Enforcement Report - Week of January 10, 2018

Class I Drugs Event

Event ID:
78073

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
09/20/2017

Voluntary / Mandated:
Voluntary: Firm Initiated

Center Classification Date:
01/04/2018

Initial Firm Notification of Consignee or Public:
Press Release

Recalling Firm:
Natures Supplement
2525 N Dixie Hwy
Lake Worth FL United States

Distribution Pattern:
Florida

Associated Products

Product Description:
Enhanced Vegetal Vigra 200 mg Capsules, 8 count bottles, Manufacturer: Hand-shaking (Int'l) Cop. USA, ADD: Hand-shaking Mansion, the 5th Ave., Stanford, USA --- UPC# 8931028556885

Product Quantity:
308 bottles

Reason for Recall:
Marketed without an Approved NDA/ANDA; FDA analysis found product to be tainted with Sildenafil.

Recall Number:
D-0149-2018

Code Information:
All lots, Exp. 02/23/2020

Class I Drugs Event

Event ID:
78332

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
10/20/2017

Voluntary / Mandated:
Voluntary: Firm Initiated

Center Classification Date:
01/04/2018

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Pfizer Inc.
235 E 42nd St
New York NY United States

Distribution Pattern:
Nationwide in the USA

Associated Products

Product Description:
diphenoxylate hydrochloride and atropine sulfate tablets, USP, 2.5 mg/0.025 mg, a) 100-count bottle (NDC 59762-1061-1), b) 1000-count bottle (NDC 59762-1061-2), Rx Only, Distributed by: Greenstone LLC. Peapack, NJ 07977

Product Quantity:
183437 bottles

Reason for Recall:
SUPERPOTENT: Weight variations resulting in tablets that are sub and super potent

Recall Number:
D-0150-2018

Code Information:
Lots: a) R83962, R93347, R93348, R93349, R93350, R93351, R93352, Exp. 2021 OCT 31; S57831, S57832, S57834, Exp. 2021 NOV 30 b) R93356, R93357, R93358, R97310, Exp. 2021 OCT 31.

Class I Drugs Event

Event ID:
78396

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
10/27/2017

Voluntary / Mandated:
Voluntary: Firm Initiated

Center Classification Date:
01/04/2018

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Fresenius Kabi USA, LLC
5200 Corporate Pkwy
Wilson NC United States

Distribution Pattern:
Nationwide in the USA

Associated Products

Product Description:
Midazolam Injection, USP, Preservative Free, 2 mg / 2 mL (1 mg / mL), 24 X 2mL Prefilled single-use syringes per carton, Rx only, Fresenius Kabi Lake Zurich, IL 60047, NDC 76045-001-20

Product Quantity:
203136 syringes

Reason for Recall:
Labeling: Label MIX-UP. Blister Packages, Labeled as Midazolam injection, USP, 2 mg / 2 ml, Containing Syringes of Ondansetron Injection, USP, 4 mg / 2 mL

Recall Number:
D-0152-2018

Code Information:
Lot: 6400048

Class II Drugs Event

Event ID:
78332

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
10/20/2017

Voluntary / Mandated:
Voluntary: Firm Initiated

Center Classification Date:
01/04/2018

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Pfizer Inc.
235 E 42nd St
New York NY United States

Distribution Pattern:
Nationwide in the USA

Associated Products

Product Description:
Zoloft (sertraline HCl) tablets 25 mg* 30-count bottle, Rx only, Distributed by Roerig Division of Pfizer Inc., NY, NY, 10017 NDC 0049-4960-30

Product Quantity:
1972 bottles

Reason for Recall:
SUPERPOTENT: Weight variations resulting in tablets that are sub and super potent

Recall Number:
D-0151-2018

Code Information:
Lot: S84026