Enforcement Report - Week of December 17, 2025

Class II Drugs Event

Event ID:
97855

Product Type:
Drugs

Status:
Ongoing

Date Terminated:
N/A

Recall Initiation Date:
10/24/2025

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
12/05/2025

Initial Firm Notification of Consignee or Public:
N/A

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

Distribution Pattern:
Nationwide in the USA

Associated Products

Product Description:
Lanthanum Carbonate chewable tablets, 1000mg*, 10x9 bottles per patient pack carton, Rx Only, Manufactured by: Invagen Pharmaceuticals, Inc., Hauppauge, NY 11786, Manufactured for : Cipla USA, Inc., 10 Independence Boulevard, Suite 300, Warren, NJ 07059, NDC 69097-936-98.

Product Quantity:
1180 boxes

Reason for Recall:
Failed stability specifications: Out of specification for hardness test

Recall Number:
D-0217-2026

Code Information:
lot# NB240315, exp 12/31/2025

Product Description:
Lanthanum Carbonate chewable tablets, 1000mg*, 10x9 bottles per patient pack carton, Rx Only, Manufactured by: Invagen Pharmaceuticals, Inc., (a subsidary of Cipla Ltd) Hauppauge, NY 11786, Manufactured for: Exelan Pharmaceuticals, Inc., Boca Raton, FL 33422, Carton NDC 76282-478-90; Bottle NDC 76282-478-13.

Product Quantity:
N/A

Reason for Recall:
Failed stability specifications: Out of specification for hardness test

Recall Number:
D-0218-2026

Code Information:
Lot# NB240314, exp 12/31/2025

Class II Drugs Event

Event ID:
97936

Product Type:
Drugs

Status:

Date Terminated:

Ongoing

Recall Initiation Date:
11/05/2025

Center Classification Date:
12/10/2025

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

Distribution Pattern:
Nationwide.

N/A

Voluntary / Mandated:
Voluntary: Firm initiated

Initial Firm Notification of Consignee or Public:
Letter

Associated Products

Product Description:
Sertraline Hydrochloride Tablets USP, 100 mg, 90 Tablets bottles, Rx Only, Manufactured by: Lupin Pharmaceuticals, Inc., Naples, FL 34108, NDC 68180-353-09.

Product Quantity:
52,128 bottles

Reason for Recall:
Defective container - seal not adhering to bottles

Recall Number:
D-0227-2026

Code Information:
Lot # QB00865, exp. date Feb 2028

Class II Drugs Event

Event ID:
97974

Status:
Ongoing

Recall Initiation Date:
11/14/2025

Center Classification Date:
12/09/2025

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

Distribution Pattern:
Nationwide in the US

Product Type:
Drugs

Date Terminated:
N/A

Voluntary / Mandated:
Voluntary: Firm initiated

Initial Firm Notification of Consignee or Public:
Letter

Associated Products

Product Description:
Cinacalcet Hydrochloride Tablets, 30 mg, 30 Tablets per bottle, Rx Only, Manufactured for: Cipla USA, Inc., 10 Independence Boulevard, Suite 300, Warren, NJ 07059. NDC: 69097-410-02

Product Quantity:
63,504 bottles

Reason for Recall:

CGMP Deviations: the presence of a nitrosamine impurity, N-nitroso-cinacalcet, above the acceptable daily intake (ADI) limits.

Recall Number:
D-0224-2026

Code Information:
Lot, expiry: Lot 4PB0109, exp 1/31/2026; Lot 5PB0172, exp 1/31/2027

Product Description:
Cinacalcet Hydrochloride Tablets, 60 mg, 30 Tablets per bottle, Rx Only, Manufactured for: Cipla USA, Inc., 10 Independence Boulevard, Suite 300, Warren, NJ 07059. NDC: 69097-411-02

Product Quantity:
15,744 bottles

Reason for Recall:
CGMP Deviations: the presence of a nitrosamine impurity, N-nitroso-cinacalcet, above the acceptable daily intake (ADI) limits.

Recall Number:
D-0225-2026

Code Information:
Lot 5PB0164, exp 1/31/2027

Product Description:
Cinacalcet Hydrochloride Tablets, 90 mg, 30 Tablets per bottle, Rx Only, Manufactured for: Cipla USA, Inc., 10 Independence Boulevard, Suite 300, Warren, NJ 07059. NDC: 69097-412-02

Product Quantity:
12,576 bottles

Reason for Recall:
CGMP Deviations: the presence of a nitrosamine impurity, N-nitroso-cinacalcet, above the acceptable daily intake (ADI) limits.

Recall Number:
D-0226-2026

Code Information:
Lot 5PB0183, exp 1/31/2027

Class II Drugs Event

Event ID:
97990

Product Type:
Drugs

Status:
Ongoing

Date Terminated:
N/A

Recall Initiation Date:
11/13/2025

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
12/08/2025

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

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

Distribution Pattern:
FL, MA, MI & OH

Associated Products

Product Description:
Ganirelix Acetate Injection, 250 mcg/0.5mL, Single-dose Sterile Prefilled Syringe, 27 gauge by 1/2' needle, Rx only, Manufactured for: Lupin Pharmaceuticals, Inc., Naples, FL 34108, United States, Manufactured by: Lupin Limited, Nagpur - 441108, INDIA, NDC 70748-274-01

Product Quantity:
32736 vials

Reason for Recall:
Failed impurities/degradation specifications: out of specification results for Ganirelix acetate acrylic acid adduct impurity.

Recall Number:
D-0220-2026

Code Information:
Lot #: WB00006, Exp 12/31/2026

Class II Drugs Event

Event ID:
98040

Product Type:
Drugs

Status:
Ongoing

Date Terminated:
N/A

Recall Initiation Date:
11/20/2025

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
12/08/2025

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Fagron Compounding Services
8710 E 34th St N
Wichita, KS 67226-2636
United States

Distribution Pattern:
U.S. Nationwide.

Associated Products

Product Description:
Tropicamide 1%/Cyclopentolate 1%/Phenylephrine 2.5%/Ketorolac 0.5% Topical Ophthalmic Solution, 0.5mL Single-Use Syringe, For Topical Ophthalmic Use Only. Not for IV Use. Fagron Sterile Services, 8710 E 34th St N, Wichita, KS 67226. NDC: 71266-8240-01

Product Quantity:
2980 syringes

Reason for Recall:
Incorrect Product Formulation

Recall Number:
D-0221-2026

Code Information:
Lot#: C274-000047958; Exp. December 19, 2025

Class III Drugs Event

Event ID:
97957

Product Type:
Drugs

Status:
Ongoing

Date Terminated:
N/A

Recall Initiation Date:
11/11/2025

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
12/05/2025

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Dr. Reddy's Laboratories, Inc.
600 College Rd E Ste 4000
Princeton, NJ 08540-6636
United States

Distribution Pattern:
Distributed Nationwide

Associated Products

Product Description:
Varenicline Tablets, 1mg, 56 Tablets, Rx only, Distributor: Dr. Reddy's Laboratories Inc., Princeton, NJ 08540, Made in India, NDC 43598-908-56

Product Quantity:
4800 54-count bottles

Reason for Recall:
Sub potent drug: during the 9-month stability test conducted, the assay value for the affected lot was below specification limit.

Recall Number:
D-0219-2026

Code Information:
Lot # F2400244, Exp Date: 10/31/2026

Class III Drugs Event

Event ID:
98014

Product Type:
Drugs

Status:
Ongoing

Date Terminated:
N/A

Recall Initiation Date:
11/18/2025

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
12/09/2025

Initial Firm Notification of Consignee or Public:
Letter

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

Distribution Pattern:
U.S. Nationwide

Associated Products

Product Description:
Nebivolol Tablets, 20 mg, 90 Tablets, Rx Only, Manufactured by: Glenmark Pharmaceuticals Limited, Pithampur, Madhya Pradesh 454775, India, Manufactured for Avkare, Pulaski, TN 38478, Product of Italy, NDC 42291-874-90.

Product Quantity:
672 90-count bottles

Reason for Recall:
Cross Contamination with Other Products

Recall Number:
D-0222-2026

Code Information:
Lot# 17240988; Exp. 05/31/2026

Class III Drugs Event

Event ID:
98077

Product Type:
Drugs

Status:
Ongoing

Date Terminated:
N/A

Recall Initiation Date:
11/26/2025

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
12/09/2025

Initial Firm Notification of Consignee or Public:
N/A

Recalling Firm:
Winder Laboratories, LLC
716 Patrick Industrial Ln
Winder, GA 30680-8333
United States

Distribution Pattern:
U.S. Nationwide

Associated Products

Product Description:
Morphine Sulfate Oral Solution 100 mg / 5 mL (20 mg* / mL), 30 mL, Rx Only, For Oral Use Only, Manufactured By: /winder Laboratories, LLC, Winder, GA 30680. NDC: 75826-131-01

Product Quantity:
3,528 30 mL Bottles

Reason for Recall:
Correct Labeled Product Mispack-Size stated on carton label did not match the size of the bottle in the carton.

Recall Number:
D-0223-2026

Code Information:
Lot 1312405; Exp 09/28/2027