Enforcement Report - Week of September 13, 2023

Class II Drugs Event

Event ID:
92868

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
08/11/2023

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
09/07/2023

Initial Firm Notification of Consignee or Public:
Letter

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

Distribution Pattern:
Affected product was distributed to nineteen (19) consignees within the united states.

Associated Products

Product Description:
Sodium Fluoride 1.1%, SODIUM FLUORIDE Prescription Dental Toothpaste, 5000 ppm Fluoride Plus Mild Cleaning System Spearmint NET WT. 1.8 OZ. (51g), Rx only, NDC 42291-741-51, Manufactured for: AvKARE Pulaski, TN 38478

Product Quantity:
35,184 tubes

Reason for Recall:
Cases of Sodium Fluoride 1.1% Prescription Dental Toothpaste may contain cartons labeled as Capsaicin Cream 0.025% but contain correctly labeled tubes of Sodium Fluoride 1.1% Prescription Dental Toothpaste

Recall Number:
D-1146-2023

Code Information:
Lot # P23025 Exp. 02/24/2025

Product Description:
Capsaicin Cream 0.025%, External Analgesic Cream, Penetrating Pain Relief, NET WT. 2.1 OZ. (60g) NDC 50268-195-60, Manufactured for: AvKARE, Pulaski, TN 38478

Product Quantity:
35,184 cartons

Reason for Recall:
Product mix-up: Cartons labeled Capsaicin Cream 0.025% may contain tubes of Sodium Fluoride 1.1% Prescription Dental Toothpaste

Recall Number:
D-1147-2023

Code Information:
Lot # P22078; Exp. 11/30/2024

Class III Drugs Event

Event ID:
92706

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
07/18/2023

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
09/06/2023

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Ascend Laboratories, LLC
339 Jefferson Rd Ste 101
Parsippany NJ United States

Distribution Pattern:
The recall product was distributed nationwide.

Associated Products

Product Description:
Fosfomycin Tromethamine Granules for Oral Solution, 3 g single- dose sachet, Rx only, Manufactured by: Alkem Laboratories Ltd., INDIA, Distributed by: Ascend Laboratories, LLC, Parsippany, NJ 07054, NDC# 67877-749-57

Product Quantity:
99,516 sachets

Reason for Recall:
Failed Impurities/Degradation Specifications: Out-of-specification results observed for the organic impurities test at 6 months, RT Stability.

Recall Number:
D-1145-2023

Code Information:
Lot #22121970, 22122158, 22121971, 22122189, 22122190, 22122277, 22122278, Exp June 2024; 22122521, 22122522, 22122523, Exp July 2024; 22123328, 22123329, 22123330, Exp September 2024.

Class III Drugs Event

Event ID:
92897

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
08/16/2023

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
09/06/2023

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Esperion
3891 Ranchero Dr Ste 150
Ann Arbor MI United States

Distribution Pattern:
Nationwide USA

Associated Products

Product Description:
Nexlizet (bempedoic acid and ezetimibe), 180ng/18mg, 30 tablets, Rx only, Manufactured for: Esperion Therapeutics, Inc, Ann Arbor, MI 48108, NDC 72426-818-03

Product Quantity:
45,240 bottles

Reason for Recall:
Failed dissolution specifications: below specification results at stability 12-month

Recall Number:

D-1143-2023

Code Information:
Lot# 1904872, Exp 1/31/2025; 1950377, Exp 6/30/2025

Class III Drugs Event

Event ID:
92900

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
08/14/2023

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
09/06/2023

Initial Firm Notification of Consignee or Public:
E-Mail

Recalling Firm:
Caplin Steriles Limited
895 & 897 Survey No
Gummidipoondi India

Distribution Pattern:
Nationwide in Tennessee

Associated Products

Product Description:
Milrinone Lactate Injection, USP 20mg/20 mL (1mg/mL), packaged in 10 x 20 mL vials per carton, NDC 72485-502-01 (single vial), Rx only, Distributed by: Armas Pharmaceuticals, Inc. Freehold, NJ 07728(USA) Manufactured by: Caplin Steriles Limited, India, NDC 72485-502-10

Product Quantity:
19, 820 vials

Reason for Recall:
Failed Impurities/Degradation Specifications

Recall Number:
D-1144-2023

Code Information:
Lot #: 90000228

Not Yet Classified Drugs Event

Event ID:
92950

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
08/25/2023

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Marlex Pharmaceuticals, Inc.
65 Lukens Dr
New Castle DE United States

Distribution Pattern:
Product was distributed to 5 distributors who may have further distributed the product nationwide.

Associated Products

Product Description:
Digoxin 0.125mg NDC# 10135-0747-01

Product Quantity:
94/100 count bottles

Reason for Recall:
Labeling: Label Mix-Up

Recall Number:

Code Information:
Lot # E3810, expiration date 02/25

Product Description:
Digoxin 0.25mg NDC 10135-0748-01

Product Quantity:
94/100 count bottles

Reason for Recall:
Labeling: Label Mix-Up

Recall Number:

Code Information:
E3811, expiration date 02/25