

Enforcement Report - Week of May 4, 2022

Class II Drugs Event

Event ID:

89938

Product Type:

Drugs

Status:

Ongoing

Date Terminated:**Recall Initiation Date:**

04/04/2022

Voluntary / Mandated:

Voluntary: Firm initiated

Center Classification Date:

04/27/2022

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 the USA

Associated Products

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:

16,329 vials

Reason for Recall:

CGMP Deviations: prior to October 1, 2021, environmental and personnel monitoring Out of Action Limit (OOAL) excursions were not being properly investigated

Recall Number:

D-0795-2022

Code Information:

Lots: E24026 BUD: 5/26/2022, E42112 BUD: 5/12/2022, E48024 BUD: 2/2/2022, F24014 BUD: 6/14/2022, G48028 BUD: 7/28/2022, H24016 BUD: 8/16/2022, H42010 BUD 8/10/2022, H48030 BUD: 8/11/2022, I47003 BUD: 8/11/2022

Product Description:

Diluent for Reconstitution Each ML contains: 1.5% Benzyl Alcohol NF, Sterile Water for Injection USP, 10 mL Multi-Dose vial, Rx Only, Olympia
Pharmaceuticals 6700 Conroy Rd., Ste. 155, Orlando, FL 32835. 73198-0113-10

Product Quantity:

45,935 vials

Reason for Recall:

CGMP Deviations: prior to October 1, 2021, environmental and personnel monitoring Out of Action Limit (OOAL) excursions were not being properly investigated

Recall Number:

D-0796-2022

Code Information:

Lots: D41012 BUD 4/12/2022, D41212 BUD: 4/12/2022, D47026 BUD: 4/26/2022, E41017 BUD: 5/17/2022, E41018 BUD: 5/18/2022, E47004 BUD: 5/4/2022, E47024 BUD: 5/24/2022, E47026 BUD: 5/26/2022, E48005 BUD: 5/5/2022, G47014 BUD: 7/14/2022, H48816 BUD: 8/16/2022

Product Description:

Sermorelin Acetate, Lyophilized powder for reconstitution, Multi-Dose vials, Packaged as a) 3 mg per vial, NDC 73198-0060-00; b) 9 mg NDC
73198-0059-00, Rx Only, Olympia Pharmaceuticals 6700 Conroy Rd., Ste. 155, Orlando, FL 32835.

Product Quantity:

18060 vials

Reason for Recall:

CGMP Deviations: prior to October 1, 2021, environmental and personnel monitoring Out of Action Limit (OOAL) excursions were not being properly investigated

Recall Number:

D-0797-2022

Code Information:

Lots: a) D41019 BUD: 4/19/2022; b) D41112 BUD: 4/12/2022, D47028 BUD: 4/28/2022, F24009 BUD: 3/4/2022, F41001 BUD: 6/1/2022, G48006 BUD: 7/14/2022, G48008 BUD: 7/8/2022, G48012 BUD: 7/12/2022, G48014 BUD: 7/14/2022, G48019 BUD: 7/9/2022, I24009 BUD: 9/9/2022, I41107 BUD: 9/7/2022

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 vial, Rx Only Olympia Pharmaceuticals 6700 Convoy Rd., Ste. 155, Orlando, FL 32835. NDC: 73198-0018-10.

Product Quantity:

1871 vials

Reason for Recall:

CGMP Deviations: prior to October 1, 2021, environmental and personnel monitoring Out of Action Limit (OOAL) excursions were not being properly investigated

Recall Number:

D-0798-2022

Code Information:

Lots: D41219 BUD: 4/19/2022, I24C13 BUD: 9/13/2022

Product Description:

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

Product Quantity:

6916 vials

Reason for Recall:

CGMP Deviations: prior to October 1, 2021, environmental and personnel monitoring Out of Action Limit (OOAL) excursions were not being properly investigated

Recall Number:

D-0799-2022

Code Information:

Lots: a) D41412 BUD: 4/22/2022, E41F10 BUD: 5/10/2022, E41G10 BUD: 5/10/2022, F24D21 BUD: 6/21/2022 ; b) D41512 BUD: 4/12/2022; c) F42B21 BUD: 6/21/2022, H42B03 BUD: 8/3/2022, H42C03 BUD: 8/3/2022

Product Description:

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

Product Quantity:

800 vials

Reason for Recall:

CGMP Deviations: prior to October 1, 2021, environmental and personnel monitoring Out of Action Limit (OOAL) excursions were not being properly investigated

Recall Number:

D-0800-2022

Code Information:

Lots: D41C19 BUD: 4/19/2022, I42C13 BUD: 9/13/2022, I42B13 BUD: 9/13/2022

Product Description:

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

Product Quantity:

1318 vials

Reason for Recall:

CGMP Deviations: prior to October 1, 2021, environmental and personnel monitoring Out of Action Limit (OOAL) excursions were not being properly investigated

Recall Number:

D-0801-2022

Code Information:

Lots: D41E20 BUD: 4/20/2022, D41F20 BUD: 4/20/2022, G41C13 BUD: 7/13/2022, G41B13 BUD: 7/13/2022

Product Description:

AT-1, Papaverine 8mg/ml . Phentolamine 2mg/ml . Atropine 0.2mg/ml, Multi-Dose 10 ml vial, Rx Only, Olympia Pharmaceuticals 6700 Convoy Rd., Ste. 155, Orlando, FL 32835. NDC 73198-0039-10

Product Quantity:

310 vials

Reason for Recall:

CGMP Deviations: prior to October 1, 2021, environmental and personnel monitoring Out of Action Limit (OOAL) excursions were not being properly investigated

Recall Number:

D-0802-2022

Code Information:

Lots: F41C28 BUD: 6/28/2022, F41B28 BUD: 6/28/2022

Product Description:

NB-243, Papaverine 30mg/ml . Phentolamine 3mg/ml . Alprostadil 20mcg/ml, 10ml Multi-Dose vials, Rx Only, Olympia Pharmaceuticals 6700 Convoy Rd., Ste. 155, Orlando, FL 32835. NDC 73198-0009-10

Product Quantity:

3509 vials

Reason for Recall:

CGMP Deviations: prior to October 1, 2021, environmental and personnel monitoring Out of Action Limit (OOAL) excursions were not being properly investigated

Recall Number:

D-0803-2022

Code Information:

Lots: I24C28 BUD: 9/28/2022, D41I19 BUD: 4/19/2022, F41321 BUD: 6/21/2022, I24128 BUD: 9/28/2022

Product Description:

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

Product Quantity:

4129 vials

Reason for Recall:

CGMP Deviations: prior to October 1, 2021, environmental and personnel monitoring Out of Action Limit (OOAL) excursions were not being properly investigated

Recall Number:

D-0804-2022

Code Information:

Lots: a) E24510 BUD: 5/10/2022, E24610 BUD: 5/10/2022; b) H42H03 BUD: 8/3/2022, E24810 BUD: 5/10/2022, H42203 BUD: 8/3/2022

Product Description:

T-101, Papaverine 17.65 mg/mL . Phentolamine 0.59 mg/mL . Alprostadil 5.9 mcg/mL. Packaged as a) 10 mL Multi-Dose vial, NDC 73198-0014-10; b) 5 mL Multi-Dose vial, NDC 73198-0014-05; Rx Only, Olympia Pharmaceuticals 6700 Convoy Rd., Ste. 155, Orlando, FL 32835.

Product Quantity:

2437 vials

Reason for Recall:

CGMP Deviations: prior to October 1, 2021, environmental and personnel monitoring Out of Action Limit (OOAL) excursions were not being properly investigated

Recall Number:

D-0805-2022

Code Information:

Lots: a) E41B10 BUD: 5/10/2022; b) E41B08 BUD: 5/10/2022, I41C08 BUD: 9/8/2022, I41D08 BUD: 9/8/2022, E41C10 BUD: 5/10/2022

Product Description:

SB-4, Papaverine 30 mg/mL . Phentolamine 3 mg/mL . Alprostadil 40 mcg/mL, 10 mL Multi-Dose vial, Rx Only, Olympia Pharmaceuticals 6700 Convoy Rd., Ste. 155, Orlando, FL 32835. NDC 73198-0023-10.

Product Quantity:

1740 vials

Reason for Recall:

CGMP Deviations: prior to October 1, 2021, environmental and personnel monitoring Out of Action Limit (OOAL) excursions were not being properly investigated

Recall Number:

D-0806-2022

Code Information:

Lots: E41C18 BUD: 5/18/2022, E41D18 BUD: 5/18/2022, G42D20 BUD: 7/20/2022, G42B20 BUD: 7/20/2022

Product Description:

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

Product Quantity:

1110 vials

Reason for Recall:

CGMP Deviations: prior to October 1, 2021, environmental and personnel monitoring Out of Action Limit (OOAL) excursions were not being properly investigated

Recall Number:

D-0807-2022

Code Information:

Lots: E48B18 BUD: 5/18/2022, E48D18 BUD: 5/18/2022, H24D31 BUD: 8/31/2022; E48C18 BUD: 5/18/2022

Product Description:

SB-6, Papaverine 30 mg/mL . Phentolamine 3 mg/mL . PGE 60 mcg/mL, Multi-Dose 10 mL vial, Rx Only, Olympia Pharmaceuticals 6700 Convoy Rd., Ste. 155, Orlando, FL 32835. NDC 73198-0025-10.

Product Quantity:

336 vials

Reason for Recall:

CGMP Deviations: prior to October 1, 2021, environmental and personnel monitoring Out of Action Limit (OOAL) excursions were not being properly investigated

Recall Number:

D-0808-2022

Code Information:

Lots: E41H18 BUD: 5/18/2022, G41319 BUD: 7/19/2022

Product Description:

ST-1, Papaverine 30 mg/mL . Phentolamine 1.5 mg/mL . Alprostadil 50 mcg/ml, 10 mL Multi-Dose vial, Rx Only, Olympia Pharmaceuticals 6700 Convoy Rd., Ste. 155, Orlando, FL 32835. NDC 73198-0011-10.

Product Quantity:

525 vials

Reason for Recall:

CGMP Deviations: prior to October 1, 2021, environmental and personnel monitoring Out of Action Limit (OOAL) excursions were not being properly investigated

Recall Number:

D-0809-2022

Code Information:

Lots: H24F03 BUD: 8/3/2022, H24E03 BUD: 8/3/2022

Product Description:

ST-2, Papaverine 30 mg/mL . Phentolamine 3 mg/mL . Alprostadil 100 mcg/mL, 10 mL Multi-Dose vial, Rx Only, Olympia Pharmaceuticals 6700 Convoy Rd., Ste. 155, Orlando, FL 32835. NDC 73198-0012-10.

Product Quantity:

2005 vials

Reason for Recall:

CGMP Deviations: prior to October 1, 2021, environmental and personnel monitoring Out of Action Limit (OOAL) excursions were not being properly investigated

Recall Number:

D-0810-2022

Code Information:

Lots: F41C21 BUD: 6/21/2022, G42013 BUD: 7/13/2022, H41C31 BUD: 8/31/2022, F41D21 BUD: 6/21/2022

Product Description:

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

Product Quantity:

1679 vials

Reason for Recall:

CGMP Deviations: prior to October 1, 2021, environmental and personnel monitoring Out of Action Limit (OOAL) excursions were not being properly investigated

Recall Number:

D-0811-2022

Code Information:

Lots: E42B12 BUD: 5/12/2022, E42C12 BUD: 5/12/2022, E42D12 BUD: 5/12/2022, H24B23 BUD: 8/23/2022, H24C23 BUD: 8/23/2022, H24D23 BUD: 8/23/2022

Product Description:

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

Product Quantity:

1647 vials

Reason for Recall:

CGMP Deviations: prior to October 1, 2021, environmental and personnel monitoring Out of Action Limit (OOAL) excursions were not being properly investigated

Recall Number:

D-0812-2022

Code Information:

Lots: E41027 BUD: 5/27/2022, I24E13 BUD: 9/13/2022

Product Description:

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

Product Quantity:

1849 vials

Reason for Recall:

CGMP Deviations: prior to October 1, 2021, environmental and personnel monitoring Out of Action Limit (OOAL) excursions were not being properly investigated

Recall Number:

D-0813-2022

Code Information:

Lots: a) E47B18 BUD: 5/18/2022; b) E47C18 BUD: 5/18/2022, H24G31 BUD: 8/31/2022

Product Description:

RE-2, Papaverine 30 mg/mL . Phentolamine 3 mg/mL . Alprostadil 300 mcg/mL, Multi-Dose 10 mL vial, Rx Only, Olympia Pharmaceuticals 6700 Convoy Rd., Ste. 155, Orlando, FL 32835. NDC 73198-0016-10.

Product Quantity:

2201 vials

Reason for Recall:

CGMP Deviations: prior to October 1, 2021, environmental and personnel monitoring Out of Action Limit (OOAL) excursions were not being properly investigated

Recall Number:

D-0814-2022

Code Information:

Lots: E42G11 BUD: 5/11/2022, H41003 BUD: 8/3/2022; H41B03 BUD: 8/3/2022

Product Description:

BIMIX-3, Papaverine 30 mg/mL . Phentolamine 3 mg/mL, 10 mL Multi-Dose vial, Rx Only, Olympia Pharmaceuticals 6700 Convoy Rd., Ste. 155, Orlando, FL 32835. NDC 73198-0027-10.

Product Quantity:

388 vials

Reason for Recall:

CGMP Deviations: prior to October 1, 2021, environmental and personnel monitoring Out of Action Limit (OOAL) excursions were not being properly investigated

Recall Number:

D-0815-2022

Code Information:

Lot: F24C10 BUD: 6/10/2022

Product Description:

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

Product Quantity:

2887 vials

Reason for Recall:

CGMP Deviations: prior to October 1, 2021, environmental and personnel monitoring Out of Action Limit (OOAL) excursions were not being properly investigated

Recall Number:

D-0816-2022

Code Information:

Lots: F41414 BUD: 6/14/2022, F41C14 BUD: 6/14/2022, I24E28 BUD: 9/28/2022, I24F28 BUD: 9/28/2022

Product Description:

PGE-1, Alprostadil 40 mcg/mL, 10ml Multi-Dose vial, Rx Only, Olympia Pharmaceuticals 6700 Convoy Rd., Ste. 155, Orlando, FL 32835. NDC 73198-0028-10.

Product Quantity:

821 vials

Reason for Recall:

CGMP Deviations: prior to October 1, 2021, environmental and personnel monitoring Out of Action Limit (OOAL) excursions were not being properly investigated

Recall Number:

D-0817-2022

Code Information:

Lots: I24028 BUD: 9/28/2022, F47C30 BUD: 6/30/2022, F47B30 BUD: 6/30/2022

<p>Product Description: PGE-2, Alprostadil 80 mcg/mL, 10ml Multi-Dose vial, Rx Only, Olympia Pharmaceuticals 6700 Convoy Rd., Ste. 155, Orlando, FL 32835. NDC 73198-0029-10.</p> <p>Product Quantity: 460 vials</p> <p>Reason for Recall: CGMP Deviations: prior to October 1, 2021, environmental and personnel monitoring Out of Action Limit (OOAL) excursions were not being properly investigated</p> <p>Recall Number: D-0818-2022</p> <p>Code Information: Lot: F48102 BUD: 6/2/2022</p>

<p>Product Description: PGE-3, Alprostadil 150 mcg/mL, 10ml Multi-Dose vial, Rx Only, Olympia Pharmaceuticals 6700 Convoy Rd., Ste. 155, Orlando, FL 32835. NDC 73198-0030-10.</p> <p>Product Quantity: 410 vials</p> <p>Reason for Recall: CGMP Deviations: prior to October 1, 2021, environmental and personnel monitoring Out of Action Limit (OOAL) excursions were not being properly investigated</p> <p>Recall Number: D-0819-2022</p> <p>Code Information: Lot: G24C19 BUD: 7/19/2022</p>

<p>Product Description: T-50, Papaverine 8 mg/mL . Phentolamine 0.29 mg/mL . Alprostadil 2.9 mcg/mL, 10ml Multi-Dose vial, Rx Only, Olympia Pharmaceuticals 6700 Convoy Rd., Ste. 155, Orlando, FL 32835. NDC 73198-0022-10.</p> <p>Product Quantity: 1097 vials</p> <p>Reason for Recall: CGMP Deviations: prior to October 1, 2021, environmental and personnel monitoring Out of Action Limit (OOAL) excursions were not being properly investigated</p> <p>Recall Number: D-0820-2022</p> <p>Code Information: Lots: G24F01 BUD: 7/1/2022, G41316 BUD: 7/16/2022, H24B03 BUD: 8/3/2022, H24C03 BUD: 8/3/2022</p>

<p>Product Description: Formula F2, Papaverine 9 mg/mL . Phentolamine 1 mg/mL . Alprostadil 10 mcg/mL . Atropine 0.1 mg/mL, 10 mL Multi-Dose vial, Rx Only, Olympia Pharmaceuticals 6700 Convoy Rd., Ste. 155, Orlando, FL 32835. NDC 73198-0002-10.</p> <p>Product Quantity: 257 vials</p> <p>Reason for Recall: CGMP Deviations: prior to October 1, 2021, environmental and personnel monitoring Out of Action Limit (OOAL) excursions were not being properly investigated</p> <p>Recall Number: D-0821-2022</p> <p>Code Information: Lots: G48C20 BUD: 7/20/2022, G48B20 BUD: 7/22/2022</p>

<p>Product Description: Phenylephrine 1 mg/mL, 5 mL Multi-Dose vial, Rx Only, Olympia Pharmaceuticals 6700 Convoy Rd., Ste. 155, Orlando, FL 32835. NDC 73198-</p>

0021-05.

Product Quantity:

4521 vials

Reason for Recall:

CGMP Deviations: prior to October 1, 2021, environmental and personnel monitoring Out of Action Limit (OOAL) excursions were not being properly investigated

Recall Number:

D-0822-2022

Code Information:

Lot: H47030 BUD: 8/30/2022

Product Description:

Testosterone Cypionate 200 mg/mL (in Grapeseed Oil), Packaged in a) 10 mL Multi-Dose vial, NDC 73198-0054-10; b) 5 mL Multi-Dose vial, NDC 73198-0054-05, Rx Only, Olympia Pharmaceuticals 6700 Convoy Rd., Ste. 155, Orlando, FL 32835.

Product Quantity:

7161 vials

Reason for Recall:

CGMP Deviations: prior to October 1, 2021, environmental and personnel monitoring Out of Action Limit (OOAL) excursions were not being properly investigated

Recall Number:

D-0823-2022

Code Information:

Lots: a) D48027 BUD: 4/27/2022, E47017 BUD: 5/17/2022, F42007 BUD: 6/7/2022, F42107 BUD: 6/7/2022, F42207 BUD: 6/7/2022, F48009 BUD: 6/9/2022, F48109 BUD: 6/9/2022, H47003 BUD: 8/3/2022; b) F24024 BUD: 6/24/2022

Product Description:

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

Product Quantity:

3962 vials

Reason for Recall:

CGMP Deviations: prior to October 1, 2021, environmental and personnel monitoring Out of Action Limit (OOAL) excursions were not being properly investigated

Recall Number:

D-0824-2022

Code Information:

Lots: a) E48019 BUD: 5/19/2022, F42109 BUD: 6/9/2022, F42C09 BUD: 6/9/2022, G47012 BUD: 7/12/2022, G47112 BUD: 7/12/2022; b) F42B09 BUD: 6/9/2022

Product Description:

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

Product Quantity:

1276 vials

Reason for Recall:

CGMP Deviations: prior to October 1, 2021, environmental and personnel monitoring Out of Action Limit (OOAL) excursions were not being properly investigated

Recall Number:

D-0825-2022

Code Information:

Lots: E48020 BUD: 5/20/2022 and G47006 BUD: 7/6/2022

Product Description:

Hydroxocobalamin B12, 1 mg/mL, 30 mL Multi-Dose vial, Rx Only, Olympia Pharmaceuticals 6700 Convoy Rd., Ste. 155, Orlando, FL 32835. NDC 73198-0080-30.

Product Quantity:

6431 vials

Reason for Recall:

CGMP Deviations: prior to October 1, 2021, environmental and personnel monitoring Out of Action Limit (OOAL) excursions were not being properly investigated

Recall Number:

D-0826-2022

Code Information:

Lots: D48026 BUD: 4/26/2022, E48025 BUD: 5/25/2022, G48B21 BUD: 7/21/2022, G48C21 BUD: 7/21/2022

Product Description:

Sincalide. Lyophilized powder for reconstitution. 5 mcg per Multi-Dose vial, Rx Only, Olympia Pharmaceuticals 6700 Convoy Rd., Ste. 155, Orlando, FL 32835. NDC 73198-0082-00.

Product Quantity:

1770 vials

Reason for Recall:

CGMP Deviations: prior to October 1, 2021, environmental and personnel monitoring Out of Action Limit (OOAL) excursions were not being properly investigated

Recall Number:

D-0827-2022

Code Information:

Lots: F24018 BUD: 6/18/2022 and G47021 BUD: 7/21/2022

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:**Reason for Recall:**

Failed Reconstitution time

Recall Number:

D-0828-2022

Code Information:

Lot: F41116 BUD: 6/16/2022,

Class II Drugs Event

Event ID:

89944

Status:

Ongoing

Recall Initiation Date:

04/15/2022

Center Classification Date:

04/27/2022

Recalling Firm:Teva Pharmaceuticals USA Inc
400 Interpace Pkwy Bldg A
Parsippany NJ United States**Distribution Pattern:**

Nationwide within the United States

Product Type:

Drugs

Date Terminated:**Voluntary / Mandated:**

Voluntary: Firm initiated

Initial Firm Notification of Consignee or Public:

Associated Products

Product Description:

Lidocaine 2.5% and Prilocaine 2.5% Cream, USP, packaged in a) 5 g tubes (NDC 0591-2070-72), b) 30 g tubes (NDC 0591-2070-30), Rx Only, Manufactured by: Teligent Pharma, Inc., Buena, NJ 08310, USA, Distributed by: Actavis Pharma, Inc., Parsippany, NJ 07054, USA

Product Quantity:

353964 units

Reason for Recall:

cGMP Deviations

Recall Number:

D-0794-2022

Code Information:

Lot #: a) 16291, Exp. Date 01/2024;16469, Exp. Date 02/2024; b)16255, Exp. Date 11/2022; 16256, 16412 Exp. Date 02/2024; 16257, 16258, Exp. Date 12/2022; 16505, 6506, Exp. Date 03/2024; 16627,16786, 16787,16820, Exp. Date 04/2024.

Class II Drugs Event

Event ID:

89968

Product Type:

Drugs

Status:

Ongoing

Date Terminated:**Recall Initiation Date:**

04/06/2022

Voluntary / Mandated:

Voluntary: Firm initiated

Center Classification Date:

04/26/2022

Initial Firm Notification of Consignee or Public:

E-Mail

Recalling Firm:

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

Distribution Pattern:

Product was distributed to customers in AK and PA.

Associated Products

Product Description:

Losartan Potassium 50 mg Tablet, a) 30-count blister card (NDC# 70518-3282-1), b) 60-count blister card (NDC: 70518-3282-0), Rx Only, MFG by: Lupin Pharma, Baltimore, MD 21202.

Product Quantity:

433/30 count blister cards, 33/60 count blister cards

Reason for Recall:

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

Recall Number:

D-0788-2022

Code Information:

Lot # B1467803-120621, exp. date 06/30/2022 Lot # J0585793-121721, exp. date 12/31/2022

Class II Drugs Event

Event ID:

90001

Product Type:

Drugs

Status:

Ongoing

Date Terminated:

Recall Initiation Date:

04/12/2022

Voluntary / Mandated:

Voluntary: Firm initiated

Center Classification Date:

04/26/2022

Initial Firm Notification of Consignee or Public:

Letter

Recalling Firm:

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

Distribution Pattern:

Nationwide within the U.S to CA, IN and FL.

Associated Products

Product Description:

Losartan Potassium Tab. USP 50mg, Pkg Size: 30, Mfg: Lupin Pharmaceuticals, Inc., Preferred Pharmaceuticals, Inc.

Product Quantity:

44 Bottles of 90 Tablets 33 Bottles of 30 Tablets

Reason for Recall:

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

Recall Number:

D-0789-2022

Code Information:

Lot: E1321O, Exp.: 5/31/2023 Lot: E2521H, Exp.: 5/31/2023 Lot: E2621F, Exp.: 5/31/2023

Class II Drugs Event

Event ID:

90029

Product Type:

Drugs

Status:

Ongoing

Date Terminated:**Recall Initiation Date:**

04/25/2022

Voluntary / Mandated:

Voluntary: Firm initiated

Center Classification Date:

04/27/2022

Initial Firm Notification of Consignee or Public:

Letter

Recalling Firm:

Glenmark Pharmaceuticals Inc., USA
750 Corporate Dr
Mahwah NJ United States

Distribution Pattern:

USA nationwide

Associated Products

Product Description:

Zonisamide Capsules USP, 25 mg, packaged in 100-count bottles, Rx Only, Manufactured by: Glenmark Pharmaceuticals, Inc., USA Monroe, NC 28110, Manufactured for: Glenmark Pharmaceuticals Inc., USA Mahwah, NJ 07430, NDC 68462-128-01

Product Quantity:

11,136 bottles

Reason for Recall:

cGMP deviations

Recall Number:

D-0791-2022

Code Information:

Lot #: 29200052, Exp 4/30/2023

Product Description:

Zonisamide Capsules, USP, 50 mg, packaged in 100-count bottles, Rx only, Manufactured by: Glenmark Pharmaceuticals, Inc., USA Monroe, NC 28110, Manufactured for: Glenmark Pharmaceuticals Inc., USA Mahwah, NJ 07430, NDC 68462-129-01

Product Quantity:

12,003 bottles

Reason for Recall:

cGMP deviations

Recall Number:

D-0792-2022

Code Information:

Lot #: 29200064, Exp 5/31/2023

Product Description:

Zonisamide Capsules, USP, 100 mg, packaged in: a) 100-count bottle (NDC 68462-130-01); b) 500-count bottle (NDC 68462-130-05), Rx only, Manufactured by: Glenmark Pharmaceuticals, Inc., USA Monroe, NC 28110, Manufactured for: Glenmark Pharmaceuticals Inc., USA Mahwah, NJ 07430

Product Quantity:

a) 7,044 bottles; b) 1,014 bottles

Reason for Recall:

cGMP deviations

Recall Number:

D-0793-2022

Code Information:

a) Lot #: 29200053, Exp 4/30/2023; b) Lot #: 29200054, Exp 4/30/2023

Class II Drugs Event

Event ID:

90067

Product Type:

Drugs

Status:

Ongoing

Date Terminated:**Recall Initiation Date:**

04/21/2022

Voluntary / Mandated:

Voluntary: Firm initiated

Center Classification Date:

04/25/2022

Initial Firm Notification of Consignee or Public:

Letter

Recalling Firm:Torco Race Fuels
2527 W Dallas Ave
Apache Junction AZ United States**Distribution Pattern:**

Distributed in the USA

Associated Products

Product Description:

TORCO RACING FUELS HAND SANITIZER, Alcohol Antiseptic 80% Topical Solution, Hand Sanitizer Non-Sterile Solution, FDA Approved, 76590-8347-1, 3780 mL, 3.78 Liters (1 Gallon). Torco Race Fuels 2527 W. Dallas Ave. Apache Junction, AZ, 85120

Product Quantity:

127 gallons

Reason for Recall:

CGMP Deviations: FDA analysis found product to contain acetaldehyde and acetal above specification limits.

Recall Number:

D-0786-2022

Code Information:

No lot or Expiration date on Product

Class III Drugs Event

Event ID:

89905

Product Type:

Drugs

Status:

Ongoing

Date Terminated:**Recall Initiation Date:**

03/29/2022

Voluntary / Mandated:

Voluntary: Firm initiated

Center Classification Date:

04/25/2022

Initial Firm Notification of Consignee or Public:

Letter

Recalling Firm:

AptaPharma Inc.
1533 Union Ave
Pennsauken NJ United States

Distribution Pattern:

IL only

Associated Products

Product Description:

Wal-Tussin DM (dextromethorphan HBr/Guaifenesin), 12 FL OZ (354 mL) bottles, Distributed By: Walgreen Co. 200 Wilmot Rd., Deerfield, IL 60015, NDC 0363-0324-28.

Product Quantity:

117,552 units

Reason for Recall:

Incorrect/Undeclared Excipient: Product contains alcohol

Recall Number:

D-0787-2022

Code Information:

All lots

Class III Drugs Event

Event ID:

90003

Product Type:

Drugs

Status:

Ongoing

Date Terminated:**Recall Initiation Date:**

04/12/2022

Voluntary / Mandated:

Voluntary: Firm initiated

Center Classification Date:

04/26/2022

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:

Alabama

Associated Products**Product Description:**

Cyanocobalamin Injection, USP, 1000 mcg per mL, For Intramuscular or Subcutaneous Use Only, 25 x 1 mL Vials, Rx only, Manufactured by: Eugia Pharma Specialties Limited, Hyderabad India for BluePoint Laboratories. NDC for Carton: 68001-509-60; NDC for vial: 68001-509-59

Product Quantity:

97,975 vials

Reason for Recall:

Subpotent Drug: Out of specification for assay.

Recall Number:

D-0790-2022

Code Information:

Lots: CCC210008, CCC210009, Exp. 01/23

Not Yet Classified Drugs Event**Event ID:**

89902

Product Type:

Drugs

Status:

Ongoing

Date Terminated:**Recall Initiation Date:**

03/30/2022

Voluntary / Mandated:

Voluntary: Firm initiated

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

Press Release

Recalling Firm:

Conopco DBA Unilever
700 Sylvan Ave
Englewood Cliffs NJ United States

Distribution Pattern:

USA nationwide

Associated Products**Product Description:**

Suave 24-Hour Protection Aerosol Antiperspirant Powder, 4 oz. bottle (UPC 079400751508), 6 oz. bottle (UPC 079400784902), Dist. By Unilever, Trumbull, CT 06611

Product Quantity:**Reason for Recall:**

Chemical contamination: with Benzene

Recall Number:**Code Information:**

all lots

Product Description:

Suave 24-Hour Protection Aerosol Antiperspirant Fresh, 6 oz. bottle, Unilever, UPC 079400785503, Dist. By Unilever, Trumbull, CT 06611

Product Quantity:**Reason for Recall:**

Chemical contamination: with Benzene

Recall Number:

Code Information:

all lots

Not Yet Classified Drugs Event

Event ID:

89970

Product Type:

Drugs

Status:

Ongoing

Date Terminated:**Recall Initiation Date:**

04/12/2022

Voluntary / Mandated:

Voluntary: Firm initiated

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

Letter

Recalling Firm:

Mylan Pharmaceuticals Inc
3711 Collins Ferry Rd
Morgantown WV United States

Distribution Pattern:

USA nationwide.

Associated Products

Product Description:

Insulin Glargine (insulin glargine-yfgn) Injection, 100 units/mL (U-100), packaged in a 10 mL Multiple-Dose vial inside a carton, Rx only, Manufactured by: Mylan Pharmaceuticals Inc., Morgantown, WV 26505, Manufactured for: Mylan Specialty L.P., Morgantown, WV 26505, NDC 49502-393-80

Product Quantity:

89,665 vials

Reason for Recall:

Labeling: Missing label.

Recall Number:**Code Information:**

Lot #: BF21002800, Exp 8/2023