

Enforcement Report - Week of January 18, 2023

Class II Drugs Event

Event ID:

91114

Status:

Ongoing

Recall Initiation Date:

11/02/2022

Center Classification Date:

01/11/2023

Recalling Firm:

Direct Rx
94 Worldwide Dr
Dawsonville GA United States

Distribution Pattern:

FL

Product Type:

Drugs

Date Terminated:**Voluntary / Mandated:**

Voluntary: Firm initiated

Initial Firm Notification of Consignee or Public:

Letter

Associated Products

Product Description:

Moxifloxacin Ophthalmic Solution, 0.5%, 3 mL, Rx Only, Packaged and Distributed By: Direct Rx, LLC 94 Worldwide Drive, Dawsonville, GA 30534, NDC 72189-0334-05

Product Quantity:

11 bottles

Reason for Recall:

cGMP deviation: discontinue of stability support for product.

Recall Number:

D-0101-2023

Code Information:

Lot #: 07MA2232, Exp. 4/30/23

Class II Drugs Event

Event ID:

91295

Status:

Ongoing

Recall Initiation Date:

12/12/2022

Center Classification Date:

01/09/2023

Recalling Firm:

Lupin Pharmaceuticals Inc.
Harborplace Tower 111 S Calvert St Fl 21st
Baltimore MD United States

Distribution Pattern:

Distributed Nationwide in the USA

Product Type:

Drugs

Date Terminated:**Voluntary / Mandated:**

Voluntary: Firm initiated

Initial Firm Notification of Consignee or Public:

Letter

Associated Products

Product Description:

Rifampin Capsules USP, 300 mg, 30-count bottle; Rx Only, Manufactured for: Lupin Pharmaceuticals Baltimore, Maryland 21202, Manufactured by: Lupin Limited Aurangabad 431 210 India. NDC 68180-659-06

Product Quantity:

16,056 30 count bottles

Reason for Recall:

Failed Impurities/Degradation Specifications: Failure observed in related substance testing during long term stability study.

Recall Number:

D-0100-2023

Code Information:

Lot # A200171, Exp 12/2023

Class II Drugs Event

Event ID:

91345

Product Type:

Drugs

Status:

Ongoing

Date Terminated:**Recall Initiation Date:**

12/20/2022

Voluntary / Mandated:

Voluntary: Firm initiated

Center Classification Date:

01/06/2023

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 one account in PA.

Associated Products

Product Description:

Rifampin Capsules, 300 mg, 30 count blister card, Rx only, Mfg: Lupin Pharma, Baltimore, MD 21202, original NDC 68180-0659-07, Repackaged by: RemedyRepack Inc., Indiana, PA 15701, Repackaged NDC 70518-2404-00.

Product Quantity:

132 Cards of 30 = 3960 Tablets

Reason for Recall:

Failed Impurities/Degradation specifications

Recall Number:

D-0098-2023

Code Information:

Lot #: J0599794-022322, exp. date 02/28/2023; J0621369-052622, exp. date 06/30/2023

Class II Drugs Event

Event ID:

91443

Product Type:

Drugs

Status:

Ongoing

Date Terminated:**Recall Initiation Date:**

12/30/2022

Voluntary / Mandated:

Voluntary: Firm initiated

Center Classification Date:

01/12/2023

Initial Firm Notification of Consignee or Public:

Two or more of the following: Email, Fax, Letter, Press Release, Telephone, Visit

Recalling Firm:Northern VA Compounders PLLC
23475 Rock Haven Way Suite 105
Sterling VA United States**Distribution Pattern:**

Nationwide in the USA

Associated Products**Product Description:**

Mitomycin Injection Solution, 4mg/ml, packaged in a 10 mL Multiple-Dose vial, Rx Only, Compounded by: Akina Pharmacy, 23475 Rock Haven Way Suite 105, Sterling, VA 20166.

Product Quantity:

2 vials

Reason for Recall:

Lack of Assurance of Sterility

Recall Number:

D-0102-2023

Code Information:

Lot#: 12062022@7, Exp 1/20/2023; 12072022@32, Exp 1/22/2023

Product Description:

QuadMix Plus (PGE1/Papaverine HCl/Phentolamine Mesylate/Atropine) 20mcg/30mg/2mg/0.2mg/mL INJECTABLE, packaged in 2.5 mL Multiple-Dose vials, Rx Only, Compounded by: Akina Pharmacy, 23475 Rock Haven Way Suite 105, Sterling, VA 20166.

Product Quantity:

78 vials

Reason for Recall:

Lack of Assurance of Sterility

Recall Number:

D-0103-2023

Code Information:

Lot#: 11182022@1, Exp 1/2/2023; 12012022@9, Exp 1/15/2023; 11142022@8, Exp 12/29/2022; 11292022@10, Exp 1/13/2023

Product Description:

QuadMix Standard 002 (PGE1/Papaverine HCl/Phentolamine Mesylate/Atropine) 10mcg/30mg/2mg/0.2MG/ML INJECTABLE, packaged in 2.5 mL Multiple-Dose vials, Rx Only, Compounded by: Akina Pharmacy, 23475 Rock Haven Way Suite 105, Sterling, VA 20166.

Product Quantity:

12 vials

Reason for Recall:

Lack of Assurance of Sterility

Recall Number:

D-0104-2023

Code Information:

Lot#: 12012022@11, Exp 1/15/2023

Product Description:

QuadMix Super 001 (PGE1/Papaverine HCl/Phentolamine Mesylate/Atropine) 40mcg/30mg/2mg/0.4mg/mL INJECTABLE, packaged in 2.5 mL Multiple-Dose vials, Rx Only, Compounded by: Akina Pharmacy, 23475 Rock Haven Way Suite 105, Sterling, VA 20166.

Product Quantity:

56 vials

Reason for Recall:

Lack of Assurance of Sterility

Recall Number:

D-0105-2023

Code Information:

Lot#: 11162022@7, Exp 12/31/2022

Product Description:

TriMix Original (PGE1/Papaverine HCl/Phentolamine Mesylate) 5.88mcg/18mg/0.6mg/mL INJECTABLE, packaged in 2.5 mL Multiple-Dose vials, Rx Only, Compounded by: Akina Pharmacy, 23475 Rock Haven Way Suite 105, Sterling, VA 20166.

Product Quantity:

750 vials

Reason for Recall:

Lack of Assurance of Sterility

Recall Number:

D-0106-2023

Code Information:

Lot#: 11142022@17, Exp 12/29/2022; 11262022@7, Exp 1/10/2023; 12022022@3, Exp 1/16/2023

Product Description:

QuadMix Standard 001 (PGE1/Papaverine HCl/Phentolamine Mesylate/Atropine) 10mcg/30mg/1mg/0.2mg/mL INJECTABLE, packaged in 2.5 mL Multiple-Dose vials, Rx Only, Compounded by: Akina Pharmacy, 23475 Rock Haven Way Suite 105, Sterling, VA 20166.

Product Quantity:

39 vials

Reason for Recall:

Lack of Assurance of Sterility

Recall Number:

D-0107-2023

Code Information:

Lot#: 11162022@10, Exp 12/31/2022; 12052022@9, Exp 1/19/2023

Product Description:

QuadMix Super 002 (PGE1/Papaverine HCl/Phentolamine Mesylate/Atropine) 40mcg/30mg/4mg/0.4mg/mL INJECTABLE, packaged in 2.5 mL Multiple-Dose vials, Rx Only, Compounded by: Akina Pharmacy, 23475 Rock Haven Way Suite 105, Sterling, VA 20166.

Product Quantity:

6 vials

Reason for Recall:

Lack of Assurance of Sterility

Recall Number:

D-0108-2023

Code Information:

Lot#: 12062022@1, Exp 1/20/2023

Product Description:

Prostaglandin (E1) Injection Solution, 10 mcg/ml, packaged in 2.5 mL Multiple-Dose vials, Rx Only, Compounded by: Akina Pharmacy, 23475 Rock Haven Way Suite 105, Sterling, VA 20166.

Product Quantity:

4 vials

Reason for Recall:

Lack of Assurance of Sterility

Recall Number:

D-0109-2023

Code Information:

Lot#: 12012022@7, Exp 1/15/2023

Product Description:

Prostaglandin (E1) Injection Solution, 20 mcg/ml, 2.5 mL Multiple-Dose vials, Rx Only, Compounded by: Akina Pharmacy, 23475 Rock Haven Way Suite 105, Sterling, VA 20166.

Product Quantity:

4 vials

Reason for Recall:

Lack of Assurance of Sterility

Recall Number:

D-0110-2023

Code Information:

Lot#: 11212022@5, Exp 1/5/2023

Product Description:

Prostaglandin (E1) Injection Solution, 25mcg/ml, 2.5 mL Multiple-Dose vials, Rx Only, Compounded by: Akina Pharmacy, 23475 Rock Haven Way Suite 105, Sterling, VA 20166.

Product Quantity:

108 vials

Reason for Recall:

Lack of Assurance of Sterility

Recall Number:

D-0111-2023

Code Information:

Lot#: 11252022@12, Exp 1/9/2023

Product Description:

Prostaglandin (E1) Injection Solution, 40mcg/ml, 2.5 mL Multiple-Dose vials, Rx Only, Compounded by: Akina Pharmacy, 23475 Rock Haven Way Suite 105, Sterling, VA 20166.

Product Quantity:

2 vials

Reason for Recall:

Lack of Assurance of Sterility

Recall Number:

D-0112-2023

Code Information:

Lot#: 12052022@11, Exp 1/19/2023

Product Description:

TriMix Injection (PGE1/Papaverine HCl/Phentolamine Mesylate) 30mcg/60mg/2mg/mL INJECTABLE, 2.5 mL Multiple-Dose vials, Rx Only, Compounded by: Akina Pharmacy, 23475 Rock Haven Way Suite 105, Sterling, VA 20166.

Product Quantity:

2 vials

Reason for Recall:

Lack of Assurance of Sterility

Recall Number:

D-0113-2023

Code Information:

Lot#: 11142022@12, Exp 12/29/2022

Product Description:

TriMix Injection (PGE1/Papaverine HCl/Phentolamine Mesylate) 40mcg/30mg/2mg/mL INJECTABLE, 2.5 mL Multiple-Dose vials, Rx Only, Compounded by: Akina Pharmacy, 23475 Rock Haven Way Suite 105, Sterling, VA 20166.

Product Quantity:

4 vials

Reason for Recall:

Lack of Assurance of Sterility

Recall Number:

D-0114-2023

Code Information:

Lot#: 11142022@11, Exp 12/29/2022

Product Description:

TriMix Injection (PGE1/Papaverine HCl/Phentolamine Mesylate) 60mcg/30mg/3mg/mL INJECTABLE, 2.5 mL Multiple-Dose vials, Rx Only, Compounded by: Akina Pharmacy, 23475 Rock Haven Way Suite 105, Sterling, VA 20166.

Product Quantity:

2 vials

Reason for Recall:

Lack of Assurance of Sterility

Recall Number:

D-0115-2023

Code Information:

Lot#: 11182022@2, Exp 1/2/2023

Product Description:

TriMix Injection (PGE1/Papaverine HCl/Phentolamine Mesylate) 100mcg/30mg/3mg/mL INJECTABLE, 2.5 mL Multiple-Dose vials, Rx Only, Compounded by: Akina Pharmacy, 23475 Rock Haven Way Suite 105, Sterling, VA 20166.

Product Quantity:

4 vials

Reason for Recall:

Lack of Assurance of Sterility

Recall Number:

D-0116-2023

Code Information:

Lot#: 11212022@7, Exp 1/5/2023

Product Description:

TriMix Plus 001 (PGE1/Papaverine HCl/Phentolamine Mesylate) 20mcg/30mg/2mg/mL INJECTABLE, 2.5 mL Multiple-Dose vials, Rx Only, Compounded by: Akina Pharmacy, 23475 Rock Haven Way Suite 105, Sterling, VA 20166.

Product Quantity:

525 vials

Reason for Recall:

Lack of Assurance of Sterility

Recall Number:

D-0117-2023

Code Information:

Lot#: 11252022@5, Exp 1/9/2023; 12012022@12, Exp 1/15/2023

Product Description:

TriMix Injection (PGE1/Papaverine HCl/Phentolamine Mesylate) 11.8mcg/18mg/0.6mg/mL INJECTABLE, packaged in 2.5 mL Multiple-Dose vials, Rx Only, Compounded by: Akina Pharmacy, 23475 Rock Haven Way Suite 105, Sterling, VA 20166.

Product Quantity:

8 vials

Reason for Recall:

Lack of Assurance of Sterility

Recall Number:

D-0118-2023

Code Information:

Lot#: 11262022@8, Exp 1/10/2023; 11302022@12, Exp 1/14/2023

Product Description:

Methylcobalamin Injection Solution, 12.5mg/ml, packaged in 2 mL Multiple-Dose vials, Rx Only, Compounded by: Akina Pharmacy, 23475 Rock Haven Way Suite 105, Sterling, VA 20166.

Product Quantity:

2 vials

Reason for Recall:

Lack of Assurance of Sterility

Recall Number:

D-0119-2023

Code Information:

Lot#: 11292022@16, Exp 1/13/2023

Product Description:

QuadMix Injectable (PGE1/Papaverine HCl/Phentolamine Mesylate/Atropine) 20mcg/20mg/2mg/0.2mg/mL INJECTABLE, 2.5 mL Multiple-Dose vials, Rx Only, Compounded by: Akina Pharmacy, 23475 Rock Haven Way Suite 105, Sterling, VA 20166.

Product Quantity:

2 vials

Reason for Recall:

Lack of Assurance of Sterility

Recall Number:

D-0120-2023

Code Information:

Lot#: 11292022@12, Exp 1/13/2023

Product Description:

TriMix Injection (PGE1/Papaverine HCl/Phentolamine) 100mcg/30mg/2mg/mL INJECTABLE, packaged in 2.5 mL Multiple-Dose vials, Rx Only, Compounded by: Akina Pharmacy, 23475 Rock Haven Way Suite 105, Sterling, VA 20166.

Product Quantity:

8 vials

Reason for Recall:

Lack of Assurance of Sterility

Recall Number:

D-0121-2023

Code Information:

Lot#: 11252022@15, Exp 1/9/2023; 11302022@9, Exp 1/14/2023; 12022022@5, Exp 1/16/2023

Product Description:

BiMix Injection (Papaverine HCl/Phentolamine Mesylate) 30mg/0.5mg/mL INJECTABLE, packaged in 2.5 mL Multiple-Dose vials, Rx Only, Compounded by: Akina Pharmacy, 23475 Rock Haven Way Suite 105, Sterling, VA 20166.

Product Quantity:

4 vials

Reason for Recall:

Lack of Assurance of Sterility

Recall Number:

D-0122-2023

Code Information:

Lot#: 12062022@3, Exp 1/20/2023

Product Description:

TriMix Plus 002 (PGE1/Papaverine HCl/Phentolamine Mesylate) 25mcg/30mg/2mg/mL INJECTABLE, packaged in 2.5 mL Multiple-Dose vials, Rx Only, Compounded by: Akina Pharmacy, 23475 Rock Haven Way Suite 105, Sterling, VA 20166.

Product Quantity:

36 vials

Reason for Recall:

Lack of Assurance of Sterility

Recall Number:

D-0123-2023

Code Information:

Lot#: 12062022@4, Exp 1/20/2023

Product Description:

QuadMix Injectable (PGE1/Papaverine HCl/Phentolamine Mesylate/Atropine) 50mcg/40mg/4mg/0.4mg/mL INJECTABLE, packaged in 2.5 mL Multiple-Dose vials, Rx Only, Compounded by: Akina Pharmacy, 23475 Rock Haven Way Suite 105, Sterling, VA 20166.

Product Quantity:

2 vials

Reason for Recall:

Lack of Assurance of Sterility

Recall Number:

D-0124-2023

Code Information:

Lot#: 12082022@8, Exp 1/22/2023

Product Description:

BiMix STD 001 (Papaverine HCl/Phentolamine Mesylate) 30mg/1mg/mL INJECTABLE, 2.5 mL Multiple-Dose vials, Rx Only, Compounded by: Akina Pharmacy, 23475 Rock Haven Way Suite 105, Sterling, VA 20166.

Product Quantity:

1200 vials

Reason for Recall:

Lack of Assurance of Sterility

Recall Number:

D-0125-2023

Code Information:

Lot#: 10252022@3, Exp 1/31/2023

Product Description:

TriMix Injection (PGE1/Papaverine HCl/Phentolamine Mesylate) 10mcg/20mg/1mg/mL INJECTABLE, packaged in 2.5 mL Multiple-Dose vials, Rx Only, Compounded by: Akina Pharmacy, 23475 Rock Haven Way Suite 105, Sterling, VA 20166.

Product Quantity:

2 vials

Reason for Recall:

Lack of Assurance of Sterility

Recall Number:

D-0126-2023

Code Information:

Lot#: 11212022@8, Exp 1/5/2023

Class II Drugs Event

Event ID:

91450

Product Type:

Drugs

Status:

Ongoing

Date Terminated:**Recall Initiation Date:**

01/06/2023

Voluntary / Mandated:

Voluntary: Firm initiated

Center Classification Date:

01/09/2023

Initial Firm Notification of Consignee or Public:

Letter

Recalling Firm:

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

Distribution Pattern:

Nationwide in the USA.

Associated Products

Product Description:

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

Product Quantity:

38,830 syringes

Reason for Recall:

Lack of Assurance of Sterility

Recall Number:

D-0099-2023

Code Information:

Lot: RC2011A, Exp. 2/22/2023