

# Enforcement Report - Week of May 24, 2023

## Class II Drugs Event

**Event ID:**

92074

**Product Type:**

Drugs

**Status:**

Ongoing

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

04/11/2023

**Voluntary / Mandated:**

Voluntary: Firm initiated

**Center Classification Date:**

05/15/2023

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

E-Mail

**Recalling Firm:**

Sanofi-Aventis U.S. LLC

55 Corporate Dr

Bridgewater NJ United States

**Distribution Pattern:**

Nationwide in the USA

## Associated Products

**Product Description:**

Admelog, insulin lispro injection, 100 units/mL (U-100), 3mL multi-dose vial, Rx Only, Sanofi-Aventis U.S. LLC, Bridgewater, NJ 08807 A Sanofi Company. NDC 0024-5926-05

**Product Quantity:**

51,325 vials

**Reason for Recall:**

Lack of Assurance of Sterility: Malformed crimped collar seal

**Recall Number:**

D-0575-2023

**Code Information:**

Lot # 3F497B, EXP 12-31-2025

## Class II Drugs Event

**Event ID:**

92239

**Product Type:**

Drugs

**Status:**

Ongoing

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

05/01/2023

**Voluntary / Mandated:**

Voluntary: Firm initiated

**Center Classification Date:**

05/16/2023

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

Letter

**Recalling Firm:**

RemedyRepack Inc.

625 Kolter Dr Ste 4

Indiana PA United States

**Distribution Pattern:**

Product was distributed to three direct account in PA.

## Associated Products

**Product Description:**

LORazepam Injection, 2mg / mL Single Dose vial 1ml vial, Rx Only, MFG Akorn Lake Forest IL 60045, Repackaged by: RemedyRepack Inc., Indiana PA 15701, Source NDC # 17478-0040-001, Remedy NDC 70518-2268-00

**Product Quantity:**

9,038 vials

**Reason for Recall:**

CGMP Deviations: Discontinuation of the Quality program by manufacturer that would assure product meet the identity, strength, quality, and purity characteristics that they are purported or represented to possess.

**Recall Number:**

D-0576-2023

**Code Information:**

Lot # B2169656-032223, B2169663-032223, B2169680-032223, B2169713-032223, B2109085-021423, B2109094-021423, B2049229-010623, B2049235-010623, Exp. Date 04/30/2025; B2049224-010623, B2027905-122222, B2027920-122222, B2027941-122222, B2027968-122222, B2027979-122222, B2027989-122222, B2005343-120922, B2005333-120922, Exp. Date 03/31/2025; B1970782-112122, Exp. Date 01/31/2025; B1878510-092922, Exp. Date 11/30/2024; B1904609-101322, B1866210-092222, Exp. Date 12/31/2024; B1711316-060222, B1711328-060222, Exp. Date 09/30/2024; B1660244-042522, Exp. Date 07/31/2024; B1660288-042522, B1617673-032422, Exp. Date 06/30/2024; B1617737-032422, B1617744-032422, B1563407-021422, B1563498-021422, Exp. Date 05/31/2024; B1539158-012822, B1518050-011222, B1498175-122921, Exp. Date 04/30/2024; B1498194-122921, B1455889-112621, B1455918-112621, Exp. Date 03/31/2024; B1455901-112621, B1396346-101421, B1383216-100721, Exp. Date 01/31/2024; B1383214-100721, B1353451-091721, B1353463-091721, B1353480-091721, B1274069-071521, B1274079-071521, B1274052-071521, B1234313-061721, B1234339-061721, B1203592-052721, B1203608-052721, B1163740-042921, Exp. Date 09/30/2023; B1163745-042921, B1163747-042921, B1140139-040821, Exp. Date 05/31/2023.

**Product Description:**

Ketotifen Fumarate 0.025 %, Antihistamine eye drops, 5mL bottle, MFG: Akorn, Lake Forrest IL 60045, Repackaged by: RemedyRepack Inc., Indiana, PA 15701, NDC 70518-1142-00; Source NDC # 17477-0717-10;

**Product Quantity:**

12 5mL bottles

**Reason for Recall:**

CGMP Deviations: Discontinuation of the Quality program by manufacturer that would assure product meet the identity, strength, quality, and purity characteristics that they are purported or represented to possess.

**Recall Number:**

D-0577-2023

**Code Information:**

Lot # B1643789-041022, EXP 03/31/2024; B1894150-100722, B1891573-100622, EXP. 7/31/2024

**Product Description:**

Pyrazinamide, 500 mg Tablet, packaged in a) 29 x 30-count card, NDC # 70518-2534-01; b) 1 x 100 UD box, NDC # 70518-2534-00, MFG: Akorn, Lake Forest, IL 60045, Repackaged by : RemedyRepack Inc., PA 15701. Mfg NDC # 61748-0012-01

**Product Quantity:**

29 x 30-count card, 1 x 100 UD box

**Reason for Recall:**

CGMP Deviations: Discontinuation of the Quality program by manufacturer that would assure product meet the identity, strength, quality, and purity characteristics that they are purported or represented to possess.

**Recall Number:**

D-0578-2023

**Code Information:**

Lot: a) B2110254-021423, exp. date 08/17/2023; b) J0684183-022323, exp. date 02/28/2024;

## Class II Drugs Event

**Event ID:**

92292

**Product Type:**

Drugs

**Status:**

Ongoing

**Date Terminated:**

**Recall Initiation Date:**

05/09/2023

**Voluntary / Mandated:**

Voluntary: Firm initiated

**Center Classification Date:**

05/16/2023

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

Letter

**Recalling Firm:**

B. Braun Medical Inc  
2525 McGaw Ave  
Irvine CA United States

**Distribution Pattern:**

Nationwide in the USA

## Associated Products

**Product Description:**

Heparin Sodium, 25,000 USP units per 250mL, (100 USP units per mL) in 5% Dextrose injection, 250 ml Excel Container, B. Braun Medical Inc. Bethlehem, PA 18018, USA; API from Spain NDC: 0264-9587-20,

**Product Quantity:**

1,380

**Reason for Recall:**

Subpotent: Low anti-factor IIa Potency.

**Recall Number:**

D-0579-2023

**Code Information:**

Lot Number: J1P154N, Exp: 31 May, 2023,

## Class II Drugs Event

**Event ID:**

92320

**Product Type:**

Drugs

**Status:**

Ongoing

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

05/11/2023

**Voluntary / Mandated:**

Voluntary: Firm initiated

**Center Classification Date:**

05/15/2023

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

Letter

**Recalling Firm:**

Hikma Pharmaceuticals USA Inc.  
2 Esterbrook Ln  
Cherry Hill NJ United States

**Distribution Pattern:**

Nationwide in the USA and Puerto Rico

## Associated Products

**Product Description:**

Lorazepam Injection, USP, 2mg/mL, 1 mL vial (NDC 0641-6044-01), packaged in 25 x 1 mL Vials per carton (NDC 0641-6044-25), Rx only, Manufactured by West-Ward, Eatontown, NJ 07724.

**Product Quantity:**

1,352,475 vials

**Reason for Recall:**

Failed Impurities/Degradation Specifications: Out-of-specification results for total related compounds observed during retain steting due to the elevated Related Compound-C.

**Recall Number:**

D-0574-2023

**Code Information:**

Lots: 070086, 070128, Exp. 07/2023

## Class II Drugs Event

**Event ID:**

92341

**Status:**

Ongoing

**Recall Initiation Date:**

05/15/2023

**Center Classification Date:**

05/18/2023

**Recalling Firm:**

Astral SteriTech Private Ltd.  
911 G I D C Makarpura  
Vadodara India

**Distribution Pattern:**

Nationwide within the United States

**Product Type:**

Drugs

**Date Terminated:****Voluntary / Mandated:**

Voluntary: Firm initiated

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

Letter

## Associated Products

**Product Description:**

Ampicillin for Injection, USP 250 mg per vial, Rx only, Mfg. for: Piramal Critical Care, Bethlehem, PA 18017 USA, NDC 66794-220-41

**Product Quantity:**

70,040 vials

**Reason for Recall:**

Lack of Assurance of Sterility

**Recall Number:**

D-0580-2023

**Code Information:**

All lots within expiry.

**Product Description:**

Ampicillin for Injection, USP 500 mg per vial, Rx only, Mfg. for: Piramal Critical Care, Bethlehem, PA 18017 USA, NDC 66794-221-41

**Product Quantity:**

17,350 vials

**Reason for Recall:**

Lack of Assurance of Sterility

**Recall Number:**

D-0581-2023

**Code Information:**

All lots within expiry.

**Product Description:**

Ampicillin for Injection, USP 1g per vial, Rx only, Mfg. for: Piramal Critical Care, Bethlehem, PA 18017 USA, NDC 66794-222-41

**Product Quantity:**

89,690 vials

**Reason for Recall:**

Lack of Assurance of Sterility

**Recall Number:**

D-0582-2023

**Code Information:**

All lots within expiry.

**Product Description:**

Ampicillin for Injection, USP 2g per vial, Rx only, Mfg. for: Piramal Critical Care, Bethlehem, PA 18017 USA, NDC 66794-223-41

**Product Quantity:**

45,160 vials

**Reason for Recall:**

Lack of Assurance of Sterility

**Recall Number:**

D-0583-2023

**Code Information:**

All lots within expiry.

**Product Description:**

Ampicillin for Injection, USP 10 g per Pharmacy Bulk Package, Rx only, Mfg. for: Piramal Critical Care, Bethlehem, PA 18017 USA, NDC 66794-224-15

**Product Quantity:**

8,925 bottles

**Reason for Recall:**

Lack of Assurance of Sterility

**Recall Number:**

D-0584-2023

**Code Information:**

All lots within expiry.

**Product Description:**

Ampicillin for Injection, USP, 250 mg per vial, Rx only, Manufactured for: Xellia Pharmaceuticals USA, LLC, Buffalo Grove, IL 60089, NDC 70594-084-02

**Product Quantity:**

53,220 vials

**Reason for Recall:**

Lack of Assurance of Sterility

**Recall Number:**

D-0585-2023

**Code Information:**

All lots within expiry.

**Product Description:**

Ampicillin for Injection, USP 500 mg per vial, Rx only, Manufactured for: Xellia Pharmaceuticals USA, LLC, Buffalo Grove, IL 60089, NDC 70594-085-02

**Product Quantity:**

59,530 vials

**Reason for Recall:**

Lack of Assurance of Sterility

**Recall Number:**

D-0586-2023

**Code Information:**

All lots within expiry.

**Product Description:**

Ampicillin for Injection, USP 1g per vial, Rx only, Manufactured for: Xellia Pharmaceuticals USA, LLC, Buffalo Grove, IL 60089, NDC 70594-086-02

**Product Quantity:**

80,850 vials

**Reason for Recall:**

Lack of Assurance of Sterility

**Recall Number:**

D-0587-2023

**Code Information:**

All lots within expiry.

**Product Description:**

Ampicillin for Injection, USP 2 g per vial, Rx only, Manufactured for: Xellia Pharmaceuticals USA, LLC, Buffalo Grove, IL 60089, NDC 70594-087-02

**Product Quantity:**

220,340 vials

**Reason for Recall:**

Lack of Assurance of Sterility

**Recall Number:**

D-0588-2023

**Code Information:**

All lots within expiry.

**Product Description:**

Ampicillin for Injection, USP 10 grams per Pharmacy Bulk Package, Rx only, Manufactured for: Xellia Pharmaceuticals USA, LLC, Buffalo Grove, IL 60089, NDC 70594-088-01

**Product Quantity:**

7,214 bottles

**Reason for Recall:**

Lack of Assurance of Sterility

**Recall Number:**

D-0589-2023

**Code Information:**

All lots within expiry.

**Product Description:**

Ampicillin and Sulbactam for Injection, USP 1.5 gram per vial, Rx only, Manufactured for: Civica Inc. Lehi Utah 84043, NDC 72572-021-10

**Product Quantity:**

59,040 vials

**Reason for Recall:**

Lack of Assurance of Sterility

**Recall Number:**

D-0590-2023

**Code Information:**

All lots within expiry.

**Product Description:**

Ampicillin and Sulbactam for Injection, USP 3 gram per vial, Rx only, Manufactured for: Civica Inc. Lehi Utah 84043, NDC 72572-022-10

**Product Quantity:**

419,680 vials

**Reason for Recall:**

Lack of Assurance of Sterility

**Recall Number:**

D-0591-2023

**Code Information:**

All lots within expiry.

**Product Description:**

Ampicillin and Sulbactam for Injection, USP 1.5 grams per vial, Rx only, Mfd for Meitheal Pharmaceuticals Chicago, IL 60631, NDC 71288-005-20

**Product Quantity:**

236,610 vials

**Reason for Recall:**

Lack of Assurance of Sterility

**Recall Number:**

D-0592-2023

**Code Information:**

All lots within expiry.

**Product Description:**

Ampicillin and Sulbactam for Injection, USP 3 grams per vial, Rx only, Mfd for Meitheal Pharmaceuticals Chicago, IL 60631, NDC 71288-006-30

**Product Quantity:**

1,229,090 vials

**Reason for Recall:**

Lack of Assurance of Sterility

**Recall Number:**

D-0593-2023

**Code Information:**

All lots within expiry.

**Product Description:**

Ampicillin and Sulbactam for Injection, USP 15 grams per Pharmacy Bulk Package, Rx only, Mfd for Meitheal Pharmaceuticals Chicago, IL 60631, NDC 71288-007-75

**Product Quantity:**

35,087 bottles

**Reason for Recall:**

Lack of Assurance of Sterility

**Recall Number:**

D-0594-2023

**Code Information:**

All lots within expiry.

**Product Description:**

Ampicillin and Sulbactam for Injection, USP 1.5 grams per vial, Rx only, Mfg. for: Piramal Critical Care, Bethlehem, PA 18017 USA, NDC 66794-206-41

**Product Quantity:**

357,550 vials

**Reason for Recall:**

Lack of Assurance of Sterility

**Recall Number:**

D-0595-2023

**Code Information:**

All lots within expiry.

**Product Description:**

Ampicillin and Sulbactam for Injection, USP 1.5 grams per vial, Rx only, Mfg. for: Piramal Critical Care, Bethlehem, PA 18017 USA, NDC 66794-241-41

**Product Quantity:**

58,770 vials

**Reason for Recall:**

Lack of Assurance of Sterility

**Recall Number:**

D-0596-2023

**Code Information:**

All lots within expiry.

**Product Description:**

Ampicillin and Sulbactam for Injection, USP 3 grams per vial, Rx only, Mfg. for: Piramal Critical Care, Bethlehem, PA 18017 USA, NDC 66794-207-41

**Product Quantity:**

1,001,110 vials

**Reason for Recall:**

Lack of Assurance of Sterility

**Recall Number:**

D-0597-2023

**Code Information:**

All lots within expiry.

**Product Description:**

Ampicillin and Sulbactam for Injection, USP 15 grams per Pharmacy Bulk Package, Rx only, Mfg. for: Piramal Critical Care, Bethlehem, PA 18017 USA, NDC 66794-208-15

**Product Quantity:**

11,555 bottles

**Reason for Recall:**

Lack of Assurance of Sterility

**Recall Number:**

D-0598-2023

**Code Information:**

All lots within expiry.

**Product Description:**

Ampicillin and Sulbactam for Injection, USP 15 grams per Pharmacy Bulk Package, Rx only, Mfg. for: Piramal Critical Care, Bethlehem, PA 18017 USA, NDC 66794-243-15

**Product Quantity:**

6,127 bottles

**Reason for Recall:**

Lack of Assurance of Sterility

**Recall Number:**

D-0599-2023

**Code Information:**

All lots within expiry.

**Product Description:**

Ampicillin and Sulbactam for Injection, USP 3 grams vials, Rx only, Mfg. for: Piramal Critical Care, Bethlehem, PA 18017 USA, NDC 66794-242-41

**Product Quantity:**

91,860 vials

**Reason for Recall:**

Lack of Assurance of Sterility

**Recall Number:**

D-0600-2023

**Code Information:**

All lots within expiry.

**Product Description:**

Ampicillin and Sulbactam for Injection, USP 1.5 grams per vial, Rx only, Manufactured for: Xellia Pharmaceuticals USA, LLC, Buffalo Grove, IL



60089, NDC 70594-081-02

**Product Quantity:**

119,340 vials

**Reason for Recall:**

Lack of Assurance of Sterility

**Recall Number:**

D-0601-2023

**Code Information:**

All lots within expiry.

**Product Description:**

Ampicillin and Sulbactam for Injection, USP 3 grams per vial, Rx only, Manufactured for: Xellia Pharmaceuticals USA, LLC, Buffalo Grove, IL 60089, NDC 70594-082-02

**Product Quantity:**

591,160 vials

**Reason for Recall:**

Lack of Assurance of Sterility

**Recall Number:**

D-0602-2023

**Code Information:**

All lots within expiry.

**Product Description:**

Ampicillin and Sulbactam for Injection, USP 15 grams per Pharmacy Bulk Package, Rx only, Manufactured for: Xellia Pharmaceuticals USA, LLC, Buffalo Grove, IL 60089, NDC 70594-083-01

**Product Quantity:**

23,187 bottles

**Reason for Recall:**

Lack of Assurance of Sterility

**Recall Number:**

D-0603-2023

**Code Information:**

All lots within expiry.

**Product Description:**

Cefepime for Injection, USP 1 gram per vial, Rx only, Manufactured for: Civica Inc. Lehi Utah 84043, NDC 72572-057-10

**Product Quantity:**

101,550 vials

**Reason for Recall:**

Lack of Assurance of Sterility

**Recall Number:**

D-0604-2023

**Code Information:**

All lots within expiry.

**Product Description:**

Cefepime for Injection, USP 2 grams per vial, Rx only, Manufactured for: Civica Inc. Lehi Utah 84043, NDC 72572-058-10

**Product Quantity:**

124,010 vials

**Reason for Recall:**

Lack of Assurance of Sterility

**Recall Number:**

D-0605-2023

**Code Information:**

All lots within expiry.

**Product Description:**

Cefepime for Injection, USP 2 grams per vial, Rx only, Mfd. for Meitheal Pharmaceuticals Chicago, IL 60631, NDC 71288-009-20

**Product Quantity:**

107,320 vials

**Reason for Recall:**

Lack of Assurance of Sterility

**Recall Number:**

D-0606-2023

**Code Information:**

All lots within expiry.

**Product Description:**

Cefepime for Injection, USP 1 gram per vial, Rx only, Mfg. for: Piramal Critical Care Bethlehem, PA 18017 USA, NDC 66794-209-41

**Product Quantity:**

41,320 vials

**Reason for Recall:**

Lack of Assurance of Sterility

**Recall Number:**

D-0607-2023

**Code Information:**

All lots within expiry.

**Product Description:**

Cefepime for Injection, USP 2 grams per vial, Rx only, Mfg. for: Piramal Critical Care Bethlehem, PA 18017 USA, NDC 66794-210-41

**Product Quantity:**

51,280 vials

**Reason for Recall:**

Lack of Assurance of Sterility

**Recall Number:**

D-0608-2023

**Code Information:**

All lots within expiry.

**Product Description:**

Cefepime for Injection, USP 1 gram per vial, Manufactured for: Xellia Pharmaceuticals USA, LLC, Buffalo Grove, IL 60089, NDC 70594-089-02

**Product Quantity:**

550,160 vials

**Reason for Recall:**

Lack of Assurance of Sterility

**Recall Number:**

D-0609-2023

**Code Information:**

All lots within expiry.

**Product Description:**

Cefepime for Injection, USP 2 grams per vial, Rx only, Manufactured for: Xellia Pharmaceuticals USA, LLC, Buffalo Grove, IL 60089, NDC 70594-090-02

**Product Quantity:**

964,420 vials

**Reason for Recall:**

Lack of Assurance of Sterility

**Recall Number:**

D-0610-2023

**Code Information:**

All lots within expiry.

**Product Description:**

Ceftriaxone for Injection, USP 250 mg per vial, Rx only, Mfg. for: Piramal Critical Care, Bethlehem, PA 18017, NDC 66794-211-42

**Product Quantity:**

66,250 vials

**Reason for Recall:**

Lack of Assurance of Sterility

**Recall Number:**

D-0611-2023

**Code Information:**

All lots within expiry.

**Product Description:**

Ceftriaxone for Injection, USP 500 mg per vial, Rx only, Mfg. for: Piramal Critical Care, Bethlehem, PA 18017, NDC 66794-212-42

**Product Quantity:**

65,950 vials

**Reason for Recall:**

Lack of Assurance of Sterility

**Recall Number:**

D-0612-2023

**Code Information:**

All lots within expiry.

**Product Description:**

Ceftriaxone for Injection, USP 1 gram per vial, Rx only, Mfg. for: Piramal Critical Care, Bethlehem, PA 18017, NDC 66794-213-42

**Product Quantity:**

73,475 vials

**Reason for Recall:**

Lack of Assurance of Sterility

**Recall Number:**

D-0613-2023

**Code Information:**

All lots within expiry.

**Product Description:**

Ceftriaxone for Injection, USP 2 grams per vial, Rx only, Mfg. for: Piramal Critical Care, Bethlehem, PA 18017, NDC 66794-214-42

**Product Quantity:**

41,500 vials

**Reason for Recall:**

Lack of Assurance of Sterility

**Recall Number:**

D-0614-2023

**Code Information:**

All lots within expiry.

**Product Description:**

Ceftriaxone for Injection, USP 10 grams per Pharmacy Bulk Package, Mfg. for: Piramal Critical Care, Bethlehem, PA 18017, NDC 66794-215-15

**Product Quantity:**

9,040 bottles

**Reason for Recall:**

Lack of Assurance of Sterility

**Recall Number:**

D-0615-2023

**Code Information:**

All lots within expiry.

**Product Description:**

Ceftriaxone for Injection, USP 250 mg per vial, Rx only, Manufactured for: Xellia Pharmaceuticals USA, LLC, Buffalo Grove, IL 60089, NDC 70594-094-02

**Product Quantity:**

66,125 vials

**Reason for Recall:**

Lack of Assurance of Sterility

**Recall Number:**

D-0616-2023

**Code Information:**

All lots within expiry.

**Product Description:**

Ceftriaxone for Injection, USP 500 mg per vial, Rx only, Manufactured for: Xellia Pharmaceuticals USA, LLC, Buffalo Grove, IL 60089, NDC 70594-095-02

**Product Quantity:**

66,175 vials

**Reason for Recall:**

Lack of Assurance of Sterility

**Recall Number:**

D-0617-2023

**Code Information:**

All lots within expiry.

**Product Description:**

Ceftriaxone for Injection, USP, 1 grams per vial, Rx only, Manufactured for: Xellia Pharmaceuticals USA, LLC, Buffalo Grove, IL 60089, NDC 70594-096-02

**Product Quantity:**

739,750 vials

**Reason for Recall:**

Lack of Assurance of Sterility

**Recall Number:**

D-0618-2023

**Code Information:**

All lots within expiry.

**Product Description:**

Ceftriaxone for Injection, USP, 2 grams per vial, Rx only, Manufactured for: Xellia Pharmaceuticals USA, LLC, Buffalo Grove, IL 60089, NDC 70594-097-02

**Product Quantity:**

243,825 vials

**Reason for Recall:**

Lack of Assurance of Sterility

**Recall Number:**

D-0619-2023

**Code Information:**

All lots within expiry.

**Product Description:**

Ceftriaxone for Injection, USP 10 grams per Pharmacy Bulk Package, Rx only, Manufactured for: Xellia Pharmaceuticals USA, LLC, Buffalo Grove, IL 60089, NDC 70594-098-01

**Product Quantity:**

7,940 bottles

**Reason for Recall:**

Lack of Assurance of Sterility

**Recall Number:**

D-0620-2023

**Code Information:**

All lots within expiry.

**Product Description:**

Piperacillin and Tazobactam for Injection, USP, 3.375 grams per vial, Rx only, Manufactured for: Civica Inc. Lehi Utah 84043, NDC 72572-576-10

**Product Quantity:**

1,288,510 vials

**Reason for Recall:**

Lack of Assurance of Sterility

**Recall Number:**

D-0621-2023

**Code Information:**

All lots within expiry.

**Product Description:**

Piperacillin and Tazobactam for Injection, USP, 4.5 grams per vial, Rx only, Manufactured for: Civica Inc. Lehi Utah 84043, NDC 72572-577-10

**Product Quantity:**

204,860 vials

**Reason for Recall:**

Lack of Assurance of Sterility

**Recall Number:**

D-0622-2023

**Code Information:**

All lots within expiry.

**Product Description:**

Piperacillin and Tazobactam for Injection, USP, 2.25 grams per vial, Rx only, Mfd for Meitheal Pharmaceuticals Chicago, IL 60631, NDC 71288-002-31

**Product Quantity:**

110,660 vials

**Reason for Recall:**

Lack of Assurance of Sterility

**Recall Number:**

D-0623-2023

**Code Information:**

All lots within expiry.

**Product Description:**

Piperacillin and Tazobactam for Injection, USP 3.375 grams per vial, Rx only, Mfd for Meitheal Pharmaceuticals Chicago, IL 60631, NDC 71288-003-31

**Product Quantity:**

893,950 vials

**Reason for Recall:**

Lack of Assurance of Sterility

**Recall Number:**

D-0624-2023

**Code Information:**

All lots within expiry.

**Product Description:**

Piperacillin and Tazobactam for Injection, USP 4.5 grams per vial, Rx only, Mfd for Meitheal Pharmaceuticals Chicago, IL 60631, NDC 71288-004-51

**Product Quantity:**

249,080 vials

**Reason for Recall:**

Lack of Assurance of Sterility

**Recall Number:**

D-0625-2023

**Code Information:**

All lots within expiry.

**Product Description:**

Piperacillin and Tazobactam for Injection, USP, 2.25 grams per vial, Rx only, Mfg. for: Piramal Critical Care, Bethlehem, PA 18017, NDC66794-216-41

**Product Quantity:**

112,640 vials

**Reason for Recall:**

Lack of Assurance of Sterility

**Recall Number:**

D-0626-2023

**Code Information:**

All lots within expiry.

**Product Description:**

Piperacillin and Tazobactam for Injection, USP, 3.375 grams per vial, Rx only, Mfg. for: Piramal Critical Care, Bethlehem, PA 18017, NDC 66794-217-41

**Product Quantity:**

223,590 vials

**Reason for Recall:**

Lack of Assurance of Sterility

**Recall Number:**

D-0627-2023

**Code Information:**

All lots within expiry.

**Product Description:**

Piperacillin and Tazobactam for Injection, USP, 4.5 grams per vial, Rx only, Mfg. for: Piramal Critical Care, Bethlehem, PA 18017, NDC 66794-218-41

**Product Quantity:**

138,610 vials

**Reason for Recall:**

Lack of Assurance of Sterility

**Recall Number:**

D-0628-2023

**Code Information:**

All lots within expiry.

**Product Description:**

Piperacillin and Tazobactam for Injection, USP 2.25 g per vial,s Rx only, Manufactured for: Xellia Pharmaceuticals USA, LLC, Buffalo Grove, IL 60089, NDC 70594-078-02

**Product Quantity:**

169,520 Vials

**Reason for Recall:**

Lack of Assurance of Sterility

**Recall Number:**

D-0629-2023

**Code Information:**

All lots within expiry.

**Product Description:**

Piperacillin and Tazobactam for Injection, UPS, 3.375 grams per vial, Rx only, Manufactured for: Xellia Pharmaceuticals USA, LLC, Buffalo Grove, IL 60089, NDC 70594-079-02

**Product Quantity:**

936,680 vials

**Reason for Recall:**

Lack of Assurance of Sterility

**Recall Number:**

D-0630-2023

**Code Information:**

All lots within expiry.

**Product Description:**

Piperacillin and Tazobactam for Injection, USP, 4.5 grams per vial, Rx only, Manufactured for: Xellia Pharmaceuticals USA, LLC, Buffalo Grove, IL 60089, NDC 70594-080-02

**Product Quantity:**

393,930 vials

**Reason for Recall:**

Lack of Assurance of Sterility

**Recall Number:**

D-0631-2023

**Code Information:**

All lots within expiry.

## Class II Drugs Event

**Event ID:**

92348

**Status:**

Ongoing

**Recall Initiation Date:**

05/02/2023

**Center Classification Date:**

05/18/2023

**Recalling Firm:**

Apollo Care, LLC  
3801 Mojave Ct Ste 101  
Columbia MO United States

**Product Type:**

Drugs

**Date Terminated:****Voluntary / Mandated:**

Voluntary: Firm initiated

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

Letter

**Distribution Pattern:**

Missouri only

## Associated Products

**Product Description:**

PHENYLEphrine HCl Injection, 1 mg per 10 mL (100 mcg/mL), Single-Use Syringe, Solution for IV Use Only. Apollo Care, LLC, 3801 Mojave Ct., Suite 101, Columbia, MO 65202. NDC: 71170-010-10

**Product Quantity:**

2265 syringes

**Reason for Recall:**

Lack of Assurance of Sterility

**Recall Number:**

D-0632-2023

**Code Information:**

Lot #: AC-016606, Exp. Date 05/06/2023; AC-016636, Exp. Date 07/09/2023; AC-016643, Exp. Date 07/31/2023

**Product Description:**

Succinylcholine Cl Injection, 100 mg per 5 mL (20 mg/mL), Single-Use Syringe, Rx only, Apollo Care, LLC, 3801 Mojave Ct., Suite 101, Columbia, MO 65202. NDC 71170-020-05

**Product Quantity:**

90 syringes

**Reason for Recall:**

Lack of Assurance of Sterility

**Recall Number:**

D-0633-2023

**Code Information:**

Lot #: AC-016607, Exp. Date 05/09/2023

**Product Description:**

FentaNYL 50 mcg/mL (2,500mcg Total Dose), 50 mL Syringe, Rx Only, Apollo Care, LLC, 3801 Mojave Ct., Suite 101, Columbia, MO 65202. NDC 71170-910-25

**Product Quantity:**

790 syringes

**Reason for Recall:**

Lack of Assurance of Sterility

**Recall Number:**

D-0634-2023

**Code Information:**

Lot #: AC-016624, Exp. Date 06/10/2023

**Product Description:**

Ketamine Injection, 50 mg per 5 mL (10 mg/mL), Single-Use Syringe, Rx only, Apollo Care, LLC, 3801 Mojave Ct., Suite 101, Columbia, MO 65202. NDC 71170-050-05

**Product Quantity:**

2040 syringes

**Reason for Recall:**

Lack of Assurance of Sterility

**Recall Number:**

D-0635-2023

**Code Information:**

Lot #: AC-016627, Exp. Date 06/17/2023; AC-016635, Exp. Date 07/08/2023; AC-016662, Exp. Date 09/30/2023

**Product Description:**

VANComycin 1.5g added to 500 mL of 0.9% Sodium Chloride Injection, Rx only, Apollo Care, LLC, 3801 Mojave Ct., Suite 101, Columbia, MO



65202. NDC 71170-185-50

**Product Quantity:**

2040 bags

**Reason for Recall:**

Lack of Assurance of Sterility

**Recall Number:**

D-0636-2023

**Code Information:**

Lot#: AC-016629, Exp. Date 05/13/2023; AC-016646, Exp. Date 06/24/2023

**Product Description:**

Norepinephrine 8 mg added to 250 mL 0.9% Sodium Chloride Injection, Rx Only, Apollo Care, LLC, 3801 Mojave Ct., Suite 101, Columbia, MO  
65202. NDC 71170-550-25

**Product Quantity:**

1617 bags

**Reason for Recall:**

Lack of Assurance of Sterility

**Recall Number:**

D-0637-2023

**Code Information:**

Lot#: AC-016631, Exp. Date 05/29/2023; AC-016655, Exp. Date 08/07/2023

**Product Description:**

VANComycin 1.25g added to 250 mL of 0.9% Sodium Chloride Injection, Rx Only, Apollo Care, LLC, 3801 Mojave Ct., Suite 101, Columbia, MO  
65202. NDC 71170-284-25

**Product Quantity:**

1113 bags

**Reason for Recall:**

Lack of Assurance of Sterility

**Recall Number:**

D-0638-2023

**Code Information:**

Lot #: AC-016647, Exp. Date 06/28/2023

**Product Description:**

VANComycin 1.25g added to 250 mL of 0.9% Sodium Chloride Injection, Rx Only, Apollo Care, LLC, 3801 Mojave Ct., Suite 101, Columbia, MO  
65202. NDC 71170-264-25

**Product Quantity:**

1113 bags

**Reason for Recall:**

Lack of Assurance of Sterility

**Recall Number:**

D-0639-2023

**Code Information:**

Lot #: AC-016647, Exp. Date 06/28/2023

**Product Description:**

VANComycin 1 g added to 250 mL of 0.9% Sodium Chloride Injection, Rx Only, Apollo Care, LLC, 3801 Mojave Ct., Suite 101, Columbia, MO  
65202. NDC 71170-254-25

**Product Quantity:**

1622 bags

**Reason for Recall:**

Lack of Assurance of Sterility

**Recall Number:**

D-0640-2023

**Code Information:**

Lot #: AC-016641, Exp. Date 06/03/2023; AC-016653 Exp. Date 07/26/2023

**Product Description:**

VANComycin 1.75 g added to 500 mL of 0.9% Sodium Chloride Injection, Rx Only, Apollo Care, LLC, 3801 Mojave Ct., Suite 101, Columbia, MO 65202. NDC 71170-194-50

**Product Quantity:**

240 bags

**Reason for Recall:**

Lack of Assurance of Sterility

**Recall Number:**

D-0641-2023

**Code Information:**

Lot #: AC-016648, Exp. Date 07/01/2023

**Product Description:**

VANComycin 2g added to 500 mL of 0.9% Sodium Chloride Injection, Rx Only. Apollo Care, LLC, 3801 Mojave Ct., Suite 101, Columbia, MO 65202. NDC 71170-204-50

**Product Quantity:**

413 bags

**Reason for Recall:**

Lack of Assurance of Sterility

**Recall Number:**

D-0642-2023

**Code Information:**

Lot #: AC-016638, Exp. Date 05/27/2023

**Product Description:**

VANComycin 2.5 g added to 500 mL of 0.9% Sodium Chloride Injection, Rx Only, Apollo Care, LLC, 3801 Mojave Ct., Suite 101, Columbia, MO 65202. NDC 71170-224-50

**Product Quantity:**

54 bags

**Reason for Recall:**

Lack of Assurance of Sterility

**Recall Number:**

D-0643-2023

**Code Information:**

Lot #: AC-016649, Exp. Date 07/01/2023

**Product Description:**

Norepinephrine 4 mg added to 250 mL of 5% Dextrose Injection, Rx Only, Apollo Care, LLC, 3801 Mojave Ct., Suite 101, Columbia, MO 65202. NDC 71170-500-25

**Product Quantity:**

682 bags

**Reason for Recall:**

Lack of Assurance of Sterility

**Recall Number:**

D-0644-2023

**Code Information:**

Lot #: AC-016640, Exp. Date 06/16/2023; AC-016670, Exp. Date 08/29/2023

**Product Description:**

VANComycin 750mg added to 250 mL of 0.9% Sodium Chloride Injection, Rx Only, Apollo Care, LLC, 3801 Mojave Ct., Suite 101, Columbia, MO

65202. NDC 71170-255-25

**Product Quantity:**

491 bags

**Reason for Recall:**

Lack of Assurance of Sterility

**Recall Number:**

D-0645-2023

**Code Information:**

Lot #: AC-016632, Exp. Date 05/24/2023

**Product Description:**

FentaNYL 500 mcg (2mcg/mL) and Ropivacaine HCL 250 mg (0.1%) added to 250 mL 0.9% Sodium Chloride Injection, Rx Only, Apollo Care, LLC, 3801 Mojave Ct., Suite 101, Columbia, MO 65202. NDC 71170-950-25

**Product Quantity:**

308 bags

**Reason for Recall:**

Lack of Assurance of Sterility

**Recall Number:**

D-0646-2023

**Code Information:**

Lot #: AC-016644, Exp. Date 05/08/2023; AC-016659, Exp. Date 09/26/2023

**Product Description:**

VANComycin 1.5g added to 250 mL of 0.9% Sodium Chloride Injection, Rx only, Apollo Care, LLC, 3801 Mojave Ct., Suite 101, Columbia, MO 65202. NDC 71170-184-25

**Product Quantity:**

646 bags

**Reason for Recall:**

Lack of Assurance of Sterility

**Recall Number:**

D-0647-2023

**Code Information:**

Lot #: AC-016633, Exp. Date 05/24/2023; AC-016651, Exp. Date 07/22/2023