Enforcement Report - Week of July 12, 2023

Class II Drugs Event

Event ID:
92584

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
06/26/2023

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
07/06/2023

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Strides Pharma Inc.
2 Tower Center Blvd Ste 1102
East Brunswick NJ United States

Distribution Pattern:
Nationwide in the USA.

Associated Products

Product Description:
Losartan Potassium Tablets, USP, 25 mg, 1000 film coated tablets per bottle, Rx Only, Manufactured by: Vivimed Life Sciences Private Limited, Plot No. 101, 102, 107 & 108, SIDCO Pharmaceutical Complex, Alathur, Kanchipuram- 603 110, Tamilnadu, India, NDC 64380-933-08

Product Quantity:
2,700 HDPE Bottles

Reason for Recall:
Presence of Foreign Substance: Presence of a small piece of blue plastic embedded in the tablet.

Recall Number:
D-0895-2023

Code Information:
Lot#: 7901903A, exp. date 04/2024

Class II Drugs Event

Event ID:
92607

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
06/23/2023

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
06/30/2023

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Amerisource Health Services LLC
2550 John Glenn Ave Ste A
Columbus OH United States

Distribution Pattern:
Nationwide in the USA

Associated Products

Product Description:
Tizanidine Tablets, USP, 4 mg, 100 Tablets (10 tablets x 10 unit dose blister packs) per carton, Rx Only, Packaged and Distributed by: American Health Packaging, Columbus, Ohio 43217, NDC 68084-645-01 (carton), barcode (01) 003 68084 645 11 2.

Product Quantity:
4,971 cartons

Reason for Recall:
Failed Dissolution Specifications: this repackaged product was recalled by the manufacturer, Dr. Reddy's Laboratories, Inc., due to out of specification results for dissolution.

Recall Number:
D-0892-2023

Code Information:
Lot 1004835, Exp 7/31/2023

Class II Drugs Event

Event ID:
92625

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
06/26/2023

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
07/05/2023

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Preferred Pharmaceuticals, Inc.
1250 N Lakeview Ave Ste O
Anaheim CA United States

Distribution Pattern:
Nationwide within the United States

Associated Products

Product Description:
Tizanidine Hydrochloride Tablet 4mg, packaged in a) 20 count-bottles (NDC 68788-7781-2), b)30-count bottles (NDC: 68788-7781-3), c) 60-count bottles, (NDC: 68788-7781-6), d) 90-count bottles (NDC: 68788-7781-9), e) 120-count bottles (NDC: 68788-7781-8), Rx only, Mfg: Dr. Reddy's Laboratories Limited.

Product Quantity:
541 Bottles

Reason for Recall:
Failed Stability Specifications

Recall Number:
D-0894-2023

Code Information:
Lot#: a) H1621S, Exp: 12/31/2023; b) H2321C, Exp: 12/31/2023; c) H0421B, Exp: 12/31/2023; d) H1721E, H1921T, H3121M, Exp: 12/31/2023, e) H2021G, Exp: 12/31/2023