Enforcement Report - Week of June 15, 2022

Class II Drugs Event

Event ID:
89646

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
04/13/2022

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
06/09/2022

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:
USA nationwide.

Associated Products

Product Description:
EPI-PEN 2-PAK (epinephrine injection, USP), Single-Dose Auto-Injectors 0.3 mg, Rx only, Manufactured for: Mylan Specialty LP., NDC 49502-500-02

Product Quantity:
5 cartons

Reason for Recall:
cGMP deviations: Temperature abuse

Recall Number:
D-0993-2022

Code Information:
McKesson Medical-Surgical (MMS) is not able to identify the particular lot number received by a particular consignee for the recalled prescription products. Each letter includes the date it was distributed to customers and the dates that impacted product may have been shipped to the customer. The letters clearly explain that consignees should identify product received from MMS between June 1 and September 30, 2021. A consignee should be able to use its own records to determine whether it received an impacted product from MMS during that timeframe and whether it still has any of that product in inventory. The recall notification letter informs consignees that they may contact Sedgwick if they have any questions.

Product Description:
Miocol-E (acetylcholine chloride intraocular solution) 20 mg/2mL (10 mg/mL), Rx only, Manufacturer: Bausch & Lomb, NDC 24208-539-20

Product Quantity:
45 kits

Reason for Recall:
cGMP deviations: Temperature abuse

Recall Number:
D-0994-2022

Code Information:
McKesson Medical-Surgical (MMS) is not able to identify the particular lot number received by a particular consignee for the recalled prescription products. Each letter includes the date it was distributed to customers and the dates that impacted product may have been shipped to the customer. The letters clearly explain that consignees should identify product received from MMS between June 1 and September 30, 2021. A consignee should be able to use its own records to determine whether it received an impacted product from MMS during that timeframe and whether it still has any of that product in inventory. The recall notification letter informs consignees that they may contact Sedgwick if they have any questions.

Product Description:
TobraDex (tobramycin and dexamethasone), Ophthalmic Ointment, 3.5 gm, Rx only, Manufacturer: Novartis, NDC 0078-0876-01

Product Quantity:
3 tubes

Reason for Recall:
cGMP deviations: Temperature abuse

Recall Number:
D-0995-2022

Code Information:
McKesson Medical-Surgical (MMS) is not able to identify the particular lot number received by a particular consignee for the recalled prescription products. Each letter includes the date it was distributed to customers and the dates that impacted product may have been shipped to the customer. The letters clearly explain that consignees should identify product received from MMS between June 1 and September 30, 2021. A consignee should be able to use its own records to determine whether it received an impacted product from MMS during that timeframe and whether it still has any of that product in inventory. The recall notification letter informs consignees that they may contact Sedgwick if they have any questions.

Product Description:
Topex (benzocaine 20%), Topical Anesthetic Gel Strawberry, 1 oz, Rx only, Manufacturer: DS Healthcare, NDC 0699-5116-01

Product Quantity:
24 bottles

Reason for Recall:
cGMP deviations: Temperature abuse

Recall Number:
D-0996-2022

Code Information:
McKesson Medical-Surgical (MMS) is not able to identify the particular lot number received by a particular consignee for the recalled prescription products. Each letter includes the date it was distributed to customers and the dates that impacted product may have been shipped to the customer.

Product Description:
Azithromycin for Injection USP Vial, 500 mg per vial, Rx only, Manufacturer: Auromedics Pharma LLC, NDC 55150-174-10

Product Quantity:
13 carton/10 vials each

Reason for Recall:
cGMP deviations: Temperature abuse

Recall Number:
D-0997-2022

Code Information:
McKesson Medical-Surgical (MMS) is not able to identify the particular lot number received by a particular consignee for the recalled prescription products. Each letter includes the date it was distributed to customers and the dates that impacted product may have been shipped to the customer.

Product Description:
Bupivacaine HCl Injection, single dose vial, Preservative Free 0.5%, 10mL (25/ct), Rx only, Manufacturer: Auromedics Pharma LLC, NDC 55150-169-10

Product Quantity:
224 cartons/10 vials each

Reason for Recall:
cGMP deviations: Temperature abuse

Recall Number:
D-0998-2022

Code Information:
McKesson Medical-Surgical (MMS) is not able to identify the particular lot number received by a particular consignee for the recalled prescription products. Each letter includes the date it was distributed to customers and the dates that impacted product may have been shipped to the customer.

Product Description:
Bupivacaine HCl Injection, single dose vial, 0.5%, 30 mL/5 mg/mL, Rx only, Manufacturer: Auromedics Pharma LLC, NDC 55150-0170-30

Product Quantity:
4 cartons/25 vials each

Reason for Recall:
cGMP deviations: Temperature abuse

Recall Number:
D-0999-2022

Code Information:
McKesson Medical-Surgical (MMS) is not able to identify the particular lot number received by a particular consignee for the recalled prescription products. Each letter includes the date it was distributed to customers and the dates that impacted product may have been shipped to the customer.

Product Description:
Bupivacaine HCl Injection, Multi dose vial, 0.25%, 50 mL/2.5 mg/mL, Rx only, Manufacturer: Auromedics Pharma LLC, NDC 55150-0249-50

Product Quantity:
34 cartons/ 25 vials each

Reason for Recall:
cGMP deviations: Temperature abuse

Recall Number:
D-1000-2022

Code Information:
McKesson Medical-Surgical (MMS) is not able to identify the particular lot number received by a particular consignee for the recalled prescription products. Each letter includes the date it was distributed to customers and the dates that impacted product may have been shipped to the customer.

Product Description:
Bupivacaine HCl Injection, Multi dose vial, 0.50%, 50 mL/5 mg/mL, Rx only, Manufacturer: Auromedics Pharma LLC, NDC 55150-0250-50

Product Quantity:
16 cartons/24 vials each

Reason for Recall:
cGMP deviations: Temperature abuse

Recall Number:
D-1001-2022

Code Information:
McKesson Medical-Surgical (MMS) is not able to identify the particular lot number received by a particular consignee for the recalled prescription products. Each letter includes the date it was distributed to customers and the dates that impacted product may have been shipped to the customer.

Product Description:
Bupivacaine HCl Injection, Single Dose Vial, 0.75%, 10 mL/7.5 mg/mL, Rx only, Manufacturer: Auromedics Pharma LLC, NDC 55150-0171-10

Product Quantity:
32 cartons/25 vials each

Reason for Recall:
cGMP deviations: Temperature abuse

Recall Number:
D-1002-2022

Code Information:
McKesson Medical-Surgical (MMS) is not able to identify the particular lot number received by a particular consignee for the recalled prescription products. Each letter includes the date it was distributed to customers and the dates that impacted product may have been shipped to the customer.

Product Description:
Dexmedetomidine HCL Single Dose Vial 200 mcg per 2 mL (100mcg/mL), Rx only, Manufacturer: Auromedics Pharma LLC, NDC 55150-0209-02

Product Quantity:
5 cartons/2 ml single dose vials

Reason for Recall:
cGMP deviations: Temperature abuse

Recall Number:
D-1003-2022

Code Information:
McKesson Medical-Surgical (MMS) is not able to identify the particular lot number received by a particular consignee for the recalled prescription products. Each letter includes the date it was distributed to customers and the dates that impacted product may have been shipped to the customer.

Product Description:
Lidocaine Patch, 5%, 30-count box, Rx only, Manufacturer: Rhodes Pharmaceuticals, NDC 42858-0118-30

Product Quantity:
1 carton/30 patches

Reason for Recall:
cGMP deviations: Temperature abuse

Recall Number:
D-1004-2022

Code Information:
McKesson Medical-Surgical (MMS) is not able to identify the particular lot number received by a particular consignee for the recalled prescription products. Each letter includes the date it was distributed to customers and the dates that impacted product may have been shipped to the customer.

Product Description:
Olanzapine single dose vial Lyophilized, 10 mg, Rx only, MFG: Auromedics Pharma LLC, NDC# 55150-0308-01

Product Quantity:
2 cartons/2 single dose vials

Reason for Recall:
cGMP deviations: Temperature abuse

Recall Number:
D-1005-2022

Code Information:
McKesson Medical-Surgical (MMS) is not able to identify the particular lot number received by a particular consignee for the recalled prescription products. Each letter includes the date it was distributed to customers and the dates that impacted product may have been shipped to the customer.

Product Description:
Arzol (Silver Nitrate Applicator), (Silver Nitrate 75%, Potassium Nitrate 25%), 100-count box, Rx only, Manufacturer: Arzol Chemical Co, NDC 12870-0001-02

Product Quantity:
18 vials

Reason for Recall:
cGMP deviations: Temperature abuse

Recall Number:
D-1006-2022

Code Information:
McKesson Medical-Surgical (MMS) is not able to identify the particular lot number received by a particular consignee for the recalled prescription products. Each letter includes the date it was distributed to customers and the dates that impacted product may have been shipped to the customer.

Product Description:
Sumatriptan Injection, USP, 6mg/0.5 mL, packaged in a box of 5 x 0.5 mL single-dose vials, Rx only, Manufacturer: Auromedics Pharma LLC, NDC 55150-0173-01

Product Quantity:
16 single dose vials

Reason for Recall:
cGMP deviations: Temperature abuse

Recall Number:
D-1007-2022

Code Information:
McKesson Medical-Surgical (MMS) is not able to identify the particular lot number received by a particular consignee for the recalled prescription products. Each letter includes the date it was distributed to customers and the dates that impacted product may have been shipped to the customer.

Product Description:
Betadine 5%, Sterile Ophthalmic Prep Solution, (povidine-iodine ophthalmic solution), 1 fl. oz. (30 mL), Rx only, Mfd for: Alcon Surgical Inc., NDC 0065-0411-30

Product Quantity:
799 cartons/1 bottle each

Reason for Recall:
cGMP deviations: Temperature abuse

Recall Number:
D-1008-2022

Code Information:
McKesson Medical-Surgical (MMS) is not able to identify the particular lot number received by a particular consignee for the recalled prescription products. Each letter includes the date it was distributed to customers and the dates that impacted product may have been shipped to the customer.

Product Description:
Ampicillin for Injection, USP, 1 g per vial, 10-count box, Rx only, Distributed by: Auromedics Pharma, NDC 55150-113-10

Product Quantity:
10 cartons/10 vials each

Reason for Recall:
cGMP deviations: Temperature abuse

Recall Number:
D-1009-2022

Code Information:
McKesson Medical-Surgical (MMS) is not able to identify the particular lot number received by a particular consignee for the recalled prescription products. Each letter includes the date it was distributed to customers and the dates that impacted product may have been shipped to the customer.

Product Description:
Epidural Tray, Nerve Block Single shot, Rx only, # 182207, MFG: Avanos Medical Sales LLC

Product Quantity:
1 case

Reason for Recall:
cGMP deviations: Temperature abuse

Recall Number:
D-1010-2022

Code Information:
McKesson Medical-Surgical (MMS) is not able to identify the particular lot number received by a particular consignee for the recalled prescription products. Each letter includes the date it was distributed to customers and the dates that impacted product may have been shipped to the customer.

Product Description:
Dihydroergotamine Mesylate, Injection, USP, 1mg/mL, packaged in box of 5 x 1 mL ampules, Rx only, Manufactured for: Perrigo, Minneapolis, MN, NDC 0574-0850-10

Product Quantity:
1 carton

Reason for Recall:
cGMP deviations: Temperature abuse

Recall Number:
D-1011-2022

Code Information:
McKesson Medical-Surgical (MMS) is not able to identify the particular lot number received by a particular consignee for the recalled prescription products. Each letter includes the date it was distributed to customers and the dates that impacted product may have been shipped to the customer.

Product Description:
EPI-Pen Jr, 2-PAK, (epinephrine injection, USP) Single-Dose Auto-Injectors 0.15 mg, packaged in 2 count carton, Rx only, MFG: Mylan Pharma, NDC 49502-501-02

Product Quantity:
4 cartons/2 auto injectors each

Reason for Recall:
cGMP deviations: Temperature abuse

Recall Number:
D-1012-2022

Code Information:
McKesson Medical-Surgical (MMS) is not able to identify the particular lot number received by a particular consignee for the recalled prescription products. Each letter includes the date it was distributed to customers and the dates that impacted product may have been shipped to the customer.

Product Description:
Epinephrine Injection, USP, Single-Dose Auto-Injectors 0.3 mg, packaged in 2 count carton, Rx only, MFG: Mylan Pharma, NDC 49502-102-02

Product Quantity:
55 packs

Reason for Recall:
cGMP deviations: Temperature abuse

Recall Number:
D-1013-2022

Code Information:
McKesson Medical-Surgical (MMS) is not able to identify the particular lot number received by a particular consignee for the recalled prescription products. Each letter includes the date it was distributed to customers and the dates that impacted product may have been shipped to the customer.

Product Description:
Epinephrine Injection, USP, Single-Dose Auto-Injectors 0.15 mg, packaged in 2 count carton, Rx only, MFG: Mylan Pharma NDC 49502-101-02

Product Quantity:
30 packs

Reason for Recall:
cGMP deviations: Temperature abuse

Recall Number:
D-1014-2022

Code Information:
McKesson Medical-Surgical (MMS) is not able to identify the particular lot number received by a particular consignee for the recalled prescription products. Each letter includes the date it was distributed to customers and the dates that impacted product may have been shipped to the customer.

Product Description:
Firmagon (degarelix for injection) 80 mg, Maintenance Dose (28 days), packaged in a kit, Rx only, MFG: Ferring Pharmaceuticals Inc., NDC 55566-8303-01

Product Quantity:
25 kits

Reason for Recall:
cGMP deviations: Temperature abuse

Recall Number:
D-1015-2022

Code Information:
McKesson Medical-Surgical (MMS) is not able to identify the particular lot number received by a particular consignee for the recalled prescription products. Each letter includes the date it was distributed to customers and the dates that impacted product may have been shipped to the customer.

Product Description:
Firmagon (degarelix for injection) 240 mg, Starting Dose, packaged in a kit, Rx only, MFG: Ferring Pharmaceuticals Inc., NDC 55566-8403-01

Product Quantity:
15 boxes

Reason for Recall:
cGMP deviations: Temperature abuse

Recall Number:
D-1016-2022

Code Information:
McKesson Medical-Surgical (MMS) is not able to identify the particular lot number received by a particular consignee for the recalled prescription products. Each letter includes the date it was distributed to customers and the dates that impacted product may have been shipped to the customer.

Product Description:
GlucaGen (glucagon) for injection, 1 mg per vial, single dose kit, Rx only, Manufactured for: Boehringer Mannheim, NDC 0597-0260-10

Product Quantity:
187 vials

Reason for Recall:
cGMP deviations: Temperature abuse

Recall Number:
D-1017-2022

Code Information:
McKesson Medical-Surgical (MMS) is not able to identify the particular lot number received by a particular consignee for the recalled prescription products. Each letter includes the date it was distributed to customers and the dates that impacted product may have been shipped to the customer.

Product Description:
Albuterol Sulfate Inhalation Solution, 0.021%, 0.63 mg/3mL, packaged in 30 x 3 mL Sterile Unit-Dose Vials, Rx only, MFG: Nephron Pharma, NDC 0487-0301-01

Product Quantity:
1 carton/30 pouches each

Reason for Recall:
cGMP deviations: Temperature abuse

Recall Number:
D-1018-2022

Code Information:
McKesson Medical-Surgical (MMS) is not able to identify the particular lot number received by a particular consignee for the recalled prescription products. Each letter includes the date it was distributed to customers and the dates that impacted product may have been shipped to the customer.

Product Description:
Albuterol Sulfate Inhalation Solution 0.083%, 2.5 mg/3mL, packaged in 5 x 3 mL unit-dose vials, Rx only, Manufactured by: Nephron Pharma, NDC 0487-9501-03

Product Quantity:
23 pouches

Reason for Recall:
cGMP deviations: Temperature abuse

Recall Number:
D-1019-2022

Code Information:
McKesson Medical-Surgical (MMS) is not able to identify the particular lot number received by a particular consignee for the recalled prescription products. Each letter includes the date it was distributed to customers and the dates that impacted product may have been shipped to the customer.

Product Description:
Albuterol Sulfate Inhalation Solution 0.083%, 2.5 mg/3mL, packaged in 25 X 3mL unit-dose vials, Rx only, MFG by: Nephron Pharma, NDC 0487-9501-25

Product Quantity:
96 pouches

Reason for Recall:
cGMP deviations: Temperature abuse

Recall Number:
D-1020-2022

Code Information:
McKesson Medical-Surgical (MMS) is not able to identify the particular lot number received by a particular consignee for the recalled prescription products. Each letter includes the date it was distributed to customers and the dates that impacted product may have been shipped to the customer.

Product Description:
Adrenalin (epinephrine injection, USP) 30 mg/30 mL (1mg/mL), 30 mL multiple dose vial, Rx only, MFG: Par Pharma, NDC 42023-168-01

Product Quantity:
58 cartons

Reason for Recall:
cGMP deviations: Temperature abuse

Recall Number:
D-1022-2022

Code Information:
McKesson Medical-Surgical (MMS) is not able to identify the particular lot number received by a particular consignee for the recalled prescription products. Each letter includes the date it was distributed to customers and the dates that impacted product may have been shipped to the customer.

Product Description:
Albuterol Sulfate Inhalation Aerosol HFA with Dose Indicator, 90 mcg, 200 metered inhalations, Rx only, Manufactured for: PAR Pharmaceutical, NDC 0254-1007-52

Product Quantity:
5 aerosols

Reason for Recall:
cGMP deviations: Temperature abuse

Recall Number:
D-1023-2022

Code Information:
McKesson Medical-Surgical (MMS) is not able to identify the particular lot number received by a particular consignee for the recalled prescription products. Each letter includes the date it was distributed to customers and the dates that impacted product may have been shipped to the customer.

Product Description:
Albuterol Sulfate Inhalation Aerosol HFA 90 mcg, with Dose Indicator, 200 metered inhalations, Rx only, Distributed by: Sandoz Inc., NDC 0781-7296-85

Product Quantity:
1 aerosol

Reason for Recall:
cGMP deviations: Temperature abuse

Recall Number:
D-1024-2022

Code Information:
McKesson Medical-Surgical (MMS) is not able to identify the particular lot number received by a particular consignee for the recalled prescription products. Each letter includes the date it was distributed to customers and the dates that impacted product may have been shipped to the customer.

Product Description:
Amoxicillin Capsules, USP, 500 mg, 100-count bottle, Rx only, MFG: Sandoz Pharma, NDC 0781-2613-01

Product Quantity:
12 bottles

Reason for Recall:
cGMP deviations: Temperature abuse

Recall Number:
D-1025-2022

Code Information:
McKesson Medical-Surgical (MMS) is not able to identify the particular lot number received by a particular consignee for the recalled prescription products. Each letter includes the date it was distributed to customers and the dates that impacted product may have been shipped to the customer.

Product Description:
Aparaclonidine Ophthalmic Solution 0.5% as base, 0.5%, 5 mL bottle, Rx only, MFG:Sandoz Pharma, NDC 61314-665-05

Product Quantity:
21 bottles

Reason for Recall:
cGMP deviations: Temperature abuse

Recall Number:
D-1026-2022

Code Information:
McKesson Medical-Surgical (MMS) is not able to identify the particular lot number received by a particular consignee for the recalled prescription products. Each letter includes the date it was distributed to customers and the dates that impacted product may have been shipped to the customer.

Product Description:
Aprepitant Capsule, USP, 40 mg, 1 capsule per unit dose package, Rx only, MFG: Sandoz Pharma, NDC 0781-2321-06

Product Quantity:
29 boxes

Reason for Recall:
cGMP deviations: Temperature abuse

Recall Number:
D-1027-2022

Code Information:
McKesson Medical-Surgical (MMS) is not able to identify the particular lot number received by a particular consignee for the recalled prescription products. Each letter includes the date it was distributed to customers and the dates that impacted product may have been shipped to the customer.

Product Description:
Betamethasone Dipropionate Cream USP, 0.05%, 45 grams tube, Rx only, MFG: Sandoz Pharma, NDC 0168-0055-46

Product Quantity:
1 tube

Reason for Recall:
cGMP deviations: Temperature abuse

Recall Number:
D-1028-2022

Code Information:
McKesson Medical-Surgical (MMS) is not able to identify the particular lot number received by a particular consignee for the recalled prescription products. Each letter includes the date it was distributed to customers and the dates that impacted product may have been shipped to the customer.

Product Description:
Ciprofloxacin Ophthalmic Solution 0.3%, 10 mL bottle, Rx only, Manufactured by: Alcon Laboratories, Inc., NDC 61314-0656-10

Product Quantity:
1 bottle

Reason for Recall:
cGMP deviations: Temperature abuse

Recall Number:
D-1029-2022

Code Information:
McKesson Medical-Surgical (MMS) is not able to identify the particular lot number received by a particular consignee for the recalled prescription products. Each letter includes the date it was distributed to customers and the dates that impacted product may have been shipped to the customer.

Product Description:
Spinal Tray (A4058-25 Spinal Tray 25G Whitacre No Epinephrine), Rx only, Manufacturer: Smiths Medical ASD, Inc., NJ

Product Quantity:
8 cases

Reason for Recall:
cGMP deviations: Temperature abuse

Recall Number:
D-1030-2022

Code Information:
McKesson Medical-Surgical (MMS) is not able to identify the particular lot number received by a particular consignee for the recalled prescription products. Each letter includes the date it was distributed to customers and the dates that impacted product may have been shipped to the customer.

Product Description:
Sterile Water for Injection USP, 2000 mL, Rx only, Baxter Healthcare Corp., NDC 0338-0013-06

Product Quantity:
unknown

Reason for Recall:
cGMP deviations: Temperature abuse

Recall Number:
D-1031-2022

Code Information:
McKesson Medical-Surgical (MMS) is not able to identify the particular lot number received by a particular consignee for the recalled prescription products. Each letter includes the date it was distributed to customers and the dates that impacted product may have been shipped to the customer.

Product Description:
Doxycycline Capsules, USP, 100 mg, 50-count bottle, Rx only, Distributed by: Sun Pharmaceuticals, NDC 63304-616-50

Product Quantity:
3 bottles

Reason for Recall:
cGMP deviations: Temperature abuse

Recall Number:
D-1032-2022

Code Information:
McKesson Medical-Surgical (MMS) is not able to identify the particular lot number received by a particular consignee for the recalled prescription products. Each letter includes the date it was distributed to customers and the dates that impacted product may have been shipped to the customer.

Product Description:
BSS Sterile Irrigating Solution (balanced salt solution), 15 mL bottle, Rx only, MFG: Alcon Surgical Inc, NDC 0065-0795-15

Product Quantity:
13 bottles

Reason for Recall:
cGMP deviations: Temperature abuse

Recall Number:
D-1033-2022

Code Information:
McKesson Medical-Surgical (MMS) is not able to identify the particular lot number received by a particular consignee for the recalled prescription products. Each letter includes the date it was distributed to customers and the dates that impacted product may have been shipped to the customer.

Product Description:
BSS Sterile Irrigating Solution (balanced salt solution), 500 mL bottle, Rx only, MFG: Alcon Surgical Inc, NDC 0065-0795-50

Product Quantity:
4 bottles

Reason for Recall:
cGMP deviations: Temperature abuse

Recall Number:
D-1034-2022

Code Information:
McKesson Medical-Surgical (MMS) is not able to identify the particular lot number received by a particular consignee for the recalled prescription products. Each letter includes the date it was distributed to customers and the dates that impacted product may have been shipped to the customer.

Product Description:
Isopto Atropine (atropine sulfate ophthalmic solution) 1%, 5mL bottle, MFG: Alcon Surgical, NDC 0065-0303-55

Product Quantity:
13 bottles

Reason for Recall:
cGMP deviations: Temperature abuse

Recall Number:
D-1035-2022

Code Information:
McKesson Medical-Surgical (MMS) is not able to identify the particular lot number received by a particular consignee for the recalled prescription products. Each letter includes the date it was distributed to customers and the dates that impacted product may have been shipped to the customer.

Product Description:
MIOSTAT (Carbachol Intraocular Solution, USP) 0.01%, 1.5 mL, Rx only, MFG: Alcon Surgical Inc., NDC 0065-0023-15

Product Quantity:
8 boxes/12 vials each

Reason for Recall:
cGMP deviations: Temperature abuse

Recall Number:
D-1036-2022

Code Information:
McKesson Medical-Surgical (MMS) is not able to identify the particular lot number received by a particular consignee for the recalled prescription products. Each letter includes the date it was distributed to customers and the dates that impacted product may have been shipped to the customer.

Product Description:
Meclizine Hydrochloride Tablets, USP, 25 mg, 50-count cartons (5 x10 unit dose), 10 Tablets per card, 5 cards per carton, Rx only, MFG: Avkare Inc., NDC 50268-523-15

Product Quantity:
1 box/50 blister packs per box

Reason for Recall:
cGMP deviations: Temperature abuse

Recall Number:
D-1037-2022

Code Information:
McKesson Medical-Surgical (MMS) is not able to identify the particular lot number received by a particular consignee for the recalled prescription products. Each letter includes the date it was distributed to customers and the dates that impacted product may have been shipped to the customer.

Product Description:
Glucagen (glucagon) for injection, packaged in a 10-count box, (10 vials each containing 1 mg per vial), Rx only, MFG: Boehringer Mannheim, NDC 0597-0053-45

Product Quantity:
1 carton/10 vials per carton

Reason for Recall:
cGMP deviations: Temperature abuse

Recall Number:
D-1038-2022

Code Information:
McKesson Medical-Surgical (MMS) is not able to identify the particular lot number received by a particular consignee for the recalled prescription products. Each letter includes the date it was distributed to customers and the dates that impacted product may have been shipped to the customer.

Product Description:
Naltrexone Hydrochloride Tablets, USP, 50 mg, 100-count bottle, Rx only, MFG: Mallinckrodt Inc., NDC 0406-1170-03

Product Quantity:
4 bottles/30 tablets per bottle

Reason for Recall:
cGMP deviations: Temperature abuse

Recall Number:
D-1039-2022

Code Information:
McKesson Medical-Surgical (MMS) is not able to identify the particular lot number received by a particular consignee for the recalled prescription products. Each letter includes the date it was distributed to customers and the dates that impacted product may have been shipped to the customer.

Product Description:
Ipratropium Bromide Inhalation Solution, 0.02%, 0.5 mg/2.5 mL, packaged in 25-count box (25 x 2.5 mL sterile unit-dose vials), Rx only, MFG: Nephron Pharma, NDC 0487-9801-25

Product Quantity:
57 pouches

Reason for Recall:
cGMP deviations: Temperature abuse

Recall Number:
D-1040-2022

Code Information:
McKesson Medical-Surgical (MMS) is not able to identify the particular lot number received by a particular consignee for the recalled prescription products. Each letter includes the date it was distributed to customers and the dates that impacted product may have been shipped to the customer.

Product Description:
ClomiPHENE Citrate Tablets, USP 50 mg, 30-count bottle, Rx only, MFG: PAR Pharma, NDC 49884-701-55

Product Quantity:
240 cartons/3 blister packs per carton

Reason for Recall:
cGMP deviations: Temperature abuse

Recall Number:
D-1041-2022

Code Information:
McKesson Medical-Surgical (MMS) is not able to identify the particular lot number received by a particular consignee for the recalled prescription products. Each letter includes the date it was distributed to customers and the dates that impacted product may have been shipped to the customer.

Product Description:
Olanzapine Orally Disintegrating Tablets, USP 10 mg, 30-count box unit dose tablets (3 blister cards each containing 10 tablets), Rx only, MFG: PAR PHARMA, NDC 49884-321-55

Product Quantity:
30 cartons/3 blister packs per carton

Reason for Recall:
cGMP deviations: Temperature abuse

Recall Number:
D-1042-2022

Code Information:
McKesson Medical-Surgical (MMS) is not able to identify the particular lot number received by a particular consignee for the recalled prescription products. Each letter includes the date it was distributed to customers and the dates that impacted product may have been shipped to the customer.

Product Description:
Lidocaine Patch 5%, 30-count carton, Rx only, MFG: Qualitest Products, NDC 0603-1880-16

Product Quantity:
3 cartons/30 pouches per carton

Reason for Recall:
cGMP deviations: Temperature abuse

Recall Number:
D-1043-2022

Code Information:
McKesson Medical-Surgical (MMS) is not able to identify the particular lot number received by a particular consignee for the recalled prescription products. Each letter includes the date it was distributed to customers and the dates that impacted product may have been shipped to the customer.

Product Description:
Ciprofloxacin Ophthalmic Solution 0.3%, 5 mL bottle, Rx only, MFG: Sandoz Pharma, NDC 61314-656-05

Product Quantity:
7 bottles

Reason for Recall:
cGMP deviations: Temperature abuse

Recall Number:
D-1044-2022

Code Information:
McKesson Medical-Surgical (MMS) is not able to identify the particular lot number received by a particular consignee for the recalled prescription products. Each letter includes the date it was distributed to customers and the dates that impacted product may have been shipped to the customer.

Product Description:
Hydrocortisone Ointment USP, 2.5%, NET WT 28.35 g (1 oz) tube, Rx only, MFG: Sandoz Pharma, NDC 0168-0146-30

Product Quantity:
1 tube

Reason for Recall:
cGMP deviations: Temperature abuse

Recall Number:
D-1045-2022

Code Information:
McKesson Medical-Surgical (MMS) is not able to identify the particular lot number received by a particular consignee for the recalled prescription products. Each letter includes the date it was distributed to customers and the dates that impacted product may have been shipped to the customer.

Product Description:
HydrOXYzine Pamoate Capsules, USP, 50 mg, 100-count bottle, Rx only, MFG: Sandoz Pharma, NDC 0185-0615-01

Product Quantity:
30 bottles/100 capsules per bottle

Reason for Recall:
cGMP deviations: Temperature abuse

Recall Number:
D-1046-2022

Code Information:
McKesson Medical-Surgical (MMS) is not able to identify the particular lot number received by a particular consignee for the recalled prescription products. Each letter includes the date it was distributed to customers and the dates that impacted product may have been shipped to the customer.

Product Description:
Lidocaine and Prilocaine Cream, 2.5%/2.5%, 5 gram tubes, Rx only, MFG: Sandoz Pharma, NDC 0168-0357-56

Product Quantity:
23 tubes

Reason for Recall:
cGMP deviations: Temperature abuse

Recall Number:
D-1047-2022

Code Information:
McKesson Medical-Surgical (MMS) is not able to identify the particular lot number received by a particular consignee for the recalled prescription products. Each letter includes the date it was distributed to customers and the dates that impacted product may have been shipped to the customer.

Product Description:
Metronidazole Vaginal Gel USP, 0.75% with 5 applicators, Net Wt. 70 g tube, Rx only, MFG: Sandoz, NDC 0781-7077-87

Product Quantity:
7 tubes

Reason for Recall:
cGMP deviations: Temperature abuse

Recall Number:
D-1048-2022

Code Information:
McKesson Medical-Surgical (MMS) is not able to identify the particular lot number received by a particular consignee for the recalled prescription products. Each letter includes the date it was distributed to customers and the dates that impacted product may have been shipped to the customer.

Product Description:
Nitrostat (Nitroglycerin Sublingual Tablets, USP) 0.4 mg/tablet, 25-count bottle, Rx only, Distributed by: Pfizer Parke-Davis, Division of Pfizer Inc., NDC 0071-0418-13

Product Quantity:
1 carton/4 bottles per carton/25 tablets per bottle

Reason for Recall:
cGMP deviations: Temperature abuse

Recall Number:
D-1049-2022

Code Information:
McKesson Medical-Surgical (MMS) is not able to identify the particular lot number received by a particular consignee for the recalled prescription products. Each letter includes the date it was distributed to customers and the dates that impacted product may have been shipped to the customer.

Product Description:
Xylocaine - MPF (lidocaine HCl and epinephrine injection, USP), 1%, 300 mg/30 mL, single dose vial, 5-count box, Rx only, MFG: App Pharmaceuticals LLC, NDC 63323-0487-31

Product Quantity:
1 vial

Reason for Recall:
cGMP deviations: Temperature abuse

Recall Number:
D-1050-2022

Code Information:
McKesson Medical-Surgical (MMS) is not able to identify the particular lot number received by a particular consignee for the recalled prescription products. Each letter includes the date it was distributed to customers and the dates that impacted product may have been shipped to the customer.

Product Description:
Glucagon Emergency Kit for Low Blood Sugar, Glucagon for Injection, 1 mg per vial Diluent for Glucagon, 1ml syringe, Rx only, MFG: Eli Lilly, NDC 0002-8031-01

Product Quantity:
13 syringes

Reason for Recall:
cGMP deviations: Temperature abuse

Recall Number:
D-1051-2022

Code Information:
McKesson Medical-Surgical (MMS) is not able to identify the particular lot number received by a particular consignee for the recalled prescription products. Each letter includes the date it was distributed to customers and the dates that impacted product may have been shipped to the customer.

Product Description:
Xylocaine + Epinephrine, multi dose vial 1%, packaged in a) 20 mL, 25-count box (NDC 63323-482-27) b) 50 mL, 25-count box (NDC 63323-482-57), Rx only, MFG: Fresenius Kabi USA LLC

Product Quantity:
76 trays/25 vials per tray

Reason for Recall:
cGMP deviations: Temperature abuse

Recall Number:
D-1052-2022

Code Information:
McKesson Medical-Surgical (MMS) is not able to identify the particular lot number received by a particular consignee for the recalled prescription products. Each letter includes the date it was distributed to customers and the dates that impacted product may have been shipped to the customer.

Product Description:
Xylocaine + Epinephrine, multi dose vial 2%, 20 mL, 25 count box, Rx only, MFG: Fresenius Kabi USA LLC, NDC 63323-483-27

Product Quantity:
33 trays/25 vials per tray

Reason for Recall:
cGMP deviations: Temperature abuse

Recall Number:
D-1053-2022

Code Information:
McKesson Medical-Surgical (MMS) is not able to identify the particular lot number received by a particular consignee for the recalled prescription products. Each letter includes the date it was distributed to customers and the dates that impacted product may have been shipped to the customer.

Product Description:
Doxycycline Hyclate Tablets, USP, 100 mg, 50-count carton (10 tablets each blister pack x 5), Rx only, MFG: Major Pharma, NDC 0904-0430-06

Product Quantity:
108 cartons/50 blisters per carton

Reason for Recall:
cGMP deviations: Temperature abuse

Recall Number:
D-1054-2022

Code Information:
McKesson Medical-Surgical (MMS) is not able to identify the particular lot number received by a particular consignee for the recalled prescription products. Each letter includes the date it was distributed to customers and the dates that impacted product may have been shipped to the customer.

Product Description:
Ibuprofen Tablets USP, 400 mg, 100-count unit dose box, Rx only, MFG: Major Pharma, NDC 0904-5853-61

Product Quantity:
1 carton/100 blisters per carton

Reason for Recall:
cGMP deviations: Temperature abuse

Recall Number:
D-1055-2022

Code Information:
McKesson Medical-Surgical (MMS) is not able to identify the particular lot number received by a particular consignee for the recalled prescription products. Each letter includes the date it was distributed to customers and the dates that impacted product may have been shipped to the customer.

Product Description:
Metronidazole tablets, USP 250 mg, 100-count unit dose box, Rx only, MFG: Major Pharma, NDC 0904-1453-61

Product Quantity:
3 boxes/100 blisters per box

Reason for Recall:
cGMP deviations: Temperature abuse

Recall Number:
D-1056-2022

Code Information:
McKesson Medical-Surgical (MMS) is not able to identify the particular lot number received by a particular consignee for the recalled prescription

products. Each letter includes the date it was distributed to customers and the dates that impacted product may have been shipped to the customer.

Product Description:
Promethazine HCl Tablets, USP, 25 mg, 100-count unit dose box, Rx only, MFG: Major Pharma, NDC 0904-6461-61

Product Quantity:
16 cartons/100 blisters packs per carton

Reason for Recall:
cGMP deviations: Temperature abuse

Recall Number:
D-1057-2022

Code Information:
McKesson Medical-Surgical (MMS) is not able to identify the particular lot number received by a particular consignee for the recalled prescription products. Each letter includes the date it was distributed to customers and the dates that impacted product may have been shipped to the customer.

Product Description:
Sodium Bicarbonate Tablets, 600 mg, 1000-count bottle, MFG: Major Pharma, NDC 0536-1047-10

Product Quantity:
1 bottle/1000 tablets per bottle

Reason for Recall:
cGMP deviations: Temperature abuse

Recall Number:
D-1058-2022

Code Information:
McKesson Medical-Surgical (MMS) is not able to identify the particular lot number received by a particular consignee for the recalled prescription products. Each letter includes the date it was distributed to customers and the dates that impacted product may have been shipped to the customer.

Product Description:
Sulfamethoxazole and Trimethoprim Tablets, USP, 800mg/160mg, 100-count unit dose box, Rx only, MFG: Major Pharma, NDC 0904-2725-61

Product Quantity:
32 cartons/100 blister packs per carton

Reason for Recall:
cGMP deviations: Temperature abuse

Recall Number:
D-1059-2022

Code Information:
McKesson Medical-Surgical (MMS) is not able to identify the particular lot number received by a particular consignee for the recalled prescription products. Each letter includes the date it was distributed to customers and the dates that impacted product may have been shipped to the customer.

Product Description:
Medroxyprogesterone acetate injectable suspension, 150 mg/mL, 1 mL single dose vial, Rx only, MFG: NorthStarRx/Teva Pharma USA , NDC 16714-981-01

Product Quantity:
780 vials

Reason for Recall:
cGMP deviations: Temperature abuse

Recall Number:
D-1060-2022

Code Information:
McKesson Medical-Surgical (MMS) is not able to identify the particular lot number received by a particular consignee for the recalled prescription products. Each letter includes the date it was distributed to customers and the dates that impacted product may have been shipped to the customer.

Product Description:
MethyLPREDNISolone Acetate Injectable Suspension USP, 40 mg/mL, packaged in a) single dose vial (NDC 6714-088-01) b) 25-count box (NDC16714-088-25), Rx only, MFG: NorthstarRx/Teva Pharma USA

Product Quantity:
885 vials

Reason for Recall:
cGMP deviations: Temperature abuse

Recall Number:
D-1061-2022

Code Information:
McKesson Medical-Surgical (MMS) is not able to identify the particular lot number received by a particular consignee for the recalled prescription products. Each letter includes the date it was distributed to customers and the dates that impacted product may have been shipped to the customer.

Product Description:
MethyLPREDNISolone Acetate Injectable Suspension, USP, 200 mg/5 mL (40 mg/mL), 5 mL Multiple Dose Vial, Rx only, MFG: NorthstarRx/Teva Pharma USA , NDC 16714-089-01

Product Quantity:
263 vials

Reason for Recall:
cGMP deviations: Temperature abuse

Recall Number:
D-1062-2022

Code Information:
McKesson Medical-Surgical (MMS) is not able to identify the particular lot number received by a particular consignee for the recalled prescription products. Each letter includes the date it was distributed to customers and the dates that impacted product may have been shipped to the customer.

Product Description:
MethyLPREDNISolone Acetate Injectable Suspension, USP, 400 mg/10 mL (40 mg/mL), 10 mL Multiple Dose Vial, Rx only, MFG: NorthstarRx/Teva Pharma USA, NDC 16714-090-01

Product Quantity:
363 vials

Reason for Recall:
cGMP deviations: Temperature abuse

Recall Number:
D-1063-2022

Code Information:
McKesson Medical-Surgical (MMS) is not able to identify the particular lot number received by a particular consignee for the recalled prescription products. Each letter includes the date it was distributed to customers and the dates that impacted product may have been shipped to the customer.

Product Description:
MethyLPREDNISolone Acetate Injectable Suspension USP, 400 mg/5 mL (80 mg/mL), 5 mL Multiple Dose Vial, Rx only, MFG: NorthstarRx/Teva Pharma USA, NDC 16714-473-01

Product Quantity:

Reason for Recall:
cGMP deviations: Temperature abuse

Recall Number:
D-1064-2022

Code Information:
McKesson Medical-Surgical (MMS) is not able to identify the particular lot number received by a particular consignee for the recalled prescription products. Each letter includes the date it was distributed to customers and the dates that impacted product may have been shipped to the customer.

Product Description:
Ketoconazole Cream, 2%, Net Wt 60 grams tube, Rx only, MFG: Nycomed Inc, NDC 0168-0099-60

Product Quantity:
6 tubes

Reason for Recall:
cGMP deviations: Temperature abuse

Recall Number:
D-1065-2022

Code Information:
McKesson Medical-Surgical (MMS) is not able to identify the particular lot number received by a particular consignee for the recalled prescription products. Each letter includes the date it was distributed to customers and the dates that impacted product may have been shipped to the customer.

Product Description:
Clonidine Hydrochloride Tablets, USP, 0.1 mg, 100-count bottle, Rx only, MFG: Teva/Actavis, NDC 00228-2127-10

Product Quantity:
63 bottles/100 count

Reason for Recall:
cGMP deviations: Temperature abuse

Recall Number:
D-1066-2022

Code Information:
McKesson Medical-Surgical (MMS) is not able to identify the particular lot number received by a particular consignee for the recalled prescription products. Each letter includes the date it was distributed to customers and the dates that impacted product may have been shipped to the customer.

Product Description:
Levalbuterol Tartrate HFA Inhalation Aerosol, 45 mcg/actuation, 200 metered inhalations, Rx only, MFG: Teva Pharma USA, NDC 0591-2927-54

Product Quantity:
2 inhalers

Reason for Recall:
cGMP deviations: Temperature abuse

Recall Number:
D-1067-2022

Code Information:
McKesson Medical-Surgical (MMS) is not able to identify the particular lot number received by a particular consignee for the recalled prescription products. Each letter includes the date it was distributed to customers and the dates that impacted product may have been shipped to the customer.

Product Description:
Lidocaine Patch 5%, 30-count box, Rx only, MFG: Teva Pharma USA, NDC 0591-3525-30

Product Quantity:
1 carton/30 pouches

Reason for Recall:
cGMP deviations: Temperature abuse

Recall Number:
D-1068-2022

Code Information:
McKesson Medical-Surgical (MMS) is not able to identify the particular lot number received by a particular consignee for the recalled prescription products. Each letter includes the date it was distributed to customers and the dates that impacted product may have been shipped to the customer.

Product Description:
Medroxyprogesterone acetate injectable suspension, USP, 150 mg/mL, 1 mL vials, packaged in a) single dose vial (NDC 0703-6801-01), b) 25-count box single dose vials (NDC 0703-6801-04), Rx only, MFG: Teva Pharma USA

Product Quantity:
89 cartons/25 vials per carton and 3 cartons/1 vial

Reason for Recall:
cGMP deviations: Temperature abuse

Recall Number:
D-1069-2022

Code Information:
McKesson Medical-Surgical (MMS) is not able to identify the particular lot number received by a particular consignee for the recalled prescription products. Each letter includes the date it was distributed to customers and the dates that impacted product may have been shipped to the customer.

Product Description:
MethyLPREDNISolone Acetate Injectable Suspension, USP, 40 mg/mL, packaged in a) 1 mL single dose vial (NDC 0703-0031-01), b) 25-count box (NDC 0703-0031-04), Rx only, MFG: Teva Pharma USA

Product Quantity:
983 cartons/1 vial each and 107 cartons/25 vials each

Reason for Recall:
cGMP deviations: Temperature abuse

Recall Number:
D-1070-2022

Code Information:
McKesson Medical-Surgical (MMS) is not able to identify the particular lot number received by a particular consignee for the recalled prescription products. Each letter includes the date it was distributed to customers and the dates that impacted product may have been shipped to the customer.

Product Description:
MethyLPREDNISolone Acetate Injectable Suspension, USP, 200mg/5mL (40 mg/mL), 5 mL multi-dose vial, Rx only, MFG: Teva Pharma USA, NDC 0703-0043-01

Product Quantity:
65 cartons/1 vial each

Reason for Recall:
cGMP deviations: Temperature abuse

Recall Number:
D-1071-2022

Code Information:
McKesson Medical-Surgical (MMS) is not able to identify the particular lot number received by a particular consignee for the recalled prescription products. Each letter includes the date it was distributed to customers and the dates that impacted product may have been shipped to the customer.

Product Description:
MethyLPREDNISolone Acetate Injectable Suspension USP, 400 mg/10 mL (40 mg/mL), 10 mL multi-dose vial, Rx only, MFG: Teva Pharma USA, NDC 0703-0045-01

Product Quantity:
796 cartons/1 vial each

Reason for Recall:
cGMP deviations: Temperature abuse

Recall Number:
D-1072-2022

Code Information:
McKesson Medical-Surgical (MMS) is not able to identify the particular lot number received by a particular consignee for the recalled prescription products. Each letter includes the date it was distributed to customers and the dates that impacted product may have been shipped to the customer.

Product Description:
MethyLPREDNISolone Acetate Injectable Suspension USP, 80 mg/mL, packaged in a) 1 mL single dose vial (NDC 0703-0051-01) b) 25-count box (NDC 0703-0051-04), Rx only, MFG: Teva Pharma USA

Product Quantity:
1088 cartons/1 vial each and 63 cartons/25 vials each

Reason for Recall:
cGMP deviations: Temperature abuse

Recall Number:
D-1073-2022

Code Information:
McKesson Medical-Surgical (MMS) is not able to identify the particular lot number received by a particular consignee for the recalled prescription products. Each letter includes the date it was distributed to customers and the dates that impacted product may have been shipped to the customer.

Product Description:
MethyLPREDNISolone Acetate Injectable Suspension USP, 400 mg/5mL (80 mg/mL), 5 mL multi-dose vials, Rx only, MFG: Teva Pharma USA,

NDC 0703-0063-01

Product Quantity:
816 cartons/1 vial each

Reason for Recall:
cGMP deviations: Temperature abuse

Recall Number:
D-1074-2022

Code Information:
McKesson Medical-Surgical (MMS) is not able to identify the particular lot number received by a particular consignee for the recalled prescription products. Each letter includes the date it was distributed to customers and the dates that impacted product may have been shipped to the customer.

Product Description:
Mupirocin Ointment, USP 2%, 22 grams tube, Rx only, MFG: Teva Pharma USA, NDC 0093-1010-42, MFG: Teva Pharma USA

Product Quantity:
5 tubes

Reason for Recall:
cGMP deviations: Temperature abuse

Recall Number:
D-1075-2022

Code Information:
McKesson Medical-Surgical (MMS) is not able to identify the particular lot number received by a particular consignee for the recalled prescription products. Each letter includes the date it was distributed to customers and the dates that impacted product may have been shipped to the customer.

Product Description:
Proair, HFA (albuterol sulfate) Inhalation Aerosol 90 mcg per actuation, 200 metered inhalations, Rx only, MFG: Teva Pharma USA, NDC 59310-579-22

Product Quantity:
56 inhalers

Reason for Recall:
cGMP deviations: Temperature abuse

Recall Number:
D-1076-2022

Code Information:
McKesson Medical-Surgical (MMS) is not able to identify the particular lot number received by a particular consignee for the recalled prescription products. Each letter includes the date it was distributed to customers and the dates that impacted product may have been shipped to the customer.

Product Description:
Propofol Injectable Emulsion, USP, 200 mg/ 20 mL (10 mg/mL), packaged in a) 50 mL vial, in packs of 20 (NDC 00591-2136-51), b) 100 mL vial, in packs of 10 (NDC 00591-2136-68), Rx only, MFG: Teva Pharma USA

Product Quantity:
31 cartons/10 & 25 vials each

Reason for Recall:
cGMP deviations: Temperature abuse

Recall Number:
D-1077-2022

Code Information:
McKesson Medical-Surgical (MMS) is not able to identify the particular lot number received by a particular consignee for the recalled prescription products. Each letter includes the date it was distributed to customers and the dates that impacted product may have been shipped to the customer.

Product Description:
Propofol Injectable Emulsion, USP 200 mg per 20 mL (10 mg per mL), twenty-five 20 mL vials, Rx only, MFG: Teva Pharma USA, NDC 0591-2136-95

Product Quantity:
564 cartons/25 vials each

Reason for Recall:
cGMP deviations: Temperature abuse

Recall Number:
D-1078-2022

Code Information:
McKesson Medical-Surgical (MMS) is not able to identify the particular lot number received by a particular consignee for the recalled prescription products. Each letter includes the date it was distributed to customers and the dates that impacted product may have been shipped to the customer.

Product Description:
Vecuronium Bromide for Injection, 10 mg (1mg/ mL) vial, 10-count box, Rx only, MFG: Teva Pharma USA, NDC 0703-2914-03

Product Quantity:
20 cartons/10 vials each

Reason for Recall:
cGMP deviations: Temperature abuse

Recall Number:
D-1079-2022

Code Information:
McKesson Medical-Surgical (MMS) is not able to identify the particular lot number received by a particular consignee for the recalled prescription products. Each letter includes the date it was distributed to customers and the dates that impacted product may have been shipped to the customer.

Product Description:
Revonto (dantrolene sodium for injection), 20 mg/vial, 6-count box, Rx only, MFG: US WorldMeds, Inc., NDC 27505-003-67

Product Quantity:
16 cartons/6 vials each

Reason for Recall:
cGMP deviations: Temperature abuse

Recall Number:
D-1080-2022

Code Information:
McKesson Medical-Surgical (MMS) is not able to identify the particular lot number received by a particular consignee for the recalled prescription products. Each letter includes the date it was distributed to customers and the dates that impacted product may have been shipped to the customer.

Product Description:
Revonto (dantrolene sodium for injection), 20 mg/vial, 6-count box, Rx only, MFG: US WorldMeds, Inc., NDC 78670-003-67

Product Quantity:
49 cartons/6 vials each

Reason for Recall:
cGMP deviations: Temperature abuse

Recall Number:
D-1081-2022

Code Information:
McKesson Medical-Surgical (MMS) is not able to identify the particular lot number received by a particular consignee for the recalled prescription products. Each letter includes the date it was distributed to customers and the dates that impacted product may have been shipped to the customer.

Product Description:
Recothrom Thrombin Topical (Recombinant), 5,000 units, packaged in a box containing a 5000-unit vial of RECOTHROM with a 5-mL prefilled diluent syringe (containing sterile 0.9% sodium chloride, USP), a sterile needle-free transfer device, a 5-mL sterile empty syringe, and a pre-printed label, Rx only, MFG: Baxter, NDC# 0338-0322-01

Product Quantity:
110 cartons/5000 units each

Reason for Recall:
cGMP deviations: Temperature abuse

Recall Number:
D-1082-2022

Code Information:
McKesson Medical-Surgical (MMS) is not able to identify the particular lot number received by a particular consignee for the recalled prescription products. Each letter includes the date it was distributed to customers and the dates that impacted product may have been shipped to the customer.

Product Description:
Transderm Scop (scopolamine) Transdermanl System, 1 mg/ 3 days, 10 (patches) transdermal Systems Multipack, Rx only, MFG: Baxter Healthcare Corp, NDC 10019-553-03

Product Quantity:
56 cartons/10 patches each

Reason for Recall:
cGMP deviations: Temperature abuse

Recall Number:
D-1083-2022

Code Information:
McKesson Medical-Surgical (MMS) is not able to identify the particular lot number received by a particular consignee for the recalled prescription products. Each letter includes the date it was distributed to customers and the dates that impacted product may have been shipped to the customer.

Product Description:
E-Z-HD (Barium Sulfate for Oral Suspension), 98% w/w, 340 g bottle, Rx only, MFG: Bracco Diagnostics Inc., NDC 32909-764-01

Product Quantity:
19 cases

Reason for Recall:
cGMP deviations: Temperature abuse

Recall Number:
D-1084-2022

Code Information:
McKesson Medical-Surgical (MMS) is not able to identify the particular lot number received by a particular consignee for the recalled prescription products. Each letter includes the date it was distributed to customers and the dates that impacted product may have been shipped to the customer.

Product Description:
E-Z-Gas II, Effervescent Granules, Net Weight: 4 g, 50 packets per box, MFG: Bracco Diagnostics Inc., NDC 0270-9020-01 (discontinued), NDC 10361-793-01 (current)

Product Quantity:
16 boxes/50 pouches per box

Reason for Recall:
cGMP deviations: Temperature abuse

Recall Number:
D-1085-2022

Code Information:
McKesson Medical-Surgical (MMS) is not able to identify the particular lot number received by a particular consignee for the recalled prescription products. Each letter includes the date it was distributed to customers and the dates that impacted product may have been shipped to the customer.

Product Description:
Gastrografin (Diatrizoate Meglumine and Diatrizoate Sodium Solution USP), packaged in: Twenty-four 30 mL single dose bottles, Rx only, MFG: Bracco Diagnostics Inc., NDC 0270-0445-35

Product Quantity:
1 case

Reason for Recall:
cGMP deviations: Temperature abuse

Recall Number:
D-1086-2022

Code Information:
McKesson Medical-Surgical (MMS) is not able to identify the particular lot number received by a particular consignee for the recalled prescription products. Each letter includes the date it was distributed to customers and the dates that impacted product may have been shipped to the customer.

Product Description:
Kinevac (Sincalide for Injection), 5mcg per vial, 10 vials per box, Rx only, MFG: Bracco Diagnostics Inc., NDC 0270-0556-15

Product Quantity:
5 boxes

Reason for Recall:
cGMP deviations: Temperature abuse

Recall Number:
D-1087-2022

Code Information:
McKesson Medical-Surgical (MMS) is not able to identify the particular lot number received by a particular consignee for the recalled prescription products. Each letter includes the date it was distributed to customers and the dates that impacted product may have been shipped to the customer.

Product Description:
Levofloxacin Tablets, 500 mg, 100-count unit dose box, Rx only, MFG: Major Pharma, NDC 0904-6352-61

Product Quantity:
1 box/100 blisters packs per box

Reason for Recall:
cGMP deviations: Temperature abuse

Recall Number:
D-1088-2022

Code Information:
McKesson Medical-Surgical (MMS) is not able to identify the particular lot number received by a particular consignee for the recalled prescription products. Each letter includes the date it was distributed to customers and the dates that impacted product may have been shipped to the customer.

Product Description:
Celestone Soluspan (betamethasone sodium phosphate and betametasone acetate injectable suspension 6 mg/mL, 30 mg/5mL, multidose vial, Rx only, MFG: Merck Company, NDC 0085-4320-01

Product Quantity:
51 vials

Reason for Recall:
cGMP deviations: Temperature abuse

Recall Number:
D-1089-2022

Code Information:
McKesson Medical-Surgical (MMS) is not able to identify the particular lot number received by a particular consignee for the recalled prescription products. Each letter includes the date it was distributed to customers and the dates that impacted product may have been shipped to the customer.

Product Description:
Proventil HFA, (Albuterol Sulfate Inhalation Aerosol), 200 metered inhalations, Rx only, MFG: Merck Company, NDC 0085-1132-04

Product Quantity:
22 inhalers

Reason for Recall:
cGMP deviations: Temperature abuse

Recall Number:
D-1090-2022

Code Information:
McKesson Medical-Surgical (MMS) is not able to identify the particular lot number received by a particular consignee for the recalled prescription products. Each letter includes the date it was distributed to customers and the dates that impacted product may have been shipped to the customer.

Product Description:
Duraclon (clonidine HCl injection, USP), 1000 mcg/10 mL (100 mcg/mL), 10 mL single-dose vial, Rx only, MFG: Mylan Pharma, NDC 67457-218-10

Product Quantity:
9 vials

Reason for Recall:
cGMP deviations: Temperature abuse

Recall Number:
D-1091-2022

Code Information:
McKesson Medical-Surgical (MMS) is not able to identify the particular lot number received by a particular consignee for the recalled prescription products. Each letter includes the date it was distributed to customers and the dates that impacted product may have been shipped to the customer.

Product Description:
Loperamide Hydrochloride capsules, USP, 2 mg, 100-count bottle, Rx only, MFG: Mylan Pharma, NDC 0378-2100-01

Product Quantity:
1 bottle/100 capsules

Reason for Recall:
cGMP deviations: Temperature abuse

Recall Number:
D-1092-2022

Code Information:
McKesson Medical-Surgical (MMS) is not able to identify the particular lot number received by a particular consignee for the recalled prescription products. Each letter includes the date it was distributed to customers and the dates that impacted product may have been shipped to the customer.

Product Description:
Prazosin Hydrochloride Capsules, USP, 1 mg, 100-count bottle, Rx only, MFG: Mylan Pharma, NDC 0378-1101-01

Product Quantity:
8 bottles/100 tablets each

Reason for Recall:
cGMP deviations: Temperature abuse

Recall Number:
D-1093-2022

Code Information:
McKesson Medical-Surgical (MMS) is not able to identify the particular lot number received by a particular consignee for the recalled prescription products. Each letter includes the date it was distributed to customers and the dates that impacted product may have been shipped to the customer.

Product Description:
Labetalol Hydrochloride Tablets, USP, 100 mg, 100-count bottle, Rx only, MFG: Par Pharma, NDC 49884-122-01

Product Quantity:
1 bottle/100 tablets

Reason for Recall:
cGMP deviations: Temperature abuse

Recall Number:
D-1094-2022

Code Information:
McKesson Medical-Surgical (MMS) is not able to identify the particular lot number received by a particular consignee for the recalled prescription products. Each letter includes the date it was distributed to customers and the dates that impacted product may have been shipped to the customer.

Product Description:
Bupivacaine Hydrochloride, USP 0.5% (5mg/mL), 25 vials x 50 mL per box, Rx only, MFG: Pfizer, NDC 0409-1163-01

Product Quantity:
30 vials

Reason for Recall:
cGMP deviations: Temperature abuse

Recall Number:
D-1095-2022

Code Information:
McKesson Medical-Surgical (MMS) is not able to identify the particular lot number received by a particular consignee for the recalled prescription

products. Each letter includes the date it was distributed to customers and the dates that impacted product may have been shipped to the customer.

Product Description:
Depo-Medrol (methylprednisolone acetate injectable suspension, USP) 40 mg/mL, 1 mL single-dose vial, Rx only, MFG: Pfizer, NDC 0009-3073-03

Product Quantity:
2 cartons

Reason for Recall:
cGMP deviations: Temperature abuse

Recall Number:
D-1096-2022

Code Information:
McKesson Medical-Surgical (MMS) is not able to identify the particular lot number received by a particular consignee for the recalled prescription products. Each letter includes the date it was distributed to customers and the dates that impacted product may have been shipped to the customer.

Product Description:
Depo-Medrol (methylprednisolone acetate injectable suspension, USP) 80mg/mL, packaged in a) 1 mL single-dose vial (NDC# 0009-3475-01), b) 25-count box (NDC 0009-3475-03), Rx only, MFG: Pfizer

Product Quantity:
177 cartons

Reason for Recall:
cGMP deviations: Temperature abuse

Recall Number:
D-1097-2022

Code Information:
McKesson Medical-Surgical (MMS) is not able to identify the particular lot number received by a particular consignee for the recalled prescription products. Each letter includes the date it was distributed to customers and the dates that impacted product may have been shipped to the customer.

Product Description:
Epinephrine, ABJT 0.1 mg/mL, 10 mL, 20GX1.5 (10 pack), Rx only, MFG: Pfizer, NDC 04094-933-01

Product Quantity:
172 packs/10 per pack

Reason for Recall:
cGMP deviations: Temperature abuse

Recall Number:
D-1098-2022

Code Information:
McKesson Medical-Surgical (MMS) is not able to identify the particular lot number received by a particular consignee for the recalled prescription products. Each letter includes the date it was distributed to customers and the dates that impacted product may have been shipped to the customer.

Product Description:
Thrombin JMI, Vial 5,000IU 2/diluent, kit, Rx only, MFG: Pfizer NDC 60793-215-05

Product Quantity:
157 kits

Reason for Recall:
cGMP deviations: Temperature abuse

Recall Number:
D-1099-2022

Code Information:
McKesson Medical-Surgical (MMS) is not able to identify the particular lot number received by a particular consignee for the recalled prescription products. Each letter includes the date it was distributed to customers and the dates that impacted product may have been shipped to the customer.

Product Description:
Verapamil HCL, ampule, 2.5 mg/ML 2ML (5/pack), Rx only, MFG: Pfizer, NDC 04094-011-01

Product Quantity:
14 packs/ 5 per pack

Reason for Recall:
cGMP deviations: Temperature abuse

Recall Number:
D-1100-2022

Code Information:
McKesson Medical-Surgical (MMS) is not able to identify the particular lot number received by a particular consignee for the recalled prescription products. Each letter includes the date it was distributed to customers and the dates that impacted product may have been shipped to the customer.

Product Description:
Diphenhydramine HCl oral solution, USP, 25 mg/10 mL UD, packaged in a) 10 mL unit dose cups (NDC 0121-0978-10), b) 100-count box (NDC 0121-0978-00), Rx only, MFG: Pharmaceutical Associates Inc.

Product Quantity:
1 case/100 unit dose cups

Reason for Recall:
cGMP deviations: Temperature abuse

Recall Number:
D-1101-2022

Code Information:
McKesson Medical-Surgical (MMS) is not able to identify the particular lot number received by a particular consignee for the recalled prescription products. Each letter includes the date it was distributed to customers and the dates that impacted product may have been shipped to the customer.

Product Description:
Neomycin and Polymyxin B Sulfates and Dexamethasone Ophthalmic Ointment, 3.5 g tube, Rx only MFG: Sandoz, NDC 61314-631-36

Product Quantity:
120 tubes

Reason for Recall:
cGMP deviations: Temperature abuse

Recall Number:
D-1102-2022

Code Information:
McKesson Medical-Surgical (MMS) is not able to identify the particular lot number received by a particular consignee for the recalled prescription products. Each letter includes the date it was distributed to customers and the dates that impacted product may have been shipped to the customer.

Product Description:
Ondansetron HCL, Tab 8 mg filmcoated, 30-count bottle, Rx only, MFG: Sandoz Pharma, NDC 65862-188-30

Product Quantity:
2 bottles/500 tablets each

Reason for Recall:
cGMP deviations: Temperature abuse

Recall Number:
D-1103-2022

Code Information:
McKesson Medical-Surgical (MMS) is not able to identify the particular lot number received by a particular consignee for the recalled prescription products. Each letter includes the date it was distributed to customers and the dates that impacted product may have been shipped to the customer.

Product Description:
Pantoprazole Sodium for Injection, 40 mg/vial, 10 single-dose vials, Rx only, MFG: Sandoz Pharma, NDC 0781-3232-95

Product Quantity:
1 carton/10 vials

Reason for Recall:
cGMP deviations: Temperature abuse

Recall Number:
D-1104-2022

Code Information:
McKesson Medical-Surgical (MMS) is not able to identify the particular lot number received by a particular consignee for the recalled prescription products. Each letter includes the date it was distributed to customers and the dates that impacted product may have been shipped to the customer.

Product Description:
Prednisolone Acetate Ophthalmic Suspension, USP 1%, 5 mL bottle, Rx only, MFG: Sandoz Pharma, NDC 61314-637-05

Product Quantity:
50 bottles

Reason for Recall:
cGMP deviations: Temperature abuse

Recall Number:
D-1105-2022

Code Information:
McKesson Medical-Surgical (MMS) is not able to identify the particular lot number received by a particular consignee for the recalled prescription products. Each letter includes the date it was distributed to customers and the dates that impacted product may have been shipped to the customer.

Product Description:
Triamcinolone Acetonide cream, USP, 0.1% ,15 grams tube, Rx only, MFG: Sandoz Pharma, NDC 0168-0004-15

Product Quantity:
30 tubes

Reason for Recall:
cGMP deviations: Temperature abuse

Recall Number:
D-1106-2022

Code Information:
McKesson Medical-Surgical (MMS) is not able to identify the particular lot number received by a particular consignee for the recalled prescription products. Each letter includes the date it was distributed to customers and the dates that impacted product may have been shipped to the customer.

Product Description:
Polymyxin B Sulfate and Trimethoprim Ophthalmic Solution, USP, sterile, 0.1%, 10 mL bottle, Rx only, MFG: Sandoz Pharma, NDC 6131462810

Product Quantity:
44 bottles

Reason for Recall:
cGMP deviations: Temperature abuse

Recall Number:
D-1107-2022

Code Information:
McKesson Medical-Surgical (MMS) is not able to identify the particular lot number received by a particular consignee for the recalled prescription products. Each letter includes the date it was distributed to customers and the dates that impacted product may have been shipped to the customer.

Product Description:
Tropicamide Ophthalmic Solution, USP 1%, 3 mL bottle, Rx only, MFG: Sandoz Pharma, NDC 6131435502

Product Quantity:
31 bottles

Reason for Recall:
cGMP deviations: Temperature abuse

Recall Number:
D-1108-2022

Code Information:
McKesson Medical-Surgical (MMS) is not able to identify the particular lot number received by a particular consignee for the recalled prescription products. Each letter includes the date it was distributed to customers and the dates that impacted product may have been shipped to the customer.

Product Description:
Pilocarpine HCL Ophthalmic Solution, USP 2%, 15 mL, Rx only, MFG: Somerset Therapeutics, Inc., NDC 7006919101

Product Quantity:
1 carton

Reason for Recall:
cGMP deviations: Temperature abuse

Recall Number:
D-1109-2022

Code Information:
McKesson Medical-Surgical (MMS) is not able to identify the particular lot number received by a particular consignee for the recalled prescription products. Each letter includes the date it was distributed to customers and the dates that impacted product may have been shipped to the customer.

Product Description:
Metoprolol tablets 50 mg, 100-count botte, Rx only, MFG: Sun Pharmaceuticals, NDC 57664-0477-52

Product Quantity:
1 box

Reason for Recall:
cGMP deviations: Temperature abuse

Recall Number:
D-1110-2022

Code Information:
McKesson Medical-Surgical (MMS) is not able to identify the particular lot number received by a particular consignee for the recalled prescription products. Each letter includes the date it was distributed to customers and the dates that impacted product may have been shipped to the customer.

Product Description:
Sumatriptan Succinate Tablets, 100 mg, 9 (1 x 9) Unit-of- use tablets box, Rx only, MFG: Sun Pharmaceuticals, NDC 62756-522-69

Product Quantity:
1 carton/9 blister packs

Reason for Recall:
cGMP deviations: Temperature abuse

Recall Number:
D-1111-2022

Code Information:
McKesson Medical-Surgical (MMS) is not able to identify the particular lot number received by a particular consignee for the recalled prescription products. Each letter includes the date it was distributed to customers and the dates that impacted product may have been shipped to the customer.

Product Description:
Geodon for injection (ziprasidone mesylate), 20 mg/mL, 1 mL single dose vial, Rx only, MFG: Viatris, NDC 0049-3920-83

Product Quantity:
1 carton/10 vials

Reason for Recall:
cGMP deviations: Temperature abuse

Recall Number:
D-1112-2022

Code Information:
McKesson Medical-Surgical (MMS) is not able to identify the particular lot number received by a particular consignee for the recalled prescription products. Each letter includes the date it was distributed to customers and the dates that impacted product may have been shipped to the customer.

Product Description:
Tetracaine Hydrochloride Ophthalmic Solution, 0.5%, 4 mL bottle, Rx only, MFG: Alcon Surgical Inc., NDC 0065-0741-14

Product Quantity:
43 cartons/12 blister packs

Reason for Recall:
cGMP deviations: Temperature abuse

Recall Number:
D-1113-2022

Code Information:
McKesson Medical-Surgical (MMS) is not able to identify the particular lot number received by a particular consignee for the recalled prescription products. Each letter includes the date it was distributed to customers and the dates that impacted product may have been shipped to the customer.

Product Description:
Ofloxacin Otic Solution 0.3%, 5 mL bottle, Rx only, MFG: Amneal/Akyma Pharmaceuticals, NDC 69238-1615-3

Product Quantity:
1 carton

Reason for Recall:
cGMP deviations: Temperature abuse

Recall Number:
D-1114-2022

Code Information:
McKesson Medical-Surgical (MMS) is not able to identify the particular lot number received by a particular consignee for the recalled prescription products. Each letter includes the date it was distributed to customers and the dates that impacted product may have been shipped to the customer.

Product Description:
Diprivan (Propofol) Emulsion, 100 mg/mL, 10mL vial, Rx only, MFG: App Pharmaceutical LLC, NDC 63323-269-10

Product Quantity:
122 cartons

Reason for Recall:
cGMP deviations: Temperature abuse

Recall Number:
D-1115-2022

Code Information:
McKesson Medical-Surgical (MMS) is not able to identify the particular lot number received by a particular consignee for the recalled prescription products. Each letter includes the date it was distributed to customers and the dates that impacted product may have been shipped to the customer.

Product Description:
Diprivan (Propofol) Emulsion, 200 mg per 20 mL (10mg/mL), 20 mL vial, Rx only, MFG: App Pharmaceutical LLC, NDC 63323-269-29

Product Quantity:
46 cartons

Reason for Recall:
cGMP deviations: Temperature abuse

Recall Number:
D-1116-2022

Code Information:
McKesson Medical-Surgical (MMS) is not able to identify the particular lot number received by a particular consignee for the recalled prescription products. Each letter includes the date it was distributed to customers and the dates that impacted product may have been shipped to the customer.

Product Description:
Cefazolin for injection USP, and Dextrose Injection, USP, 1G, 50 ML duplex container, Rx only, MFG: B. Braun Medical Inc., NDC 0264-3103-11

Product Quantity:
26 cases

Reason for Recall:
cGMP deviations: Temperature abuse

Recall Number:
D-1117-2022

Code Information:
McKesson Medical-Surgical (MMS) is not able to identify the particular lot number received by a particular consignee for the recalled prescription products. Each letter includes the date it was distributed to customers and the dates that impacted product may have been shipped to the customer.

Product Description:
Cefazolin for injection USP, and Dextrose Injection, USP, 2 g, 50 mL duplex container, Rx only, MFG: B. Braun Medical Inc., NDC 0264-3105-11

Product Quantity:
39 cases

Reason for Recall:
cGMP deviations: Temperature abuse

Recall Number:
D-1118-2022

Code Information:
McKesson Medical-Surgical (MMS) is not able to identify the particular lot number received by a particular consignee for the recalled prescription products. Each letter includes the date it was distributed to customers and the dates that impacted product may have been shipped to the customer.

Product Description:
Intralipid (I.V. Fat emulsion), 20%, 250 mL bag, Rx only, MFG: Baxter Healthcare, NDC 0338-0519-09

Product Quantity:
5 cases

Reason for Recall:
cGMP deviations: Temperature abuse

Recall Number:
D-1119-2022

Code Information:
McKesson Medical-Surgical (MMS) is not able to identify the particular lot number received by a particular consignee for the recalled prescription products. Each letter includes the date it was distributed to customers and the dates that impacted product may have been shipped to the customer.

Product Description:
Intralipid (I.V. Fat emulsion), 20%, 100 mL bag, Rx only, MFG: Baxter Healthcare, NDC 0338-0519-58

Product Quantity:
2 cases

Reason for Recall:
cGMP deviations: Temperature abuse

Recall Number:
D-1120-2022

Code Information:
McKesson Medical-Surgical (MMS) is not able to identify the particular lot number received by a particular consignee for the recalled prescription products. Each letter includes the date it was distributed to customers and the dates that impacted product may have been shipped to the customer.

Product Description:
Biopsy and Aspiration Tray Bone Marrow Illinois 11GX4 (10/cs) Rx CRFPED Lidocaine Hydrochloride USP, 1%, 5mL, Rx only, MFG: Becton Dickinson

Product Quantity:
4 cases

Reason for Recall:
cGMP deviations: Temperature abuse

Recall Number:
D-1121-2022

Code Information:
McKesson Medical-Surgical (MMS) is not able to identify the particular lot number received by a particular consignee for the recalled prescription products. Each letter includes the date it was distributed to customers and the dates that impacted product may have been shipped to the customer.

Product Description:
Paracentesis/Thoracentises Tray (10/cs) Rx CRFPED, Lidocaine Hydrochloride USP, 1%, 5mL, Rx only, MFG: Becton Dickinson

Product Quantity:
5 cases

Reason for Recall:
cGMP deviations: Temperature abuse

Recall Number:
D-1122-2022

Code Information:
McKesson Medical-Surgical (MMS) is not able to identify the particular lot number received by a particular consignee for the recalled prescription products. Each letter includes the date it was distributed to customers and the dates that impacted product may have been shipped to the customer.

Class II Drugs Event

Event ID:
90257

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
05/24/2022

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
06/06/2022

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
US Specialty Formulations LLC
1401 S Albert St
Allentown PA United States

Distribution Pattern:
Product was distributed to medical facilities and a physician's office Nationwide in the USA.

Associated Products

Product Description:
Ethanol for Injection 95%, 67 mL Multi-Dose vial, Rx only, US Specialty Formulations, 1403 South Albert Street, Allentown, PA 18103, PN: 69389-06229

Product Quantity:
781 vials

Reason for Recall:
Lack of Assurance of Sterility

Recall Number:
D-0986-2022

Code Information:
Lot #: 02RP1503A, exp. date 30-Sep-22; 02RP1506A, exp. date 31-Dec-22; 02RP1516A, exp. date 30-Jun-23

Product Description:
B-Complex + Chromic Chloride (Choline Chloride 3%, Inositol 3%, Pyridoxine HCl 2%, Niacinamide 2%, Thiamine HCl 2%, Chlorobutanol 0.5%, Riboflavin 0.05%, Chromic Chloride 0.003%), 30 mL Multi-Dose Vial, packaged in 2 x 30 mL Multi-Dose Vials per carton, US Specialty Formulations, LLC, 116 Research Drive, Bethlehem, PA 18015, P/N: 234-15523

Product Quantity:
1992 vials

Reason for Recall:
Lack of Assurance of Sterility

Recall Number:
D-0987-2022

Code Information:
Lot #: 02RP1507A, exp. date 30-Jun-22; 02RP1512A, exp. date 30-Sep-22; 02RP1514A, exp. date 31-Nov-22; 02RP1515A, exp. date 31-Dec-22

Class II Drugs Event

Event ID:
90297

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
05/24/2022

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
06/08/2022

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Grato Holdings, Inc.
201 Apple Blvd
Woodbine IA United States

Distribution Pattern:
Nationwide within the USA

Associated Products

Product Description:
Homeopathic EarAche Drops, 0.33 FL OZ (10 mL) bottles, Distributed by: RITE AID, 30 Hunter Lane, Camp Hill, PA 17011. NDC 11822-3644-3

Product Quantity:
16,374 bottles

Reason for Recall:
Microbial contamination of non-sterile product.

Recall Number:
D-0989-2022

Code Information:
Lot #: G11639, Exp. Date 09/24

Product Description:
Homeopathic EarAche Ear Drops, 0.33 FL OZ (10 mL) bottles, Distributed by: CVS Pharmacy, Inc., One CVS Drive, Woonsocket, RI 02895. NDC 59779-568-15

Product Quantity:
50,640 bottles

Reason for Recall:
Microbial contamination of non-sterile product.

Recall Number:
D-0990-2022

Code Information:
Lot #: G11639, Exp. Date 09/24

Product Description:
Earache Drops, 0.33 FL OZ (10 mL) bottles, Distributed by: Walgreen Co., 200 Wilmot Rd., Deerfield, IL 60015. NDC 0363-3233-15

Product Quantity:
31,872 bottles

Reason for Recall:
Microbial contamination of non-sterile product.

Recall Number:
D-0991-2022

Code Information:
Lot #: G11639, Exp. Date 09/24

Class III Drugs Event

Event ID:
89646

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
04/13/2022

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
06/09/2022

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:
USA nationwide.

Associated Products

Product Description:
Ipratropium Bromide 0.5 mg and Albuterol Sulfate 3 mg Inhalation Solution 3mL vial, packaged in a) 30-count (NDC 0487-0201-03), b) 60-count (NDC 0487-0201-60), Rx only, MFG: Nephron Pharma

Product Quantity:
56 pouches

Reason for Recall:
cGMP deviations: Temperature abuse

Recall Number:
D-1021-2022

Code Information:
McKesson Medical-Surgical (MMS) is not able to identify the particular lot number received by a particular consignee for the recalled prescription products. Each letter includes the date it was distributed to customers and the dates that impacted product may have been shipped to the customer.

Class III Drugs Event

Event ID:
90176

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
05/10/2022

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
06/06/2022

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Novartis Pharmaceuticals Corporation
1 Health Plz
East Hanover NJ United States

Distribution Pattern:
Nationwide within the United States

Associated Products

Product Description:
Xiidra (lifitegrast ophthalmic solution), packaged in a) 60 Single-Use Containers: 12 pouches x 5 single-use containers (0.2 mL each vial) (NDC

0078-0911-12) and b) 5- Single-Use Containers (NDC 0078-0911-05) Rx Only, Manufactured by: The Ritedose Corporation, Columbia, SC 29203, Distributed by: Novartis Pharmaceuticals Corporation, East Hanover, NJ 07936.

Product Quantity:
1,187,092 vials

Reason for Recall:
Failed Impurities/Degradation Specifications.

Recall Number:
D-0982-2022

Code Information:
Lot #:a) and b) 20E21, 20E22, 20E53, 20E54, 20E95, 20E96, 20ED1, 20ED2, 20ED3, 20EK1 Exp. Date 4/2023; 20F27, 20F28, 20F66, 20F67,20FH6, Exp. Date 05/2023; 20G47, 20G48, 20G49, 20G57, 20GB8, 20GE5, 20GE6, Exp. Date 06/2023; 20M41, 20M42, 20M56, 20M66, 20M67, 20MA4, Exp. Date 07/2023; 20S20, 20S22, 20S44, 20S94, Exp. Date 10/2023; 20SA6, 20SA7, 20SE0, Exp. Date 10/2023, 20TE2, 20TG5, Exp. Date 11/2023.

Product Description:
Xiidra (lifitegrast ophthalmic solution) 5%, packaged in a) 60 Single-Use Containers: 12 pouches x 5 single-use containers (0.2 mL each vial) (NDC 54092-606-01) and b) 5-Single-Use Containers (NDC 54092-606-06), Rx Only, Manufactured for: Shire US Inc., 300 Shire Way, Lexington, MA 02421.

Product Quantity:
1,253,862 vials

Reason for Recall:
Failed Impurities/Degradation Specifications.

Recall Number:
D-0983-2022

Code Information:
Lot #: a) and b)19E31, 19E32, 19E85, 19E86, 19EC0, 19EG8 & 19EG9, Exp. Date 05/2022; 19F13, 19FB0 & 19FC5, Exp. Date 6/2022;19G33, 19G34,19GJ8, Exp. Date 07/2022;19M25, 19M26 & 19M68, Exp. Date 08/2022;19NC0, 19NC1, 19NF2,19NF3, Exp. Date 09/2022;19P26, 19P59, 19P60,19P85,19P86 19P87, Exp. Date 10/2022;19S55, 19S03, 19S04, 19S05,19S07, Exp. Date 11/2022; 19T06, 19T60, 19T61, Exp. Date 12/2022; 20A38, 20A39, 20A64, 20A65, 20AA1, 20AA2, 20AC8, 20AC9, 20AE7, Exp. Date 01/2023; 20B24, 20B25, 20B55, 20B56, 20B57 & 20B58, Exp. Date 02/2023

Product Description:
Xiidra (lifitegrast ophthalmic solution) 5% PROFESSIONAL SAMPLE, packaged in a) 5 single-use containers (0.2 mL each vial) (NDC 0078-0911-95) and b) 4 pouches x 5 single-use containers (NDC 0078-0911-94), Rx Only, Manufactured by: The Ritedose Corporation Columbia, SC 29203; Distributed by: Novartis Pharmaceuticals Corporation East Hanover, NJ 07936.

Product Quantity:
279,179 vials

Reason for Recall:
Failed Impurities/Degradation Specifications.

Recall Number:
D-0984-2022

Code Information:
Lot #: a) and b) 20DJ3, Exp. Date 03/2023.

Product Description:
Xiidra (lifitegrast ophthalmic solution) 5% PROFESSIONAL SAMPLE, packaged in a) 5 single-use containers (0.2 mL each vial) (NDC 54092-606-07) and b) 4 pouches x 5 single-use containers (NDC 54092-606-04), Rx Only, Manufactured for: Shire US Inc., 300 Shire Way, Lexington, MA 02421.

Product Quantity:
279,179 vials

Reason for Recall:
Failed Impurities/Degradation Specifications.

Recall Number:
D-0985-2022

Code Information:
Lot #: a) and b) 19F39, Exp. Date 06/2022; 19P27, Exp. Date 10/2022; 20CD1, Exp. Date 03/2023

Class III Drugs Event

Event ID:
90239

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
05/18/2022

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
06/07/2022

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:
Product was distributed nationwide in the US Market

Associated Products

Product Description:
Alprostadil Injection USP 500 mcg/mL, 1 mL Single Dose Vial, 5 vials per Carton, Rx Only, Carton NDC 0703-1501-02, Distributed by: Teva Pharmaceuticals USA, Inc., Parsippany, NJ 07054, Vial NDC 0703-1501-01

Product Quantity:
3109 cartons

Reason for Recall:
Failed Impurities/Degradation Specifications; out-of-specification results for impurities obtained during routine stability testing

Recall Number:
D-0988-2022

Code Information:
Lot #:100022404, Exp Date 10/2022; Lot #:100023333, Exp Dat 12/2022

Not Yet Classified Drugs Event

Event ID:
90289

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
04/15/2022

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:

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

Recalling Firm:
Valor Compounding Pharmacy, Inc DBA Valor Compounding Pharmacy
2461 Shattuck Ave
Berkeley CA United States

Distribution Pattern:
CA

Associated Products

Product Description:
Tacrolimus (Brand Capsules) 0.5 mg/mL Suspension, Valor Compounding Pharmacy, 2461 Shattuck Ave., Berkeley, CA 94704, Rx, This is a compounded medication.

Product Quantity:
1,966mls in 12 oz; 2 oz; 16 oz and 6 oz bottles

Reason for Recall:
Subpotent drug

Recall Number:

Code Information:
lot: 03312022@29, BUD: 6/10/2022.

Product Description:
Tacrolimus (Brand Capsules) 0.5 mg/mL Suspension, Valor Compounding Pharmacy, 2461 Shattuck Ave., Berkeley, CA 94704, Rx, This is a compounded medication.

Product Quantity:
950mls in 1x8 0z and 2x16 0z bottles.

Reason for Recall:
Subpotent drug

Recall Number:

Code Information:
lot: 04272022@35, BUD: 7/7/2022.