Enforcement Report - Week of January 28, 2026

Class II Drugs Event

Event ID:
98227

Product Type:
Drugs

Status:
Ongoing

Date Terminated:
N/A

Recall Initiation Date:
12/30/2025

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
01/22/2026

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Zydus Pharmaceuticals (USA) Inc
73 Route 31 N
Pennington, NJ 08534-3601
United States

Distribution Pattern:
US Nationwide.

Associated Products

Product Description:
Icosapent Ethyl capsules, 1 gram, 120-count bottles, Rx only, Manufactured by: Softgel Healthcare Pvt. Ltd., India, Distributed by: Zydus Pharmaceuticals (USA) Inc., Pennington, NJ 08534, NDC 70710-1592-07

Product Quantity:
22,896 bottles

Reason for Recall:
Subpotent Drug: Due oxidation caused by leakage of the contents of the Icosapent Ethyl 1g capsules. Use of the affected product may lead to inconsistent therapeutic effects and an increase in potential gastrointestinal side effects in some patients.

Recall Number:
D-0295-2026

Code Information:
Lot # S2520304, S2520333, Exp 2/28/2027; S2540186, Exp 4/30/2027

Class II Drugs Event

Event ID:
98289

Product Type:
Drugs

Status:
Ongoing

Date Terminated:
N/A

Recall Initiation Date:
01/10/2026

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
01/21/2026

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Graviti Pharmaceuticals Private Limited
E & 621 Patancheru Mandal Isnapur Village Rd; Survey No 621
Hyderabad
India

Distribution Pattern:
U.S. Nationwide

Associated Products

Product Description:
Furosemide Tablets, USP 40 mg, 1,000 Tablets, Rx Only, Manufactured for: Rising Pharmaceuticals Inc., East Brunswick, NJ 08816, Manufactured by: Graviti Pharmaceuticals Pvt. Ltd. Telangana - 502307, India, NDC 64980-563-10.

Product Quantity:
4212 bottles

Reason for Recall:
Presence of Foreign Substance

Recall Number:
D-0293-2026

Code Information:
Lot# FUB125042G; Exp. 05/13/2027

Class II Drugs Event

Event ID:
98307

Product Type:
Drugs

Status:
Ongoing

Date Terminated:
N/A

Recall Initiation Date:
01/16/2026

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
01/21/2026

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Specialty Process Labs LLC
2001 W Lone Cactus Dr Ste B
Phoenix, AZ 85027-2648
United States

Distribution Pattern:
U.S. Nationwide

Associated Products

Product Description:
Thyroid, USP, Rx only, Net Wt: 0.50kg, For Manufacturing, Processing or Repackaging Use Only, Specialty Process Labs, Phoenix, AZ 85034, NDC 81305-100-02

Product Quantity:
58 gms

Reason for Recall:
Subpotent Drug

Recall Number:
D-0294-2026

Code Information:
Lot #H22254-1XV; Exp. 01/31/2027

Class III Drugs Event

Event ID:
98193

Product Type:
Drugs

Status:
Ongoing

Date Terminated:
N/A

Recall Initiation Date:
12/22/2025

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
01/20/2026

Initial Firm Notification of Consignee or Public:
Letter

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

Distribution Pattern:
Nationwide in the USA

Associated Products

Product Description:
Diclofenac Sodium Topical Gel, 1%, NET WT 100 g (3.53 oz), Manufactured by: DPT Laboratories, Ltd., 307 E Josephine Street, San Antonio, TX 78215. NDC: 76282-103-39

Product Quantity:
92,376 tubes

Reason for Recall:
Failed PH Specifications

Recall Number:
D-0291-2026

Code Information:
Batch XHBG; Exp. 08/31/2027