

Enforcement Report - Week of April 17, 2024

Class I Drugs Event

Event ID:
94025

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
02/15/2024

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
04/08/2024

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Eugia US LLC
279 Princeton Hightstown Rd
East Windsor NJ United States

Distribution Pattern:
Nationwide in the USA

Associated Products

<p>Product Description: Methocarbamol Injection, USP 1000mg/10mL, (100mg/mL), 10 mL Single-Dose Vial packed 25 vials per carton, Rx Only, Mfd. in India for: Eugia US LLC. E. Windsor, NJ 08520, NDC 55150-223-10</p> <p>Product Quantity: 1,552 10ml x 25/carton</p> <p>Reason for Recall: Presence of Particulate Matter</p> <p>Recall Number: D-0440-2024</p> <p>Code Information: Lot #: 3MC23011, Exp 11/30/2026</p>
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Class II Drugs Event

Event ID:
94271

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
03/21/2024

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
04/05/2024

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Lupin Pharmaceuticals Inc.
Harborplace Tower 111 S Calvert St Fl 21st
Baltimore MD United States

Distribution Pattern:
Nationwide within the United States

Associated Products

Product Description:
 Rifampin Capsules USP, 300mg, 30-count bottles, Rx only, Manufactured for: Lupin Pharmaceuticals, Inc. Baltimore, Maryland 21202, Manufactured by: Lupin Limited Aurangabad 431 210 India, NDC 6818-0659-06

Product Quantity:
 26,352 bottles

Reason for Recall:
 Subpotent Drug

Recall Number:
 D-0437-2024

Code Information:
 Lot #: A201064, Exp. Date March 2024

Class II Drugs Event

Event ID: 94294	Product Type: Drugs
Status: Ongoing	Date Terminated:
Recall Initiation Date: 03/28/2024	Voluntary / Mandated: Voluntary: Firm initiated
Center Classification Date: 04/08/2024	Initial Firm Notification of Consignee or Public: Letter
Recalling Firm: Teva Pharmaceuticals USA, Inc 400 Interpace Pkwy Bldg A Parsippany NJ United States	
Distribution Pattern: Nationwide in the USA	

Associated Products

Product Description:
 Isotretinoin Capsules, USP 40mg, 30-count 3x10 blister packs per carton, Rx Only, Manufactured For: Teva Pharmaceuticals USA, Inc., Parsippany, NJ 07054, Blister Pack NDC 0591-2436-45, Carton NDC 0591-2436-15

Product Quantity:
 5,304 3x10-cartons

Reason for Recall:
 Superpotent Drug: The 3-month stability result for assay was found to be above specification limit

Recall Number:
 D-0439-2024

Code Information:
 Lot #: 100044259, Exp 06/30/2025.

Class II Drugs Event

Event ID: 94296	Product Type: Drugs
Status: Ongoing	Date Terminated:
Recall Initiation Date: 03/27/2024	Voluntary / Mandated: Voluntary: Firm initiated

Center Classification Date:
04/05/2024

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
NATCO Pharma Limited
Pharma Division, Kothur Village
Rangareddy India

Distribution Pattern:
Nationwide in the US

Associated Products

<p>Product Description: Lansoprazole Delayed-Release Capsules USP, 15 mg, Acid reducer 24 Hour, Treats Frequent Heartburn, 14 capsules per bottle, Manufactured by: Natco Pharma Limited Kothur- 509 228, India, Distributed by: Rising Pharma Holdings, Inc. East Brunswick, NJ. 08816. NDC 16571-742-41</p> <p>Product Quantity: 30 bottles</p> <p>Reason for Recall: CGMP Deviations</p> <p>Recall Number: D-0438-2024</p> <p>Code Information: Lot#: 411988, Exp date: 05/31/2025</p>
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