

# Enforcement Report - Week of February 4, 2026

## Class II Drugs Event

<b>Event ID:</b>	<b>Product Type:</b>
98178	Drugs
<b>Status:</b>	<b>Date Terminated:</b>
Ongoing	N/A
<b>Recall Initiation Date:</b>	<b>Voluntary / Mandated:</b>
12/22/2025	Voluntary: Firm initiated
<b>Center Classification Date:</b>	<b>Initial Firm Notification of Consignee or Public:</b>
01/23/2026	Letter

**Recalling Firm:**  
 Baxter Healthcare Corporation  
 1 Baxter Pkwy  
 Deerfield, IL 60015-4625  
 United States

**Distribution Pattern:**  
 Nationwide

## Associated Products

<b>Product Description:</b>
Sterile Water for Irrigation, 250 mL, Single-Dose Plastic Bottle, Rx Only, Baxter Healthcare Corporation Deerfield, IL 60015 NDC: 0338-0004-02.
<b>Product Quantity:</b>
125,496 bottles
<b>Reason for Recall:</b>
Presence of particulate matter: plastic particles from the bottle rim were observed floating into the solution
<b>Recall Number:</b>
D-0296-2026
<b>Code Information:</b>
Lot #: G171359, expiry: 05/31/2027

## Class II Drugs Event

<b>Event ID:</b>	<b>Product Type:</b>
98216	Drugs
<b>Status:</b>	<b>Date Terminated:</b>
Ongoing	N/A
<b>Recall Initiation Date:</b>	<b>Voluntary / Mandated:</b>
12/19/2025	Voluntary: Firm initiated
<b>Center Classification Date:</b>	<b>Initial Firm Notification of Consignee or Public:</b>
01/27/2026	Letter
<b>Recalling Firm:</b>	
Sato Pharmaceutical Co., Ltd Ahc Building 1-5-27 Tokyo Japan	
<b>Distribution Pattern:</b>	
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:**

**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.