Enforcement Report - Week of December 28, 2022

Class II Drugs Event

Event ID:
91279

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
12/07/2022

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
12/23/2022

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 by major distribution chains nationwide.

Associated Products

Product Description:
Quinapril Tablets USP, 20 mg (90 pack), Rx Only, Manufactured for: Lupin Pharmaceuticals, Inc. Baltimore, Maryland 21202, by: Lupin Limited, Goa 403 722 India, NDC# 68180-558-09

Product Quantity:
23,736

Reason for Recall:
CGMP Deviations: Detection of N-Nitroso-quinapril impurity above the acceptable daily intake limit.

Recall Number:
D-0089-2023

Code Information:
Lot #: G102929, Exp 04/2023

Product Description:
Quinapril Tablets USP, 40 mg (90 pack), Rx Only, Manufactured for: Lupin Pharmaceuticals, Inc. Baltimore, Maryland 21202, by: Lupin Limited, Goa 403 722 India, NDC# 68180-554-09

Product Quantity:
30,612 bottles

Reason for Recall:
CGMP Deviations: Detection of N-Nitroso-quinapril impurity above the acceptable daily intake limit.

Recall Number:
D-0088-2023

Code Information:
Lot #: G100533, G100534, Exp. 12/2022; G203071, Exp. 03/2024

Class II Drugs Event

Event ID:
91311

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
12/01/2022

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
12/19/2022

Initial Firm Notification of Consignee or Public:

Recalling Firm:
SUN PHARMACEUTICAL INDUSTRIES INC
2 Independence Way
Princeton NJ United States

Distribution Pattern:
Nationwide within the United States

Associated Products

Product Description:
Oxcarbazepine Tablets 600mg, packaged in a) 100- count bottles (NDC 62756-185-88), b) 500-count bottles (NDC 62756-185-13), c)1000-count bottles (NDC 62756-185-18), Rx Only, Distributed by: Sun Pharmaceutical Industries, Inc. Cranbury, NJ 08512, Manufactured by: Sun Pharmaceutical Industries Limited Halol-Baroda Highway, Halol-389 350, Gujarat, India.

Product Quantity:
Lot HAC1474A: 4296 Bottles, Lot HAC1474B: 145 Bottles, Lot HAC1503A: 2124 Bottles

Reason for Recall:
Presence of foreign substance

Recall Number:
D-0085-2023

Code Information:
a) Lot HAC1474A, Expires 03/2023 b) Lot HAC1503A, Expires 03/2023 c) Lot HAC1474B, Expires 03/2023

Class II Drugs Event

Event ID:
91319

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
12/16/2022

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
12/22/2022

Initial Firm Notification of Consignee or Public:

Recalling Firm:
Aurolife Pharma, LLC
2400 US Highway 130
Dayton NJ United States

Distribution Pattern:
Nationwide in the USA and Puerto Rico.

Associated Products

Product Description:
Glycopyrrolate Tablets, USP, 1 mg, 100 tablets, Rx Only, Distributed by: Aurobindo Pharma USA, Inc., East Windsor, NJ 08520, NDC 13107-014-01

Product Quantity:
7344 bottles

Reason for Recall:
Failed Impurities/Degradation Specifications

Recall Number:
D-0087-2023

Code Information:
Lots: 01422002A1, Expiry: 12/2023; 01421078A3, Expiry: 09/2023