

# Enforcement Report - Week of March 12, 2025

## Class II Drugs Event

**Event ID:**

96242

**Status:**

Ongoing

**Recall Initiation Date:**

02/06/2025

**Center Classification Date:**

03/03/2025

**Recalling Firm:**

SUN PHARMACEUTICAL INDUSTRIES INC  
2 Independence Way  
Princeton, NJ 08540-6620  
United States

**Distribution Pattern:**

Nationwide within in the USA.

**Product Type:**

Drugs

**Date Terminated:**

N/A

**Voluntary / Mandated:**

Voluntary: Firm initiated

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

Letter

## Associated Products

**Product Description:**

Morphine Sulfate Extended-Release Tablets, 100 mg, 100-count bottles, Rx Only, Manufactured by: Ohm Laboratories Inc., New Brunswick, NJ 08901. Distributed by: Sun Pharmaceutical Industries, Inc., Cranbury, NJ 08512. NDC 63304-452-01

**Product Quantity:**

9840 bottles

**Reason for Recall:**

Failed Dissolution Specifications

**Recall Number:**

D-0249-2025

**Code Information:**

Lot #: AD16615, Exp. Date 07/2025

## Class II Drugs Event

**Event ID:**

96291

**Status:**

Ongoing

**Recall Initiation Date:**

02/13/2025

**Center Classification Date:**

03/06/2025

**Recalling Firm:**

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

**Distribution Pattern:**

USA Nationwide

**Product Type:**

Drugs

**Date Terminated:**

N/A

**Voluntary / Mandated:**

Voluntary: Firm initiated

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

Letter

## Associated Products

**Product Description:**

Nelarabine Injection, 250mg/50mL, (5mg/mL), packaged in: a) 50 mL Single-Dose Vial, NDC 70710-1726-1; b) 6 x 50 mL Single-Dose Vial, NDC 70710-1726-8, Rx only, Manufactured by Zydus Lifesciences Ltd, Ahmedabad, India, Distributed by: Zydus Pharmaceuticals (USA) Inc, Pennington, NJ

**Product Quantity:**

36,978 vials

**Reason for Recall:**

Failed Impurities/Degradation Specifications

**Recall Number:**

D-0255-2025

**Code Information:**

Lot: a) P300072, P300073 Exp. Feb-2025; P300153, Exp. Jun-25; P300195, Exp. Aug-2025; P400014, P400017, Exp. Dec-2025; P400070, Exp. Feb-2026; P400112, May-2026; P400142, Exp. Jul-2026; b) P300068, Exp. Feb-2025; P300154, Exp. Jun-2025; P400015, P400018, Exp. Dec-2025; P400068, Exp. Feb-2026; P400114, Exp. May-2026; P400139, Exp. Jul-2026.

**Product Description:**

Nelarabine Injection, 250mg/50mL, (5mg/mL), packaged in: a) 50 mL Single-Dose Vial, NDC 70710-1839-1; b) 6 x 50 mL Single-Dose Vial, NDC 70710-1839-8, Rx only, Manufactured by Zydus Lifesciences Ltd, Ahmedabad, India, Distributed by: Zydus Pharmaceuticals (USA) Inc, Pennington, NJ

**Product Quantity:**

1,893 vials

**Reason for Recall:**

Failed Impurities/Degradation Specifications

**Recall Number:**

D-0256-2025

**Code Information:**

Lot: a) P300197, Exp. Aug-2025; P400113, Exp. May-26; b) P300169, Exp. Jun-2025; P400115, Exp. May-2026.

## Class II Drugs Event

**Event ID:**

96308

**Product Type:**

Drugs

**Status:**

Ongoing

**Date Terminated:**

N/A

**Recall Initiation Date:**

02/17/2025

**Voluntary / Mandated:**

Voluntary: Firm initiated

**Center Classification Date:**

03/05/2025

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

Letter

**Recalling Firm:**

Safecor Health, LLC  
4060 Business Park Dr Ste B  
Columbus, OH 43204-5047  
United States

**Distribution Pattern:**

Nationwide in the USA

## Associated Products

**Product Description:**

Ergocalciferol - Vitamin D Supplement - 10 mcg (400 Units) per 0.05 mL Oral Syringe, Delivers: 0.05 mL Oral Solution, Mfg by: Westminster, Pkg by: Safecor Health, LLC, Columbus, OH 43204, NDC: 69367028302.

**Product Quantity:**

3069 Oral Syringes

**Reason for Recall:**

Defective Delivery System: Leakage observed after oral solution was repackaged into unit-dose syringes.

**Recall Number:**

D-0250-2025

**Code Information:**

Lot #: 24300812, Exp 01/31/2025; 24530836, Exp 07/19/2025

**Product Description:**

Simethicone 20 mg per 0.3 mL Oral Syringe, Delivers: 0.3 mL, Oral Drops, Mfg By: Rugby, Pkg by: Safecor Health, LLC, Columbus, OH 43204, NDC: 00536130375.

**Product Quantity:**

10992 Oral Syringes

**Reason for Recall:**

Defective Delivery System: Leakage observed after oral solution was repackaged into unit-dose syringes.

**Recall Number:**

D-0251-2025

**Code Information:**

Lot #: 24201295, Exp 02/05/2025; 24210364, Exp 02/20/2025; 24231720, Exp 02/27/2025; 24500770, Exp 06/26/2025; 24471182, Exp 06/20/2025; 25031031, Exp 07/22/2025.

**Product Description:**

Ferrous Sulfate 7.5 mg Iron/0.5 mL Oral Syringe, Delivers: 0.5 mL, Iron Supplement Drops, Mfg by: Akron Pharma, Pkg by: Safecor, Columbus, OH 43204. NDC: a) 71399748005, b) 39328055750, c) 69618007059.

**Product Quantity:**

1535 Oral Syringes

**Reason for Recall:**

Defective Delivery System: Leakage observed after oral solution was repackaged into unit-dose syringes.

**Recall Number:**

D-0252-2025

**Code Information:**

Lot #: a) 24250093, Exp 03/07/2025; 24321592, Exp 04/04/2025; 24280320, Exp 03/27/2025; b) 24371268, Exp 04/19/2025; c) 24400519, Exp 04/07/2025; 24500768, Exp 06/24/2025; 25040972, Exp 07/25/2025.

**Product Description:**

Lorazepam 0.5 mg per 0.25 mL Oral Syringe, Delivers: 0.25 mL, Oral Concentrate, Rx Only, Refrigerate, Mfg by: PAI, Pkg by: Safecor Health, LLC, Columbus, OH 43204, NDC: a) 00054353244, b) 00121077001, c) 65162068784.

**Product Quantity:**

3465 Oral Syringes

**Reason for Recall:**

Defective Delivery System: Leakage observed after oral solution was repackaged into unit-dose syringes.

**Recall Number:**

D-0253-2025

**Code Information:**

Lot #: a) 24210274, Exp 01/31/2025; 24401700, Exp 04/25/2025; b) 24251067, Exp 03/25/2025; 24421733, Exp 06/03/2025; c) 24261384, Exp 03/24/2025; 24370127, Exp 04/28/2025.

**Product Description:**

Morphine Sulfate 5 mg per 0.25 mL Oral Syringe, Delivers: 0.25 mL, Oral Solution, Rx Only, Mfg by: Hikma, Pkg by: Safecor Health, LLC, Columbus, OH 43204, NDC: a) 00406800312, b) 00406800330, c) 00054051750.

**Product Quantity:**

12390 Oral Syringes

**Reason for Recall:**

Defective Delivery System: Leakage observed after oral solution was repackaged into unit-dose syringes.

**Recall Number:**

D-0254-2025

**Code Information:**

Lot #s: a) 24220672, Exp 02/19/2025; 24280145, Exp 03/18/2025; 24240711, Exp 03/19/2025; b) 24180729, Exp 01/23/2025; 25030427, Exp 07/17/2025; c) 24360865, 24360864, Exp 03/31/2025; 24480235, Exp 06/21/2025.