

Enforcement Report - Week of December 20, 2023

Class II Drugs Event

Event ID:

93482

Product Type:

Drugs

Status:

Ongoing

Date Terminated:
Recall Initiation Date:

11/22/2023

Voluntary / Mandated:

Voluntary: Firm initiated

Center Classification Date:

12/13/2023

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:

Product was distributed to 3 wholesale/distributor accounts.

Associated Products

Product Description:

Penicillamine Tablets USP 250 mg, 100-count bottle, Rx Only, Manufactured for: Lupin Pharmaceuticals, Inc. Baltimore, MD 21202 Manufactured by: Lupin Limited, Nagpur-441 108, India, NDC# 70748-153-01

Product Quantity:
Reason for Recall:

Failed Dissolution Specifications

Recall Number:

D-0148-2024

Code Information:

Lot # M200498, Exp. June 2024

Class II Drugs Event

Event ID:

93542

Product Type:

Drugs

Status:

Ongoing

Date Terminated:
Recall Initiation Date:

12/04/2023

Voluntary / Mandated:

Voluntary: Firm initiated

Center Classification Date:

12/14/2023

Initial Firm Notification of Consignee or Public:

Letter

Recalling Firm:

SUN PHARMACEUTICAL INDUSTRIES INC
2 Independence Way
Princeton NJ United States

Distribution Pattern:

Nationwide

Associated Products

Product Description:

Liothyronine Sodium Tablets, USP 5 mcg, 100-count bottle, Rx Only, Distributed by: Sun Pharmaceutical Industries, Inc. Cranbury, NJ 08512

Manufactured by: Sun Pharmaceutical Industries Ltd. Survey No. 259/15, Dadra-396 191, (U.T. of D & NH), India. NDC 62756-589-88

Product Quantity:

96,192 bottles

Reason for Recall:

Failed Impurities/Degradation Specifications

Recall Number:

D-0150-2024

Code Information:

Lot DND0059A Expires 12/2023 Lot DND0060A Expires 12/2023 Lot DND0061A Expires 12/2023 Lot DND0062A Expires 01/2024 Lot DND0063A Expires 01/2024 Lot DND0064A Expires 01/2024 Lot DND0065A Expires 01/2024 Lot DND0180A Expires 01/2024 Lot DND0181A Expires 01/2024 Lot DND0182A Expires 01/2024 Lot DND0183A Expires 01/2024 Lot DND0184A Expires 01/2024 Lot DND0597A Expires 02/2024

Class III Drugs Event

Event ID:

93429

Product Type:

Drugs

Status:

Ongoing

Date Terminated:**Recall Initiation Date:**

11/20/2023

Voluntary / Mandated:

Voluntary: Firm initiated

Center Classification Date:

12/13/2023

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

Siegfried Barbera, SL
Ronda De St Maria 158
Barbera Del Valles Spain

Distribution Pattern:

Nationwide

Associated Products

Product Description:

Votrient (pazopanib) 200 mg tablets, 120-count bottle, Rx Only, Manufactured by: Siegfried Barbera, S.L., Barbera del Valles, Spain, Distributed by: Novartis Pharmaceuticals Corp., East Hanover, N.J. 07936, NDC 0078-1077-66

Product Quantity:

2016

Reason for Recall:

Failed Dissolution Specifications

Recall Number:

D-0149-2024

Code Information:

Lot# ME2713; Exp. 02/2025 Lot # MF8286, ML1860; Exp. 04/2025