Enforcement Report - Week of August 17, 2022

Class II Drugs Event

Event ID:
90541

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
06/29/2022

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
08/05/2022

Initial Firm Notification of Consignee or Public:
Letter

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

Distribution Pattern:
nationwide

Associated Products

Product Description:
Telmisartan and Hydrochlorothiazide Tablets USP, 80 mg/25 mg, 30 Tablets, Rx Only, Manufactured by: Glenmark Pharmaceuticals Ltd., Plot no 2, Phase-2, Pharma Zone, SEZ Pithampur, District Dhar, Madhya Pradesh 454775, India, Manufactured for: Glenmark Pharmaceuticals Inc, USA, Mahwah, NJ 07430, NDC 68462-842-13.

Product Quantity:
72288 units

Reason for Recall:
Packaging : Blister package issues.

Recall Number:
D-1305-2022

Code Information:
Lots 17210935 & 17210936., Exp Date 05/2023 Lot 17211206, Exp Date 06/2023 Lots 17211652, 17211655 & 17211658, Exp Date 08/2023

Product Description:
Telmisartan and Hydrochlorothiazide Tablets USP, 80 mg/12.5 mg, 30 Tablets, Rx Only, Manufactured by: Glenmark Pharmaceuticals Ltd., Plot no 2, Phase-2, Pharma Zone, SEZ Pithampur, District Dhar, Madhya Pradesh 454775, India, Manufactured for: Glenmark Pharmaceuticals Inc,m USA, Mahwah, NJ 07430, NDC 68462-841-13.

Product Quantity:

Reason for Recall:
Packaging : Blister package issues.

Recall Number:
D-1306-2022

Code Information:
Lots 17210929 & 17210930, Exp Date 05/2023; Lot 17211203, Exp Date 06/2023 & Lots 17211643, 17211646 & 17211649, Exp Date 08/2023

Class II Drugs Event

Event ID:
90553

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
06/29/2022

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
08/05/2022

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Mckesson Medical-Surgical Inc. Corporate Office
9954 Maryland Drive Deep Run Iii Ste. 4000
Richmond VA United States

Distribution Pattern:
Nationwide in the USA.

Associated Products

Product Description:
Triple Antibiotic Ointment, Bacitracin zinc, Neomycin sulfate, Polymixin B sulfate, First Aid Antibiotic, Triple Antibiotic Ointment, 144 packets per box, Net wt. per packet 0.5 g, Honeywell Safety Products, NDC 0498-0750-36.

Product Quantity:
6 boxes

Reason for Recall:
CGMP Deviations: products were stored outside the drug label specifications.

Recall Number:
D-1311-2022

Code Information:
Part# 231209G

Product Description:
Bisacodyl Suppositories, Fast Acting Stimulant Laxative, 100 suppositories per box, 10 mg each, Health Star, NDC 57896-443-01.

Product Quantity:
45 boxes

Reason for Recall:
CGMP Deviations: products were stored outside the drug label specifications.

Recall Number:
D-1312-2022

Code Information:
Part# 444-01-HST

Product Description:
Naphcon A eye drops, Naphazoline HCl 0.025% and Pheniramine Maleate 0.3%, Redness Reliever and Antihistamine Eye Drops, Sterile, 15 mL (0.5 FL OZ) bottle per box, Alcon, a Novartis company, NDC 0065-0085-15.

Product Quantity:
12 boxes

Reason for Recall:
CGMP Deviations: products were stored outside the drug label specifications.

Recall Number:
D-1313-2022

Code Information:
Part# 0065008515

Product Description:
Systane, Lubricant Eye Drops, Polyethylene Glycol 400 0.4% Lubricant, Propylene Glycol 0.3% Lubricant, Original, Long Lasting Dry Eye Relief, Sterile, a) 15 mL (0.5 FL OZ) NDC 0065-0429-15, b) 30 mL (1 FL OZ) NDC 0065-0429-30, bottle per box, Alcon Surgical Inc.

Product Quantity:
47 bottles

Reason for Recall:
CGMP Deviations: products were stored outside the drug label specifications.

Recall Number:
D-1314-2022

Code Information:
Part# a) 0065042915, b) 0065042930

Product Description:
Eye-stream, eye wash solution, sterile, 4 FL OZ (118 mL) bottle per box, Alcon, NDC 0065-0530-04.

Product Quantity:
16 boxes

Reason for Recall:
CGMP Deviations: products were stored outside the drug label specifications.

Recall Number:
D-1315-2022

Code Information:
Part# 0065053004

Product Description:
Systane Balance, Lubricant Eye Drops, Propylene Glycol 0.6% lubricant, Restorative Formula, Sterile, 10 mL (1/3 FL OZ) bottle per box, Alcon, NDC 0065-1433-02.

Product Quantity:
12 boxes

Reason for Recall:
CGMP Deviations: products were stored outside the drug label specifications.

Recall Number:
D-1316-2022

Code Information:
Part# 0065143302

Product Description:
Systane Zaditor, ketotifen fumarate ophthalmic solution 0.035%, Antihistamine eye drops, Eye Itch Relief, up to 12 Hours, Sterile, 30 day supply, 5mL (0.17 FL OZ) bottle per box, Alcon, NDC 0065-4011-05.

Product Quantity:
9 boxes

Reason for Recall:
CGMP Deviations: products were stored outside the drug label specifications.

Recall Number:
D-1317-2022

Code Information:
Part# 0065401105

Product Description:
Debrox, Carbamide Peroxide, Earwax Removal Aid, 0.5 FL OZ (15 mL) bottle per box), MedTech Products Inc., NDC 63029-321-01.

Product Quantity:
131 boxes

Reason for Recall:
CGMP Deviations: products were stored outside the drug label specifications.

Recall Number:
D-1318-2022

Code Information:
Part# 04203710478

Product Description:
Miralax (Polyethylene Glycol 3350), Powder for Solution, Osmotic Laxative, 30 Once-Daily Doses, Net WT 17.9 OZ (510 g) bottle, Bayer Healthcare Pharmaceuticals, NDC 11523-7234-4.

Product Quantity:
67 bottles

Reason for Recall:
CGMP Deviations: products were stored outside the drug label specifications.

Recall Number:
D-1319-2022

Code Information:
Part# 11523723404

Product Description:
GenTeal Tears, Lubricant Eye Ointment, Night-Time Ointment, Sterile, 3.5 gm (0.12 FL OZ) per box, Alcon, NDC 0065-0518-01.

Product Quantity:
40 boxes

Reason for Recall:
CGMP Deviations: products were stored outside the drug label specifications.

Recall Number:
D-1320-2022

Code Information:
Part# 30065051801

Product Description:
Pataday, Once Daily Relief, Olopatadine hydrochloride ophthalmic solution 0.2%, Antihistamine, Eye Allergy Itch Relief, Once Daily, Sterile, 2.5 mL (0.085 FL OZ) bottle per box, Alcon, NDC 0065-8150-01.

Product Quantity:
1 box

Reason for Recall:
CGMP Deviations: products were stored outside the drug label specifications.

Recall Number:
D-1321-2022

Code Information:
Part# 00065815001

Product Description:
A&D Original Ointment, Diaper Rash Ointment & Skin Protectant, 16 oz. Jar, Bayer Healthcare Pharmaceutica, NDC 11523-0096-3.

Product Quantity:
1 Jar

Reason for Recall:
CGMP Deviations: products were stored outside the drug label specifications.

Recall Number:
D-1322-2022

Code Information:
NA

Product Description:
Dakin's Solution, a) sodium hypochlorite 0.125%, quarter strength, NDC 0436-0672-16, b) sodium hypochlorite 0.25%, half strength, NDC 0436-0936-16, c) sodium hypochlorite 0.5% full strength, NDC 0436-0946-16, Antimicrobial, 473 mL (16 fl oz) bottle, Century Pharmaceuticals, Inc.

Product Quantity:
113 bottles

Reason for Recall:
CGMP Deviations: products were stored outside the drug label specifications.

Recall Number:
D-1323-2022

Code Information:
NA

Product Description:
Asthmanefrin Racephinephrine Inhalation Solution Bronchodilator, For temporary relief of mild symptoms of intermittent asthma, Preservative Free, Sterile, For Oral Inhalation Only, 30 vials per box, Nephron Pharmaceuticals Corporation, NDC 0487-2784-01.

Product Quantity:
1 box

Reason for Recall:
CGMP Deviations: products were stored outside the drug label specifications.

Recall Number:
D-1324-2022

Code Information:
NA

Product Description:
Racepinephrine Inhalation Solution, USP 2.25%, Bronchodilator, For Oral Inhalation Only, Sulfite Free, Preservative Free, 30 x 0.5 mL Sterile Unit-of-Use Vials, each in a foil pouch, per carton, Nephron Pharmaceuticals Corporation, NDC 0487-5901-99.

Product Quantity:
23 cartons

Reason for Recall:
CGMP Deviations: products were stored outside the drug label specifications.

Recall Number:
D-1325-2022

Code Information:
NA

Product Description:
Sterile Alcohol Prep Pads, Sterile, Latex Free, 100 large pads per box, manufactured for: Dynarex Corporation, NY 10962, NDC 67777-121-16.

Product Quantity:
10 boxes

Reason for Recall:
CGMP Deviations: products were stored outside the drug label specifications.

Recall Number:
D-1326-2022

Code Information:
Part# 1116

Product Description:
Alcohol Swabsticks, Antiseptic, 50 4" saturated individual packets per box, Manufactured for: Dynarex Corporation, NY 10962, Made in Mexico, NDC 67777-300-01 (current NDC) NDC# 67777-120-10 (discontinued)

Product Quantity:

Reason for Recall:
CGMP Deviations: products were stored outside the drug label specifications.

Recall Number:
D-1327-2022

Code Information:
Part# 1203

Class II Drugs Event

Event ID:
90583

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
07/11/2022

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
08/05/2022

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Hikma Pharmaceuticals USA Inc.
2 Esterbrook Ln
Cherry Hill NJ United States

Distribution Pattern:
Nationwide in the USA

Associated Products

Product Description:
Lorazepam Injection, USP, 2mg/mL, 1 mL vial, 25 vials per carton, RX Only, Manufactured by West-Ward Eatontown, NJ 07724, Carton NDC# 0641-6044-25, Vial NDC# 0641-6044-01

Product Quantity:
4,739,000 vials

Reason for Recall:
Failed Impurities/Degradation Specifications: Out-of-specification results observed for total related compounds during testing of retain samples.

Recall Number:
D-1307-2022

Code Information:
Lot # 060064, Exp. 06/2023, 070084, Exp. 07/2023, 070126, Exp. 07/2023, 080091, Exp. 08/2023, 080060, Exp. 08/2023

Product Description:
Ativan Injection (lorazepam injection, USP), 2mg/mL, 1 mL vial, 25 vials per carton, RX Only, Manufactured by West-Ward Eatontown, NJ 07724, Carton NDC# 0641-6001-25, Vial NDC# 0641-6001-01

Product Quantity:
301,400 vials

Reason for Recall:
Failed Impurities/Degradation Specifications: Out-of-specification results observed for total related compounds during testing of retain samples.

Recall Number:
D-1308-2022

Code Information:
Lot # 060064Z, Exp. 06/2023

Product Description:
Lorazepam Injection, USP, 2mg/mL, 1 mL vial, 25 vial per carton, Rx Only, Novaplus, Manufactured by Hikma Berkeley Heights, NJ 07922. Carton NDC# 0641-6048-25, Vial NDC# 0641-6048-01

Product Quantity:
713,550 vials

Reason for Recall:
Failed Impurities/Degradation Specifications: Out-of-specification results observed for total related compounds during testing of retain samples.

Recall Number:
D-1309-2022

Code Information:
Lot # 070088, exp. date 07/2023

Product Description:
Lorazepam Injection, USP, 4mg/mL, 1 mL vial, 25 vial per carton, Rx Only, Novaplus, Manufactured by Hikma Berkeley Heights, NJ 07922. Carton NDC# NDC# 0641-6045-25, Vial NDC# 0641-6045-01

Product Quantity:
82,700 vials

Reason for Recall:
Failed Impurities/Degradation Specifications: Out-of-specification results observed for total related compounds during testing of retain samples.

Recall Number:
D-1310-2022

Code Information:
Lot # 070096, exp. date 07/2023

Class II Drugs Event

Event ID:
90634

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
07/19/2022

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
08/09/2022

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Strides Pharma Inc.
2 Tower Center Blvd Ste 1102
East Brunswick NJ United States

Distribution Pattern:
US Nationwide

Associated Products

Product Description:
Prednisone Tablets USP, 20 mg, 100-count bottle, Rx Only, Manufactured by: Strides Pharma Science Ltd., Bengaluru - 562106, India, Distributed by: Strides Pharma Inc., East Brunswick, NJ 08816, NDC 64380-785-06.

Product Quantity:
1032 bottles

Reason for Recall:
Presence of foreign tablet: 2.5 mg tablet in a 20 mg bottle of Prednisone Tablets

Recall Number:
D-1330-2022

Code Information:
Lot #: 7248988B, Exp 9/2023

Class II Drugs Event

Event ID:
90653

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
07/25/2022

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
08/09/2022

Initial Firm Notification of Consignee or Public:
Letter

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

Distribution Pattern:
Nationwide within the United States

Associated Products

Product Description:
FentaNYL Citrate in 0.9% Sodium Chloride 1 mg per 100 mL (10 mcg per mL) IV bags, Rx only, SterRx, 141 Idaho Ave., Plattsburgh, NY, 12903, NDC 70324-327-01.

Product Quantity:
720 bags

Reason for Recall:
Lack of Assurance of Sterility

Recall Number:
D-1331-2022

Code Information:
Lot #: CHI, Exp. Date Dec 22, 2022

Product Description:
fentaNYL Citrate in 0.9% Sodium Chloride, 2.5 mg per 250 mL, (10 mcg per mL) IV bags, Rx Only, SterRx, 141 Idaho Avenue, Plattsburgh, NY 12903, NDC 70324-327-02.

Product Quantity:
360 bags

Reason for Recall:
Lack of Assurance of Sterility

Recall Number:
D-1332-2022

Code Information:
Lot #: CHL, Exp. Date Dec 29, 2022

Class II Drugs Event

Event ID:
90702

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
08/02/2022

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
08/05/2022

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
CIPLA
10 Independence Blvd
Warren NJ United States

Distribution Pattern:
Nationwide in the USA

Associated Products

Product Description:
Difluprednate Ophthalmic Emulsion 0.05%, For Ophthalmic Use Only, Sterile, 5 mL bottles, Manufactured by Cipla Ltd., India, Manufactured for: Cipla USA, Inc., NJ 07059, NDC 69097-341-35.

Product Quantity:
7,992 bottles

Reason for Recall:
Lack of Assurance of Sterility: Complaints received of defective container closure.

Recall Number:
D-1328-2022

Code Information:
Lot # DEG3LC2, Exp 05/2023

Class III Drugs Event

Event ID:
90594

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
07/22/2022

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
08/11/2022

Initial Firm Notification of Consignee or Public:
Letter

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

Distribution Pattern:
Distributed in Ohio

Associated Products

Product Description:
Azacitidine for Injection 100mg/vial Lyophilized Powder, Rx Only, Mfd. in Romania By: Sindan Pharma SRL For BluePoint Laboratories, NDC 68001-313-56

Product Quantity:
4162 cartons

Reason for Recall:
Subpotent Drug - Out of specification (OOS) result obtained during monitoring stability study for Assay. Results below specification.

Recall Number:
D-1334-2022

Code Information:
Lot: FE22001A, Exp 01/2024

Class III Drugs Event

Event ID:
90637

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
07/20/2022

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
08/08/2022

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
AVKARE Inc.
615 N 1st St
Pulaski TN United States

Distribution Pattern:
Nationwide within the United States

Associated Products

Product Description:
Lamotrigine Tablets, USP 100 mg, 1000-count bottles, Rx Only, Manufactured for: AvKARE, Inc. Pulaski, TN 38478, NDC 42291-367-10, UPC 3 42291 36710 4

Product Quantity:
8328 bottles

Reason for Recall:
Labeling: Label Error on Declared Strength

Recall Number:
D-1329-2022

Code Information:
Lot #: 42581 Exp. 12/2024; 42484 Exp. 11/2024; 41204 Exp. 05/2024; 38723 Exp. 02/2023; 37623 Exp. 10/2022