

Enforcement Report - Week of February 4, 2026

Class II Drugs Event

Event ID:

98178

Product Type:

Drugs

Status:

Ongoing

Date Terminated:

N/A

Recall Initiation Date:

12/22/2025

Voluntary / Mandated:

Voluntary: Firm initiated

Center Classification Date:

01/23/2026

Initial Firm Notification of Consignee or Public:

Letter

Recalling Firm:

Baxter Healthcare Corporation

1 Baxter Pkwy

Deerfield, IL 60015-4625

United States

Distribution Pattern:

Nationwide

Associated Products

Product Description:

Sterile Water for Irrigation, 250 mL, Single-Dose Plastic Bottle, Rx Only, Baxter Healthcare Corporation Deerfield, IL 60015 NDC: 0338-0004-02.

Product Quantity:

125,496 bottles

Reason for Recall:

Presence of particulate matter: plastic particles from the bottle rim were observed floating into the solution

Recall Number:

D-0296-2026

Code Information:

Lot #: G171359, expiry: 05/31/2027

Class II Drugs Event

Event ID:

98216

Product Type:

Drugs

Status:

Ongoing

Date Terminated:

N/A

Recall Initiation Date:

12/19/2025

Voluntary / Mandated:

Voluntary: Firm initiated

Center Classification Date:

01/27/2026

Initial Firm Notification of Consignee or Public:

Letter

Recalling Firm:

Sato Pharmaceutical Co., Ltd

Ahc Building 1-5-27

Tokyo

Japan

Distribution Pattern:

CA and HI

Associated Products

Product Description:

INON ACE Antacid tablets (magnesium aluminosilicate, magnesium hydroxide and simethicone), 75-count bottle, Manufactured by: Sato Pharmaceutical Co., Ltd., NDC 49873-402-01

Product Quantity:

3,640 bottles

Reason for Recall:

Failed Disintegration Specifications: above the time expected.

Recall Number:

D-0298-2026

Code Information:

Lot#: PWXT, Exp 1/31/2027

Class II Drugs Event

Event ID:

98278

Product Type:

Drugs

Status:

Ongoing

Date Terminated:

N/A

Recall Initiation Date:

01/15/2026

Voluntary / Mandated:

Voluntary: Firm initiated

Center Classification Date:

01/28/2026

Initial Firm Notification of Consignee or Public:

Letter

Recalling Firm:

Greenstone Llc
100 Route 206 North
Peapack, NJ 07977
United States

Distribution Pattern:

Nationwide within the United States

Associated Products

Product Description:

methylprednisolone tablets, USP Dosepak, 4 mg, 1 Blister Card per Carton containing 21 Tablets, Rx only, Distributed by: Greenstone LLC, Peapack, NJ 07977. NDC 59762-4440-2

Product Quantity:

3456 cartons

Reason for Recall:

Labeling: Not Elsewhere Classified. Incorrect orientation of the blister foil applied to the blister cavities, which results in incorrect dosing information when following the directions on the foil.

Recall Number:

D-0299-2026

Code Information:

Lot # LG7675, Exp. Date Nov 2026

Class III Drugs Event

Event ID:

98156

Product Type:

Drugs

Status:

Ongoing

Date Terminated:

N/A

Recall Initiation Date:**Voluntary / Mandated:**

12/15/2025

Voluntary: Firm initiated

Center Classification Date:

01/28/2026

Initial Firm Notification of Consignee or Public:

Letter

Recalling Firm:

NOVADOZ PHARMACEUTICALS LLC
20 Duke Rd Ste A
Piscataway, NJ 08854-3714
United States

Distribution Pattern:

US Nationwide.

Associated Products

Product Description:
Glycopyrrolate Oral Solution, 1 mg/5 mL, 16 oz. (473 mL), Rx only, Manufactured by: MSN Pharmaceuticals Inc., Piscataway, NJ 08854, Distributed by: Novadoz Pharmaceuticals LLC, Piscataway, NJ 08854, NDC 72205-070-72

Product Quantity:
N/A

Reason for Recall:
Failed Impurities/Degradation Specifications

Recall Number:
D-0300-2026

Code Information:
Lot # CB2505159A, CB2505160A, Exp Date: 04/2027; Lot # CB2505161A, Exp Date: 05/2027

Class III Drugs Event

Event ID:

98198

Product Type:

Drugs

Status:

Ongoing

Date Terminated:

N/A

Recall Initiation Date:

12/26/2025

Voluntary / Mandated:

Voluntary: Firm initiated

Center Classification Date:

01/26/2026

Initial Firm Notification of Consignee or Public:

Letter

Recalling Firm:

Haleon US Holdings LLC
184 Liberty Corner Rd Ste 200
Warren, NJ 07059-6870
United States

Distribution Pattern:

Nationwide in the USA

Associated Products

Product Description:
parodontax (cetylpyridinium chloride)ACTIVE GUM HEALTH, Mouthwash, Mint. Net Wt 16.9 FL OZ (500 mL), Distributed by Haleon, Warren, NJ 07059. NDC 0135-0651-02

Product Quantity:
84,764 bottles

Reason for Recall:
Labeling: Incorrect or Missing Lot and/or Exp Date: Potential for missing or illegible lot and expiration date coding on the bottles.

Recall Number:

D-0297-2026

Code Information:

Lot #: 0665363, Exp 08/31/2027. Lot number and Exp Date may not appear on the 500 mL bottle.