

Enforcement Report - Week of June 1, 2022

Class II Drugs Event

Event ID:
90127

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
05/02/2022

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
05/20/2022

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 FL, SC and VA

Associated Products

<p>Product Description: Losartan HCTZ 100/25 mg, 90 count bottles NDC# 70518-2578-00 Repackaged NDC Original NDC # 68180-0217-09</p> <p>Product Quantity: 26/90 count bottles = 2,340 tablets</p> <p>Reason for Recall: CGMP Deviations- AZIDO Impurity levels observed to be above acceptable limits.</p> <p>Recall Number: D-0886-2022</p> <p>Code Information: Lot # B1329507-082921, exp. date 08/31/2022 B1348363-091421, exp. date 09/30/2022 B1387286-101021, exp. date 10/31/2022 B1390974-101221, exp. date 10/31/2022 B1426010-110521, exp. date 11/30/2022</p>
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<p>Product Description: Losartan HCTZ 100/12.5 mg, 90 count bottles NDC# 70518-2564-00 Repackaged NDC Original NDC # 68180-0216-09</p> <p>Product Quantity: 30 bottles/90 count = 2,700 tablets</p> <p>Reason for Recall: CGMP Deviations- AZIDO Impurity levels observed to be above acceptable limits.</p> <p>Recall Number: D-0887-2022</p> <p>Code Information: Lot # B1364261-092721, exp. date 09/30/2022 B1377667-100521, exp. date 10/31/2022 B1412576-102621, exp. date 10/31/2022 B1436925-111321, exp. date 11/30/2022</p>
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Class II Drugs Event

Event ID:
90134

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
05/04/2022

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
05/20/2022

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
RemedyRepack Inc.
625 Kolter Dr Ste 4
Indiana PA United States

Distribution Pattern:
Recalled product was distributed to Florida.

Associated Products

<p>Product Description: Losartan HCTZ 50/12.5 mg, 90 count bottle Original NDC# 33342-0050-10 Repackaged NDC# 70518-3231-00</p> <p>Product Quantity: 22 bottles/90 count each</p> <p>Reason for Recall: CGMP Deviations- AZIDO Impurity levels observed to be above acceptable limits</p> <p>Recall Number: D-0885-2022</p> <p>Code Information: Lot # B1377711-100521, exp. date 10/31/2022 B1412137-102621, exp. date 10/31/2022</p>

Class II Drugs Event

Event ID:
90148

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
05/03/2022

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
05/24/2022

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

Recalling Firm:
Preferred Pharmaceuticals, Inc.
1250 N Lakeview Ave Ste O
Anaheim CA United States

Distribution Pattern:
Within the U.S in FL and CA.

Associated Products

<p>Product Description: Losartan Potassium & HCTZ Tablets 50mg/12.5 mg, hydrochlorothiazide USP 12.5, Pkg Size: 90, NDC: 68788-7758-09.</p> <p>Product Quantity: 31 bottles of 90 tables (Lot: K1721D); 5 bottles of 90 tablets (K1021E).</p> <p>Reason for Recall: CGMP Deviations- AZIDO Impurity levels observed to be above acceptable limits</p> <p>Recall Number: D-0891-2022</p> <p>Code Information: Lot: K1721D, EXP: 4/30/2023, NDC: 68788-7758-09; Lot: K1021E, EXP: 7/31/2023, NDC: 68788-7758-09.</p>

<p>Product Description: Losartan Potassium & HCTZ Tablets 50mg/12.5 mg, hydrochlorothiazide USP 12.5 mg, Pkg Size: 30, NDC: 68788-7758-03.</p> <p>Product Quantity: 47 Bottles of 30 Tabs (K1721E); 35 Bottles of 30 Tabs (H3021Q).</p>

Reason for Recall:

CGMP Deviations- AZIDO Impurity levels observed to be above acceptable limits

Recall Number:

D-0892-2022

Code Information:

Lot: K1721E, EXP: 4/30/2023, NDC: 68788-7758-03; Lot: H3021Q, EXP: 2/28/2023, NDC: 68788-7758-03.

Class II Drugs Event**Event ID:**

90162

Product Type:

Drugs

Status:

Ongoing

Date Terminated:**Recall Initiation Date:**

05/06/2022

Voluntary / Mandated:

Voluntary: Firm initiated

Center Classification Date:

05/20/2022

Initial Firm Notification of Consignee or Public:

Letter

Recalling Firm:Noven Pharmaceuticals Inc
11960 Sw 144th St
Miami FL United States**Distribution Pattern:**

Nationwide to the U.S. Market

Associated Products**Product Description:**

Daytrana (methylphenidate transdermal system) Delivers 10 mg over 9 hours (1.1 mg/hr) Contains: 30 Patches, Rx only, Manufactured for Noven Therapeutics, LLC, Miami, FL 33186, By Noven Pharmaceuticals, Inc., Miami, FL, 33186, NDC 68968-5552-3

Product Quantity:

274, 110 patches

Reason for Recall:

Defective Delivery System: customer complaints exceeded respective action limits.

Recall Number:

D-0889-2022

Code Information:

Lot: 90764 Exp. 08/2022

Class II Drugs Event**Event ID:**

90200

Product Type:

Drugs

Status:

Ongoing

Date Terminated:**Recall Initiation Date:**

05/11/2022

Voluntary / Mandated:

Voluntary: Firm initiated

Center Classification Date:

05/24/2022

Initial Firm Notification of Consignee or Public:

Letter

Recalling Firm:Direct Rx
94 Worldwide Dr
Dawsonville GA United States**Distribution Pattern:**

FL

Associated Products

Product Description:

Losartan Pot/HCTZ 100/12.5 mg 90 Tabs NDC 72189-290-90 Packaged and Distributed By: Direct Rx Dawsonville, GA 30534 Mfg. For Macleods Pharma USA, Inc. Plainsboro, NJ 08540

Product Quantity:

11 bottles

Reason for Recall:

CGMP Deviations- AZIDO Impurity levels observed to be above acceptable limits .

Recall Number:

D-0893-2022

Code Information:

Lot: 25OC2116 Exp. 5/31/23

Product Description:

Losartan Pot/HCTZ 50/12.5 mg 90 Tabs NDC 72189-297-90 Packaged and Distributed By: Direct Rx Dawsonville, GA 30534 Mfg. For Macleods Pharma USA, Inc. Plainsboro, NJ 08540

Product Quantity:

6 bottles

Reason for Recall:

CGMP Deviations- AZIDO Impurity levels observed to be above acceptable limits .

Recall Number:

D-0894-2022

Code Information:

Lots: 19NO2108 Exp. 1/31/25; 19NO2114 Exp. 1/31/25; 22NO2126 Exp. 1/31/25

Product Description:

Losartan Pot/HCTZ 100/25 mg 90 Tabs NDC 72189-289-90 Packaged and Distributed By: Direct Rx Dawsonville, GA 30534 Mfg. For Macleods Pharma USA, Inc. Plainsboro, NJ 08540

Product Quantity:

11 bottles

Reason for Recall:

CGMP Deviations- AZIDO Impurity levels observed to be above acceptable limits .

Recall Number:

D-0895-2022

Code Information:

Lots: 08NO2102 Exp. 1/31/25; 17NO2118 Exp. 1/31/25; 18NO2123 Exp. 1/31/25; 25OC2114 Exp. 1/31/25; 22NO2105 Exp. 1/31/25

Class II Drugs Event

Event ID:

90204

Product Type:

Drugs

Status:

Ongoing

Date Terminated:
Recall Initiation Date:

05/09/2022

Voluntary / Mandated:

Voluntary: Firm initiated

Center Classification Date:

05/25/2022

Initial Firm Notification of Consignee or Public:

Letter

Recalling Firm:

Olympia Compounding Pharmacy dba Olympia Pharmacy
6700 Conroy Rd Ste 155
Orlando FL United States

Distribution Pattern:

Distributed Nationwide in th USA, Puerto Rico and US Virgin Islands

Associated Products

Product Description:

QM-4 Papaverine 30 mg/mL Phentolamine 3 mg/mL Alprostadil 300 mcg/mL Atropine 0.2 mg/mL, Multi-Dose 10 mL vial, Rx Only, Olympia Pharmaceuticals, 6700 Conroy Rd., Ste. 155 Orlando, FL 32835, NDC 73198-0020-10

Product Quantity:

914 vials

Reason for Recall:

Lack of assurance of sterility.

Recall Number:

D-0897-2022

Code Information:

Lot: L24F08 BUD: 12/8/2022

Product Description:

RE-1 Papaverine 30 mg/mL Phentolamine 3 mg/mL Alprostadil 200 mcg/mL, packaged as a) 2.5 mL Multi Dose vial, NDC 73198-0015-03; b) 10 mL Multi Dose vial, NDC 73198-0015-10; Rx Only, Olympia Pharmaceuticals, 6700 Conroy Rd., Ste. 155 Orlando, FL 32835

Product Quantity:

482 vials

Reason for Recall:

Lack of assurance of sterility.

Recall Number:

D-0898-2022

Code Information:

Lots: B24E09-22 BUD: 02/09/2023; B24F09-22 BUD: 02/09/2023

Product Description:

RE-2 Papaverine 30 mg/mL Phentolamine 3 mg/mL Alprostadil 300 mcg/mL, Packaged as a) 2.5 mL Multi Dose vial, NDC 73198-0016-03; b) 10 mL Multi Dose vial, NDC 73198-0016-10; Rx Only, Olympia Pharmaceuticals, 6700 Conroy Rd., Ste. 155 Orlando, FL 32835

Product Quantity:

1710 vials

Reason for Recall:

Lack of assurance of sterility.

Recall Number:

D-0899-2022

Code Information:

Lots: K24B09, K24C09 BUD: 11/09/2022

Product Description:

SB-5 Papaverine 30 mg/mL Phentolamine 3 mg/mL PGE 50 mcg/mL, Multi-Dose 10 mL vial, Rx Only, Olympia Pharmaceuticals 6700 Conroy Rd., Ste. 155 Orlando, FL 32835, NDC 73198-0024-10

Product Quantity:

75 vials

Reason for Recall:

Lack of assurance of sterility.

Recall Number:

D-0900-2022

Code Information:

Lot: B24D02-22 BUD: 02/02/2023

Product Description:

SB-6 Papaverine 30 mg/mL Phentolamine 3 mg/mL PGE 60 mcg/mL, Packaged in a) 5 mL Multi-Dose vial, NDC 73198-0025-05; b) 10 mL, Multi-Dose vial, NDC 73198-0025-10; Rx Only, Olympia Pharmaceuticals, 6700 Conroy Rd., Ste. 155 Orlando, FL 32835

Product Quantity:

874 vials

Reason for Recall:

Lack of assurance of sterility.

Recall Number:

D-0901-2022

Code Information:

Lots: L24D14, L24C14 BUD: 12/14/2022

Product Description:

Sermorelin Acetate Lyophilized powder for reconstitution 9 mg Per Multi-Dose Vial, Rx Only, Olympia Pharmaceuticals, 6700 Conroy Rd., Ste. 155 Orlando, FL 32835, NDC 73198-0059-00

Product Quantity:

4459 vials

Reason for Recall:

Lack of assurance of sterility.

Recall Number:

D-0902-2022

Code Information:

Lots: L24115 BUD: 12/15/2022; A24203 BUD: 01/03/2023; A24106 BUD: 01/06/2023

Product Description:

Diluent for Reconstitution Multi-Dose 10 mL vial, Rx Only, Olympia Pharmaceuticals, 6700 Conroy Rd., Ste. 155 Orlando, FL 32835, NDC 73198-0113-10

Product Quantity:

42,722 vials

Reason for Recall:

Lack of assurance of sterility.

Recall Number:

D-0903-2022

Code Information:

Lots: J24125, J24025 BUD: 10/25/2022; K24002 BUD: 11/2/2022; L24013, L24213 BUD: 12/13/2022; A24003 BUD: 1/3/2023; A24404 BUD: 1/4/2023; A24031-22 BUD: 1/31/2023; B24001-22 BUD: 2/1/2023

Product Description:

Sodium Bicarbonate 8.4% MDV Injection, Multi-Dose 30 mL vial, Rx Only, Olympia Pharmaceuticals, 6700 Conroy Rd., Ste. 155 Orlando, FL 32835, NDC 73198-0101-30

Product Quantity:

1466 vials

Reason for Recall:

Lack of assurance of sterility.

Recall Number:

D-0904-2022

Code Information:

Lot: L41002 BUD: 6/2/2022

Product Description:

Sodium Selenite 200 mg/mL, Multi-Dose 30 mL vial, Rx Only, Olympia Pharmaceuticals, 6700 Conroy Rd., Ste. 155 Orlando, FL 32835, NDC 73198-0074-30

Product Quantity:

2333 vials

Reason for Recall:

Lack of assurance of sterility.

Recall Number:

D-0905-2022

Code Information:

Lots: L24014 BUD: 6/14/2022; B24024-22 BUD: 8/24/2022

Product Description:

Sodium Tetradecyl Sulfate 0.3% Injection, Multi-Dose 30 mL vial, Rx Only, Olympia Pharmaceuticals, 6700 Conroy Rd., Ste. 155 Orlando, FL 32835, NDC 73198-0121-30

Product Quantity:

943 vials

Reason for Recall:

Lack of assurance of sterility.

Recall Number:

D-0906-2022

Code Information:

Lot: B24309-22 BUD: 8/9/2022

Product Description:

Sodium Tetradecyl Sulfate 1.5% MDV Injection, Multi-Dose 30 mL vial, Rx Only, Olympia Pharmaceuticals, 6700 Conroy Rd., Ste. 155 Orlando, FL 32835, NDC 73198-0122-30

Product Quantity:

480 vials

Reason for Recall:

Lack of assurance of sterility.

Recall Number:

D-0907-2022

Code Information:

Lot: B24308-22 BUD: 8/8/2022

Product Description:

Sodium Tetradecyl Sulfate 5% MDV Injection, Multi-Dose 5 mL vial, Rx Only, Olympia Pharmaceuticals, 6700 Conroy Rd., Ste. 155 Orlando, FL 32835, NDC 73198-0102-05

Product Quantity:

588 vials

Reason for Recall:

Lack of assurance of sterility.

Recall Number:

D-0908-2022

Code Information:

Lot: L24306 BUD: 6/6/2022

Product Description:

T-105 Papaverine 30 mg/mL Phentolamine 1 mg/mL PGE 10 mcg/mL, Packaged as a) 2.5 mL Multi-Dose vial NDC 73198-0005-03; b) 5 mL Multi Dose vial, NDC 73198-0005-05, Rx Only, Olympia Pharmaceuticals, 6700 Conroy Rd., Ste. 155 Orlando, FL 32835

Product Quantity:

3312 vials

Reason for Recall:

Lack of assurance of sterility.

Recall Number:

D-0909-2022

Code Information:

Lots: K41J09, K41I09 BUD: 11/9/2022; B24B22-22 BUD: 2/22/2023

Product Description:

T-106 Papaverine 30 mg/mL Phentolamine 1 mg/mL Alprostadil 25 mcg/mL, Packaged as a) 5 mL Multi-Dose vial NDC 73198-0013-05; b) 10 mL Multi-Dose vial NDC 73198-0013-10, Rx Only, Olympia Pharmaceuticals, 6700 Conroy Rd., Ste. 155 Orlando, FL 32835

Product Quantity:

3185 vials

Reason for Recall:

Lack of assurance of sterility.

Recall Number:

D-0910-2022

Code Information:

Lot: K24F09 BUD: 11/9/2022

Product Description:

Testosterone Cypionate 200 mg/mL in Grapeseed Oil, Multi-Dose 10 mL vial, Rx Only, Olympia Pharmaceuticals, 6700 Conroy Rd., Ste. 155 Orlando, FL 32835, NDC 73198-0054-10

Product Quantity:

2198 vials

Reason for Recall:

Lack of assurance of sterility.

Recall Number:

D-0911-2022

Code Information:

Lots: J48011, J42011 BUD: 10/11/2022; J24C12 BUD: 10/12/2022;

Product Description:

Testosterone Cypionate 200 mg/mL in Sesame Oil, Packaged in a) 5 mL Multi-Dose vial NDC, 73198-0055-05; b) 10 mL Multi-Dose vial NDC 73198-0055-10; Rx Only, Olympia Pharmaceuticals, 6700 Conroy Rd., Ste. 155 Orlando, FL 32835.

Product Quantity:

33 vials

Reason for Recall:

Lack of assurance of sterility.

Recall Number:

D-0912-2022

Code Information:

Lot: J24B13 BUD: 10/13/2022

Product Description:

Tri-Immune Boost Glutathione 200 mg/mL Ascorbic Acid 200 mg/mL Zinc Sulfate 2.5 mg/mL Multi-Dose 30 mL vial, Rx Only, Olympia Pharmaceuticals, 6700 Conroy Rd., Ste. 155 Orlando, FL 32835, NDC 73198-0104-30

Product Quantity:

2260 vials

Reason for Recall:

Lack of assurance of sterility.

Recall Number:

D-0913-2022

Code Information:

Lots: B24D01-22, B24C01-22 BUD: 6/1/2022

Product Description:

Ultratest Testosterone Cypionate 160 mg/mL Testosterone Propionate 40 mg/mL, Multi-Dose 10 mL vial, Rx Only, Olympia Pharmaceuticals 6700 Conroy Rd., Ste. 155 Orlando, FL 32835, NDC 73198-0058-10

Product Quantity:

520 vials

Reason for Recall:

Lack of assurance of sterility.

Recall Number:

D-0914-2022

Code Information:

Lots: J24014, J24114 BUD: 10/14/2022

Product Description:

Vitamin D3 (50,000 IU/mL) Multi-Dose 30 mL vial, Rx Only, Olympia Pharmaceuticals, 6700 Conroy Rd., Ste. 155 Orlando, FL 32835, NDC 73198-0075-30

Product Quantity:

3083 vials

Reason for Recall:

Lack of assurance of sterility.

Recall Number:

D-0915-2022

Code Information:

Lots: L24009 BUD: 6/9/2022; L24028 BUD: 6/28/2022

Product Description:

Zinc Chloride (0.5 mg/mL), Multi-Dose 30 mL vial, Rx Only, Olympia Pharmaceuticals, 6700 Conroy Rd., Ste. 155 Orlando, FL 32835, NDC 73198-0071-30

Product Quantity:

1291 vials

Reason for Recall:

Lack of assurance of sterility.

Recall Number:

D-0916-2022

Code Information:

Lot: K24024 BUD: 5/24/2022

Product Description:

Alpha Lipoic Acid 25 mg/mL, Multi-Dose 30 mL vial, Rx Only, Olympia Pharmaceuticals, 6700 Conroy Rd., Ste. 155 Orlando, FL 32835, NDC 73198-0076-30

Product Quantity:

3286 vials

Reason for Recall:

Lack of assurance of sterility.

Recall Number:

D-0917-2022

Code Information:

Lots: L24C06, L24B06 BUD: 6/6/2022; B41023-22 BUD: 8/23/2022

Product Description:

Preserved Ascorbic Acid 500 mg/mL, Multi-Dose 30 mL vial, Rx Only, Olympia Pharmaceuticals, 6700 Conroy Rd., Ste. 155 Orlando, FL 32835 NDC 73198-0079-30

Product Quantity:

7420 vials

Reason for Recall:

Lack of assurance of sterility.

Recall Number:

D-0918-2022

Code Information:

Lots: A24B2022, A24C05 BUD: 7/5/2022; A24C12-22 BUD 7/12/2022; A24C18-22 BUD: 7/18/2022; A24C20-22 BUD: 7/20/2022

Product Description:

AT-6 Papaverine 40 mg/mL Phentolamine 4 mg/mL Atropine 0.3 mg/mL, Multi-Dose 10 mL vial, Rx Only, Olympia Pharmaceuticals, 6700 Conroy Rd., Ste. 155 Orlando, FL 32835 NDC 73198-0040-10

Product Quantity:

528 vials

Reason for Recall:

Lack of assurance of sterility.

Recall Number:

D-0919-2022

Code Information:

Lot: K24409 BUD: 11/9/2022

Product Description:

Bimix-3 Papaverine 30 mg/mL Phentolamine 3 mg/mL, Packaged as a) 2.5 mL Multi-Dose Vial, NDC73198-0027-03; b) 10 mL Multi-Dose Vial, NDC 73198-0027-10; Rx Only, Olympia Pharmaceuticals, 6700 Conroy Rd., Ste. 155 Orlando, FL 32835

Product Quantity:

1287 vials

Reason for Recall:

Lack of assurance of sterility.

Recall Number:

D-0920-2022

Code Information:

Lots: J24F20, J24E20 BUD: 10/20/2022, B24G22-22, B24F22-22 BUD: 2/22/2023

Product Description:Calcium Chloride 10% (100 mg/mL), Multi-Dose 30 mL vial, Rx Only, Olympia Pharmaceuticals, 6700 Conroy Rd., Ste. 155 Orlando, FL 32835
NDC 73198-0064-30**Product Quantity:**

5443 vials

Reason for Recall:

Lack of assurance of sterility.

Recall Number:

D-0921-2022

Code Information:

Lots: B24C21-22 BUD: 8/21/2022, B24B21-22 BUD: 8/21/2022, A24010-22 BUD: 7/10/2022, A24110-22 BUD: 7/10/2022

Product Description:Cyanocobalamin 2 mg/mL, Multi-Dose 10 mL vial, Rx Only, Olympia Pharmaceuticals, 6700 Conroy Rd., Ste. 155 Orlando, FL 32835, NDC
73198-0115-10**Product Quantity:**

1282 vials

Reason for Recall:

Lack of assurance of sterility.

Recall Number:

D-0922-2022

Code Information:

Lots: B24115-22 BUD: 8/15/2022; L24001 BUD: 6/1/2022

Product Description:Pyridoxine 100 mg/mL, Multi-Dose 30 mL vial, Rx Only, Olympia Pharmaceuticals, 6700 Conroy Rd., Ste. 155 Orlando, FL 32835, NDC 73198-
0066-30**Product Quantity:**

1306 vials

Reason for Recall:

Lack of assurance of sterility.

Recall Number:

D-0923-2022

Code Information:

Lot: A24018-22 BUD: 7/18/2022

Product Description:Dexpanthenol 250 mg/mL Multi-Dose 30 mL Rx Only, Olympia Pharmaceuticals, 6700 Conroy Rd., Ste. 155 Orlando, FL 32835, NDC 73198-
0070-30**Product Quantity:**

1296 vials

Reason for Recall:

Lack of assurance of sterility.

Recall Number:

D-0924-2022

Code Information:

Lot: L24016 BUD: 6/16/2022

Product Description:FA Papaverine 20 mg/mL Phentolamine 2 mg/mL Alprostadil 20 mcg/mL Atropine 0.2 mg/mL, Multi-Dose 10 mL vial, Rx Only, 6700 Olympia
Pharmaceuticals, Conroy Rd., Ste. 155 Orlando, FL 32835, NDC 73198-0006-10**Product Quantity:**

1159 vials

Reason for Recall:

Lack of assurance of sterility.

Recall Number:

D-0925-2022

Code Information:

Lot: B41C22-22 BUD: 2/22/2023

Product Description:

Folic Acid 1 mg/mL Hydroxocobalamin 1 mg/mL, Multi-Dose 30 mL vial, Rx Only, Olympia Pharmaceuticals, 6700 Conroy Rd., Ste. 155 Orlando, FL 32835, NDC 73198-0112-30

Product Quantity:

2441 vials

Reason for Recall:

Lack of assurance of sterility.

Recall Number:

D-0926-2022

Code Information:

Lots: L24007 BUD: 6/7/2022; B24017-22 BUD: 8/17/2022

Product Description:

Formula F1 Papaverine 1.8 mg/mL Phentolamine 0.2 mg/mL Alprostadil 18 mcg/mL Atropine 0.02 mg/mL, Packaged as a)2.5 mL Multi-Dose vial, NDC 73198-0001-03; b) 10 mL Multi-Dose vial, NDC 73198-0001-10; Rx Only, Olympia Pharmaceuticals, 6700 Conroy Rd., Ste. 155 Orlando, FL 32835

Product Quantity:

1703 vials

Reason for Recall:

Lack of assurance of sterility.

Recall Number:

D-0927-2022

Code Information:

Lots: K41C09, K41B09 BUD: 11/9/2022, and A24C19-22 BUD: 1/19/2023

Product Description:

Formula F2 Papaverine 9 mg/mL Phentolamine 1 mg/mL Alprostadil 10 mcg/mL Atropine 0.1 mg/mL, Multi-Dose 10 mL vial, Rx Only, Olympia Pharmaceuticals, 6700 Conroy Rd., Ste. 155 Orlando, FL 32835, NDC 73198-0002-10

Product Quantity:

72 vials

Reason for Recall:

Lack of assurance of sterility.

Recall Number:

D-0928-2022

Code Information:

Lot: A24F19-22 BUD: 1/19/2023

Product Description:

Formula F9 Papaverine 0.9 mg/mL Phentolamine 0.1 mg/mL PGE 20 mcg/mL Atropine 0.01 mg/mL, Multi-Dose 10 mL vial, Rx Only, Olympia Pharmaceuticals, 6700 Conroy Rd., Ste. 155 Orlando, FL 32835, NDC 73198-0004-10

Product Quantity:

205 vials

Reason for Recall:

Lack of assurance of sterility.

Recall Number:

D-0929-2022

Code Information:

Lot: B24G02-22 BUD: 2/2/2023

Product Description:

Lidocaine 2% (20 mg/mL), Multi-Dose 30 mL vial, Rx Only, Olympia Pharmaceuticals, 6700 Conroy Rd., Ste. 155 Orlando, FL 32835, NDC 73198-0097-30

Product Quantity:

1195 vials

Reason for Recall:

Lack of assurance of sterility.

Recall Number:

D-0930-2022

Code Information:

Lots: L246022 BUD: 6/22/2022; B24208-22 BUD: 8/8/2022

Product Description:

Lidocaine 1%/Epinephrine 1:100,000/mL, Multi-Dose 30 mL vial, Rx Only, Olympia Pharmaceuticals 6700 Conroy Rd., Ste. 155 Orlando, FL 32835, NDC 73198-0099-30

Product Quantity:

310 vials

Reason for Recall:

Lack of assurance of sterility.

Recall Number:

D-0931-2022

Code Information:

Lot: K41023 BUD: 5/23/2022

Product Description:

Lipo-Mino-Mix Pyridoxine HCL (B6) 2 mg/mL Methionine 12.4 mg/mL Inositol 25 mg/mL Choline Chloride 25 mg/mL Thiamine HCL (B1) 50 mg/mL Riboflavin5P04 (B2) 5 mg/mL, Packaged as a) 10 mL Multi-Dose vial, NDC 73198-0130-10; b) 30 mL Multi-Dose vial, NDC 73198-0130-30; Rx Only, Olympia Pharmaceuticals, 6700 Conroy Rd., Ste. 155 Orlando, FL 32835

Product Quantity:

3762 vials

Reason for Recall:

Lack of assurance of sterility.

Recall Number:

D-0932-2022

Code Information:

Lots: A24103 BUD: 7/3/2022; B41B01-22 BUD: 8/1/2022

Product Description:

Lipostat-Plus Methionine 25 mg/mL Inositol 50 mg/mL Choline Chloride 50 mg/mL Cyanocobalamin 1 mg/mL Pyridoxine HCL 175 mcg/mL, Multi-Dose 30 mL vial, Rx Only, Olympia Pharmaceuticals, 6700 Conroy Rd., Ste. 155 Orlando, FL 32835. NDC 73198-0047-30.

Product Quantity:

4843 vials

Reason for Recall:

Lack of assurance of sterility.

Recall Number:

D-0933-2022

Code Information:

Lots: A24H26-22, A24G26-22 BUD: 7/26/2022, K24130 BUD: 5/30/2022

Product Description:

Lipostat Plus SF Inositol 50 mg/mL Choline Chloride 50 mg/mL Cyanocobalamin 1 mg/mL Pyridoxine HCL 175 mcg/mL Multi-Dose 30 mL vial, Rx Only, Olympia Pharmaceuticals, 6700 Conroy Rd., Ste. 155 Orlando, FL 32835. NDC 73198-0048-30

Product Quantity:

1571 vials

Reason for Recall:

Lack of assurance of sterility.

Recall Number:

D-0934-2022

Code Information:

Lot: K24030 BUD: 5/30/2022

Product Description:

Magnesium Chloride, 200 mg/mL, Multi-Dose 30 mL vial, Rx Only, Olympia Pharmaceuticals, 6700 Conroy Rd., Ste. 155 Orlando, FL 32835. NDC 73198-0072-30.

Product Quantity:

1597 vials

Reason for Recall:

Lack of assurance of sterility.

Recall Number:

D-0935-2022

Code Information:

Lot: A24012-22 BUD: 7/12/2022

Product Description:

Methylcobalamin 5 mg/mL, Packaged as a) Multi-Dose 10mL vial, NDC 73198-0051-10; b) Multi-Dose 30mL vial, NDC 73198-0051-30, Rx Only, Olympia Pharmaceuticals, 6700 Conroy Rd., Ste. 155 Orlando, FL 32835

Product Quantity:

12800 vials

Reason for Recall:

Lack of assurance of sterility.

Recall Number:

D-0936-2022

Code Information:

Lots: L24122, L24C22, L24B22 BUD: 6/22/2022, A24124-22 BUD: 7/24/2022, A24225-22 BUD: 7/25/2022, A24026-22 BUD: 7/26/2022, A24027-22 BUD: 7/27/2022, A24C31-22, A24B31-22 BUD: 7/31/2022

Product Description:

MICC, Methionine 25 mg/mL Inositol 50 mg/mL Choline Chloride 50 mg/mL Cyanobalamin 330 mcg/mL, Packaged as a) Multi-Dose 10 mL vial, NDC 73198-0052-10; b) Multi-Dose 30 mL vial, NDC 73198-0052-30, Rx Only, Olympia Pharmaceuticals, 6700 Conroy Rd., Ste. 155 Orlando, FL 32835

Product Quantity:

5334 vials

Reason for Recall:

Lack of assurance of sterility.

Recall Number:

D-0937-2022

Code Information:

Lots: K41F17, K41B17, K41C17, K41E17 BUD: 5/17/2022

Product Description:

Myers Cocktail, Magnesium Chloride 9.65 mg/mL Dextranthenol 4.07 mg/mL Thiamine HCL 1.62 mg/mL Riboflavin-5-Phosphate 3.23 mg/mL Pyridoxine HCL 1.63 mg/mL Niacinamide 1.62 mg/mL Calcium Gluconate 4.07 mg/mL Ascorbic Acid 64.4 mg/mL, Single-Dose 10 mL vial, Rx Only, Olympia Pharmaceuticals, 6700 Conroy Rd., Ste. 155 Orlando, FL 32835. NDC 73198-0088-10.

Product Quantity:

13679 vials

Reason for Recall:

Lack of assurance of sterility.

Recall Number:

D-0938-2022

Code Information:

Lots: L24029 BUD: 6/29/2022, A24125-22 BUD: 7/25/2022, A24331-22 BUD: 7/31/2022

Product Description:

NAD+ Nicotinamide Adenine Dinucleotide, Lyophilized powder for reconstitution, Multi-Dose 500 mg per vial, Rx Only, Olympia Pharmaceuticals, 6700 Conroy Rd., Ste. 155 Orlando, FL 32835. NDC 73198-0083-00.

Product Quantity:

8982 vials

Reason for Recall:

Lack of assurance of sterility.

Recall Number:

D-0939-2022

Code Information:

Lots: A2401422 BUD: 1/14/2023, K41001 BUD: 11/1/2022, K41130 BUD: 11/30/2022, L24113 BUD: 12/13/2022, L41102 BUD: 12/2/2022

Product Description:

NB-343 Papaverine 30 mg/mL Phentolamine 3 mg/mL PGE 30 mcg/mL, Multi-Dose 10 mL vial, Rx Only, Olympia Pharmaceuticals, 6700 Conroy Rd., Ste. 155 Orlando, FL 32835. NDC 73198-0010-10.

Product Quantity:

606 vials

Reason for Recall:

Lack of assurance of sterility.

Recall Number:

D-0940-2022

Code Information:

Lot: L24C08 BUD: 12/8/2022

Product Description:

Olympia Mineral Blend Magnesium Chloride 80 mg/mL Zinc Sulfate 1 mg/mL Manganese Sulfate 20 mcg/mL Copper Gluconate 0.2 mg/mL Sodium Selenite 18 mcg/mL, Multi-Dose 30 mL vial, Rx Only, Olympia Pharmaceuticals, 6700 Conroy Rd., Ste. 155 Orlando, FL 32835. NDC 73198-0061-30.

Product Quantity:

6113 vials

Reason for Recall:

Lack of assurance of sterility.

Recall Number:

D-0941-2022

Code Information:

Lots: L24B1 BUD: 6/16/2022, L24D16 BUDL 6/16/2022, A24C24-22, A24E24-22 BUDL 7/24/2022

Product Description:

Olympia Vita-Complex Thiamine HCL (B1) 100 mg/mL Niacinamide (B3) 100 mg/mL Riboflavin 5 P04 (B2) 2 mg/mL Dexpanthenol (B5) 2 mg/mL Pyridoxine HCL (B6) 2 mg/mL Multi-Dose 30 mL vial, Rx Only, Olympia Pharmaceuticals, 6700 Conroy Rd., Ste. 155 Orlando, FL 32835. NDC 73198-0063-30.

Product Quantity:

8664 vials

Reason for Recall:

Lack of assurance of sterility.

Recall Number:

D-0942-2022

Code Information:

Lots: B24B1422, B24E1422 BUD: 8/14/2022, B24B1522 BUD: 8/15/2022, L24B15, L24C15, L24D15 BUD: 6/15/2022

Product Description:

Ondansetron Hydrochloride, 1 mg/mL, Multi-Dose 30 mL vial, Rx Only, Olympia Pharmaceuticals, 6700 Conroy Rd., Ste. 155 Orlando, FL 32835. NDC 73198-0127-30.

Product Quantity:

911 vials

Reason for Recall:

Lack of assurance of sterility.

Recall Number:

D-0943-2022

Code Information:

Lot: B24015-22 BUD: 8/15/2022

Product Description:

PGE-3 Alprostadil 150 mcg/mL, Multi-Dose 10 mL vial, Rx Only, Olympia Pharmaceuticals, 6700 Conroy Rd., Ste. 155 Orlando, FL 32835. NDC 73198-0030-10.

Product Quantity:

421 vials

Reason for Recall:

Lack of assurance of sterility.

Recall Number:

D-0944-2022

Code Information:

Lot: L24508 BUD: 12/8/2022

Product Description:

Phenylephrine 1 mg/mL, Multi-Dose 5 mL vial, Rx Only, Olympia Pharmaceuticals, 6700 Conroy Rd., Ste. 155 Orlando, FL 32835. NDC 73198-0021-05.

Product Quantity:

9102 vials

Reason for Recall:

Lack of assurance of sterility.

Recall Number:

D-0945-2022

Code Information:

Lots: K41016 BUD: 11/16/2022 and A24025-22 BUD: 1/25/2023

Product Description:

Pyridoxine HCL 100 mg/mL, Multi-Dose 30 mL vial, Rx Only, Olympia Pharmaceuticals, 6700 Conroy Rd., Ste. 155 Orlando, FL 32835. NDC 73198-0066-30.

Product Quantity:

1306 vials

Reason for Recall:

Lack of assurance of sterility.

Recall Number:

D-0946-2022

Code Information:

Lot: A24018-22 BUD: 7/18/2022

Product Description:

QM-2 Papaverine 30 mg/mL Phentolamine 3 mg/mL Alprostadil 60 mcg/mL Atropine 0.2 mg/mL Multi-Dose 10 mL Rx Only, Olympia Pharmaceuticals, 6700 Conroy Rd., Ste. 155 Orlando, FL 32835. NDC 73198-0018-10.

Product Quantity:

619 vials

Reason for Recall:

Lack of assurance of sterility.

Recall Number:

D-0947-2022

Code Information:

Lot: K24D15 BUD: 11/15/2022

Product Description:

QM-3 Papaverine 30 mg/mL Phentolamine 3 mg/mL Alprostadil 150 mcg/mL Atropine 0.2 mg/mL, Multi-Dose 10 mL vial, Rx Only, Olympia Pharmaceuticals, 6700 Conroy Rd., Ste. 155 Orlando, FL 32835. NDC 73198-0019-10.

Product Quantity:

414 vials

Reason for Recall:

Lack of assurance of sterility.

Recall Number:

D-0948-2022

Code Information:

Lot: A24505 BUD: 1/5/2023

Product Description:

Amino Blend Glutamine 30 mg/mL Ornithine HCL 50 mg/mL Arginine HCL 100 mg/mL Lysine HCL 50 mg/mL Citrulline 50 mg/mL, Multi-Dose 30 mL vial, Rx Only, Olympia Pharmaceuticals, 6700 Conroy Rd., Ste. 155 Orlando, FL 32835.NDC 73198-0129-30.

Product Quantity:

7761 vials

Reason for Recall:

Lack of assurance of sterility.

Recall Number:

D-0949-2022

Code Information:

Lots: A24104, A24304 BUD: 7/4/2022; A24303 BUD: 7/3/2022; B2422322, B24123-22 BUD: 8/22/2022

Class II Drugs Event

Event ID:

90215

Product Type:

Drugs

Status:

Ongoing

Date Terminated:**Recall Initiation Date:**

05/13/2022

Voluntary / Mandated:

Voluntary: Firm initiated

Center Classification Date:

05/20/2022

Initial Firm Notification of Consignee or Public:

Letter

Recalling Firm:Direct Rx
94 Worldwide Dr
Dawsonville GA United States**Distribution Pattern:**

Nationwide to the U.S. market

Associated Products

Product Description:

Zonisamide Capsules USP, 100 mg, 90-count bottle, Rx Only, Packaged and Distributed By: Direct Rx Dawsonville, GA 30534, Manufactured for: Glenmark Pharmaceuticals Inc., USA Mahwah, NJ 07430, NDC 61919-775-90

Product Quantity:

16 bottles

Reason for Recall:

CGMP Deviations: Gaps in the quality system in the Quality Control microbiology laboratory.

Recall Number:

D-0888-2022

Code Information:

Lot: 23JY2124 Exp. 6/30/23

Class III Drugs Event

Event ID:

90166

Product Type:

Drugs

Status:

Ongoing

Date Terminated:**Recall Initiation Date:**

05/13/2022

Voluntary / Mandated:

Voluntary: Firm initiated

Center Classification Date:

05/25/2022

Initial Firm Notification of Consignee or Public:

Letter

Recalling Firm:

GlaxoSmithKline LLC
1011 N Arendell Ave
Zebulon NC United States

Distribution Pattern:

Nationwide in the U.S.

Associated Products**Product Description:**

Tivicay (dolutegravir) Tablets 50 mg, 30-count Bottle, Rx Only, Manufactured for: ViiV Healthcare RTP, NC 27709, NDC 49702-228-13.

Product Quantity:

328 bottles

Reason for Recall:

Labeling: incorrect or missing lot and/or expiration date. An incorrect expiration date was printed on the product labeling with an expiration date of January 2027, whereas the correct expiration date is September 2026.

Recall Number:

D-0896-2022

Code Information:

Lot: 2A9E, Exp 1/2027

Class III Drugs Event**Event ID:**

90183

Product Type:

Drugs

Status:

Completed

Date Terminated:**Recall Initiation Date:**

01/15/2021

Voluntary / Mandated:

Voluntary: Firm initiated

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

Telephone

Recalling Firm:

Calvin Scott & Company, Inc.
209 Eubank Blvd Ne
Albuquerque NM United States

Distribution Pattern:

1 physician in Alpharetta, GA

Associated Products**Product Description:**

Benzphetamine tablets, 50mg, CIII, repackaged in 30-count bottles, Eduard R. Fatakhov, MD, 401 S. Main Street, # B3, Alpharetta, GA 30009, Distributed by Calvin Scott & Co., Inc, Albuq., NM., NDC 10702-0040-50

Product Quantity:

13 bottles

Reason for Recall:

Labeling: Label Mix-up: This recall was initiated due to mislabeling of products.

Recall Number:**Code Information:**

CSI Lot: CS20274, Exp 5/22

Class III Drugs Event**Event ID:**

90197

Product Type:

Drugs

Status:

Ongoing

Date Terminated:**Recall Initiation Date:**

04/29/2022

Voluntary / Mandated:

Voluntary: Firm initiated

Center Classification Date:

05/23/2022

Initial Firm Notification of Consignee or Public:

E-Mail

Recalling Firm:

Eco Lips, Inc
6000 Huntington Ct Ne
Cedar Rapids IA United States

Distribution Pattern:

CA

Associated Products

Product Description:

Higher Education Make Out Ready Vegan Lip Balm, SPF 15, Net Wt. 0.15 oz (4.25 g) per tube, Active Ingredients: Octinoxate (7.5%), Oxybenzone (3%); Distributed by: Higher Education Skincare, 1.833.251.0388

Product Quantity:

17,000 units

Reason for Recall:

Mislabeling: The active ingredient list on the label does not match the product's actual ingredients Specifically, the label states Octinoxate 7.5% and Oxybenzone 3%, while the product therein is made with Octinoxate 7.5%, Octisalate 5%, Octocrylene 5%, and Avobenzone 3%.

Recall Number:

D-0890-2022

Code Information:

Lot 93400-21200

Not Yet Classified Drugs Event

Event ID:

90183

Product Type:

Drugs

Status:

Completed

Date Terminated:**Recall Initiation Date:**

01/15/2021

Voluntary / Mandated:

Voluntary: Firm initiated

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

Telephone

Recalling Firm:

Calvin Scott & Company, Inc.
209 Eubank Blvd Ne
Albuquerque NM United States

Distribution Pattern:

1 physician in Alpharetta, GA

Associated Products

Product Description:

Benzonatate capsules, 100mg, repackaged in 30-count bottles, Eduard R. Fatakhov, MD, 401 S. Main Street, # B3, Alpharetta, GA 30009, Distributed by Calvin Scott & Co., Inc, Albuq., NM., NDC 67877-0573-05

Product Quantity:

10 bottles

Reason for Recall:

Labeling: Label Mix-up: This recall was initiated due to mislabeling of products.

Recall Number:

Code Information:

CSI Lot: CS20180W, Exp 3/22