2200 South 43rd Avenue, Pheonix, AZ 85043, NDC: 72196-0105-1

Product Quantity:

84 bags

Reason for Recall:

Lack of Assurance of Sterility:Lack of validation data for sanitization cycles

Recall Number:

D-1110-2023

Code Information:

Lot# 36-262516, Exp 8/25/2023.

Product Description:

Cardioplegia Solution, low K, Maintenance 4:1 Plasmalyte, Low Potassium, total volume = 1047 mL, EVA Bag, Rx only, Central Admixture Pharmacy Services, Inc., 2200 South 43rd Avenue, Pheonix, AZ 85043, NDC: 72196-0211-1

Product Quantity:

100 bags

Reason for Recall:

Lack of Assurance of Sterility:Lack of validation data for sanitization cycles

Recall Number:

D-1111-2023

Code Information:

Lot# 36-262881, Exp 8/27/2023.

Product Description:

Cardioplegia Solution del Nido Formula, Total Volume = 1,052.8 mL, EVA Bag, PLASMA-LYTE A 1000 mL, Mannitol 20% 16.3 mL, Sodium Bicarbonate 8.4% 13 mL, Potassium Chloride 2 mEq/mL 13 mL, Magnesium Sulfate 4.06 mEq/mL 4 mL, Lidocaine 2% 6.5 mL, Rx Only, Central Admixture Pharmacy Services, Inc., 2200 South 43rd Avenue, Phoenix, AZ 85043, NDC: 72196-0202-1

Product Quantity:

786 Bags

Reason for Recall:

Lack of Assurance of Sterility:Lack of validation data for sanitization cycles

Recall Number:

D-1112-2023

Code Information:

Lot# 36-260068, 36-260062, 36-260070, 36-260063, 36-260064, Exp 8/29/2023; 36-260016, Exp 9/3/2023; 36-262540, 36-262536, 36-262534, Exp 9/9/2023; 36-262990, 36-262992, Exp 9/12/2023. ;

Product Description:

rocuronium 50 mg/5 mL (10 mg/mL), 5 mL Syringes, Rx only, this drug was repackaged by CAPS Inc, 2200 South 43rd Avenue, Pheonix, AZ, NDC 72196-6010-1.

Product Quantity:

3519 Syringes

Reason for Recall:

Lack of Assurance of Sterility:Lack of validation data for sanitization cycles

Recall Number:

D-1113-2023

Code Information:

Lot# 36-262729, 36-262982, 36-262981, 36-262732, 36-262731, 36-262730, Exp 10/11/2023 ;

Product Description:

Neonatal TPN Starter Bag, Amino Acids (Trophamine) 2.5%/Dextrose 10% with CALCIUM and HEPARIN, total volume = 250mL, EVA Bag, Rx only, Central Admixture Pharmacy Services, Inc., 2200 South 43rd Avenue, Pheonix, AZ 85043, NDC: 72196-0418-1

Product Quantity:

84 bags

Reason for Recall:

Lack of Assurance of Sterility:Lack of validation data for sanitization cycles

Recall Number:

D-1114-2023

Code Information:

Lot# 36-260015, Exp 8/19/2023 ;

Product Description:

Neonatal TPN Starter Bag, Amino Acids (Trophamine) 3% / Dextrose 10%, Total Volume = 250mL, IV Bag, Rx only, Central Admixture Pharmacy Services, Inc., 2200 South 43rd Avenue, Pheonix, AZ 85043, NDC: 72196-0404-1

Product Quantity:

40 bags

Reason for Recall:

Lack of Assurance of Sterility:Lack of validation data for sanitization cycles

Recall Number:

D-1115-2023

Code Information:

Lot# 36-262157, Exp 8/21/2023 ;

Product Description:

Neonatal TPN Starter Bag, Amino Acids (trophamine) 3.5%/Dextrose 10%, Total Volume = 250mL, IV Bag, Rx only, Central Admixture Pharmacy Services, Inc., 2200 South 43rd Avenue, Pheonix, AZ 85043, NDC: 72196-0406-1

Product Quantity:

200 bags

Reason for Recall:

Lack of Assurance of Sterility:Lack of validation data for sanitization cycles

Recall Number:

D-1116-2023

Code Information:

Lot# 36-262872, 36-262873, Exp 8/27/2023 ;

Product Description:

Neonatal TPN Starter Bag, Amino Acids (trophamine) 3%/Dextrose 5% with CALCIUM and HEPARIN, IV Bag, total volume = 250mL, Rx only, Central Admixture Pharmacy Services, Inc., 2200 South 43rd Avenue, Pheonix, AZ 85043. NDC: 72196-0419-1

Product Quantity:

104 bags

Reason for Recall:

Lack of Assurance of Sterility:Lack of validation data for sanitization cycles

Recall Number:

D-1117-2023

Code Information:

Lot# 36-260022, Exp 8/19/2023 ;

Product Description:

Neonatal TPN Starter Bag, Amino Acids (trophamine) 3%/Dextrose 10% with CALCIUM and HEPARIN, IV Bag, total volume = 250mL, Rx only, Central Admixture Pharmacy Services, Inc., 2200 South 43rd Avenue, Pheonix, AZ 85043, NDC: 72196-0420-1

Product Quantity:

140 bags

Reason for Recall:

Lack of Assurance of Sterility:Lack of validation data for sanitization cycles

Recall Number:

D-1118-2023

Code Information:

Lot# 36-260019, 36-260023, Exp 8/19/2023 ;

Product Description:

Neonatal TPN Starter Bag, Amino Acids (trophamine) 3%/Dextrose 10% with **low calcium** and HEPARIN, IV Bag, total volume = 250mL, Rx only, Central Admixture Pharmacy Services, Inc., 2200 South 43rd Avenue, Pheonix, AZ 85043, NDC: 72196-0428-1

Product Quantity:

136 bags

Reason for Recall:

Lack of Assurance of Sterility:Lack of validation data for sanitization cycles

Recall Number:

D-1119-2023

Code Information:

Lot# 36-262160, 36-262146, Exp 8/21/2023 ;

Product Description:

Neonatal TPN Starter Bag, Amino Acids (trophamine) 3.5% / Dextrose 10% with **low calcium** and HEPARIN, IV Bag, total volume = 250mL, Rx only, Central Admixture Pharmacy Services, Inc., 2200 South 43rd Avenue, Pheonix, AZ 85043, NDC: 72196-0429-1

Product Quantity:

132 bags

Reason for Recall:

Lack of Assurance of Sterility:Lack of validation data for sanitization cycles

Recall Number:

D-1120-2023

Code Information:

Lot# 36-260018, Exp 8/19/2023, 36-262155, Exp 8/21/2023 ;

Product Description:

Neonatal TPN Starter Bag, Amino Acids (trophamine) 3.5%/Dextrose 10% with HEPARIN, IV Bag, total volume = 250mL, Rx only, Central Admixture Pharmacy Services, Inc., 2200 South 43rd Avenue, Pheonix, AZ 85043, NDC: 72196-0431-1

Product Quantity:

92 bags

Reason for Recall:

Lack of Assurance of Sterility:Lack of validation data for sanitization cycles

Recall Number:

D-1121-2023

Code Information:

Lot# 36-262161, Exp 8/21/2023 ;

Product Description:

Neonatal TPN Starter Bag, Amino Acids (trophamine) 4%/Dextrose 10% with CALCIUM and HEPARIN, IV Bags, total volume = 250mL, Rx only, Central Admixture Pharmacy Services, Inc., 2200 South 43rd Avenue, Pheonix, AZ 85043, NDC: 72196-0422-1

Product Quantity:

108 bags

Reason for Recall:

Lack of Assurance of Sterility:Lack of validation data for sanitization cycles

Recall Number:

D-1122-2023

Code Information:

Lot# 36-260017, Exp 8/19/2023 ;

Product Description:

CARDIOPLEGIA SOLUTION, 25 mEq K, SUTTER CARDIOPLEGIA, Total Volume = 572.64 mL, IV Bag, Rx only, Central Admixture Pharmacy Services, Inc., 2200 South 43rd Avenue, Pheonix, AZ 85043, NDC: 72196-0217-1

Product Quantity:

16 bags

Reason for Recall:

Lack of Assurance of Sterility:Lack of validation data for sanitization cycles

Recall Number:

D-1123-2023

Code Information:

Lot# 36-262542, Exp 8/25/2023 ;

Product Description:

PHENYLephrine 1,000 mcg/10mL, (100mcg/mL) in 0.9% sodium chloride, 10 mL Syringe, Rx Only, CAPS, Inc., 2200 South 43rd Avenue, Phoenix, AZ 85043, NDC: 72196-6009-1

Product Quantity:

4100 syringes

Reason for Recall:

Lack of Assurance of Sterility:Lack of validation data for sanitization cycles

Recall Number:

D-1124-2023

Code Information:

Lot# 36-262312, 36-262314, 36-262311, 36-262313, Exp 10/5/2023; 36-262739, 36-262742, 36-262741, 36-262740, 36-262738, 36-262737, Exp 10/11/2023. ;

Product Description:

PHENYLephrine, added to 0.9% sodium chloride, 10mg/250ml (40mcg/mL), IV Bag, Rx Only, Central Admixture Pharmacy Services, Inc., 2200 South 43rd Avenue, Phoenix, AZ 85043, NDC: 72196-6058-1.

Product Quantity:

586 bags

Reason for Recall:

Lack of Assurance of Sterility:Lack of validation data for sanitization cycles

Recall Number:

D-1125-2023

Code Information:

Lot# 36-260034, 36-260033, Exp 10/3/2023. ;

Product Description:

PHENYLephrine added to 0.9% sodium chloride, 20mg/250ml (80 mcg/mL), IV Bag, Rx Only, Central Admixture Pharmacy Services, Inc., 2200 South 43rd Avenue, Phoenix, AZ 85043, NDC: 72196-7025-1.

Product Quantity:

297 bags

Reason for Recall:

Lack of Assurance of Sterility:Lack of validation data for sanitization cycles

Recall Number:

D-1126-2023

Code Information:

Lot# 36-260037, Exp 10/3/2023. ;

Product Description:

PHENYLephrine, added to 0.9% sodium chloride, 40mg/250ml (160mcg/mL), IV Bag, Rx Only, Central Admixture Pharmacy Services, Inc., 2200 South 43rd Avenue, Phoenix, AZ 85043, NDC: 72196-6092-1

Product Quantity:

292 bags

Reason for Recall:

Lack of Assurance of Sterility:Lack of validation data for sanitization cycles

Recall Number:

D-1127-2023

Code Information:

Lot# 36-260036, Exp 10/3/2023. ;

Product Description:

PHENYLEphrine added to 0.9% sodium chloride 50 mg/250mL (200mcg/mL), IV Bag, Rx Only, Central Admixture Pharmacy Services, Inc., 2200 South 43rd Avenue, Phoenix, AZ 85043. NDC:72196-7039-1

Product Quantity:

340 bags

Reason for Recall:

Lack of Assurance of Sterility:Lack of validation data for sanitization cycles

Recall Number:

D-1128-2023

Code Information:

Lot# 36-260038, Exp 10/3/2023. ;

Product Description:

EPINEPHrine, 2 mg added to dextrose 5% 250mL, Concentration = 8 mcg/mL, IV Bag, Rx Only, Central Admixture Pharmacy Services, Inc., 2200 South 43rd Avenue, Phoenix, AZ 85043, NDC: 72196-6030-1.

Product Quantity:

340 bags

Reason for Recall:

Lack of Assurance of Sterility:Lack of validation data for sanitization cycles

Recall Number:

D-1129-2023

Code Information:

Lot# 36-260049, Exp 10/3/2023. ;

Product Description:

EPINEPHrine added to 0.9% sodium chloride, 4mg/250mL (16 mcg/mL), IV Bag, RX only, Central Admixture Pharmacy Services, Inc., 2200 South 43rd Avenue, Phoenix, AZ 85043, NDC: 72196-8093-1.

Product Quantity:

292 bags.

Reason for Recall:

Lack of Assurance of Sterility:Lack of validation data for sanitization cycles

Recall Number:

D-1130-2023

Code Information:

Lot# 36-260047, Exp 10/3/2023. ;

Product Description:

EPINEPHrine added to dextrose 5%, 4mg/250ml (16 mcg/mL), IV Bag, Rx Only, Central Admixture Pharmacy Services, Inc., 2200 South 43rd Avenue, Phoenix, AZ 85043, NDC: 72196-7018-1.

Product Quantity:

554 bags

Reason for Recall:

Lack of Assurance of Sterility:Lack of validation data for sanitization cycles

Recall Number:

D-1131-2023

Code Information:

Lot# 36-262162, 36-262163, Exp 10/5/2023. ;

Product Description:

oxyTOCIN 30 units added to Lactated Ringer's 500 mL, IV Bag, Rx only, Cental Admixture Pharmacy Services, Inc., 2200 South 43rd Avenue, Pheonix, AZ 85043, NDC: 72196-6039-1

Product Quantity:

1,996 bags.

Reason for Recall:

Lack of Assurance of Sterility:Lack of validation data for sanitization cycles

Recall Number:

D-1132-2023

Code Information:

Lot# 36-260043, 36-260039, Exp 9/8/2023; 36-262220, Exp 9/10/2023; 36-262526, 36-262525, 36-262524, Exp 9/14/2023. ;

Product Description:

oxyTOCIN 30 units added to 0.9% sodium chloride 500 mL, IV Bag, Rx only, CAPS, Central Admixture Pharmacy Services, Inc., 2200 South 43rd Avenue, Pheonix, AZ 85043, NDC: 72196-6044-1

Product Quantity:

2643 bags

Reason for Recall:

Lack of Assurance of Sterility:Lack of validation data for sanitization cycles

Recall Number:

D-1133-2023

Code Information:

Lot# 36-260031, 36-260027, Exp 10/3/2023; 36-262533,36-262532, 36-262531, 36-262530, 36-262529, 36-262528, 36-262527, Exp 10/9/2023. ;

Product Description:

oxyTOCIN, 40 units added to 0.9% sodium chloride 1000 mL, IV Bag, Rx Only, Central Admixture Pharmacy Services, Inc., 2200 South 43rd Avenue, Pheonix, AZ 85043, NDC: 72196-8069-1

Product Quantity:

298 bags

Reason for Recall:

Lack of Assurance of Sterility:Lack of validation data for sanitization cycles

Recall Number:

D-1134-2023

Code Information:

Lot# 36-260050, Exp 10/3/2023. ;

Product Description:

heparin added to 0.9% sodium chloride, 2500 units/500mL (5 units/mL), IV Bag, Rx only, Cental Admixture Pharmacy Services, Inc., 2200 South 43rd Avenue, Pheonix, AZ 85043, NDC: 72196-8100-1

Product Quantity:

577 bags

Reason for Recall:

Lack of Assurance of Sterility:Lack of validation data for sanitization cycles

Recall Number:

D-1135-2023

Code Information:

Lot# 36-260045, 36-260046, Exp 9/13/2023. ;

Product Description:

vancomycin added to 0.9% Sodium Chloride, 1.25 g/250 mL (5 mg/mL), 250mL Excel Bag, Rx only, Central Admixture Pharmacy Services, Inc., 2200 South 43rd Avenue, Phoenix, AZ 85043, NDC: 72196-6074-1

Product Quantity:

477 bags

Reason for Recall:

Lack of Assurance of Sterility:Lack of validation data for sanitization cycles

Recall Number:

D-1136-2023

Code Information:

Lot# 36-262215, 36-262216, Exp 10/5/2023. ;

Product Description:

dilTIAZem 125mg/125mL (1 mg/mL), added to 0.9% sodium chloride, IV Bag, Rx Only, Central Admixture Pharmacy Services, Inc., 2200 South 43rd Avenue, Phoenix, AZ 85043, NDC: 72196-6055-1

Product Quantity:

235 bags

Reason for Recall:

Lack of Assurance of Sterility:Lack of validation data for sanitization cycles

Recall Number:

D-1137-2023

Code Information:

Lot# 36-262537, Exp 9/19/2023. ;

Product Description:

dilTIAZem 125mg/125mL (1 mg/mL), added to dextrose 5%, IV Bag, RX only, Central Admixture Pharmacy Services, Inc., 2200 South 43rd Avenue, Phoenix, AZ 85043, NDC: 72196-6054-1

Product Quantity:

703 bags.

Reason for Recall:

Lack of Assurance of Sterility:Lack of validation data for sanitization cycles

Recall Number:

D-1138-2023

Code Information:

Lot# 36-260048, Exp 9/13/2023; 36-262174, Exp 9/15/2023; 36-262523, Exp 9/19/2023. ;

Class II Drugs Event

Event ID:

92931

Product Type:

Drugs

Status:

Ongoing

Date Terminated:**Recall Initiation Date:**

08/11/2023

Voluntary / Mandated:

Voluntary: Firm initiated

Center Classification Date:

08/29/2023

Initial Firm Notification of Consignee or Public:

Letter

Recalling Firm:Baxter Healthcare Corporation
1 Baxter Pkwy
Deerfield IL United States**Distribution Pattern:**

Nationwide in the USA

Associated Products

Product Description:

DIANEAL Low Calcium (2.5 mEq/L) Peritoneal Dialysis Solution 1.5% Dextrose, packaged in a) 2000 mL AMBU-FLEX II Container bag, Product

Code L5B4825, NDC 0941-0409-06; b) 5000 mL AMBU-FLEX II Container bag, Product Code L5B4826, NDC 0941-0409-07; and c) 6000 mL AMBU-FLEX II Container bag, Product Code L5B9770, NDC 0941-0409-01, Rx Only, Baxter Healthcare Corporation, Deerfield, IL 60015 USA.

Product Quantity:

a) 44,520; b) 60,762; c) 483,912

Reason for Recall:

Lack of Assurance of Sterility: Potential presence of leaks originating from the Luer component.

Recall Number:

D-1140-2023

Code Information:

a) Lots Y403948, Exp 30-Sep-2024; Lot Y406277, Exp 31-Oct-2024. b) Lot 408790, Exp 30-Nov-2024 and c) Lots Y403740, Y403740A, Exp 30-Sep-2024; Lots Y405638, Y405805, Y407304, Y407304A Exp 31-Oct-2024; Lots Y407717, Y407717A, Y408554, Exp 30-Nov-2024; Lot Y420075, Exp 30-Apr-2025

Product Description:

Dianeal PD-2 Peritoneal Dialysis Solution with 1.5% Dextrose, 5000 mL AMBU-FLEX II Container with yellow pull ring, Rx Only, Baxter Healthcare Corporation, Deerfield, IL 60015 USA Product code L5B5193 NDC 0941-0411-07

Product Quantity:

22,112 bags

Reason for Recall:

Lack of Assurance of Sterility: Potential presence of leaks originating from the Luer component.

Recall Number:

D-1141-2023

Code Information:

Lot Y406734, Exp 31-Oct-2024

Class III Drugs Event

Event ID:

92894

Product Type:

Drugs

Status:

Ongoing

Date Terminated:**Recall Initiation Date:**

08/17/2023

Voluntary / Mandated:

Voluntary: Firm initiated

Center Classification Date:

08/29/2023

Initial Firm Notification of Consignee or Public:

Letter

Recalling Firm:

Lundbeck LLC
6 Parkway North Blvd Ste 400
Deerfield IL United States

Distribution Pattern:

Nationwide within the U.S.

Associated Products

Product Description:

Sabril (vigabatrin) for Oral Solution, 500 mg, 50 Packets, Rx only, Manufactured by: Patheon, Cincinnati, OH 45237, NDC 67386-211-65

Product Quantity:

10,543 cartons

Reason for Recall:

Cross contamination with other products

Recall Number:

D-1142-2023

Code Information:

Lot#: 3207333A, 3207334A, Exp 03/2027; 3214707A, 3214709A, 3214710A, Exp 02/2028 .

Class III Drugs Event

Event ID:

92922

Product Type:

Drugs

Status:

Ongoing

Date Terminated:**Recall Initiation Date:**

08/23/2023

Voluntary / Mandated:

Voluntary: Firm initiated

Center Classification Date:

08/29/2023

Initial Firm Notification of Consignee or Public:

Letter

Recalling Firm:

Contract Pharmaceuticals Limited Canada

7600 East Danbro Cres

Mississauga Canada

Distribution Pattern:

Nationwide in the USA.

Associated Products

Product Description:

Clindamycin Phosphate Topical Solution USP, 1%, 60 mL bottle, Rx only, Manufactured by: Contract Pharmaceuticals Limited Canada, Mississauga, Ontario, Canada, Manufactured for: Glasshouse Pharmaceuticals Limited Canada, Mississauga, Ontario, Canada, NDC# 71428-003-60

Product Quantity:

11,350 bottles

Reason for Recall:

Defective Container: slow leakage under the cap

Recall Number:

D-1139-2023

Code Information:

Lot # 118920, exp. January 2024.

Not Yet Classified Drugs Event

Event ID:

92892

Product Type:

Drugs

Status:

Ongoing

Date Terminated:**Recall Initiation Date:**

08/03/2023

Voluntary / Mandated:

Voluntary: Firm initiated

Center Classification Date:**Initial Firm Notification of Consignee or Public:**

Letter

Recalling Firm:

APG SEVEN, INC

12030 Sw 129th Ct Ste 205

Miami FL United States

Distribution Pattern:

Nationwide in the USA through on line sales and possibly some retail stores.

Associated Products

Product Description:

Vegetal Vigra, 200mg capsules, 8-count bottle, Manufacturer: Hand-shaking (Int'l) Corp. USA ADD: Hand-shaking Mansion, the 5th Ave., Stanford, USA. UPC 8 931028 556885

Product Quantity:

120 bottles

Reason for Recall:

Marketed Without an Approved NDA/ANDA: FDA analysis found the product to be tainted with sildenafil.

Recall Number:**Code Information:**

All lots dated to Expire. 01/2025