Enforcement Report - Week of July 30, 2025

Class II Drugs Event

Event ID:
97110

Product Type:
Drugs

Status:
Ongoing

Date Terminated:
N/A

Recall Initiation Date:
04/21/2025

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
07/21/2025

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 23233
United States

Distribution Pattern:
Within the U.S - OH, VA, FL.

Associated Products

Product Description:
PROLIA (denosumab), injection, 60mg/mL, For Subcutaneous Use Only, Rx Only, Manufactured by: Amgen Inc., Thousand Oaks, CA 91320, NDC 55513-710-21

Product Quantity:
6 Pre-filled syringes

Reason for Recall:
CGMP Deviations; potential temperature excursions due to transit delays

Recall Number:
D-0538-2025

Code Information:
Lot: 1180924, Expiration date: 6/30/2027.

Product Description:
EVENITY, (romosozumab -aqqg) injection, 105mg/1.17 mL, For Subcutaneous Use Only, Rx Only, Manufactured by: Amgen Inc., Thousand Oaks, CA 91320, NDC 55513-880-02.

Product Quantity:
2 Pre-filled syringes

Reason for Recall:
CGMP Deviations; potential temperature excursions due to transit delays

Recall Number:
D-0539-2025

Code Information:
Lot: 1178382, Expiration date: 3/31/2027

Product Description:
BENLYSTA (belimumab) for injection, 400 mg/20 mL vial, Rx only, NDC 49401-102-01, GSK.

Product Quantity:
3 Vials

Reason for Recall:
CGMP Deviations; potential temperature excursions due to transit delays

Recall Number:
D-0540-2025

Code Information:
Lot: YK4W, Expiration date: 4/30/2029

Class II Drugs Event

Event ID:
97159

Product Type:
Drugs

Status:
Ongoing

Date Terminated:
N/A

Recall Initiation Date:
06/27/2025

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
07/21/2025

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Lupin Pharmaceuticals Inc.
5801 Pelican Bay Blvd Suite 500
Naples, FL 34108-2755
United States

Distribution Pattern:
Nationwide.

Associated Products

Product Description:
clomiPRAMINE Hydrochloride Capsules USP 25 mg, 100 count bottles, 5801 Pelican Bay Boulevard, Suite 500, Naples, Florida 34108, NDC# 68180-492-01

Product Quantity:
2,724 bottles

Reason for Recall:
Failed Impurities/Degradation Specifications: an out of specification result observed in degradation product test (any unspecified degradation product) during retention sample testing at expiry.

Recall Number:
D-0537-2025

Code Information:
Lot # M300464, exp. date June, 2025

Class II Drugs Event

Event ID:
97170

Product Type:
Drugs

Status:
Ongoing

Date Terminated:
N/A

Recall Initiation Date:
06/30/2025

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
07/22/2025

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Cipla USA, Inc.
10 Independence Blvd
Warren, NJ 07059-2730
United States

Distribution Pattern:
Distributed Nationwide in the USA

Associated Products

Product Description:
Budesonide Inhalation Suspension, 0.5mg/2ml, 30 single-dose ampules per carton, five per pouch, RX Only, Manufactured by: Cipla Ltd. Indore SEZ, Pithampur, India. Manufactured for: Ciple USA, Inc. 10 Independence Boulevard, Suite 300, Warren, NJ 07059. NDC# 69097-319-86 (pouch), 69097-319-87 (carton)

Product Quantity:
13,680 ampoules

Reason for Recall:
Lack of Assurance of Sterility: A market complaint was received for leakage and empty ampoule.

Recall Number:
D-0541-2025

Code Information:
Batch # 4IA0505, Exp 09/31/2026

Class II Drugs Event

Event ID:
97183

Product Type:
Drugs

Status:
Ongoing

Date Terminated:
N/A

Recall Initiation Date:
07/09/2025

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
07/21/2025

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Imprimis NJOF, LLC
1705 Route 46 Ste 6B
Ledgewood, NJ 07852-9720
United States

Distribution Pattern:
Nationwide in the USA

Associated Products

Product Description:
Epinephrine Lidocaine HCL, 0.25mg/mL and 7.5 mg/mL, 20x1 mL Vials per carton, Rx Only, Imprimis NJOF, 1705 Route 46 West, Unit 6B Ledgewood, NJ, 07852 NDC: 71384-641-01

Product Quantity:
6,880 vials

Reason for Recall:
Sub-Potent Drug: Subpotent assay results during stability testing.

Recall Number:
D-0535-2025

Code Information:
Lot: 24DEC017, Exp. 07/12/2025.

Class III Drugs Event

Product Description:
Tropicamide-Proparacaine-Phenylephrine-Ketorolac, Sterile Ophthalmic Solution, 1% 0.5% 2.5% 0.5%, 5mL, 2x5ML vial per carton, Rx Only,

Imprimis NJOF, LLC, 1705 Route 46 West, Unit 6B, Ledgewood, NJ 07852, NDC 71384-733-05.

Product Quantity:
2,890 vials

Reason for Recall:
Sub-Potent Drug: Subpotent assay results during stability testing.

Recall Number:
D-0536-2025

Code Information:
Lot: 25MAR032, Exp. 07/16/2025.