Enforcement Report - Week of June 23, 2021

Class II Drugs Event

Event ID:
87923

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
05/11/2021

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
06/11/2021

Initial Firm Notification of Consignee or Public:
Press Release

Recalling Firm:
DASH XCLUSIVE
610 S Verdugo Rd Apt 31
Glendale CA United States

Distribution Pattern:
Nationwide within the United States

Associated Products

Product Description:
Imperia Elita Vitaccino Coffee, 10 g sachets, 15 sachets per box, Global Beauty Technologies, Manufactured for: Imperia-Elita Ltd. & Co, KG D-35435 Wettenberg

Product Quantity:
25 pieces (boxes containing 15 sachets)

Reason for Recall:
Marketed without an approved NDA/ANDA: FDA analysis determined presence of the pharmaceutical ingredients Sibutramine and Fluoxetine

Recall Number:
D-0628-2021

Code Information:
All Lots

Class II Drugs Event

Event ID:
88070

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
06/09/2021

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
06/16/2021

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
World Source Llc
145 Oakwoods Dr
Wakefield RI United States

Distribution Pattern:
Product was distributed to two hospitals in NY.

Associated Products

Product Description:
QiYu Hand Sanitizer Gel, ethanol, 500 mL bottles (pump), Manufacturer Guangzhou Minghui Cosmetics Co., Ltd., Baiyun District, Guanzhou

Product Quantity:
6,300 bottles

Reason for Recall:
Subpotent

Recall Number:
D-0632-2021

Code Information:
Manufacturer's lot # 20200320, exp. date March 2022 WorldSource LLC, Item # TCM004

Class III Drugs Event

Event ID:
88041

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
06/04/2021

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
06/11/2021

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Dr. Reddy's Laboratories, Inc.
107 College Rd E
Princeton NJ United States

Distribution Pattern:
Nationwide within the United States

Associated Products

Product Description:
Atorvastatin Calcium Tablets, USP 10 mg, 500-count bottles, Rx Only, Dr. Reddy's Mfd. By: Dr. Reddy's Laboratories Limited, Bachupally, 500-090 India, NDC 55111-121-05.

Product Quantity:
5984 bottles

Reason for Recall:
Failed Impurities/Degradation Specifications: due to presence of ATV cyclo IP and FP impurities

Recall Number:
D-0629-2021

Code Information:
Lot #: C905064, C905065, Exp. Date 07/2021

Class III Drugs Event

Event ID:
88091

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
06/09/2021

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
06/16/2021

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
AVKARE Inc.
615 N 1st St
Pulaski TN United States

Distribution Pattern:
Distributed in Los Angeles California

Associated Products

Product Description:
Phytonadione Tablets 5 mg, Rx Only, 30 Tablets (3x10) Unit Dose, Manufactured for: AvKARE Pulaski, TN 38478. NDC 50268-661-13

Product Quantity:
10 cartons

Reason for Recall:
Failed Impurities Specification: Out of specification when measuring the impurity degradant D level.

Recall Number:
D-0631-2021

Code Information:
Lot: 38617 Exp. 10/2022