

Enforcement Report - Week of January 7, 2026

Class II Drugs Event

Event ID:

98100

Status:

Ongoing

Recall Initiation Date:

12/19/2025

Center Classification Date:

12/31/2025

Recalling Firm:

Novo Nordisk Inc.
800 Scudders Mill Rd
Plainsboro, NJ 08536-1606
United States

Distribution Pattern:

Nationwide within the United States.

Product Type:

Drugs

Date Terminated:

N/A

Voluntary / Mandated:

Voluntary: Firm initiated

Initial Firm Notification of Consignee or Public:

Letter

Associated Products

Product Description:

Wegovy (semaglutide) Injection, 0.5 mg/0.5 mL, 4 Single-Dose Prefilled Pens, Manufactured by: Novo Nordisk A/S, DK-2880 Bagsvaerd, Denmark, Product of Denmark, Novo Nordisk A/S, Novo Nordisk Inc., Plainsboro, NJ 08536, NDC 0169-4505-14

Product Quantity:

N/A

Reason for Recall:

Presence of Particulate Matter: Hair was found in a prefilled syringe

Recall Number:

D-0244-2026

Code Information:

Lot #: RZFHD52, RZFW93; Exp Date 10/31/2026

Product Description:

Wegovy (semaglutide) Injection, 1 mg/0.5 mL, 4 Single-Dose Prefilled Pens, Manufactured by: Novo Nordisk A/S, DK-2880 Bagsvaerd, Denmark, Product of Denmark, Novo Nordisk A/S, Novo Nordisk Inc., Plainsboro, NJ 08536, NDC 0169-4501-14

Product Quantity:

N/A

Reason for Recall:

Presence of Particulate Matter: Hair was found in a prefilled syringe

Recall Number:

D-0245-2026

Code Information:

Lot #: RZFYK06, RZFYA53; Exp Date 3/31/2027

Class II Drugs Event

Event ID:

98142

Status:

Ongoing

Product Type:

Drugs

Date Terminated:

N/A

Recall Initiation Date:

12/17/2025

Voluntary / Mandated:

Voluntary: Firm initiated

Center Classification Date:

12/30/2025

Initial Firm Notification of Consignee or Public:

Letter

Recalling Firm:

CareFusion 213, LLC
1550 Northwestern Dr
El Paso, TX 79912-8000
United States

Distribution Pattern:

Nationwide within the United States

Associated Products

Product Description:

BD Chloraprep" Triple Swabsticks (Chlorhexidine gluconate (CHG), 2% w/v and Isopropyl alcohol (IPA), 70% v/v), 5.25 mL Applicator, CareFusion 213, LLC, El Paso, TX 79912, NDC 54365-401-29

Product Quantity:

106,400 units

Reason for Recall:

Lack of Assurance of Sterility

Recall Number:

D-0243-2026

Code Information:

Lot #: 5086623, Exp. Date 03/31/2028

Class II Drugs Event

Event ID:

98233

Product Type:

Drugs

Status:

Ongoing

Date Terminated:

N/A

Recall Initiation Date:

12/30/2025

Voluntary / Mandated:

Voluntary: Firm initiated

Center Classification Date:

12/31/2025

Initial Firm Notification of Consignee or Public:

Letter

Recalling Firm:

Glenmark Pharmaceuticals Inc., USA
619 River Dr
Elmwood Park, NJ 07407-1317
United States

Distribution Pattern:

Nationwide within the United States

Associated Products

Product Description:

Onandsetron Orally Disintegrating Tablets, USP, 4mg, 30 Tablets (3 blistercards each containing 10 tablets), Rx only, Manufactured for: Glenmark Pharmaceuticals Inc., USA Mahwah, NJ 07430, Product of India, NDC 68462-157-13

Product Quantity:

96,948 packs

Reason for Recall:

Defective container: Preferred Pharmaceuticals received a letter from the manufacturer Glenmark, that the blister packs are not fully sealed and tablets falling out. Preferred Pharmaceuticals purchased the finished product and repackaged the product for sale.

Recall Number:

D-0246-2026

Code Information:

Lot #: 19251311, Exp Date April 2027

Class III Drugs Event

Event ID:

98184

Product Type:

Drugs

Status:

Ongoing

Date Terminated:

N/A

Recall Initiation Date:

12/19/2025

Voluntary / Mandated:

Voluntary: Firm initiated

Center Classification Date:

12/31/2025

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:

Nationwide in the USA

Associated Products

Product Description:

traZODONE Hydrochloride Tablets, USP, 100mg, 1,000 Tablets, Rx only, Manufactured by: Zydus Lifesciences Ltd., India, Distributed by: Zydus Pharmaceuticals (USA) Inc., Pennington, NJ 08534, NDC 68382-806-10

Product Quantity:

2,136 1000-count bottles

Reason for Recall:

Failed Tablet/Capsule Specifications: Product complaint received that some tablets had a dent on the plain side of the tablet surface.

Recall Number:

D-0247-2026

Code Information:

Lot # EA00237A, Exp Date: 04/30/2027