Enforcement Report - Week of July 24, 2024

Class I Drugs Event

Event ID:
94715

Product Type:
Drugs

Status:
Ongoing

Date Terminated:
N/A

Recall Initiation Date:
05/30/2024

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
07/17/2024

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Glenmark Pharmaceuticals Inc., USA
750 Corporate Dr
Mahwah, NJ 07430-2009
United States

Distribution Pattern:
Nationwide

Associated Products

Product Description:
Potassium Chloride Extended-Release Capsules, USP, (750 mg) 10 mEq K, 100-count bottle, Rx Only, Manufactured by: Glenmark Pharmaceuticals Ltd. Plot No. 2, Phase-2, Pharma Zone SEZ, Pithampur, Dist.-Dhar, Madhya Pradesh 454 775, India, Manufactured for: Glenmark Pharmaceuticals Inc, USA, Mahwah, NJ 07430. NDC 68462-357-01

Product Quantity:
285,840 bottles

Reason for Recall:
Failed Dissolution Specifications

Recall Number:
D-0604-2024

Code Information:
Lot#: 17221446, 17221445, Exp May-31-24; 17221393, 17221403, 17221405, 17221503, 17221508, Exp Jun-30-24; 17221567, 17221566, 17221719, 17221731, Exp Jul-31-24; 17221891, 17221892, 17221900, 17221992, 17222022, Exp Aug-31-24; 17222056, 17222043, 17222068, 17222079, 17222099, 17222103, 17222114, 17222119, 17222188, 17222199, 17222209, 17222200, Exp Sep-30-24; 17222265, 17222269, Exp Oct-31-24; 17222527, 17222530, 17222583, 17222586, 17230051, 17230075, 17230067, Exp Nov-30-24;

Product Description:
Potassium Chloride Extended-Release Capsules, USP, (750 mg) 10 mEq K, 500-count bottle, Rx Only, Manufactured by: Glenmark Pharmaceuticals Ltd. Plot No. 2, Phase-2, Pharma Zone SEZ, Pithampur, Dist.-Dhar, Madhya Pradesh 454 775, India, Manufactured for: Glenmark Pharmaceuticals Inc, USA, Mahwah, NJ 07430. NDC 68462-357-05

Product Quantity:
36,630 bottles

Reason for Recall:
Failed Dissolution Specifications

Recall Number:
D-0605-2024

Code Information:
Lot #: 17221197, 17221386, 17221385, Exp May-31-24; 17221489, 17221504, 17221530, Exp Jun-30-24; 17221561, 17221579, 17221568, 17221702, 17221704, Exp Jul-31-24; 17221898, 17221993, 17222029, Exp Aug-31-24; 17222300, 17222304, 17222278, 17222609, 17222395, Exp Oct-31-24; 17222589, 17222605, 17222613, Exp Nov-30-24;

Class I Drugs Event

Event ID:
94782

Product Type:
Drugs

Status:
Ongoing

Date Terminated:
N/A

Recall Initiation Date:
06/05/2024

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
07/17/2024

Initial Firm Notification of Consignee or Public:
Press Release

Recalling Firm:
Homeocare Laboratories, Inc.
7 Odell Plz Ste 142-146
Yonkers, NY 10701-1407
United States

Distribution Pattern:
Nationwide to 60 Physician offices

Associated Products

Product Description:
STELLALIFE VEGA Oral Care, Spray, Unflavored, 1 fl oz (30 ml) bottles, Distributed by: StellaLife, 22875 NE 191 Street, Suite 500, Aventura, FL 33180, NDC 69685-121-01

Product Quantity:
31,811 x 1 fl. oz. spray bottle

Reason for Recall:
Microbial Contamination of Non-Sterile Products: multiple Bacillus species organisms

Recall Number:
D-0609-2024

Code Information:
Lot # 2552, exp. date 02-28-2026

Class II Drugs Event

Event ID:
94519

Product Type:
Drugs

Status:
Ongoing

Date Terminated:
N/A

Recall Initiation Date:
04/30/2024

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
07/16/2024

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Viatris Inc
1000 Mylan Blvd
Canonsburg, PA 15317-5853
United States

Distribution Pattern:
U.S. Nationwide

Associated Products

Product Description:
Cardura XL (doxazosin) extended release tablets 4mg, 30-count bottles, Rx Only, Made in Singapore, Distributed by Roerig Division of Pfizer Inc, NY, NY 10017 NDC 0049-2040-10

Product Quantity:
12,691 bottles

Reason for Recall:
Failed Impurities/Degradation Specifications

Recall Number:
D-0602-2024

Code Information:
Lot #: 8147040; Exp. June 2024 Lot #: 8163764; Exp. March 2025

Product Description:
Cardura XL (doxazosin) extended release tablets 8mg, 30-count bottles, Rx Only Made in Singapore, Distributed by Roerig Division of Pfizer Inc, NY, NY 10017 NDC 0049-2080-10

Product Quantity:
3,694 bottles

Reason for Recall:
Failed Impurities/Degradation Specifications

Recall Number:
D-0603-2024

Code Information:
Lot#: 8147041; Exp. June 2024 Lot#: 8163765; Exp. March 2025

Class II Drugs Event

Event ID:
94715

Product Type:
Drugs

Status:
Ongoing

Date Terminated:
N/A

Recall Initiation Date:
05/30/2024

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
07/17/2024

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Glenmark Pharmaceuticals Inc., USA
750 Corporate Dr
Mahwah, NJ 07430-2009
United States

Distribution Pattern:
Nationwide

Associated Products

Product Description:
Potassium Chloride Extended-Release Capsules, USP, (750 mg) 10 mEq K, 100-count bottle, Rx Only, Manufactured by: Glenmark Pharmaceuticals Ltd. Plot No. 2, Phase-2, Pharma Zone SEZ, Pithampur, Dist.-Dhar, Madhya Pradesh 454 775, India, Manufactured for: Glenmark Pharmaceuticals Inc, USA, Mahwah, NJ 07430. NDC 68462-357-01

Product Quantity:
N/A

Reason for Recall:
CGMP Deviations

Recall Number:
D-0606-2024

Code Information:
Lot #: 17230074, 17230221, Exp Dec-31-24; 17230468, 17230479, 17230553, 17230543, 17230561, Exp Jan-31-25; 17230619, 17230624, Exp Feb-28-25; 17230879, 17230890, 17230918, 17230984, 17230996, 17231002, 17231081, Exp Mar-31-25; 17231102, 17231135, 17231329, Exp Apr-30-25; 17231369, 17231513, Exp May-31-24; 17231516, 17231713, Exp Jun-30-25; 17231909, 17231903, Exp Jul-31-25; 17231943, Exp Aug-31-25; 17232166, 17232179, Exp Sep-30-25.

Product Description:
Potassium Chloride Extended-Release Capsules, USP, (750 mg) 10 mEq K, 500-count bottle, Rx Only, Manufactured by: Glenmark Pharmaceuticals Ltd. Plot No. 2, Phase-2, Pharma Zone SEZ, Pithampur, Dist.-Dhar, Madhya Pradesh 454 775, India, Manufactured for: Glenmark Pharmaceuticals Inc, USA, Mahwah, NJ 07430. NDC 68462-357-05

Product Quantity:
N/A

Reason for Recall:
CGMP Deviations

Recall Number:
D-0607-2024

Code Information:
Lot #: 17230186, 17230192, 17230213, 17230278, 17230399, Exp Dec-31-24; 17230406, 17230412, 17230427, 17230444, 17230453, 17230495, Exp Jan-31-25; 17230574, 17230585, 17230608, 17230629, Exp Feb-28-25; 17230883, 17230921, Exp Mar-31-25; 17231087, 17231339, Exp Apr-30-25; 17231360, Exp May-31-25; 17231711, 17231745, Exp Jun-30-25; 17231819, 17231820, 17231936, 17231957, Exp Jul-31-25; 17231998, 17232012, Aug-31-25; 17232110, Exp Sep-30-25; 17232114, Exp Aug-31-25; 17232119, 17232343, Exp Sep-30-25.

Class II Drugs Event

Event ID:
94782

Product Type:
Drugs

Status:
Ongoing

Date Terminated:
N/A

Recall Initiation Date:
06/05/2024

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
07/17/2024

Initial Firm Notification of Consignee or Public:
Press Release

Recalling Firm:
Homeocare Laboratories, Inc.
7 Odell Plz Ste 142-146
Yonkers, NY 10701-1407
United States

Distribution Pattern:
Nationwide to 60 Physician offices

Associated Products

Product Description:
STELLALIFE ADVANCED FORMULA Peppermint, VEGA Oral Care, Rinse, 16 fl oz (473 ml), Distributed by: StellaLife, 2875 NE 191 Street, Suite 500, Aventura, FL 33180, NDC 69685-143-16

Product Quantity:
31,110 x 16 fl. oz. bottle

Reason for Recall:
Microbial Contamination of Non-Sterile Products: presence of Terribacillus species organism

Recall Number:
D-0610-2024

Code Information:
Lot # 2550, exp. date 02-28-2026

Class II Drugs Event

Event ID:
94887

Product Type:
Drugs

Status:
Ongoing

Date Terminated:
N/A

Recall Initiation Date:
06/18/2024

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
07/17/2024

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Fresenius Medical Care Holdings, Inc.
920 Winter St Bld 920
Waltham, MA 02451-1521
United States

Distribution Pattern:
Nationwide

Associated Products

Product Description:
DELFLEX PERITONEAL DIALYSIS SOLUTION With LOW MAGNESIUM / LOW CALCIUM 4.25% DEXTROSE and attached stay "safe Exchange Set, 2500mL (Approx. 50 mL excess), Single Dose Container Sterile and Non-Pyrogenic, For Intraperitoneal Administration Only, Fresenius Medical Care NA Waltham, MA 02451, 1-800-323-5188 NDC 49230-212-94

Product Quantity:
183 cases

Reason for Recall:
This product is being recalled due to the tube weld failure presents itself as a slow leak and can be difficult to detect.

Recall Number:
D-0608-2024

Code Information:
24AU03024, exp. date 07/31/2025

Class II Drugs Event

Event ID:
94888

Product Type:
Drugs

Status:
Ongoing

Date Terminated:
N/A

Recall Initiation Date:
06/26/2024

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
07/18/2024

Initial Firm Notification of Consignee or Public:
E-Mail

Recalling Firm:
RemedyRepack Inc.
625 Kolter Dr Ste 4
Indiana, PA 15701-3571
United States

Distribution Pattern:
USA Nationwide

Associated Products

Product Description:
Potassium Chloride Micro 10mEq K (750 mg) Extended Release Capsules, 30-count blister card, Rx only, MFG: Glenmark, Mahwah, NJ 07430, Repackaged by: RemedyRepack Inc., Indiana, PA 15701, NDC 70518-1203-03

Product Quantity:
142 blister cards, 30 per blister card

Reason for Recall:
CGMP Deviations: Out of specification for dissolution

Recall Number:
D-0611-2024

Code Information:
Lot #: J0758674-021824, Exp 03/31/2025; J0751898-011424, Exp 01/31/2025

Class II Drugs Event

Event ID:
94898

Product Type:
Drugs

Status:
Ongoing

Date Terminated:
N/A

Recall Initiation Date:
06/07/2024

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
07/12/2024

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

Recalling Firm:
Brands International Corporation
594 Newpark Blvd
Newmarket
Canada

Distribution Pattern:
USA nationwide.

Associated Products

Product Description:
Oatmeal Daily Moisturizing Body Lotion (1.3% Dimethicone), 8 fl oz (236mL), packaged in an HDPE bottle 12 bottles per case, Manufactured By:/Fabrique Par: , Brands International Corp., Newmarket, ON, L3X 2S2, Made in Canada.

Product Quantity:
120,319 bottles

Reason for Recall:
Microbial Contamination of Non-Sterile Products: confirmed presence of mold contamination

Recall Number:
D-0598-2024

Code Information:
Lot# 24092009, Exp 03/27; 24094010, Exp 04/27

Class II Drugs Event

Event ID:
94899

Product Type:
Drugs

Status:
Ongoing

Date Terminated:
N/A

Recall Initiation Date:

Voluntary / Mandated:

06/28/2024

Center Classification Date:
07/18/2024

Recalling Firm:
Glenmark Pharmaceuticals Inc., USA
750 Corporate Dr
Mahwah, NJ 07430-2009
United States

Distribution Pattern:
USA Nationwide

Voluntary: Firm initiated

Initial Firm Notification of Consignee or Public:
N/A

Associated Products

Product Description:
Pravastatin Sodium Tablets, USP 80mg, packaged in a) 90-count bottle, NDC 68462-198-90; b) 500-count bottle, NDC 68462-198-05, Rx only, Manufactured by: Glenmark Pharmaceuticals Limited Pithampur, Madhya Pradesh 454775, India, Manufactured for: Glenmark Pharmaceuticals Inc., USA, Mahwah, NJ 07430,

Product Quantity:
a) 145,800 bottles; b) 1,368 bottles

Reason for Recall:
Failed Dissolution Specifications: results below specifications

Recall Number:
D-0612-2024

Code Information:
Lot#: a) 17211249, 17211264, 17211266,17211286, Exp 6/30/24; 17211525, 17211535, 17211549, Exp 7/31/24; 17211787, 17211801, 8/31/24; 17212041, 9/30/24; 17212088, 17212106, Exp 10/31/24; 17212346, 17212345, 11/30/24; 17220053, 17220054, 17220055 12/31/24; 17220309, 17220310, Exp 1/31/25; b) 17211290, 6/30/2024

Class II Drugs Event

Event ID:
94900

Status:
Ongoing

Recall Initiation Date:
06/28/2024

Center Classification Date:
07/16/2024

Recalling Firm:
Teva Pharmaceuticals USA, Inc
400 Interpace Pkwy Bldg A
Parsippany, NJ 07054-1120
United States

Distribution Pattern:
Nationwide in the USA and Puerto Rico

Product Type:
Drugs

Date Terminated:
N/A

Voluntary / Mandated:
Voluntary: Firm initiated

Initial Firm Notification of Consignee or Public:
Letter

Associated Products

Product Description:
Fludrocortisone Acetate Tablets, USP 0.1mg, Rx Only, 100 Tablets per bottle, Manufactured in Canada By: Patheon, Inc., Mississauga, ON, Canada L5N 7K9, Manufactured For: Teva Pharmaceuticals USA, Inc., North Wales, PA 19454, NDC 0555-0997-02.

Product Quantity:
116,144 bottles

Reason for Recall:
Failed Impurities/Degradation Specifications: Product is being recalled due to API related substances and unknown impurities that are above the

specification limits.

Recall Number:
D-0601-2024

Code Information:
Lot #s: CNSDH, Exp. 6/30/2024; CNWVM, CNWWH, Exp. 07/31/2024; CNXKW, CNXKY, CNXMB, CNXMH, Exp. 09/30/2024; CPBTP, CPBTV, Exp. 11/30/2024.

Class II Drugs Event

Event ID:
94914

Product Type:
Drugs

Status:
Ongoing

Date Terminated:
N/A

Recall Initiation Date:
06/27/2024

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
07/16/2024

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Zydus Pharmaceuticals (USA) Inc
73 Route 31 N
Pennington, NJ 08534-3601
United States

Distribution Pattern:
TN

Associated Products

Product Description:
Cyanocobalamin Injection, USP, 1,000mcg/mL, 1 mL Multiple-Dose Vial, Rx Only, Manufactured for: Northstar Rx LLC, Memphis, TN, 38141, Mfd. in India, NDC 16714-165-01.

Product Quantity:
432250 vials

Reason for Recall:
Presence of particulate matter: glass

Recall Number:
D-0600-2024

Code Information:
Lot #: L200253, L200281, L200301, Exp 07/31/2024

Class II Drugs Event

Event ID:
94950

Product Type:
Drugs

Status:
Ongoing

Date Terminated:
N/A

Recall Initiation Date:
07/09/2024

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
07/12/2024

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
SUN PHARMACEUTICAL INDUSTRIES INC
2 Independence Way

Princeton, NJ 08540-6620
United States

Distribution Pattern:
Nationwide in the USA and Puerto rico

Associated Products

Product Description:
Nitrofurantoin Capsules, USP (Macrocrystals), 100 mg, Rx Only, 100 capsules per bottle, Manufactured by: Sidmak Laboratories (India) Pvt. Ltd. Plot No. 20, Pharmacity, Selaqui Industrial Area, Dehradun - 248-197, Uttarakhand, India. Distributed by: Sun Pharmaceutical Industries, Inc. Cranbury, NJ 08512, NDC 57664-233-88.

Product Quantity:
5752 bottles

Reason for Recall:
Failed Dissolution Specifications

Recall Number:
D-0597-2024

Code Information:
Lot #s: 231067, 231069, Exp 04/30/2025