

Enforcement Report - Week of August 14, 2019

Class II Drugs Event

Event ID:

83074

Product Type:

Drugs

Status:

Ongoing

Date Terminated:**Recall Initiation Date:**

06/19/2019

Voluntary / Mandated:

Voluntary: Firm initiated

Center Classification Date:

08/08/2019

Initial Firm Notification of Consignee or Public:

Press Release

Recalling Firm:

RXQ Compounding LLC

340 W State St Unit 9

Athens OH United States

Distribution Pattern:

Nationwide USA

Associated Products

Product Description:

Ascorbic Acid 500 MG/ML (Non-Corn) Injection (PFV), 50 mL per vial, RXQ Compounding, 340 West State Street, Unit 9, Athens, OH 45701. NDC: 70731-0173-10

Product Quantity:**Reason for Recall:**

Crystallization

Recall Number:

D-1634-2019

Code Information:

All lots within expiry

Product Description:

Ascorbic Acid 400 MG/ML (Non-Corn) Injection Solution, 65 mL per vial, RXQ Compounding, 340 West State Street, Unit 9, Athens, OH 45701. NDC: 70731-0914-65

Product Quantity:**Reason for Recall:**

Crystallization

Recall Number:

D-1635-2019

Code Information:

All lots within expiry

Product Description:

Ascorbic Acid 500 MG/ML (Non-Corn) INJ (MDV), 50 mL per vial, RXQ Compounding, 340 West State Street, Unit 9, Athens, OH 45701. NDC: 70731-0975-50

Product Quantity:**Reason for Recall:**

Crystallization

Recall Number:

D-1636-2019

Code Information:

All lots within expiry

Product Description:

Avastin, 25MG/ML Syringe, [a) 0.1 mL NDC 70731-0197-91; b) 0.12 mL NDC 70731-0197-92; c) 0.15 mL NDC 70731-0197-93] per vial, RXQ Compounding, 340 West State Street, Unit 9, Athens, OH 45701.

Product Quantity:**Reason for Recall:**

Lack of Assurance of Sterility

Recall Number:

D-1637-2019

Code Information:

All lots within expiry

Product Description:

BUFFERED LIDOCAINE 1%+EPI 1:100,000 INJ SOL, [3ML NDC: 70731-0137-03 and 30ML NDC: 70731-0137-30] per syringe, RXQ Compounding, 340 West State Street, Unit 9, Athens, OH 45701. NDC: 70731-0137-03

Product Quantity:**Reason for Recall:**

Lack of Assurance of Sterility

Recall Number:

D-1638-2019

Code Information:

All lots within expiry

Product Description:

BUFFERED LIDOCAINE HCL 1% INJECTION SOLUTION (PF), 10ML per vial, RXQ Compounding, 340 West State Street, Unit 9, Athens, OH 45701. NDC: 70731-0139-10

Product Quantity:**Reason for Recall:**

Lack of Assurance of Sterility

Recall Number:

D-1639-2019

Code Information:

All lots within expiry

Product Description:

BUFFERED LIDOCAINE HCL 1% INJECTION SOL (PF) SYR, 0.5 ML per vial, RXQ Compounding, 340 West State Street, Unit 9, Athens, OH 45701. NDC: 70731-0139-84

Product Quantity:**Reason for Recall:**

Lack of Assurance of Sterility

Recall Number:

D-1640-2019

Code Information:

All lots within expiry

Product Description:

CALCIUM CHLORIDE 100MG/ML (PFV) INJ SOLN, 10 ML per vial, RXQ Compounding, 340 West State Street, Unit 9, Athens, OH 45701. NDC: 70731-0920-10

Product Quantity:**Reason for Recall:**

Lack of Assurance of Sterility

Recall Number:

D-1641-2019

Code Information:

All lots within expiry

Product Description:

CALCIUM GLUCONATE 5% INJECTION SOLUTION (MDV), 20 ML per vial, RXQ Compounding, 340 West State Street, Unit 9, Athens, OH 45701. NDC: 70731-0903-20

Product Quantity:**Reason for Recall:**

Lack of Assurance of Sterility

Recall Number:

D-1642-2019

Code Information:

All lots within expiry

Product Description:

Copper 0.4MG/ML (PVF) INJECTION SOLUTION, 10 ML per vial, RXQ Compounding, 340 West State Street, Unit 9, Athens, OH 45701. NDC: 70731-0925-10

Product Quantity:**Reason for Recall:**

Lack of Assurance of Sterility

Recall Number:

D-1643-2019

Code Information:

All lots within expiry

Product Description:

CYANCOBALAMIN 1200MCG/ML MDV INJECTION, 30 ML per vial, RXQ Compounding, 340 West State Street, Unit 9, Athens, OH 45701. NDC: 70731-0946-30

Product Quantity:**Reason for Recall:**

Lack of Assurance of Sterility

Recall Number:

D-1644-2019

Code Information:

All lots within expiry

Product Description:

DEXPANTHENOL 250MG/ML (MDV) INJECTION SOLN, 30ML per vial, RXQ Compounding, 340 West State Street, Unit 9, Athens, OH 45701. NDC: 70731-0932-30

Product Quantity:**Reason for Recall:**

Lack of Assurance of Sterility

Recall Number:

D-1645-2019

Code Information:

All lots within expiry

Product Description:

DEXTROSE 50% INJECTION SOLUTION (PF) SYRINGE, 50 ML per syringe, RXQ Compounding, 340 West State Street, Unit 9, Athens, OH 45701. NDC: 70731-0969-89

Product Quantity:**Reason for Recall:**

Lack of Assurance of Sterility

Recall Number:

D-1646-2019

Code Information:

All lots within expiry

Product Description:

DEXTROSE 50% INJECTION SOLUTION (PF) VIAL, 50 ML per vial, RXQ Compounding, 340 West State Street, Unit 9, Athens, OH 45701. NDC: 70731-0969-89

Product Quantity:**Reason for Recall:**

Lack of Assurance of Sterility

Recall Number:

D-1647-2019

Code Information:

All lots within expiry

Product Description:

diazepam 5 MG/ML INJECTION SOLUTION (C-IV) SYR, 2 ML per syringe, RXQ Compounding, 340 West State Street, Unit 9, Athens, OH 45701. NDC: 70731-0929-02

Product Quantity:**Reason for Recall:**

Lack of Assurance of Sterility

Recall Number:

D-1648-2019

Code Information:

All lots within expiry

Product Description:

DIMERCAPTO-PROPANESULFONIC 5% (DMPS) (PFV) INJ SOL, 5 ML per vial, RXQ Compounding, 340 West State Street, Unit 9, Athens, OH 45701. NDC: 70731-0904-05

Product Quantity:**Reason for Recall:**

Lack of Assurance of Sterility

Recall Number:

D-1649-2019

Code Information:

All lots within expiry

Product Description:

EDETATE CALCIUM DISODIUM 150MG/ML INJECTABLE, 100 ML per vial, RXQ Compounding, 340 West State Street, Unit 9, Athens, OH 45701. NDC: 70731-0934-11

Product Quantity:**Reason for Recall:**

Lack of Assurance of Sterility

Recall Number:

D-1650-2019

Code Information:

All lots within expiry

Product Description:

EDETATE DISODIUM 30% INJECTABLE, 100 ML per vial, RXQ Compounding, 340 West State Street, Unit 9, Athens, OH 45701. NDC: 70731-0931-11

Product Quantity:**Reason for Recall:**

Lack of Assurance of Sterility

Recall Number:

D-1651-2019

Code Information:

All lots within expiry

Product Description:

EDETATE DISODIUM 15% INJECTABLE, 30 ML per vial, RXQ Compounding, 340 West State Street, Unit 9, Athens, OH 45701. NDC: 70731-0922-30

Product Quantity:**Reason for Recall:**

Lack of Assurance of Sterility

Recall Number:

D-1652-2019

Code Information:

All lots within expiry

Product Description:

EDETATE DISODIUM 15% INJECTABLE, 100 ML per vial, RXQ Compounding, 340 West State Street, Unit 9, Athens, OH 45701. NDC: 70731-0922-11

Product Quantity:**Reason for Recall:**

Lack of Assurance of Sterility

Recall Number:

D-1653-2019

Code Information:

All lots within expiry

Product Description:

Edetate Disodium 150mg/mL PFV, 10 ML per Vial, RXQ Compounding, 340 West State Street, Unit 9, Athens, OH 45701. NDC 70731-0934-11

Product Quantity:**Reason for Recall:**

Lack of Assurance of Sterility

Recall Number:

D-1654-2019

Code Information:

All lots within expiry

Product Description:

EPHEDRINE 5MG/ML (PF) SYRINGE, 5 ML per syringe, RXQ Compounding, 340 West State Street, Unit 9, Athens, OH 45701. NDC: 70731-0201-85

Product Quantity:**Reason for Recall:**

Lack of Assurance of Sterility

Recall Number:

D-1655-2019

Code Information:

All lots within expiry

Product Description:

EPINEPHrine 4MG ADDED TO D5W 5%, 250 ML per bag, RXQ Compounding, 340 West State Street, Unit 9, Athens, OH 45701. NDC: 70731-0113-22

Product Quantity:**Reason for Recall:**

Lack of Assurance of Sterility

Recall Number:

D-1656-2019

Code Information:

All lots within expiry

Product Description:

EPINEPHrine 1:1000 INJECTION SOLUTION (PF) Syringe, 1 ML per syringe, RXQ Compounding, 340 West State Street, Unit 9, Athens, OH 45701. NDC: 70731-0947-01

Product Quantity:**Reason for Recall:**

Lack of Assurance of Sterility

Recall Number:

D-1657-2019

Code Information:

All lots within expiry

Product Description:

fentaNYL 0.05MG/ML INJ SOL (PF), 55ML per syringe (C-II) RXQ Compounding, 340 West State Street, Unit 9, Athens, OH 45701. NDC: 70731-0118-55

Product Quantity:**Reason for Recall:**

Lack of Assurance of Sterility

Recall Number:

D-1658-2019

Code Information:

All lots within expiry

Product Description:

FENTANYL 2MCG/ML BUPIVACAINE 0.125% IN NACL 0.9% SRY C-II, 50ML per syringe (C-II) RXQ Compounding, 340 West State Street, Unit 9, Athens, OH 45701. NDC: 70731-0207-89

Product Quantity:**Reason for Recall:**

Lack of Assurance of Sterility

Recall Number:

D-1659-2019

Code Information:

All lots within expiry

Product Description:

FOLIC ACID 10MG/ML INJECTION SOLUTION (MDV), 5 ML per vial, RXQ Compounding, 340 West State Street, Unit 9, Athens, OH 45701. NDC: 70731-0921-05

Product Quantity:**Reason for Recall:**

Lack of Assurance of Sterility

Recall Number:

D-1660-2019

Code Information:

All lots within expiry

Product Description:

FOLIC ACID 5MG/ML INJECTION SOLUTION (MDV), 10 ML per vial, RXQ Compounding, 340 West State Street, Unit 9, Athens, OH 45701. NDC: 70731-0924-10

Product Quantity:**Reason for Recall:**

Lack of Assurance of Sterility

Recall Number:

D-1661-2019

Code Information:

All lots within expiry

Product Description:

GLUTATHIONE 200MG/ML (PFV) INJECTION SOLN, 10 ML per vial, RXQ Compounding, 340 West State Street, Unit 9, Athens, OH 45701. NDC: 70731-0971-81

Product Quantity:**Reason for Recall:**

Lack of Assurance of Sterility

Recall Number:

D-1662-2019

Code Information:

All lots within expiry

Product Description:

GLUTATHIONE 200MG/ML (MDV) INJECTION SOLN, 30 ML per vial, RXQ Compounding, 340 West State Street, Unit 9, Athens, OH 45701. NDC: 70731-0906-30

Product Quantity:**Reason for Recall:**

Lack of Assurance of Sterility

Recall Number:

D-1663-2019

Code Information:

All lots within expiry

Product Description:

HYDROGEN PEROXIDE 3% INJECTABLE PFV, 30 ML per vial, RXQ Compounding, 340 West State Street, Unit 9, Athens, OH 45701. NDC: 70731-0907-30

Product Quantity:**Reason for Recall:**

Lack of Assurance of Sterility

Recall Number:

D-1664-2019

Code Information:

All lots within expiry

Product Description:

HYDROMORPHONE 0.2MG/ML IN NACL 0.9% SYR (C-II) , [a] 50 ML NDC 70731-0114-89; b) 55 ML NDC 70731-0114-95] per syringe, RXQ Compounding, 340 West State Street, Unit 9, Athens, OH 45701.

Product Quantity:**Reason for Recall:**

Lack of Assurance of Sterility

Recall Number:

D-1665-2019

Code Information:

All lots within expiry

Product Description:

HYDROXOCOBALAMIN 1000 MCG/ML (PFV), 10 ML per vial, RXQ Compounding, 340 West State Street, Unit 9, Athens, OH 45701. NDC: 70731-0949-10

Product Quantity:**Reason for Recall:**

Lack of Assurance of Sterility

Recall Number:

D-1666-2019

Code Information:

All lots within expiry

Product Description:

HYDROXOCOBALAMIN 1000 MCG/ML (MDV), 30 ML per vial, RXQ Compounding, 340 West State Street, Unit 9, Athens, OH 45701. NDC: 70731-0926-30

Product Quantity:**Reason for Recall:**

Lack of Assurance of Sterility

Recall Number:

D-1667-2019

Code Information:

All lots within expiry

Product Description:

Inositol/Choline B12:B6, 50/50/1/0.175 MG/ML INJ SOLN(Sulfa Free Lipostat), 30 ML per vial, RXQ Compounding, 340 West State Street, Unit 9, Athens, OH 45701. NDC: 70731-0999-30

Product Quantity:**Reason for Recall:**

Lack of Assurance of Sterility

Recall Number:

D-1668-2019

Code Information:

All lots within expiry

Product Description:

KETAMINE 50 MG/ML (NPV) INJECTION SOLUTION (C-III), 10 ML per vial, RXQ Compounding, 340 West State Street, Unit 9, Athens, OH 45701. NDC: 70731-0173-10

Product Quantity:**Reason for Recall:**

Lack of Assurance of Sterility

Recall Number:

D-1669-2019

Code Information:

All lots within expiry

Product Description:

KETAMINE 10 MG/ML INJ SOL SYR (C-III), [a] 2 ML NDC: 70731-0132-02; b) 5 ML NDC: 70731-0132-05] per syringe, RXQ Compounding, 340 West State Street, Unit 9, Athens, OH 45701.

Product Quantity:**Reason for Recall:**

Lack of Assurance of Sterility

Recall Number:

D-1670-2019

Code Information:

All lots within expiry

Product Description:

LIDOCAINE HCL 1% INJECTION SOLUTION (NPV), 20ML per vial, RXQ Compounding, 340 West State Street, Unit 9, Athens, OH 45701. NDC: 70731-0174-20

Product Quantity:

Reason for Recall:

Lack of Assurance of Sterility

Recall Number:

D-1671-2019

Code Information:

All lots within expiry

Product Description:

LIDOCAINE HCL 2% INJECTION SOLUTION (NPV), 20ML per vial, RXQ Compounding, 340 West State Street, Unit 9, Athens, OH 45701. NDC: 70731-0172-20

Product Quantity:**Reason for Recall:**

Lack of Assurance of Sterility

Recall Number:

D-1672-2019

Code Information:

All lots within expiry

Product Description:

MAGNESIUM 200 MG/ML/ CALCIUM GLUC 6MG/ML/ ZINC 1MG/ML, 5ML per vial, RXQ Compounding, 340 West State Street, Unit 9, Athens, OH 45701. NDC: 70731-0176-05

Product Quantity:**Reason for Recall:**

Lack of Assurance of Sterility

Recall Number:

D-1673-2019

Code Information:

All lots within expiry

Product Description:

MAGNESIUM CHLORIDE HEXAHYDRATE (MDV) 20% INJ SOLN, 50 ML per vial, RXQ Compounding, 340 West State Street, Unit 9, Athens, OH 45701. NDC: 70731-0977-50

Product Quantity:**Reason for Recall:**

Lack of Assurance of Sterility

Recall Number:

D-1674-2019

Code Information:

All lots within expiry

Product Description:

MAGNESIUM CHLORIDE HEXAHYDRATE (PFV) 20% INJ SOLN, 50 ML per vial, RXQ Compounding, 340 West State Street, Unit 9, Athens, OH 45701. NDC: 70731-0951-50

Product Quantity:**Reason for Recall:**

Lack of Assurance of Sterility

Recall Number:

D-1675-2019

Code Information:

All lots within expiry

Product Description:

MANGANESE SULFATE MONOHYDRATE (PFV) 0.1MG/ML INJ, 10 ML per syringe, RXQ Compounding, 340 West State Street, Unit 9, Athens, OH 45701. NDC: 70731-0952-10

Product Quantity:

Reason for Recall:

Lack of Assurance of Sterility

Recall Number:

D-1676-2019

Code Information:

All lots within expiry

Product Description:

METHYLCOBALAMIN 10MG/ML INJECTABLE SOLUTION (MDV), 10 ML per vial, RXQ Compounding, 340 West State Street, Unit 9, Athens, OH 45701. NDC: 70731-0130-10

Product Quantity:**Reason for Recall:**

Lack of Assurance of Sterility

Recall Number:

D-1677-2019

Code Information:

All lots within expiry

Product Description:

METHYLCOBALAMIN 1 MG/ML (MDV) INJECTABLE SOLUTION, 10 ML per vial, RXQ Compounding, 340 West State Street, Unit 9, Athens, OH 45701. NDC: 70731-0915-10

Product Quantity:**Reason for Recall:**

Lack of Assurance of Sterility

Recall Number:

D-1678-2019

Code Information:

All lots within expiry

Product Description:

METHYLCOBALAMIN (PFV) 10 MG/ML INJECTABLE, 10 ML per vial, RXQ Compounding, 340 West State Street, Unit 9, Athens, OH 45701. NDC: 70731-0902-10

Product Quantity:**Reason for Recall:**

Lack of Assurance of Sterility

Recall Number:

D-1679-2019

Code Information:

All lots within expiry

Product Description:

MIC (METHIONINE/INOSITOL/CHOLINE CHLORIDE) 25/50/50 MG/ML INJ, 30 ML per vial, RXQ Compounding, 340 West State Street, Unit 9, Athens, OH 45701. NDC: 70731-0100-30

Product Quantity:**Reason for Recall:**

Lack of Assurance of Sterility

Recall Number:

D-1680-2019

Code Information:

All lots within expiry

Product Description:

MIC B12 W/B6 (LIPOSTAT PLUS) 25/50/50/1/.175 MG/ML, 30 ML per vial, RXQ Compounding, 340 West State Street, Unit 9, Athens, OH 45701. NDC: 70731-0978-30

Product Quantity:

Reason for Recall:

Lack of Assurance of Sterility

Recall Number:

D-1681-2019

Code Information:

All lots within expiry

Product Description:

MIDAZOLAM 1MG/ML IN NACL 0.9% INJ SOL SYR (C-IV), 10 ML per syringe, RXQ Compounding, 340 West State Street, Unit 9, Athens, OH 45701. NDC: 70731-0135-86

Product Quantity:**Reason for Recall:**

Lack of Assurance of Sterility

Recall Number:

D-1682-2019

Code Information:

All lots within expiry

Product Description:

MIDAZOLAM 1MG/ML IN NACL 0.9% INJ SYR C-IV, 55 ML per syringe, RXQ Compounding, 340 West State Street, Unit 9, Athens, OH 45701. NDC: 70731-0135-55

Product Quantity:**Reason for Recall:**

Lack of Assurance of Sterility

Recall Number:

D-1683-2019

Code Information:

All lots within expiry

Product Description:

MITOMYCIN 0.04% (PF) OPH SOLN, 1ML per syringe, RXQ Compounding, 340 West State Street, Unit 9, Athens, OH 45701. NDC: 70731-0917-01

Product Quantity:**Reason for Recall:**

Lack of Assurance of Sterility

Recall Number:

D-1684-2019

Code Information:

All lots within expiry

Product Description:

MOLYBDENUM 0.025MG/ML INJECTION SOLUTION, 10ML per vial, RXQ Compounding, 340 West State Street, Unit 9, Athens, OH 45701. NDC: 70731-0964-10

Product Quantity:**Reason for Recall:**

Lack of Assurance of Sterility

Recall Number:

D-1685-2019

Code Information:

All lots within expiry

Product Description:

MORPHINE 1MG/ML IN NACL 0.9% 55ML SYR (C-II), 55 ML per vial, RXQ Compounding, 340 West State Street, Unit 9, Athens, OH 45701. NDC: 70731-0138-89

Product Quantity:**Reason for Recall:**

Lack of Assurance of Sterility

Recall Number:

D-1686-2019

Code Information:

All lots within expiry

Product Description:MOXIFLOXACIN 0.5% OPTH SOLUTION SYRINGE, 1 ML per syringe, RXQ Compounding, 340 West State Street, Unit 9, Athens, OH 45701.
NDC: 70731-0973-81**Product Quantity:****Reason for Recall:**

Lack of Assurance of Sterility

Recall Number:

D-1687-2019

Code Information:

All lots within expiry

Product Description:

NEOSTIGMINE METHYL SULFATE 1MG/ML INJ SOL SYR, 5 ML per syringe, RXQ Compounding, 340 West State Street, Unit 9, Athens, OH 45701. NDC: 70731-0143-05

Product Quantity:**Reason for Recall:**

Lack of Assurance of Sterility

Recall Number:

D-1688-2019

Code Information:

All lots within expiry

Product Description:

NIACINAMIDE 100MG/ML, 10ML per vial, RXQ Compounding, 340 West State Street, Unit 9, Athens, OH 45701. NDC: 70731-0938-10

Product Quantity:**Reason for Recall:**

Lack of Assurance of Sterility

Recall Number:

D-1689-2019

Code Information:

All lots within expiry

Product Description:ONDANSETRON 2 MG/ML INJECTION SOLUTION (NPF), 20ML per vial, RXQ Compounding, 340 West State Street, Unit 9, Athens, OH 45701.
NDC: 70731-0157-20**Product Quantity:****Reason for Recall:**

Lack of Assurance of Sterility

Recall Number:

D-1690-2019

Code Information:

All lots within expiry

Product Description:ONDANSETRON 2 MG/ML INJECTION SOLUTION (PFV), 2 ML per vial, RXQ Compounding, 340 West State Street, Unit 9, Athens, OH 45701.
NDC: 70731-0158-02

Product Quantity:**Reason for Recall:**

Lack of Assurance of Sterility

Recall Number:

D-1691-2019

Code Information:

All lots within expiry

Product Description:

PHENYLEPHRINE HCL 100 MCG/ML IN NACL 0.9% SYR, 10 ML per syringe, RXQ Compounding, 340 West State Street, Unit 9, Athens, OH 45701. NDC: 70731-0136-10

Product Quantity:**Reason for Recall:**

Lack of Assurance of Sterility

Recall Number:

D-1692-2019

Code Information:

All lots within expiry

Product Description:

PHO-TID-CHOL 50MG/ DEOXYCHOLIC 42 MG/ML INJ, 30 ML per vial, RXQ Compounding, 340 West State Street, Unit 9, Athens, OH 45701. NDC: 70731-0953-30

Product Quantity:**Reason for Recall:**

Lack of Assurance of Sterility

Recall Number:

D-1693-2019

Code Information:

All lots within expiry

Product Description:

POTASSIUM CHLORIDE 15% (2MEQ/ML) INJ SOLN, 30 ML per vial, RXQ Compounding, 340 West State Street, Unit 9, Athens, OH 45701. NDC: 70731-0954-30

Product Quantity:**Reason for Recall:**

Lack of Assurance of Sterility

Recall Number:

D-1694-2019

Code Information:

All lots within expiry

Product Description:

PREDNISOLONE 1%, MOXIFLOXACIN 0.5% OPTH SOL, 5ML per dropper bottle, RXQ Compounding, 340 West State Street, Unit 9, Athens, OH 45701. NDC: 70731-0109-05

Product Quantity:**Reason for Recall:**

Lack of Assurance of Sterility

Recall Number:

D-1695-2019

Code Information:

All lots within expiry

Product Description:

PROCAINE HCL 20 MG/ML (MDV) INJECTABLE SOLUTION, 30 ML per vial. RXQ Compounding, 340 West State Street, Unit 9, Athens, OH 45701. NDC: 70731-0987-30

Product Quantity:**Reason for Recall:**

Lack of Assurance of Sterility

Recall Number:

D-1696-2019

Code Information:

All lots within expiry

Product Description:

PROCAINE HCL (PFV) 20 MG/ML INJECTABLE SOLUTION, 30 ML per vial, RXQ Compounding, 340 West State Street, Unit 9, Athens, OH 45701. NDC: 70731-0900-30

Product Quantity:**Reason for Recall:**

Lack of Assurance of Sterility

Recall Number:

D-1697-2019

Code Information:

All lots within expiry

Product Description:

PROCAINE HCL 8% (PFV) INJECTABLE, 10ML PER VIAL, RXQ Compounding, 340 West State Street, Unit 9, Athens, OH 45701. NDC: 70731-0970-10

Product Quantity:**Reason for Recall:**

Lack of Assurance of Sterility

Recall Number:

D-1698-2019

Code Information:

All lots within expiry

Product Description:

PYRIDOXINE (MDV) 100MG/ML, 30ML PER VIAL, RXQ Compounding, 340 West State Street, Unit 9, Athens, OH 45701. NDC: 70731-0956-30

Product Quantity:**Reason for Recall:**

Lack of Assurance of Sterility

Recall Number:

D-1699-2019

Code Information:

All lots within expiry

Product Description:

PYRIDOXINE (PFV) 100MG/ML, 30ML PER VIAL. RXQ Compounding, 340 West State Street, Unit 9, Athens, OH 45701. NDC: 70731-0955-30

Product Quantity:**Reason for Recall:**

Lack of Assurance of Sterility

Recall Number:

D-1700-2019

Code Information:

All lots within expiry

Product Description:

RIBOFLAVIN 0.1% OPHTHALMIC SOLUTION SYRINGE, 2 ML per syringe. RXQ Compounding, 340 West State Street, Unit 9, Athens, OH 45701. NDC: 70731-0923-02

Product Quantity:

Reason for Recall:

Lack of Assurance of Sterility

Recall Number:

D-1701-2019

Code Information:

All lots within expiry

Product Description:

ROPIVICAINE 0.2%, INJ SOLN, 550 ML ON-Q PUMP. RXQ Compounding, 340 West State Street, Unit 9, Athens, OH 45701. NDC: 70731-0238-55

Product Quantity:**Reason for Recall:**

Lack of Assurance of Sterility

Recall Number:

D-1702-2019

Code Information:

All lots within expiry

Product Description:

RXQ CAIN (PHENYLEP 1.5%/ LIDO 1% OPTH SOL (PF), 1 ML PER VIAL, RXQ Compounding, 340 West State Street, Unit 9, Athens, OH 45701. NDC: 70731-0918-01

Product Quantity:**Reason for Recall:**

Lack of Assurance of Sterility

Recall Number:

D-1703-2019

Code Information:

All lots within expiry

Product Description:

SODIUM BICARBONATE 8.4% (1 MEQ/ML) INJ SOLN (PFV), 50 ML PER VIAL, RXQ Compounding, 340 West State Street, Unit 9, Athens, OH 45701. NDC: 70731-0957-50

Product Quantity:**Reason for Recall:**

Lack of Assurance of Sterility

Recall Number:

D-1704-2019

Code Information:

All lots within expiry

Product Description:

LIDOCAINE 0.75%/Epinephrine 0.025%/BSS 0.56ML SYR, 1 ML PER Syringe, RXQ Compounding, 340 West State Street, Unit 9, Athens, OH 45701. NDC: 70731-0919-01

Product Quantity:**Reason for Recall:**

Lack of Assurance of Sterility

Recall Number:

D-1705-2019

Code Information:

All lots within expiry

Product Description:

SOD-PHOS (PHOS 3MMOL/ML-SOD 4MEQ/ML) PFV INJ SOLN, 10 ML PER VIAL, RXQ Compounding, 340 West State Street, Unit 9, Athens, OH 45701. NDC: 70731-0905-10

Product Quantity:

Reason for Recall:

Lack of Assurance of Sterility

Recall Number:

D-1706-2019

Code Information:

All lots within expiry

Product Description:

STERILE WATER FOR INJECTION USP, [10, 30, or 50 ML] per Vial, RXQ Compounding, 340 West State Street, Unit 9, Athens, OH 45701. NDC 10 ML vial: 70731-0188-10; NDC 30 ML vial: 70731-0188-30; NDC 50 ML vial: 70731-0188-50

Product Quantity:**Reason for Recall:**

Lack of Assurance of Sterility

Recall Number:

D-1707-2019

Code Information:

All lots within expiry

Product Description:

SUCCINYLCHOLINE CHLORIDE 20MG/ML INJ SOL, 10 ML per Vial, RXQ Compounding, 340 West State Street, Unit 9, Athens, OH 45701. NDC 70731-0129-10

Product Quantity:**Reason for Recall:**

Lack of Assurance of Sterility

Recall Number:

D-1708-2019

Code Information:

All lots within expiry

Product Description:

TAURINE 50 MG/ML (MDV) INJECTABLE, 30 ML per Vial, RXQ Compounding, 340 West State Street, Unit 9, Athens, OH 45701. NDC 70731-0958-30

Product Quantity:**Reason for Recall:**

Lack of Assurance of Sterility

Recall Number:

D-1709-2019

Code Information:

All lots within expiry

Product Description:

THIAMINE HCL 100MG/ML (MDV) INJECTION, 10 ML per Vial, RXQ Compounding, 340 West State Street, Unit 9, Athens, OH 45701. NDC 70731-0950-10

Product Quantity:**Reason for Recall:**

Lack of Assurance of Sterility

Recall Number:

D-1710-2019

Code Information:

All lots within expiry

Product Description:

TRAVASOL 10% (AMINO ACID) INJECTION SOLUTION, 50 ML per Vial, RXQ Compounding, 340 West State Street, Unit 9, Athens, OH 45701. NDC 70731-0151-50

Product Quantity:

Reason for Recall:

Lack of Assurance of Sterility

Recall Number:

D-1711-2019

Code Information:

All lots within expiry

Product Description:

TURBO CAINE 2.5 (PHEN2.5/CYCLO1/ TROP1/TETRA 0.5), 0.4 ML per Syringe, RXQ Compounding, 340 West State Street, Unit 9, Athens, OH 45701. NDC 70731-0193-81

Product Quantity:**Reason for Recall:**

Lack of Assurance of Sterility

Recall Number:

D-1712-2019

Code Information:

All lots within expiry

Product Description:

TURBO DROPS (PHEN 0.625%/CYCLO 0.25%/TROP 0.25%/KETO 0.125%) OPTH SOLN, 0.4 ML per Syringe, RXQ Compounding, 340 West State Street, Unit 9, Athens, OH 45701. NDC 70731-0192-81

Product Quantity:**Reason for Recall:**

Lack of Assurance of Sterility

Recall Number:

D-1713-2019

Code Information:

All lots within expiry

Product Description:

TURBO DROPS (PHEN 10% / CYCLO 1%/ TROP 1%/ KETO 0.5%) OPTH SOLN, 5 ML per dropper bottle, RXQ Compounding, 340 West State Street, Unit 9, Athens, OH 45701. NDC 70731-0206-05

Product Quantity:**Reason for Recall:**

Lack of Assurance of Sterility

Recall Number:

D-1714-2019

Code Information:

All lots within expiry

Product Description:

TURBO DROPS (PHEN 2.5% / CYCLO 1%/ TROP 1%/ KETO 0.5%) OPTH SOLN, 5 ML per dropper bottle, RXQ Compounding, 340 West State Street, Unit 9, Athens, OH 45701. NDC 70731-0205-05

Product Quantity:**Reason for Recall:**

Lack of Assurance of Sterility

Recall Number:

D-1715-2019

Code Information:

All lots within expiry

Product Description:

VITAMIN B COMPLEX 100 (MDV), 30 ML per Vial, RXQ Compounding, 340 West State Street, Unit 9, Athens, OH 45701. NDC 70731-0976-30

Product Quantity:

Reason for Recall:

Lack of Assurance of Sterility

Recall Number:

D-1716-2019

Code Information:

All lots within expiry

Product Description:

VITAMIN B COMPLEX 100 (PFV), [2 or 30 ML] per Vial, RXQ Compounding, 340 West State Street, Unit 9, Athens, OH 45701. NDC 2 ML Vial: 70731-0961-02; NDC 30 ML Vial: 70731-0961-30

Product Quantity:**Reason for Recall:**

Lack of Assurance of Sterility

Recall Number:

D-1717-2019

Code Information:

All lots within expiry

Product Description:

ZINC SULFATE 1MG/ML INJECTION SOLUTION (PFV), 10ML per VIAL, RXQ Compounding, 340 West State Street, Unit 9, Athens, OH 45701. NDC 70731-0963-10

Product Quantity:**Reason for Recall:**

Lack of Assurance of Sterility

Recall Number:

D-1718-2019

Code Information:

All lots within expiry

Product Description:

ZINC SULFATE 1MG/ML INJECTION SOLUTION, 30ML per VIAL, RXQ Compounding, 340 West State Street, Unit 9, Athens, OH 45701. NDC 70731-0152-30

Product Quantity:**Reason for Recall:**

Lack of Assurance of Sterility

Recall Number:

D-1719-2019

Code Information:

All lots within expiry

Class II Drugs Event

Event ID:

83413

Status:

Ongoing

Recall Initiation Date:

07/23/2019

Center Classification Date:

08/02/2019

Recalling Firm:

Glenmark Pharmaceuticals Inc., USA

Product Type:

Drugs

Date Terminated:**Voluntary / Mandated:**

Voluntary: Firm initiated

Initial Firm Notification of Consignee or Public:

Letter

750 Corporate Dr
Mahwah NJ United States

Distribution Pattern:

Nationwide within the United States

Associated Products

Product Description:

Mometasone Furoate Cream USP, 0.1%, packaged in a) 15gram tubes (NDC 68462-192-17) and b) 45 gram tubes (NDC 68462-192-55), Rx Only, Manufactured by; Glenmark Pharmaceuticals Ltd At: Village: Kishanpura, Baddi Nalagari Road, District: Solan, Himachal Pradesh -173205, India Glenmark Pharmaceuticals Inc., USA Mahwah, NJ 07430

Product Quantity:**Reason for Recall:**

GMP Deviations: Glenmark received complaints stating that mometasone fuorate cream was gritty.

Recall Number:

D-1586-2019

Code Information:

a) 05171238, 05171248, 05171249, Exp. Jul-2019; 05171582, 05171612, Exp. Aug-2019; 05171674, 05171675, 05171682, Exp. Sep 2019; 05180065, 05180066, Exp. Dec 2019; 05180264, 05180264, 05180265, 05180275, 0518276, Exp. Jan 2020; 05180411, 05180412, 05180422, Exp. Jan 2020; 05180556, 05180568 Exp..Feb-2020; 05180889, 05180890, 05180896, 05180896, 05180897 Exp. Apr 2020; 05181123, 05181129, 05181134, 05181135, Exp. May 2020; 05181415, 05181425, 05181429, 05181433, Exp. Jun 2020; 05181528, Exp. Jul 2020; 05181747, 05181748, Exp. Aug 2020. b) 05171207, 05171212, 05171213, 05171232, 05171233, Exp. Jul-2019; 05171476, 05171478, 05171479, Exp. Aug 2019; 05171596, 05171597, 05171602, 05171603, Exp. Aug 2019; 05171683, 05171697, 05171698, 05171703, 05171718, 05171783, 05171788, 05171789, 05171790, 05171791, Exp. Sep 2019; 05180092, 05180093, 05180119, 05180219, 05180220, Exp. Dec 2019; 05180289, 05180291, 05180434, 05180435, Exp. Jan-2020; 05180438, 05180439, 05180443, 05180444, 05180450, 05180462, 05180572, 05180646, Exp. Feb 2020 05180648, 05180649, 05180659, 05180660, 05180671, Mar 2020; 05180870, 05180871, 05180874, 05180877, 05180900, 05180901, Exp. Apr 2020; 05181073, 05181074, 05181086, 05181087, 05181091, 05181092, 05181101, 05181102, 05181111, 05181146, 05181147, 05181148, 05181240 Exp. May 2020; 05181241, 05181248, 05181252, 05181253, 05181257, 05181265, 05181266, 05181267, 05181272, 05181309, 05181316, 05181317, 05181332 Exp. Jun 2020; 05181588, 05181602, 05181603, 05181618, 05181619, 05181621, 05181622, 05181633, 05181634 Exp. Jul 2020; 05181754, 05181772, 05181773, 05181781 Exp. Aug 2020

Class II Drugs Event

Event ID:

83492

Status:

Ongoing

Recall Initiation Date:

07/15/2019

Center Classification Date:

08/08/2019

Recalling Firm:

Unipharma, Llc.
10200 NW 67th St
Tamarac FL United States

Distribution Pattern:

Nationwide in the US.

Product Type:

Drugs

Date Terminated:**Voluntary / Mandated:**

Voluntary: Firm initiated

Initial Firm Notification of Consignee or Public:

Letter

Associated Products

Product Description:

CVS Health Children's Allergy Relief Liquid Medication Diphenhydramine HCl 12.5 mg/5 mL Oral Solution, Antihistamine, Mixed Berry Flavor, 20 Single-Use Vials per Carton, 0.17 fl. oz. (5 mL) Each, 3.4 fl. oz. (100 mL) Total Distributed by: CVS Pharmacy, Inc. One CVS Drive Woonsocket, RI 02895, NDC 69842-261-01 UPC 050428597156

Product Quantity:

48 cartons

Reason for Recall:

CGMP Deviations: Recall as a precautionary measure due to potential risk of product contamination with the bacteria B. cepacia.

Recall Number:

D-1631-2019

Code Information:

Lot: 80060 Exp. 11/30/20

Product Description:

DrKids Children's Allergy Relief Diphenhydramine HCl 12.5 mg/5 mL Antihistamine, Mixed berry Flavor, 20 Pre-measured Single-Use vials per Carton, Manufactured in USA by: Unipharma, LLC. Tamarac, FL 33321, UPC 370302255010

Product Quantity:

432 cartons

Reason for Recall:

CGMP Deviations: Recall as a precautionary measure due to potential risk of product contamination with the bacteria B. cepacia.

Recall Number:

D-1632-2019

Code Information:

Lot: 90003 Exp. 01/31/21

Product Description:

CVS Health Children's Nasal Saline Drops with Himalayan Salt Saline Nasal Moisturizer, 30 single-use vials per Carton, 0.05 fl. oz. (1.5 mL) each 1.5 fl. oz. (45 mL) total, Distributed by: CVS Pharmacy, Inc. One CVS Drive Woonsocket, RI 02895, UPC 050428598207

Product Quantity:

48 cartons

Reason for Recall:

CGMP Deviations: Recall as a precautionary measure due to potential risk of product contamination with the bacteria B. cepacia.

Recall Number:

D-1633-2019

Code Information:

Lot: 90008 Exp. 02/28/21

Class III Drugs Event

Event ID:

83210

Status:

Ongoing

Recall Initiation Date:

06/25/2019

Center Classification Date:

08/02/2019

Recalling Firm:

AAA Pharmaceutical, Inc.
681 Main St
Lumberton NJ United States

Distribution Pattern:

KS

Product Type:

Drugs

Date Terminated:**Voluntary / Mandated:**

Voluntary: Firm initiated

Initial Firm Notification of Consignee or Public:

Letter

Associated Products

Product Description:

Smart Sense Regular Strength Aspirin Tablets, 325 mg packed in a) 100 count UPC 8-8397-38781-6 and b) 500 count UPC 8-83967-38786-1 bottles, Distributed by: Kmart Corporation Hoffman Estates, IL 60179

Product Quantity:

a) 288 bottles b) 48 bottles

Reason for Recall:

Labeling; Incorrect or Missing Lot Number and/or Exp Date; Product has an incorrect expiration date of 9/2022 applied to the labeling, where the actual expiration date is 10/2021.

Recall Number:

D-1585-2019

Code Information:

a) P136370, exp 9/2022 b) P136366, exp 9/2022

Class III Drugs Event

Event ID:

83471

Product Type:

Drugs

Status:

Ongoing

Date Terminated:**Recall Initiation Date:**

02/19/2019

Voluntary / Mandated:

Voluntary: Firm initiated

Center Classification Date:

08/02/2019

Initial Firm Notification of Consignee or Public:

Letter

Recalling Firm:

American Health Packaging
2550 John Glenn Ave Ste A
Columbus OH United States

Distribution Pattern:

Nationwide within the USA and Puerto Rico

Associated Products

Product Description:

Lovastatin Tablets USP, 40 mg, packaged in a) 100-count bottles (NDC 68001-316-00) and b) 1000-count bottles (NDC 68001-316-08), Rx Only, Manufactured by: Lupin Limited, Goa 403 722 INDIA For BluePoint Laboratories.

Product Quantity:

14,360 bottles

Reason for Recall:

CGMP Deviations: Finished product made with lovastatin drug substance that was out of specification for individual impurity results.

Recall Number:

D-1584-2019

Code Information:

Lot #: a) G702705 and b) G702706, Exp. 3/31/2020