Enforcement Report - Week of July 13, 2022

Class I Drugs Event

Event ID:
90443

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
06/13/2022

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
07/05/2022

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Vi-Jon, LLC
1 Swan Dr
Smyrna TN United States

Distribution Pattern:
Distributed Nationwide in the USA

Associated Products

Product Description:
CVS Health Magnesium Citrate SALINE LAXATIVE, Oral Solution, 1.745 g, Lemon Flavor, 10 FL OZ (296 mL), Distributed by: CVS Pharmacy, Inc., One CVS Drive, Woonsocket, RI 02895, UPC 0 50428 30594 2.

Product Quantity:
98,958 bottles

Reason for Recall:
Microbial Contamination of a Non-Sterile Products: Testing of product onfirmed the presence of Gluconacetobacter Liquefaciens

Recall Number:
D-1175-2022

Code Information:
Lot: 0556808 Exp. 12/2023

Class II Drugs Event

Event ID:
89863

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
03/16/2022

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
07/07/2022

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

Recalling Firm:
Golden State Medical Supply Inc.
5187 Camino Ruiz
Camarillo CA United States

Distribution Pattern:
Nationwide in the U.S: PA, MA, OH, TX, IL, ND, HI

Associated Products

Product Description:
Enalapril Maleate Tablets, USP; 2.5 mg; 90 tablets, NDC 60429-183-90; manufactured by Taro Pharmaceutical Industries, Ltd.; packaged by GSMS, Incorporated, CA, USA.

Product Quantity:
1,471 bottles

Reason for Recall:
CGMP Deviations

Recall Number:
D-1177-2022

Code Information:
Lots: GS028301, 2.5 mg; 90 tablets, Exp.: 06/2022; Lots: GS029973, GS029974, GS031436, GS031715, GS033191, GS033940, Exp. : 10/2022; Lot: GS034212, Exp.: 12/2022; Lot: GS035315, GS035945, GS036905, GS038038, GS039199, Exp.: 04/2023; Lot: GS039200, GS040149, Exp.: 11/2023. (NDC: 60429-183-90).

Product Description:
Enalapril Maleate Tablets, USP; 5 mg; 90 tablets, NDC 60429-184-90; manufactured by Taro Pharmaceutical Industries, Ltd.; packaged by GSMS, Incorporated, CA.

Product Quantity:
9,058

Reason for Recall:
CGMP Deviations

Recall Number:
D-1178-2022

Code Information:
Lot: GS029041, GS029353, GS02986, 5 mg; 90 tablets, Exp.: 09/2022; Lot: GS030056, GS030869, GS033943, Exp.: 10/2022; Lots: GS034490, GS035197, Exp.:02/2023; Lots: GS035198, Exp.: 03/2023; Lots: GS035596, GS035947, GS036759, GS037400, Exp.: 06/2023; Lots: GS038089, GS038763, GS039559, GS040150, Exp.: 10/2023; Lots: GS040151, GS040708, GS041107, Exp.: 12/2023; Lot: GS041654, Exp.: 03/2024.

Product Description:
Enalapril Maleate Tablets, USP; 10 mg; 90 tablets, NDC 60429-185-90; manufactured by Taro Pharmaceutical Industries, Ltd.; packaged by GSMS, Incorporated, CA.

Product Quantity:
31,260 bottles

Reason for Recall:
CGMP Deviations

Recall Number:
D-1179-2022

Code Information:
Lots: GS027890, GS028177, GS028488, 10 mg; 90 tablets, Exp.: 04/2022; Lots: GS028847, GS028848, Exp.: 09/2022; GS029627, GS029862,GS030057, GS030481, GS030870, GS031060, GS031437, GS031438, GS033527, GS034231, Exp.: 10/2022; Lots: GS034810, Exp.: 01/2023; Lots: GS035240, GS035598, Exp.: 05/2023; Lots: GS036194, Exp.: 06/2023; Lots: GS036760, GS036981,GS037526, GS038177, GS038728, Exp.: 08/2023; Lots: GS038729, GS041108, Exp.: 09/2023; Lots: GS039412, GS039840, GS041109, Exp.: 12/2023; Lot: GS041655, Exp.: 01/2024; Lot: GS041656, Exp.: 05/2024. (NDC: 60429-185-90).

Product Description:
Enalapril Maleate Tablets, USP; 20 mg; 90 tablets, NDC 60429-186-90; manufactured by Taro Pharmaceutical Industries, Ltd.; packaged by GSMS, Incorporated, CA.

Product Quantity:
1,424 bottles

Reason for Recall:
CGMP Deviations

Recall Number:
D-1180-2022

Code Information:
Lots: GS035031, GS035199, 20 mg; 90 tablets, Exp.: 03/2022; Lots: GS036495, GS036904, Exp.: 05/2022; Lots: GS037401, Exp.: 09/2022; Lots: GS037986, GS038359, GS039560, Exp.: 11/2022; Lot: GS041110, Exp.: 12/2022. (NDC: 60429-186-90).

Class II Drugs Event

Event ID:
90403

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
06/10/2022

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
07/07/2022

Initial Firm Notification of Consignee or Public:

Recalling Firm:
Wedgewood Village Pharmacy, LLC
405 Heron Dr Ste 200
Swedesboro NJ United States

Distribution Pattern:
Products were distributed nationwide in the USA.

Associated Products

Product Description:
Bethanechol Chloride 1mg/ml, 80 ml Suspension bottles Banana/Strawberry, Qty:1, Wedgewood Village Pharmacy LLC, 405 Heron Dr. Ste 200, Swedesboro, NJ 08085

Product Quantity:
1 suspension bottle

Reason for Recall:
Lack of Processing Controls: Insanitary conditions observed during recent FDA Inspection

Recall Number:
D-1181-2022

Code Information:
Lot #: 000-03715131, Exp Date: 07/19/22

Product Description:
Doxycycline (as Calcium) (equivalent to 50mg/5mL), 10 mg/ml, 60 ml suspension bottles, Peppermint, Qty: 1, Wedgewood Village Pharmacy LLC, 405 Heron Dr, Ste 200, Swedesboro, NJ 08085

Product Quantity:
24 bottles

Reason for Recall:
Lack of Processing Controls: Insanitary conditions observed during recent FDA Inspection

Recall Number:
D-1182-2022

Code Information:
Lot#: 000-03852523, Exp Date: 09/01/22; Lot#: 000-03766625, Exp Date:07/10/22; Lot#: 000-03780127, Exp Date: 08/6/22; Lot#: 000-03794760, Exp Date: 08/6/22; Lot#: 000-03892723, Exp Date: 09/1/22; Lot#: 000-03641022, Exp Date: 06/17/22; Lot#: 000-03693714, Exp Date: 06/28/22; Lot#: 000-03770510, Exp Date: 08/6/22; Lot#: 000-03852462, Exp Date: 09/1/22; Lot#: 000-03840601, Exp Date: 09/1/22; Lot#: 000-03706934, Exp Date: 06/28/22; Lot#: 000-03850609, Exp Date: 09/1/22; Lot#: 000-03650269, Exp Date: 06/17/22; Lot#: 000-03870004, Exp Date: 09/1/22; Lot#: 000-03693748, Exp Date: 06/28/22; Lot#: 000-03904403, Exp Date: 09/1/22; Lot#: 000-03799564, Exp Date: 08/06/22; Lot#: 000-03723022, Exp Date: 06/28/22; Lot#: 000-03872892, Exp Date: 09/01/22; Lot#: 000-03885204, Exp Date: 09/01/22; Lot#: 000-03848586, Exp Date: 09/01/22; Lot#: 000-03903599, Exp Date: 09/01/22; Lot#: 000-03812001, Exp Date: 08/06/22;

Product Description:
Boric Acid 600 mg capsules, 14 capsules per box, Qty: 1, Wedgewood Village Pharmacy LLC, 405 Heron Drive, Ste 200, Swedesboro, NJ 08085

Product Quantity:
1 box

Reason for Recall:
Lack of Processing Controls: Insanitary conditions observed during recent FDA Inspection

Recall Number:
D-1183-2022

Code Information:
Lot#: 000-03868160, Exp Date: 09/14/22

Product Description:
Boric Acid 600 mg per suppository, 14 Vaginal Suppositories per box, Wedgewood Village Pharmacy LLC, 405 Heron Drive, Ste 200, Swedesboro, NJ 08085

Product Quantity:
14 suppositories

Reason for Recall:
Lack of Processing Controls: Insanitary conditions observed during recent FDA Inspection

Recall Number:
D-1184-2022

Code Information:
Lot#: 000-03843532 Exp Date: 09/6/22

Product Description:
Estriol 1mg/gm, Vaginal Cream, 30 gm tube, Qty: 1, Wedgewood Village Pharmacy LLC, 405 Heron Drive, Ste 200, Swedesboro, NJ 08085

Product Quantity:
1 tube

Reason for Recall:
Lack of Processing Controls: Insanitary conditions observed during recent FDA Inspection

Recall Number:
D-1185-2022

Code Information:
Lot#: 000-03807142 Exp Date: 08/27/22

Product Description:
Estriol 1mg/gm, Vaginal Cream, 60 gm tube, Qty: 1, Wedgewood Village Pharmacy LLC, 405 Heron Drive, Ste 200, Swedesboro, NJ 08085

Product Quantity:
9/18/2022

Reason for Recall:
Lack of Processing Controls: Insanitary conditions observed during recent FDA Inspection

Recall Number:
D-1186-2022

Code Information:
Lot#: 000-03866709 Exp Date: 09/18/22

Class II Drugs Event

Event ID:
90412

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
06/03/2022

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
07/07/2022

Initial Firm Notification of Consignee or Public:

Recalling Firm:
SUN PHARMACEUTICAL INDUSTRIES INC
2 Independence Way
Princeton NJ United States

Distribution Pattern:
nationwide.

Associated Products

Product Description:
Testosterone Cypionate Injection, USP, 200mg/ml, Rx Only, One Single-dose vial, Distributed by: Sun Pharmaceutical Industries Inc., Cranbury, NJ 08512, Manufactured by: Sun Pharmaceuticals Industries Ltd., Halol-Baroda Highway, Halol-389 350, Gujarat, India, NDC 62756-015-40.

Product Quantity:
27 vials

Reason for Recall:
CGMP Deviations: Manufacturing deviations were reported due to an abnormal appearance on parts of machinery.

Recall Number:
D-1176-2022

Code Information:
Lots JKX3267A & JKX3686A Exp. Date 08/2022 Lot JKX4700A, Exp Date 10/2022 Lot JKX5727A, Exp date 11/2022

Class II Drugs Event

Event ID:
90444

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
06/16/2022

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
07/05/2022

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Macleods Pharma Usa Inc
666 Plainsboro Rd Bldg 200 Ste 230
Plainsboro NJ United States

Distribution Pattern:
Distributed Nationwide and Puerto Rico.

Associated Products

Product Description:
Eszopiclone Tablets, USP 1 mg, packaged in 30-count bottles, Rx Only, Manufactured for: Macleods Pharma USA, Inc., Plainsboro, NJ 08536, Manufactured by: Macleods Pharmaceuticals Ltd., Baddi, Himachal Pradesh, INDIA, NDC 33342-299-07

Product Quantity:
168690 Tablets

Reason for Recall:
Shortfill: customer complaints of one to three tablets were reported missing from 30 count bottles.

Recall Number:
D-1174-2022

Code Information:
Lot #: BEK2009A Exp: 11/2023

Class III Drugs Event

Event ID:
90473

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
06/16/2022

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
07/01/2022

Initial Firm Notification of Consignee or Public:
Letter

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

Distribution Pattern:
Nationwide in the USA

Associated Products

Product Description:
Mometasone Furoate, Topical Solution USP, 0.1 % Lotion, a) 30 ml-bottle (NDC 68462-385-37), b) 60 ml-bottle (NDC 68462-385-02), Rx only, Manufactured by: Glenmark Pharmaceuticals Limited, Baddi Himachal Pradesh 173205, Manufactured for: Glenmark Pharmaceuticals Inc., USA Mahwah NJ 07430.

Product Quantity:
98, 307 packs

Reason for Recall:
Defective Container

Recall Number:
D-1173-2022

Code Information:
Lot # a) 05201358, Exp 06/2022; 05210287, 05210288, Exp 01/2023; 05211446, Exp 07/2023; 05211704, 05211714, Exp 08/2023; 05212217, Exp 10/2023: b) 05201358, Exp 06/2022; 05210287, 05210288, 05210424, Exp 01/2023; 05210425, 05210435, Exp 02/2023; 05211427, 05211439, 05211445, Exp 07/2023; 05211723, 05211731, 05211850, 05211864, Exp 08/2023; 05212226, 05212250, 05212261, Exp 10/2023.