Enforcement Report - Week of August 6, 2025

Class II Drugs Event

Event ID:
97053

Product Type:
Drugs

Status:
Ongoing

Date Terminated:
N/A

Recall Initiation Date:
07/11/2025

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
07/31/2025

Initial Firm Notification of Consignee or Public:
Press Release

Recalling Firm:
Nostrum Laboratories, Inc.
705 E Mulberry St
Bryan, OH 43506-1432
United States

Distribution Pattern:
nationwide within the United States

Associated Products

Product Description:
Sucralfate Tablets, USP 1 gram, packaged in a) 100-count bottles NDC 29033-0003-01, and b) 500-count bottles, NDC 29033-0003-05), Rx Only, Manufactured by: Nostrum Laboratories, Inc., Kansas City, MO 64120.

Product Quantity:
60,608 bottles

Reason for Recall:
CGMP Deviations: The recalling firm filed for Chapter 11 in September 2024. As a result, it cannot monitor the quality program and hence cannot assure that products meet the identity, strength, quality, and purity characteristics that they are purported or represented to possess, rendering the products adulterated.

Recall Number:
D-0547-2025

Code Information:
All Lots within expiry dates.

Class II Drugs Event

Event ID:
97182

Product Type:
Drugs

Status:
Ongoing

Date Terminated:
N/A

Recall Initiation Date:
07/02/2025

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
07/28/2025

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Lupin Pharmaceuticals Inc.
5801 Pelican Bay Blvd Suite 500
Naples, FL 34108-2755
United States

Distribution Pattern:
Nationwide in the US

Associated Products

Product Description:
Amlodipine and Benazepril HCl Capsules USP 2.5 mg/10 mg, 100 Capsules bottle, Rx Only, Manufactured for: Lupin Pharmaceuticals, Inc., Naples, FL, 34108, United States, Manufactured by: Lupin Limited, Goa 103 722, INDIA, NDC 68180-755-01.

Product Quantity:
7668 bottles

Reason for Recall:
Labeling: Incorrect or Missing Lot and/or Exp Date: released with wrong expiry date as Feb.2027 instead of Jan.2027

Recall Number:
D-0542-2025

Code Information:
Lot GB01616, expiration 2/28/2027

Class II Drugs Event

Event ID:
97215

Product Type:
Drugs

Status:
Ongoing

Date Terminated:
N/A

Recall Initiation Date:
07/09/2025

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
07/30/2025

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Strides Pharma, Inc.
1 Ram Ridge Rd
Chestnut Ridge, NY 10977-6714
United States

Distribution Pattern:
Product was distributed nationwide within the United States

Associated Products

Product Description:
Cinacalcet Tablets 90 mg, 30-count bottles, Rx only, Manufactured by: Strides Pharma Science Ltd. Puducherry, India; Distributed by: Strides Pharma Inc. East Brunswick, NJ 08816, NDC 64380-885-04

Product Quantity:
6,672 bottles

Reason for Recall:
Failed Dissolution Specifications.

Recall Number:
D-0546-2025

Code Information:
Lot #: 7715893A, Exp. Date 12/31/2027

Class II Drugs Event

Event ID:
97219

Product Type:
Drugs

Status:
Ongoing

Date Terminated:
N/A

Recall Initiation Date:
07/05/2025

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
07/29/2025

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
FDC Limited
B-8 MIDC Industrial Area Waluj District
Aurangabad, Maharashtra State
India

Distribution Pattern:
U.S Nationwide.

Associated Products

Product Description:
Timolol Maleate Ophthalmic Solution USP, 0.5%, Sterile, 5mL bottles, Rx only, Manufactured by: FDC Limited, Waluj, Aurangabad, Maharashtra, India, Distributed by: Rising Pharmaceuticals Inc, New Jersey, NDC 64980-514-05.

Product Quantity:
154,176 bottles

Reason for Recall:
Defective Container: spike of the cap becomes lodged in the nozzle of the product bottle.

Recall Number:
D-0543-2025

Code Information:
Lot#: 083L061, Exp.: 11/2025.

Class II Drugs Event

Event ID:
97220

Product Type:
Drugs

Status:
Ongoing

Date Terminated:
N/A

Recall Initiation Date:
07/10/2025

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
07/30/2025

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Pfizer Inc.
235 East 42nd Street
New York, NY 10017-5703
United States

Distribution Pattern:
Nationwide in the USA

Associated Products

Product Description:
Bicillin L-A (penicllin G benzathine injectable suspension), 1,200,000 units per 2 mL, 2 mL-vial, Rx Only, Distributed by Pfizer Inc., New York, NY 10001. Made in Austria, Carton NDC - 60793-701-10, Syringe NDC - 60793-701-02

Product Quantity:
50,855 2 mL vials

Reason for Recall:
CGMP Deviations; particulates identified during visual inspection

Recall Number:
D-0544-2025

Code Information:
Lots: HJ3235, Exp 09/30/26; GL2954, HP6222, Exp, 01/31/27; HR9967, Exp 05/31/27; HP6232, LT5190,Exp 09/30/27; HP6228, Exp 10/31/27;

Product Description:
Bicillin L-A (penicillin G benzathine injectable suspension), 2,400,000 units per 4 mL, 4ml-vial, Rx Only, Distributed by Pfizer Inc., New York, NY 10001, Made in Austria, Carton NDC- 60793-702-10 , Syringe NDC-60793-702-04

Product Quantity:
19,279 vials

Reason for Recall:
CGMP Deviations; particulates identified during visual inspection

Recall Number:
D-0545-2025

Code Information:
Lots GT2598, GT2599, Exp 09/30/26; HK2909, Exp 02/28/27; HR9969, Exp 04/30/27; HR9984, Exp 08/31/27.

Class II Drugs Event

Event ID:
97294

Product Type:
Drugs

Status:
Ongoing

Date Terminated:
N/A

Recall Initiation Date:
07/22/2025

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
07/31/2025

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Hikma Pharmaceuticals USA Inc.
2 Esterbrook Ln
Cherry Hill, NJ 08003-4002
United States

Distribution Pattern:
Distributed Nationwide in the USA

Associated Products

Product Description:
Lorazepam Injection, USP, 2 mg/mL, 25 x 1mL vials/carton, Rx Only, Manufactured by: Hikma Berkeley Heights, NJ 07922, NDC# 0641-6044-25

Product Quantity:
382,775 1mL vials

Reason for Recall:
Failed Impurities/Degradation Specifications: An out-of-Specification for total related compounds

Recall Number:
D-0551-2025

Code Information:
Lot # K24118, exp. date 10/31/2026