Enforcement Report - Week of April 1, 2020

Class II Drugs Event

Event ID:
85207

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
03/10/2020

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
03/23/2020

Initial Firm Notification of Consignee or Public:
Telephone

Recalling Firm:
Matthew 7:25 Inc dba Thrive Pharmacy
2683 Saint Johns Bluff Rd S Ste 135
Jacksonville FL United States

Distribution Pattern:
Florida

Associated Products

Product Description:
Buprexone Banana cream 6-0.6 mg Troche, supplied in plastic troche molds with cardboard outer sleeve, Thrive Pharmacy 2863 St Johns Bluff RD. South # 135 Jacksonville, Florida

Product Quantity:
71 troches

Reason for Recall:
Subpotent Drug

Recall Number:
D-1052-2020

Code Information:
Lot: 190918B Exp. 03/16/2020

Product Description:
Buprenorphine Watermelon 8 mg Troche, supplied in plastic troche molds with cardboard outer sleeve, Thrive Pharmacy 2863 St Johns Bluff RD. South # 135 Jacksonville, Florida

Product Quantity:
403 troches

Reason for Recall:
Subpotent Drug

Recall Number:
D-1053-2020

Code Information:
Lot: 191203F Exp. 05/31/2020

Product Description:
Buprenorphine Black Cherry 2 mg Troche, supplied in plastic troche molds with cardboard outer sleeve, Thrive Pharmacy 2863 St Johns Bluff RD. South # 135 Jacksonville, Florida

Product Quantity:
89 troches

Reason for Recall:
Subpotent Drug

Recall Number:
D-1054-2020

Code Information:
Lot: 191217A Exp. 06/14/2020

Class II Drugs Event

Event ID:
85224

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
03/16/2020

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
03/26/2020

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Glaxosmithkline Consumer Healthcare Holdings
184 Liberty Corner Rd
Warren NJ United States

Distribution Pattern:
Product was distributed throughout the United States, including Puerto Rico.

Associated Products

Product Description:
Ibuprofen 200 mg Chlorpheniramine Maleate 4mg Phenylephrine 10 mg tablets. Advil Allergy & Congestion Relief 10 and 20 count blister tray in carton NDC 0573-0196-10, item # F00573019610C, 10 ct. blister NDC 0573-0196-20, item # F00573019620C, 20 ct. blister NDC 0573-0196-10, item # F00573019610R, 10 ct. blister

Product Quantity:
471,024 blisters

Reason for Recall:
Labeling: Lacks Warning or Rx Legend- Certain lots does not include required safety warning information in the Drug Facts Panel.

Recall Number:
D-1065-2020

Code Information:
Batch/Lot Numbers: R73995, exp. date 07/31/2021 R53915, exp. date 05/31/2020 9324HA, exp. date 07/31/2021 9327HA, exp. date 07/31/2021

Product Description:
Ibuprofen 200 mg liquid filled capsules Advil Liqui-Gel Minis, 160 count bottle NDC 0573-1769-89 NDC 0573-1769-95

Product Quantity:
446,628 bottles

Reason for Recall:
Labeling: Lacks Warning or Rx Legend- Certain lots does not include required safety warning information in the Drug Facts Panel.

Recall Number:
D-1066-2020

Code Information:
Batch/Lot Numbers: R53074, exp. date 10/31/2020, item # F00573176989, 160 ct. R53075, exp. date 10/31/2020, item # F00573176989, 160 ct. R53076, exp. date 11/30/2020, item # F00573176989, 160 ct. R53077, exp. date 11/30/2020, item # F00573176989, 160 ct. R53081, exp. date 11/30/2020, item # F00573176989, 160 ct. R53901, exp. date 02/28/2021, item # F00573176989, 160 ct. R53902, exp. date 03/31/2021, item # F00573176989, 160 ct. R62780, exp. date 06/30/2021, item # F00573176989, 160 ct.

Product Description:
Ibuprofen 50 mg per 1.25 mL Oral Suspension Advil Infant Concentrated Drops White Grape 0.75 oz. and 1 oz. bottles NDC 0573-0191-75 (0.75 oz.) NDC 0573-0191-50 (1 oz.)

Product Quantity:
151,056 bottles

Reason for Recall:
Labeling: Lacks Warning or Rx Legend- Certain lots does not include required safety warning information in the Drug Facts Panel.

Recall Number:
D-1067-2020

Code Information:
Batch/Lot # R73761, exp. date 01/31/2021, Item # F00573019175, 0.75 oz. R74936, exp. date 02/28/2021, Item # F00573019175, 0.75 oz. R56290, exp. date 03/31/2020, Item # F00573019150, 1 oz. R60959, exp. date 02/28/2021, Item # F00573019150, 1 oz. R78826, exp. date 11/30/2021, Item # F00573019150, 1 oz. 9335UA, exp. date 01/31/2021, item # F00573019175A - Co-package 9336UA, exp. date 02/28/2021, item # F00573019175A - Co-package

Product Description:
Advil Sinus Congestion and Pain/Advil Allergy and Congestion Relief 8 pc with $1 IRC (mixed product display - only Advil Allergy & Congestion is impacted). NDC # 0573-2161-14 SKU# F00573216114A (original lot # R73995) Co-packaged Batch/Lot # 0045DB, 9327VB, 0017DA & 9353WA

Product Quantity:
566 blister packs

Reason for Recall:
Labeling: Lacks Warning or Rx Legend- Certain lots does not include required safety warning information in the Drug Facts Panel.

Recall Number:
D-1068-2020

Code Information:
Batch/Lot # 0045DB, exp. date 07/31/2021, original lot # R73995 9327VB, exp. date 07/31/2021, original lot # R73995 0017DA, exp. date 07/31/2021, original lot # R73995 9353WA, exp. date 07/31/2021, original lot # R73995

Product Description:
Advil Liqui-Gel Mini 160+20+20 CT (e-commerce) NDC # 0573-1715-59 SKU# F00573171559 (original lot # R53074) Co-packaged Batch/Lot # 0198FR & 3188FRB

Product Quantity:
4,104 bottles

Reason for Recall:
Labeling: Lacks Warning or Rx Legend- Certain lots does not include required safety warning information in the Drug Facts Panel.

Recall Number:
D-1069-2020

Code Information:
Batch/Lot # Lot # 0198FR, original lot # R53074, exp. date 10/31/2020 Lot # 3188FRB, original lot # R53074, exp. date 10/31/2020

Class II Drugs Event

Event ID:
85226

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
03/19/2020

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
03/25/2020

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Jubilant Draximage Inc
16751 Rte Transcanadienne
Kirkland Canada

Distribution Pattern:
Product was distributed throughout the United States.

Associated Products

Product Description:
DRAXIMAGE DTPA (KIT FOR THE PREPARATION OF TECHNETIUM TC 99M PENTETATE INJECTION), 20 mg vial, Rx only, Manufactured for: Jubilant Draximage, Inc., Kirkland, Quebec, Canada, NDC 65174-288-05, 67175-288-30

Product Quantity:
473 kits of 30 vials

Reason for Recall:
Failed Stability Specifications

Recall Number:
D-1062-2020

Code Information:
Lot # 8K143, Exp 10/31/2020.

Class II Drugs Event

Event ID:
85235

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
03/06/2020

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
03/25/2020

Initial Firm Notification of Consignee or Public:
E-Mail

Recalling Firm:
Nostrum Laboratories Inc
1800 N Topping Ave
Kansas City MO United States

Distribution Pattern:
TN, MO

Associated Products

Product Description:
Theophylline (Anhydrous) Extended-Release Tablets, 400 mg, 100-count bottle, Rx Only, Manufactured by: Nostrum Laboratories, Inc., Kansas City, MO 64120, NDC 29033-001-01.

Product Quantity:
4722 bottles

Reason for Recall:
CGMP Deviations: poor manufacturing practices resulted in Labeling: Incorrect or Missing Lot and/or Exp Date, product incorrectly labeled with incorrect lot and expiration date.

Recall Number:
D-1059-2020

Code Information:
Lot: THE190501, Exp 11/2022

Class II Drugs Event

Event ID:
85302

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
03/19/2020

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
03/25/2020

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
PAI Holdings, LLC. dba Pharmaceutical Associates Inc
1700 Perimeter Rd
Greenville SC United States

Distribution Pattern:
Nationwide in the USA.

Associated Products

Product Description:
Nystatin Oral Suspension, USP, 100,000 units per mL, Cherry/Peppermint Flavor, 16 fl oz (473 mL) bottle, Rx ONLY, pai Pharmaceutical Associates, Inc., Greenville, SC 29605; NDC 0121-0810-16.

Product Quantity:
7416 bottles

Reason for Recall:
SubPotent Drug: Low out-of-specification results for assay testing.

Recall Number:
D-1060-2020

Code Information:
Lot: BE85, Exp. 11/2020

Class III Drugs Event

Event ID:
85072

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
11/15/2019

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
03/20/2020

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Grato Holdings, Inc.
201 Apple Blvd
Woodbine IA United States

Distribution Pattern:
U.S.A. Nationwide, Israel

Associated Products

Product Description:
Colostat, Homeopathic Remedy, 1 fl. oz. (30 mL) per bottle, 20% Ethanol, Dist. by Energique, Inc., 201 Apple Blvd., Woodbine, IA 51579, NDC 44911-0411-1

Product Quantity:
659 bottles

Reason for Recall:
Labeling mix-up - Indications on product label are incorrect.

Recall Number:
D-1049-2020

Code Information:
Lot # Z56673

Class III Drugs Event

Event ID:
85273

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
03/23/2020

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
03/24/2020

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Mylan Pharmaceuticals Inc.
781 Chestnut Ridge Rd
Morgantown WV United States

Distribution Pattern:
U.S.A. Nationwide

Associated Products

Product Description:
Tacrolimus Capsules, USP 5mg, 100-count bottle, Rx only, Mylan Pharmaceuticals Inc., Morgantown, WV 26505, NDC 0378-2047-01

Product Quantity:
3,816 botlles

Reason for Recall:
Presence of foreign tablet/capsule - Potential presence of commingled one Tacrolimus 1 mg capsule in 5 mg bottles.

Recall Number:
D-1057-2020

Code Information:
Lot # 3105410, 3106268, Exp 9/2020