# Enforcement Report - Week of April 23, 2025

## Class I Drugs Event

**Event ID:**
96470

**Product Type:**
Drugs

**Status:**
Ongoing

**Date Terminated:**
N/A

**Recall Initiation Date:**
03/13/2025

**Voluntary / Mandated:**
Voluntary: Firm initiated

**Center Classification Date:**
04/16/2025

**Initial Firm Notification of Consignee or Public:**
N/A

**Recalling Firm:**
Dr. Reddy's Laboratories, Inc.
107 College Rd E
Princeton, NJ 08540-6623
United States

**Distribution Pattern:**
Nationwide in the USA

### Associated Products

**Product Description:**
Levetiracetam 0.75% in Sodium Chloride Injection 1,000 mg/100 mL (10 mg/mL), 1 x 100mL, Rx Only, Manufactured by: Gland Pharma Limited, Hyderabad, - 500 043 INDIA, Distributor: Dr. Reddy's Laboratories Inc., Princeton, NJ 08540, NDC 43598-636-52

**Product Quantity:**
4,010 bags

**Reason for Recall:**
LABELING: LABEL MIX-UP: The infusion bag is incorrectly labeled as Levetiracetam in 0.82% Sodium Chloride Injection 500 mg/100 mL, while the aluminum overwrap packaging correctly identifies the product as Levetiracetam in 0.75% Sodium Chloride Injection 1,000 mg/100 mL.

**Recall Number:**
D-0365-2025

**Code Information:**
Lot: A1540076, Exp 08/31/2026

## Class II Drugs Event

**Event ID:**
96552

**Product Type:**
Drugs

**Status:**
Ongoing

**Date Terminated:**
N/A

**Recall Initiation Date:**
03/26/2025

**Voluntary / Mandated:**
Voluntary: Firm initiated

**Center Classification Date:**
04/11/2025

**Initial Firm Notification of Consignee or Public:**
N/A

**Recalling Firm:**
Chattem Inc
1715 W 38th St
Chattanooga, TN 37409-1248
United States

**Distribution Pattern:**
Nationwide.

## Associated Products

**Product Description:**
Unisom, SleepMinis, Diphenhydramine HCl, Mini-Capsules, 25 mg, 60 Mini-Capsules bottles, Dist. by Chattem, Inc., P.O. Box 2219, Chattanooga, TN 37409-0219, USA, UPC 0 41167 00670 2

**Product Quantity:**
129,240 bottles

**Reason for Recall:**
CGMP Deviations; detection of Nitrosamine Drug Substance-Related Impurities (NDSRI), N-nitroso-desmethyl-diphenhydramine (n-dph), above the FDA Recommended Intake Limit

**Recall Number:**
D-0362-2025

**Code Information:**
LOT 22L603, EXP: Oct 2025; LOT 378999, EXP: Feb 2027

## Class II Drugs Event

**Event ID:**
96573

**Product Type:**
Drugs

**Status:**
Ongoing

**Date Terminated:**
N/A

**Recall Initiation Date:**
01/31/2025

**Voluntary / Mandated:**
Voluntary: Firm initiated

**Center Classification Date:**
04/15/2025

**Initial Firm Notification of Consignee or Public:**
E-Mail

**Recalling Firm:**
Direct Rx
94 Worldwide Dr
Dawsonville, GA 30534-6828
United States

**Distribution Pattern:**
Physicians and medical facilities in 5 states: AL, CA, FL, GA, ID

## Associated Products

**Product Description:**
CIPROFLOXACIN OPHTH SOLUTION, 0.3% 5mL bottle, Rx Only, Generic for CILOXAN, Packaged and Distributed by: DIRECT Rx, NDC 61919-795-05.

**Product Quantity:**
477 bottles.

**Reason for Recall:**
Defective Container: Unable to get the solution out of the bottle as the spike of the cap was lodged in the nozzle of the product bottle

**Recall Number:**
D-0364-2025

**Code Information:**
Lot 11SE2402, Exp Date: 11/30/2025 Lot 14NO2406, Exp Date: 12/31/2025 Lot 29OC2420, Exp Date: 11/30/2025 Lot 30SE2412, Exp Date: 11/30/2025

## Class II Drugs Event

**Event ID:**
96679

**Product Type:**
Drugs

**Status:**
Ongoing

**Date Terminated:**
N/A

**Recall Initiation Date:**
04/14/2025

**Voluntary / Mandated:**
Voluntary: Firm initiated

**Center Classification Date:**
04/16/2025

**Initial Firm Notification of Consignee or Public:**
Letter

**Recalling Firm:**
The Harvard Drug Group LLC dba Major Pharmaceuticals and Rugby Laboratories
341 Mason Rd
La Vergne, TN 37086-3606
United States

**Distribution Pattern:**
Nationwide USA

## Associated Products

**Product Description:**
ChlorproMAZINE Hydrochloride Tablets, USP, 10 mg, packaged in cartons of 100 TABLETS (10x10), Rx only, Packaged and Distributed by: Major Pharmaceuticals, Indianapolis, IN 46268, NDC 0904-7129-61

**Product Quantity:**
133 cartons

**Reason for Recall:**
CGMP deviations: presence of N-Nitroso-Desmethyl Chlorpromazine impurity above the recommended interim limit

**Recall Number:**
D-0366-2025

**Code Information:**
Lot#: N02114, Exp 12/31/2025

## Class II Drugs Event

**Event ID:**
96680

**Product Type:**
Drugs

**Status:**
Ongoing

**Date Terminated:**
N/A

**Recall Initiation Date:**
04/10/2025

**Voluntary / Mandated:**
Voluntary: Firm initiated

**Center Classification Date:**
04/14/2025

**Initial Firm Notification of Consignee or Public:**
Letter

**Recalling Firm:**
Eugia US LLC
279 Princeton Hightstown Rd
East Windsor, NJ 08520-1401
United States

**Distribution Pattern:**
Nationwide USA

## Associated Products

**Product Description:**
Testosterone Cypionate Injection, USP, CIII, 200mg per mL, Rx only, 1mL Single-Dose Vial, Distributed by Eugia US LLC, E. Windsor, NJ, Manufactured by: Eugia Specialties Limited, Telangana State, India, NDC 55150-277-01

**Product Quantity:**
36,816 vials

**Reason for Recall:**
cGMP: complaints of crystals not redissolving into solution after warming and shaking the vials.

**Recall Number:**
D-0363-2025

**Code Information:**
Lot #: 1TC24075A, Exp 11/30/2026.