Enforcement Report - Week of July 26, 2023

Class II Drugs Event

Event ID:
92564

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
06/21/2023

Voluntary / Mandated:

Center Classification Date:
07/17/2023

Initial Firm Notification of Consignee or Public:

Recalling Firm:
Dr Reddy's Laboratories Limited
Fto-Sez Unit 1, Surv. 57-59,60, 62 & 72 Sect. 9-14, 17-20, Devunipalavalasa
Ranasthalam Mandal, Srikakulam India

Distribution Pattern:
Nationwide in the USA

Associated Products

Product Description:
Tizanidine Tablets USP, 4 mg, 1000-Count bottle, Rx Only, Manufactured by Dr. Reddy's Laboratories Limited Srikakulam - 532 409 India. NDC 55111-180-10

Product Quantity:
17,548 1000-countbottles

Reason for Recall:
Failed dissolution specification: Out of specification results observed in 24-month long term stability testing.

Recall Number:
D-0923-2023

Code Information:
Lot: T2100585, T2100586, T2100587, Exp 12/2023

Class II Drugs Event

Event ID:
92565

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
05/01/2023

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
07/21/2023

Initial Firm Notification of Consignee or Public:

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

Distribution Pattern:
Nationwide in the USA

Associated Products

Product Description:
Famotidine Tablets, USP, 20mg, 200-count bottle within a carton, Distributed by: Glenmark Therapeutics Inc., USA, Mahwah, NJ 07430, Made in India, NDC 72657-113-20.

Product Quantity:
19,968 bottles

Reason for Recall:
Labeling: Label Error on Declared Strength: some cartons labeled and containing 20 mg may have an external label placed on the side of the carton indicating strength as 10 mg.

Recall Number:
D-0939-2023

Code Information:
FA2022001B, Exp 03/2025

Class II Drugs Event

Event ID:
92657

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
07/07/2023

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
07/19/2023

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
SterRx, LLC
141 Idaho Ave
Plattsburgh NY United States

Distribution Pattern:
Nationwide in the USA

Associated Products

Product Description:
Sodium Bicarbonate in 5% Dextrose Injection, 150 mEq per 1,000 mL (12.6 mg per mL), 1,000 mL Single Dose bag, packaged in 1000 mL x 6 units per case, SterRx, 141 Idaho Ave., Plattsburgh, NY 12903, NDC 70324-326-01.

Product Quantity:
137,304 bags

Reason for Recall:
Lack of Assurance of Sterility

Recall Number:
D-0930-2023

Code Information:
Lot #: 489344, Exp 25-Jul-23; 489352, Exp 26-Jul-23; 489361, Exp 27-Jul-23; 489387, 491647, Exp 28-Jul-23; 492181, Exp 29-Jul-23; 492199, 492201, Exp 2-Aug-23; 492210, 492228, Exp 3-Aug-23; 492236, 492244, Exp 4-Aug-23; 492261, Exp 5-Aug-23; 492279, 492287, Exp 8-Aug-23; 492295, 492308, Exp 9-Aug-23; 492957, 492965, Exp 19-Sep-23; 492973, 492981, Exp 20-Sep-23; 494194, 494207, Exp 21-Sep-23;494215, 494223, Exp 22-Sep-23; 494231, 495200, Exp 23-Sep-23; 495218, 495453, Exp 26-Sep-23; 495470, 495488, Exp 27-Sep-23; 495496, 495509, Exp 28-Sep-23; 495517, 495525, Exp 29-Sep-23; 495533, Exp 30-Sep-23; 495699, 495701, Exp 3-Oct-23; 495710, 495728, Exp 4-Oct-23; 496106, 497491, Exp 15-Nov-23; 497504, 497512, Exp 16-Nov-23; 497521, 497539, Exp 22-Nov-23; 497547, 497555, Exp 23-Nov-23; 497563, Exp 24-Nov-23; 497571, Exp 29-Nov-23; 497598, Exp 30-Nov-23; 497619, 498363, Exp 1-Dec-23; 498371, 498380, 498398, Exp 5-Dec-23; 498401, Exp 6-Dec-23; 498419, 498427, Exp 7-Dec-23; 498435, Exp 8-Dec-23; 498443, 498451, Exp 12-Dec-23; 498460, Exp 13-Dec-23; 498478, Exp 14-Dec-23; 498507, Exp 24-Jan-24; 498515, 498523, Exp 25-Jan-24; 498531, 498540, Exp 26-Jan-24; 498558, Exp 27-Jan-24; 498574, Exp 30-Jan-24; 498582, 499665, Exp 31-Jan-24; 500355, 500363, Exp 1-Feb-24; 500371, 500380, Exp 2-Feb-24; 500398, 500401, Exp 3-Feb-24; 500419, 500427, Exp 6-Feb-24; 500435, 500443, Exp 7-Feb-24; 500451, 500460, Exp 8-Feb-24; 500478, Exp 9-Feb-24

Product Description:
Norepinephrine 4 mg per 250 mL (16 mcg per mL) in 0.9% Sodium Chloride, 250 mL Single Dose bag, packaged in 250 mL x 12 units per case, Rx only, SterRx, 141 Idaho Ave., Plattsburgh, NY 12903, NDC 70324-552-01.

Product Quantity:
132,299 bags

Reason for Recall:
Lack of Assurance of Sterility

Recall Number:
D-0931-2023

Code Information:
Lot #: 490062, Exp 22-Jul-23; 490151, Exp 28-Jul-23; 490732, Exp 6-Aug-23; 491591, Exp 17-Aug-23; 491604, Exp 18-Aug-23; 494418, Exp 16-Nov-23; 494426, Exp 17-Nov-23; 494434, Exp 23-Nov-23; 496755, Exp 25-Nov-23; 497424, Exp 3-Dec-23; 497432, Exp 4-Dec-23; 497441, 497459, Exp 7-Dec-23; 498005, Exp 10-Dec-23; 499075, Exp 22-Jan-24; 499083, 499091, Exp 25-Jan-24; 499391, Exp 26-Jan-24; 501964, Exp 23-Mar-24; 501972, Exp 28-Mar-24; 501981, Exp 30-Mar-24; 501999, Exp 6-Apr-24; 502001, Exp 7-Apr-24

Product Description:
Norepinephrine 8 mg per 250 mL (32 mcg per mL) in 0.9% Sodium Chloride, 250 mL Single Dose bag, packaged in 250 mL x 12 units per case, Rx only, SterRx, 141 Idaho Ave., Plattsburgh, NY 12903, NDC 70324-577-01.

Product Quantity:
125,598 bags

Reason for Recall:
Lack of Assurance of Sterility

Recall Number:
D-0932-2023

Code Information:
Lot #: 490071, Exp 30-Jul-23; 490089, Exp 4-Aug-23; 490118, 490126, Exp 5-Aug-23; 490169, Exp 10-Aug-23; 491276, Exp 11-Aug-23; 491284, Exp 12-Aug-23; 491612, Exp 18-Aug-23; 497467, Exp 8-Dec-23; 497475, Exp 9-Dec-23; 499104, Exp 18-Jan-24; 499112, Exp 19-Jan-24; 499121, 499278, Exp 20-Jan-24; 499358, Exp 21-Jan-24; 502019, Exp 24-Mar-24; 502027, Exp 29-Mar-24; 502035, Exp 5-Apr-24; 503513, Exp 18-Apr-24; 504217, Exp 20-Apr-24

Product Description:
Norepinephrine 16 mg per 250 mL (64 mcg per mL) in 0.9% Sodium Chloride, 250 mL Single Dose bag, packaged in 250 mL x 12 units per carton, Rx only, SterRx, 141 Idaho Ave., Plattsburgh, NY 12903, NDC 70324-602-01.

Product Quantity:
92,148 bags

Reason for Recall:
Lack of Assurance of Sterility

Recall Number:
D-0933-2023

Code Information:
Lot #: 490097, Exp 3-Aug-23; 490142, Exp 10-Aug-23; 491292, Exp 13-Aug-23; 494442, Exp 26-Nov-23; 496763, Exp 30-Nov-23; 496771, Exp 1-Dec-23; 497408, Exp 2-Dec-23; 497416, Exp 3-Dec-23; 499438, Exp 28-Jan-24; 501032, Exp 8-Feb-24; 501059, Exp 15-Feb-24; 502043, Exp 28-Mar-24; 502051, Exp 31-Mar-24; 503505, Exp 4-Apr-24; 504031, Exp 7-Apr-24; 504250, Exp 19-Apr-24

Product Description:
Norepinephrine 32 mg per 250 mL (128 mcg per mL) in 0.9% Sodium Chloride, 250 mL Single Dose bag, packaged in 250 mL x 12 units per case, Rx only, SterRx, 141 Idaho Ave., Plattsburgh, NY 12903, NDC 70324-702-01.

Product Quantity:
2,088 bags

Reason for Recall:
Lack of Assurance of Sterility

Recall Number:
D-0934-2023

Code Information:
Lot #: 490100, Exp 27-Jul-23

Class II Drugs Event

Event ID:
92667

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
07/11/2023

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
07/18/2023

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Ascend Laboratories, LLC
339 Jefferson Rd Ste 101
Parsippany NJ United States

Distribution Pattern:
Nationwide in the USA

Associated Products

Product Description:
Fingolimod Capsules, 0.5 mg, 30-count bottle, Rx Only, Manufactured by: Alkem Laboratories Ltd., INDIA; Distributed by: Ascend Laboratories, LLC, Parsippany, NJ 07054, NDC 67877-476-30.

Product Quantity:
2652 bottles

Reason for Recall:
Failed Dissolution Specifications

Recall Number:
D-0925-2023

Code Information:
Lot 22122841, Exp August 2025

Class II Drugs Event

Event ID:
92690

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
07/10/2023

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
07/19/2023

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
New England Life Care, Inc. dba Advanced Compounding Solutions
4 Constitution Way Ste L
Woburn MA United States

Distribution Pattern:
Nationwide in the USA

Associated Products

Product Description:
SUCCINYLcholine Chloride 200 mg/10mL (20 mg/mL), 10 mL BD Syringe, Rx Only, Advanced Compounding Solutions, 4 Constitution Way Ste L Woburn, MA 01801-1042; NDC: 71546-083-10

Product Quantity:
493 syringes

Reason for Recall:
CGMP Violations- that spaces adjacent to the production area may have been compromised at the time of production.

Recall Number:
D-0926-2023

Code Information:
Lot # 20230524-23C29D, Exp 21SEP2023

Product Description:
PHENYLephrine HCl 10mg added to 0.9% Sodium Chloride 250mL, 250 mL IV Bag @60 Total volume), RX only, Advanced Compounding Solutions, 4 Constitution Way Ste L Woburn, MA 01801-1042, NDC: 71546-450-25;

Product Quantity:
82 Bags

Reason for Recall:
CGMP Violations- that spaces adjacent to the production area may have been compromised at the time of production.

Recall Number:
D-0927-2023

Code Information:
Lot # 20230524-6FBB77, Exp 21OCT2023

Product Description:
ROcuronium Bromide 50 mg/5 mL (10 mg/mL), 5mL Syringe, RX Only, Advanced Compounding Solutions, 4 Constitution Way Ste L Woburn, MA 01801-1042, NDC: 71546-090-05

Product Quantity:
500 Syringes

Reason for Recall:
CGMP Violations- that spaces adjacent to the production area may have been compromised at the time of production.

Recall Number:
D-0928-2023

Code Information:
Lot # 20230524-530F73, Exp 21OCT2023

Product Description:
Vancomycin HCl 1.5 g added to 0.9% Sodium Chloride 500 mL, 500 mL IV Bag (515 total volume), Rx Only, Advanced Compounding Solutions, 4 Constitution Way Ste L Woburn, MA 01801-1042, NDC 71546-310-50;

Product Quantity:
209 Bags

Reason for Recall:
CGMP Violations- that spaces adjacent to the production area may have been compromised at the time of production.

Recall Number:
D-0929-2023

Code Information:
Lot # 20230524-0113AB, Exp 22AUG2023

Class III Drugs Event

Event ID:
92637

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
07/05/2023

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
07/17/2023

Initial Firm Notification of Consignee or Public:
Letter

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

Distribution Pattern:
USA nationwide.

Associated Products

Product Description:
Loteprednol Etabonate Ophthalmic Suspension, 5 mg/mL (0.5%), packaged as one bottle in a carton in a) 10 mL bottle (NDC# 62756-232-55) and b) 15 mL bottle (NDC # 62756-232-56), Rx only, Distributed by: Sun Pharmaceutical Ind., Inc., NJ 08512, Manufactured by: Sun Pharmaceutical Medicare Ltd., India.

Product Quantity:
20,884 cartons

Reason for Recall:
Superpotent Drug: Out of Specification (OOS) results observed for unit dose content.

Recall Number:
D-0924-2023

Code Information:
Lot#: a) BAC0334A, Exp 06/2023; BAC0532A, Exp 11/2023 BAD0407A, Exp 08/2024 BAD0425A, Exp 08/2024; b) BAC0335A, Exp 06/2023, BAC0533A, Exp 10/2023, BAD0148A, Exp 03/2024, BAD0320A, Exp 07/2024