Enforcement Report - Week of February 21, 2024

Class II Drugs Event

Event ID:
93929

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
02/09/2024

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
02/13/2024

Initial Firm Notification of Consignee or Public:
E-Mail

Recalling Firm:
The Harvard Drug Group LLC dba Major Pharmaceuticals and Rugby Laboratories
341 Mason Rd
La Vergne TN United States

Distribution Pattern:
The product was distributed nationwide within the United States.

Associated Products

Product Description:
HydrALAZINE Hydrochloride Tablets, USP 10mg, packaged in 100-count (10x10 blister cards), Lot T04680, Rx only, Manufactured for Heritage Pharmaceuticals, Inc. Eatontown, NJ, Distributed by Major Pharmaceuticals Livonia MI. NDC 0904-6440-61

Product Quantity:
8,198 units

Reason for Recall:
an out of specification result obtained during routine stability testing for Impurities. There is a remote possibility that use of this product could cause a medically reversible or transient adverse health consequences.

Recall Number:
D-0324-2024

Code Information:
Lot #: T04680, Exp. Date 6/2024

Class II Drugs Event

Event ID:
93940

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
01/22/2024

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
02/15/2024

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
IntegraDose Compounding Services LLC
719 Kasota Ave Se
Minneapolis MN United States

Distribution Pattern:
MN

Associated Products

Product Description:
Vasopressin 2 Units/2 mL in 0.9% Sodium Chloride Sterile Syringe for Injection, Concentration: 1 Unit/mL, 2 mL Syringe, Rx Only, 719 Kasota Ave SE, Minneapolis, MN, Compounded Drug Not for Resale. Office Use Only, NDC 71139-0190-1.

Product Quantity:
1,299 syringes

Reason for Recall:
Sub-potent drug: failure to maintain potency through the duration of the labeled expiration/beyond-use date.

Recall Number:
D-0325-2024

Code Information:
Lot #s: 20230929VAS-2, Exp. 02/29/2024; 20231004VAS-2, Exp. 04/01/2024; Lot 20231010VAS-2,Exp. 04/07/2024; Lot 20231013VAS-2, Exp. 04/10/2024

Class III Drugs Event

Event ID:
93867

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
01/25/2024

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
02/12/2024

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

Associated Products

Product Description:
Nortrel (norethindrone and ethinyl estradiol tablets USP) 0.5/35, packaged in cartons, each carton contains 3 blister cards, each card contains 28 tablets, Rx only, TEVA PHARMACEUTICALS USA, INC., North Wales, PA 19454, NDC 0555-9008-67

Product Quantity:
12,916 cartons

Reason for Recall:
Discoloration: discolored tablets (shades of blue) mixed in with the white inert remainder tablets.

Recall Number:
D-0321-2024

Code Information:
Lot #: 100042978, Exp 7/31/2024

Product Description:
Nortrel 7/7/7 (norethindrone and ethinyl estradiol tablets USP- triphasic regimen), packaged in cartons, each carton contains 6 blister cards, each card contains 28 tablets, Rx only, TEVA PHARMACEUTICALS USA, INC., North Wales, PA 19454, NDC 0555-9012-58

Product Quantity:
19,824 cartons

Reason for Recall:
Discoloration: discolored tablets (shades of blue) mixed in with the white inert remainder tablets.

Recall Number:
D-0322-2024

Code Information:
Lot #: 100040731, Exp 7/31/2024