Enforcement Report - Week of March 10, 2021

Class II Drugs Event

Event ID:
87193

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
01/20/2021

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
02/26/2021

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Aurobindo Pharma USA Inc.
279 Princeton Hightstown Rd
East Windsor NJ United States

Distribution Pattern:
TX, CA, GA, PA

Associated Products

Product Description:
Famotidine Tablets USP 40mg, 1,000-count bottles, Rx only, Distributed by: Aurobindo Pharma USA, Inc. 279 Princeton-Hightstown Road East Windsor, NJ 08520 Made in India, NDC 65862-860-99

Product Quantity:
1296 bottles

Reason for Recall:
Presence of foreign tablets/capsules: Famotidine 20mg and ibuprofen 400mg tablets were found in a lot of famotidine 40mg.

Recall Number:
D-0290-2021

Code Information:
Lot #: P2000467, Exp 7/2022

Class II Drugs Event

Event ID:
87330

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
02/15/2021

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
03/03/2021

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Teva Pharmaceuticals USA
400 Interpace Pkwy
Parsippany NJ United States

Distribution Pattern:
Nationwide, including Puerto Rico

Associated Products

Product Description:
Metoclopramide Injection USP, 10 mg/2 mL (5 mg/mL), 25x2mL Single Dose Vials, Rx only, Distributed by Teva Pharmaceuticals, USA, Inc., Parsippany, NJ Vial NDC 0703-4502-01 (vial) NDC# 0703-4502-04 (tray)

Product Quantity:
9,452 cartons

Reason for Recall:
Chemical contamination; Unknown brown residue adhering to the inside of one vial.

Recall Number:
D-0297-2021

Code Information:
Lot # 31325335B, exp. date 07/2021

Class II Drugs Event

Event ID:
87373

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
02/19/2021

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
03/03/2021

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Noven Pharmaceuticals Inc
11960 Sw 144th St
Miami FL United States

Distribution Pattern:
Nationwide in the USA

Associated Products

Product Description:
Daytrana (methylphenidate transdermal system), Delivers 10 mg over 9 hours (1.1 mg/hr), Contains: 30 Patches in a foil-sealed polypropylene tray, packed in a paper carton, Rx only, Manufactured for Noven Therapeutics, LLC, Miami, FL, 33186, By Noven Pharmaceuticals, Inc., Miami, FL, 33186, NDC 68968-5552-3.

Product Quantity:
473,280 patches

Reason for Recall:
Defective Delivery System: Out of specification for mechanical peel.

Recall Number:
D-0293-2021

Code Information:
Lots #: 87579, Exp 3/2021 & 88243, Exp 7/2021.

Product Description:
Daytrana (methylphenidate transdermal system), Delivers 15 mg over 9 hours (1.6 mg/hr), Contains: 30 Patches in in a foil-sealed polypropylene tray, packed in a paper carton, Rx only, Manufactured for Noven Therapeutics, LLC, Miami, FL, 33186, By Noven Pharmaceuticals, Inc., Miami, FL, 33186, NDC 68968-5553-3.

Product Quantity:
551,670 patches

Reason for Recall:
Defective Delivery System: Out of specification for mechanical peel.

Recall Number:
D-0294-2021

Code Information:
Lots #: 87818, Exp 4/2021, 88274, Exp 5/2021 & 88531, Exp 7/2021.

Product Description:
Daytrana (methylphenidate transdermal system) Delivers 20 mg over 9 hours (2.2 mg/hr) Contains: 30 Patches in a foil-sealed polypropylene tray, packed in a paper carton, Rx only, Manufactured for Noven Therapeutics, LLC, Miami, FL, 33186, By Noven Pharmaceuticals, Inc., Miami, FL, 33186, NDC 68968-5554-3.

Product Quantity:
786,900 patches

Reason for Recall:
Defective Delivery System: Out of specification for mechanical peel.

Recall Number:
D-0295-2021

Code Information:
Lots #: 87580, Exp 4/2021, 87819, Exp 4/2021, 88244, Exp 6/2021, 88245, Exp 6/2021, 88532, Exp 06/2021 & 88533, Exp 7/2021.

Product Description:
Daytrana (methylphenidate transdermal system) Delivers 30 mg over 9 hours (3.3 mg/hr) Contains: 30 Patches in a foil-sealed polypropylene tray, packed in a paper carton, Rx only, Manufactured for Noven Therapeutics, LLC, Miami, FL, 33186, By Noven Pharmaceuticals, Inc., Miami, FL, 33186, NDC 68968-5555-3.

Product Quantity:
934,140 patches

Reason for Recall:
Defective Delivery System: Out of specification for mechanical peel.

Recall Number:
D-0296-2021

Code Information:
Lots #: 87377, Exp 3/2021, 87572, Exp 3/2021, 87581, Exp 4/2021, 87820, Exp 5/2021, 88246, Exp 6/2021, 88535, Exp 7/2021, 88536, Exp 8/2021, 88537, Exp 8/2021 & 88939, Exp 8/2021.

Class II Drugs Event

Event ID:
87411

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
02/26/2021

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
03/03/2021

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 in the USA

Associated Products

Product Description:
Progesterone Capsules, 200 mg, 100-count bottles, Rx Only, MADE IN FRANCE; Distributed by: Dr. Reddy's Laboratories, Inc., Princeton, NJ 08540; NDC 43598-350-01.

Product Quantity:
16,449 bottles

Reason for Recall:
Failed Dissolution Specifications: Out-of-specification results observed for dissolution during stability testing.

Recall Number:
D-0292-2021

Code Information:
Batch # 1399851P1, Exp 02/2021

Class III Drugs Event

Event ID:
87342

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
02/19/2021

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
03/04/2021

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Jubilant Cadista Pharmaceuticals, Inc.
207 Kiley Dr
Salisbury MD United States

Distribution Pattern:
USA nationwide, including Puerto Rico.

Associated Products

Product Description:
Methylprednisolone Tablets USP, 4 MG, packaged in a 21-count blister pack, Rx only, Jubilant Cadista Pharmaceuticals, Inc., Salisbury, MD 21801, NDC 59746-001-03

Product Quantity:
635,400 cartons

Reason for Recall:
Labeling: Illegible label: Customer complaint received of mis-alignment print of the printed dosing instructions on the blister card.

Recall Number:
D-0298-2021

Code Information:
Lot #: 20K0043P, 20K0044P, 20K0042P, Exp 08/2022; 20L0026P, 20L0027P, 20L0028P, 20L0029P, 20L0030P, Exp 09/2022

Class III Drugs Event

Event ID:
87349

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
02/22/2021

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
02/26/2021

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
SUN PHARMACEUTICAL INDUSTRIES INC
2 Independence Way
Princeton NJ United States

Distribution Pattern:
Nationwide and Australia

Associated Products

Product Description:
Cequa (cyclosporine ophthalmic solution) 0.09%, 60 Single-Use Vials (6 pouches x 10 single-use vials (0.25 mL each)), Rx only, Manufactured for Sun Pharma Global FZE by: Laboratoire Unither, Coutances, France NDC 47335-506-96

Product Quantity:
37,400 cartons/60 vials per carton

Reason for Recall:
Subpotent

Recall Number:
D-0289-2021

Code Information:
Lot 10007, exp. date 01/2022

Class III Drugs Event

Event ID:
87365

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
02/19/2021

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
03/01/2021

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:
Distributed Nationwide in the USA

Associated Products

Product Description:
Atorvastatin Calcium Tablets, 40mg, packaged in a) 90-count bottles, NDC 55111-123-90; b) 500-count bottles, NDC 55111-123-05; Rx only, Mfd By: Dr. Reddy's Laboratories Limited Srikakulam - 532 409 INDIA

Product Quantity:
10,440 90-count and 224,710 500-count bottles

Reason for Recall:
Failed Impurities/Degradation Specifications:presence of ATV cyclo IP and FP, Dihydroxy epoxy and Dieto epoxy impurities

Recall Number:
D-0291-2021

Code Information:
a) T900406, exp 3/2021 b) T000078 exp 12/2021 T000079 exp 12/2021 T000080 exp 12/2021 T000081 exp 12/2021 T000082 exp 12/2021 T000083 exp 12/2021 T000084 exp 12/2021 T000085 exp 12/2021 T000086 exp 12/2021 T000087 exp 12/2021 T000088 exp 1/2022 T000311 exp 1/2022 T000312 exp 1/2022 T000313 exp 1/2022 T000314 exp 1/2022 T000315 exp 1/2022 T000316 exp 1/2022 T000317 exp 1/2022 T000318 exp 1/2022 T000319 exp 1/2022 T000320 exp 1/2022 T000500 exp 2/2022 T000501 exp 2/2022 T000502 exp 2/2022 T000503 exp 2/2022 T000504 exp 2/2022 T000505 exp 2/2022 T000506 exp 2/2022 T000507 exp 2/2022 T000508 exp 2/2022 T000509 exp 3/2022 T000510 exp 3/2022 T000647 exp 3/2022 T000648 exp 3/2022 T000651exp 3/2022 T000652 exp 3/2022 T000653 exp 3/2022 T000654 exp 3/2022 T000875 exp 4/2022 T000876 exp 4/2022 T000877 exp 4/2022 T000878 exp 4/2022 T000879 exp 4/2022 T000880 exp 4/2022 T000881 exp 4/2022 T000882 exp 4/2022 T000883 exp 4/2022 T000884 exp 4/2022 T001120 exp 5/2022 T001121 exp 5/2022 T001122 exp 5/2022 T001124 exp 5/2022 T001125 exp 5/2022 T001126 exp 5/2022 T001127 exp 5/2022 T001128 exp 5/2022 T001129 exp 5/2022 T001130 exp 5/2022 T001260 exp 5/2022 T001261 exp 5/2022 T900506 exp 4/2021 T900507 exp 4/2021 T900508 exp 4/2021 T900655 exp 5/2021 T900656 exp 5/2021 T900657

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