Enforcement Report - Week of November 6, 2019

Class II Drugs Event

Event ID:
83887

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
09/27/2019

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
11/05/2019

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Taro Pharmaceuticals U.S.A., Inc.
3 Skyline Dr
Hawthorne NY United States

Distribution Pattern:
U.S.A. Nationwide

Associated Products

Product Description:
Ibuprofen Oral Suspension USP, 100 mg/5 mL, 4 fl. oz., (118 mL), Rx only, Manufactured by: Taro Pharmaceuticals, Inc., Brampton, Ontario, Canada L6T 1C1, Distributed by: Taro Pharmaceuticals U.S.A., Inc., Hawthorne, NY 10532, NDC 51672-1385-8

Product Quantity:
138,886 bottles

Reason for Recall:
Presence of Foreign Substance: Ibuprofen Oral Suspension USP may have small particles of an inert plastic material introduced during manufacturing.

Recall Number:
D-0298-2020

Code Information:
Lot #: K779030125, Exp 10/19; D873031376, Exp 3/20; J871233188, Exp 9/20; L866934047, Exp 11/20; A973134376, 12/20; D967635229, Exp 3/21

Product Description:
Ibuprofen Oral Suspension USP, 100 mg/5 mL, One Pint, (473 mL), Rx only, Manufactured by: Taro Pharmaceuticals Inc., Brampton, Ontario, Canada L6T 1C1, Distributed by: Taro Pharmaceuticals U.S.A., Inc., Hawthorne, NY 10532, NDC 51672-1385-9

Product Quantity:
639,325 bottles

Reason for Recall:
Presence of Foreign Substance: Ibuprofen Oral Suspension USP may have small particles of an inert plastic material introduced during manufacturing.

Recall Number:
D-0299-2020

Code Information:
Lot #: J78402968, J784129698, Exp 9/19; K765129698, K765229698, K765329698, K769329698, K778829698, K778929698, Exp 10/19; A887230568, A887330568, A887430568, Exp 12/19; B865430568, B865530568, B865630568, B869530568, B869630568, Exp 1/20; D866431198, D866531198, D866631198, D866731198, D866831198, D866931198, D872631198, D872731198, D872831198, D872931198, D873031834, Exp 3/20; E875331834, E875431834, E883831834, E883931834, E884031834, E884131834, Exp 4/20; F865131834, Exp 5/20; G879432436, G879532436, G879632436, G879732436, G879832436, G879932436, G881632436, G882232436, Exp 6/20; H865232436, H865332436, H870832436, Exp 7/20; I885233156, I885333156, I885433156, I885533156, I885633156, I885733164, Exp 8/20; J868533164, J868633164, J868733164, J868833164, J868933164 and J869033164, Exp 9/20; L866434042, L866534043, L866634044, L866734045, L866834046,

L866934422, Exp 11/20; A973134748, A973234423, A973334424, A979534425, A979634426, A979734427, A979834428, Exp 12/20; B974034749, B974134750, B974234751, B974334752, B974434753, Exp 1/21

Product Description:
Children's Ibuprofen Oral Suspension USP, 100 mg per 5 mL, Berry Flavor, Dye-Free, Alcohol Free, 4 fl. oz. (120 mL), Distributed by: Taro Pharmaceuticals U.S.A., Inc., Hawthorne, NY 10532, NDC 51672-2130-8

Product Quantity:
182,986 bottles

Reason for Recall:
Presence of Foreign Substance: Ibuprofen Oral Suspension USP may have small particles of an inert plastic material introduced during manufacturing.

Recall Number:
D-0300-2020

Code Information:
Lot #: E875131667, E875231667, Exp 4/20; J871033189, J871133189, Exp 9/20; A972934375, A973034375, Exp 12/20

Product Description:
Children's Ibuprofen Oral Suspension USP, 100 mg per 5 mL, Berry Flavor, Dye-Free, Alcohol Free, 8 fl. oz.(240 mL), Distributed by: Taro Pharmaceuticals, U.S.A., Inc., Hawthorne, NY 10532, NDC 51672-2130-1

Product Quantity:
5,190 bottles

Reason for Recall:
Presence of Foreign Substance: Ibuprofen Oral Suspension USP may have small particles of an inert plastic material introduced during manufacturing.

Recall Number:
D-0301-2020

Code Information:
Lot #: J871033187, Exp 9/20

Product Description:
Children's Ibuprofen Oral Suspension USP, 100 mg per 5 mL, Berry Flavor, Dye-Free, Alcohol Free, 4 fl. oz.(120 mL), Distributed by: Winco Foods, LLC, Boise, ID 83704, NDC 67091-321-04

Product Quantity:
5,280 bottles

Reason for Recall:
Presence of Foreign Substance: Ibuprofen Oral Suspension USP may have small particles of an inert plastic material introduced during manufacturing.

Recall Number:
D-0302-2020

Code Information:
Lot #: A972834374, Exp 12/20

Class II Drugs Event

Event ID:
84006

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
10/10/2019

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
10/28/2019

Initial Firm Notification of Consignee or Public:
Press Release

Recalling Firm:
Innoveix Pharmaceuticals Inc

3790 Arapaho Rd
Addison TX United States

Distribution Pattern:
Nationwide within the United States

Associated Products

Product Description:
Lyophilized Chorionic Gonadotropin 11,000 USP Units for Injection, Rx Only, Compounded by: Innoveix Addison, TX 75001 800-370-1910

Product Quantity:
3905 vials

Reason for Recall:
Lack of Sterility Assurance.

Recall Number:
D-0157-2020

Code Information:
Lot #: INX 530 Exp. 11/6/19; INX 535 Exp. 11/15/19; INX 540 Exp. 2/1/20; INX 545 Exp. 2/15/20; INX 550 Exp. 3/9/20; INX 555 Exp. 3/26/20; INX 560 Exp. 5/3/20; INX 565 Exp. 5/18/20; INX 570 Exp. 6/28/20; INX 575 Exp. 7/18/20

Product Description:
Lyophilized Human Chorionic Gonadotropin 5,000 USP Units For injection, Rx Only, Compounded by: Innoveix Addison, TX 75001 800-370-1910

Product Quantity:
413 vials

Reason for Recall:
Lack of Sterility Assurance.

Recall Number:
D-0158-2020

Code Information:
Lot #: INX 910 Exp. 2/7/20; INX 915 Exp. 3/12/20

Product Description:
Lyophilized Sermorelin w/ GHRP2 3 mg For injection, Rx Only, Compounded by: Innoveix Addison, TX 75001 800-370-1910

Product Quantity:
1747 vials

Reason for Recall:
Lack of Sterility Assurance.

Recall Number:
D-0159-2020

Code Information:
Lots: SER 925 Exp. 11/4/19; SER 930 Exp. 11/18/19; SER 935 Exp. 2/21/20; SER 400 Exp. 4/1/20; SER 405 Exp. 5/11/20; SER 410 Exp. 7/15/20

Product Description:
Lyophilized Human Chorionic Gonadotropin 5,500 USP Units For injection, Rx Only, Compounded by: Innoveix Addison, TX 75001 800-370-1910

Product Quantity:
290 vials

Reason for Recall:
Lack of Sterility Assurance.

Recall Number:
D-0160-2020

Code Information:
Lots: INX 50 Exp. 5/1/20

Class II Drugs Event

Event ID:
84039

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
10/18/2019

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
10/28/2019

Initial Firm Notification of Consignee or Public:
Letter

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

Distribution Pattern:
Nationwide within the United States

Associated Products

Product Description:
Prasugrel Tablets 5 mg, 30-count bottles, Rx only, Manufactured for: Mylan Pharmaceuticals Inc. Morgantown, WV 26505 U.S.A, NDC 0378-5185-93

Product Quantity:
4,272 bottles

Reason for Recall:
Failed Dissolution Specification: Low out of specification dissolution results.

Recall Number:
D-0155-2020

Code Information:
Lot #: 3089793, Exp. Date September 2020

Class II Drugs Event

Event ID:
84071

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
10/22/2019

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
10/28/2019

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Glenmark Pharmaceuticals Inc., USA
750 Corporate Dr
Mahwah NJ United States

Distribution Pattern:
Nationwide in the USA

Associated Products

Product Description:
Estradiol Vaginal Inserts USP, 10 mcg, packaged in a) 8-count Vaginal Inserts (with disposable applicators) per carton (NDC 68462-711-71) and b) 18-count Vaginal Inserts (with disposable applicators) per carton (NDC 68462-711-88), Rx only, Manufactured by: Glenmark Pharmaceuticals Ltd., Colvale-Bardez, Goa 403 513, India; Manufactured for: Glenmark Pharmaceuticals Inc., Mahwah, NJ 07430.

Product Quantity:
216,840 cartons

Reason for Recall:
Defective Delivery System: complaints for difficulty in pushing the plunger of the applicator.

Recall Number:
D-0156-2020

Code Information:
Batch numbers: a) 20180514, 20180544, Apr-2020; 20180545, 20180546, 20180588, May-2020; 20190003, Jun-2020; b) 20180515, 20180543, Apr-2020; 20180587, May-2020

Class II Drugs Event

Event ID:
84081

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
10/17/2019

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
10/28/2019

Initial Firm Notification of Consignee or Public:
Letter

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

Distribution Pattern:
CO, MO

Associated Products

Product Description:
AVKARE Ranitidine Hydrochloride Capsules 150 mg 500 Capsules Rx Only NDC 42291-735-50 UPC 342291735507 Manufactured for: AvKARE, Inc. Pulaski, TN 38478

Product Quantity:
7293 bottles

Reason for Recall:
CGMP Deviations: Impurity N-nitrosodimethylamine (NDMA) found in API

Recall Number:
D-0164-2020

Code Information:
Lot 17708 Exp.11/30/2019 Lot 18459 Exp.03/31/2020 Lot 19033 Exp.07/31/2020 Lot 19032 Exp.07/31/2020 Lot 19031 Exp.06/30/2020 Lot 20204 Exp.09/30/2020 Lot 20205 Exp.09/30/2020 Lot 20663 Exp.10/31/2020 Lot 20664 Exp.11/30/2020 Lot 20665 Exp.11/30/2020 Lot 20666 Exp.11/30/2020 Lot 21039 Exp.12/31/2020 Lot 21920 Exp.04/30/2021

Product Description:
AVKARE Ranitidine Hydrochloride Capsules 300 mg 500 Capsules Rx Only NDC 42291-736-50 UPC 342291736504 Manufactured for: AvKARE, Inc. Pulaski, TN 38478

Product Quantity:
1351 bottles

Reason for Recall:
CGMP Deviations: Impurity N-nitrosodimethylamine (NDMA) found in API

Recall Number:
D-0165-2020

Code Information:
Lot 17709 Exp.01/31/2020 Lot 18460 Exp.02/29/2020 Lot 19853 Exp.09/30/2020 Lot 22362 Exp.11/30/2020 Lot 22579 Exp.11/30/2020

Class III Drugs Event

Event ID:
83868

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
09/23/2019

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
10/29/2019

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
AuroMedics Pharma LLC
279 Princeton Hightstown Rd
East Windsor NJ United States

Distribution Pattern:
Nationwide within the United States

Associated Products

Product Description:
Ranitidine Tablets USP,150 mg, 8-count bottles, Distributed by: Dolgencorp, LLC, 100 Mission Ridge, Goodlettsville, TN 37073 Made in India NDC 55910-092-79

Product Quantity:
69696 bottles

Reason for Recall:
CGMP DEVIATIONS: One lot of Ranitidine Tablets USP, 150 mg is being recalled because some bottles were empty.

Recall Number:
D-0166-2020

Code Information:
Lot #: NBSB19001DA3, Exp. date 02/2021

Class III Drugs Event

Event ID:
83959

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
09/27/2019

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
10/30/2019

Initial Firm Notification of Consignee or Public:
E-Mail

Recalling Firm:
Arbor Pharmaceuticals Inc.
6 Concourse Pkwy Ste 1800
Atlanta GA United States

Distribution Pattern:
Nationwide in the US

Associated Products

Product Description:
Testosterone Cypionate Injection, USP, 2000 mg/10 mL, 1 mL Vial, Single-Dose, Rx only, Mfd. for: Wilshire Pharmaceuticals, Inc. Atlanta, GA 30328. NDC 52536-625-01

Product Quantity:
67934 units

Reason for Recall:
Labeling:Label Mix-up: Shipper Carton labelled Testosterone Cypionate Injection, USP, 200mg/mL, 1 ml single-dose vials, found to contain shelf cartons labelled as Testosterone Cypionate Injection USP, 200mg/mL, 10 ml multi-dose vials which contain Testosterone Cypionate Injection USP, 200mg/mL,1mL single-does vials

Recall Number:
D-0167-2020

Code Information:
lot# 23803.002B, Exp 07/2020; 23803.005A, Exp 01/2021

Class III Drugs Event

Event ID:
84082

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
10/17/2019

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
10/28/2019

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Sandoz Inc
100 College Rd W
Princeton NJ United States

Distribution Pattern:
Nationwide in the U.S.

Associated Products

Product Description:
Bimatoprost Ophthalmic Solution 0.03%, Rx Only, For Topical Application to the Upper Eyelid, Sterile, a) 3 mL bottle NDC 0781-6206-93, b) 5 mL bottle NDC 0781-6206-75, Manufactured by Alcon Laboratories, Inc. Fort Worth, Texas 76134 for Sandoz Inc., Princeton, NJ 08540, Product of Argentina.

Product Quantity:
346,929 bottles

Reason for Recall:
Labeling: Incorrect or missing package insert.

Recall Number:
D-0161-2020

Code Information:
Lot #s: a) 290635FA, 290635FB, Exp. 11/30/2019; 293230F, Exp. 6/30/2020; 294628F, 301337F, Exp. 11/30/2020; 304451FA, Exp. 1/31/2021. b) 290636FA, 290636FB, 290636FC, Exp. 11/30/2019; 293233FA, 293233FB, Exp. 5/31/2020; 293234FA, 293234FB, Exp. 6/30/2020; 294630F, 301338FA, 301338FB, 309426F, Exp. 11/30/2020; 304455FA, 304455FB Exp. 2/28/2021; 304883F, Exp. 4/30/2021; 312790F, Exp. 5/31/2021.

Product Description:
Neomycin and Polymyxin B Sulfates and Dexamethasone Ophthalmic Suspension, Rx Only, Sterile, 5 mL bottle, Manufactured by Alcon Laboratories, Inc. Fort Worth, Texas 76134 for Sandoz Inc. Princeton, NJ 08540, NDC 61314-630-06

Product Quantity:
346,929 bottles

Reason for Recall:
Labeling: Incorrect or missing package insert.

Recall Number:
D-0162-2020

Code Information:
Lot #s: 287880F, 287881F, Exp. 10/31/2019; 290555F, Exp. 11/30/2019; 293389F, Exp. 2/29/2020; 290556F, 290557F, 293386F, 293387F, Exp. 3/31/2020; 293388F, 293390F, Exp. 5/31/2020; 293391F, Exp. 6/30/2020; 293392F, Exp. 7/31/2020; 295342F, 298823F, Exp. 8/31/2020; 295344F, 295345F, 295346F, Exp. 10/31/2020; 295347F, 304496F, Exp. 11/30/2020; 298825F, Exp. 12/31/2020; 304495F, 304497F, Exp. 01/31/2021; 304963F, Exp. 3/31/2021; 304966F, Exp. 4/30/2021; 304964F, Exp. 5/31/2021.

Product Description:
Gatifloxacin Ophthalmic Solution 0.5%, For Use in the Eyes Only, Rx Only, Sterile, 2.5 mL bottle, Manufactured by Alcon Laboratories, Inc. Fort Worth, Texas 76134 for Sandoz Inc. Princeton, NJ 08540, Product of India, NDC 61314-672-25.

Product Quantity:
76,644 bottles

Reason for Recall:
Labeling: Incorrect or missing package insert.

Recall Number:
D-0163-2020

Code Information:
Lot #s: 289210F, Exp. 10/31/2019; 290632F, Exp. 10/31/2020

Class III Drugs Event

Event ID:
84106

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
10/21/2019

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
10/28/2019

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Nephron Pharmaceuticals Corporation dba Nephron Sterile Compounding Center
4500 12th Street Ext
West Columbia SC United States

Distribution Pattern:
Nationwide in the U.S.

Associated Products

Product Description:
PF-Succinylcholine Chloride Injection, USP 20 mg/mL (200 mg/10 mL), Rx Only, Single-Dose Container, 5 x 10 mL pre-filled syringes, Nephron 503B Outsourcing Facility 4500 12th St. Ext West Columbia, SC 29172, NDC 69374-919-10.

Product Quantity:
19,390 syringes

Reason for Recall:
Incorrect labeling: Incorrect or missing lot and/or exp date

Recall Number:
D-0154-2020

Code Information:
Lots: SU9079A, SU9079B, Exp 4/5/2020

Class III Drugs Event

Event ID:
84107

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
10/22/2019

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
10/28/2019

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Apotex Inc.
150 Signet Drive
North York Canada

Distribution Pattern:
IL, MS, NJ, OH, TX

Associated Products

Product Description:
Atorvastatin Calcium Tablets, USP 40 mg*, 1,000 count bottles, Rx Only, Manufactured by: Apotex Inc. Toronto, Ontario Canada M9L 1T9 Manufactured for: Apotex Corp. Weston, Florida 33326 NDC 60505-2580-8

Product Quantity:
1968 bottles

Reason for Recall:
Presence of Foreign Tablets/Capsules: a single tablet of Pravastatin 40 mg found in bottle of Atorvastatin Calcium 40 mg.

Recall Number:
D-0153-2020

Code Information:
Lot: RC5439 Exp. 03/2022

Not Yet Classified Drugs Event

Event ID:
83812

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
09/16/2019

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:

Initial Firm Notification of Consignee or Public:
Press Release

Recalling Firm:
FITOTERAPIA USA, INC
500 NW 141st Ave
Pembroke Pines FL United States

Distribution Pattern:
FL, PA, NY and Canada

Associated Products

Product Description:
Mero Macho Artificially Flavored Passion Fruit Vitamin C Liquid Supplement, 2.04 fl oz (60 mL), Manufactured By: Zaphiredelcor Cia, LTDA. Pasaje Luis Tola 9A Y Calle Juan Campuzano, Sector Carcelen, Quito-Ecuador 170302 Distributed By: Fitoterapia USA Inc., 500 NW 141 Ave. 112 Pembroke Pines, FL 33028

Product Quantity:
19000 bottles

Reason for Recall:
Marketed without an approved NDA/ANDA: Product found to be tainted with Tadalafil.

Recall Number:

Code Information:
Lot #: ZD-160-18, Exp. 09-07-2019; ZD-078-19 Exp. 27-04-2020