Enforcement Report - Week of November 6, 2019

Class II Drugs Event
Event ID: 83887
Status: Ongoing

Recall Initiation Date: 09/27/2019
Center Classification Date: 11/05/2019

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

Distribution Pattern:
U.S.A. Nationwide

Associated Products

<table>
<thead>
<tr>
<th>Product Description</th>
<th>Product Quantity</th>
<th>Reason for Recall</th>
<th>Recall Number</th>
</tr>
</thead>
<tbody>
<tr>
<td>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</td>
<td>138,866 bottles</td>
<td>Presence of Foreign Substance: Ibuprofen Oral Suspension USP may have small particles of an inert plastic material introduced during manufacturing.</td>
<td>D-0298-2020</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Product Description</th>
<th>Product Quantity</th>
<th>Reason for Recall</th>
<th>Recall Number</th>
</tr>
</thead>
<tbody>
<tr>
<td>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</td>
<td>839,325 bottles</td>
<td>Presence of Foreign Substance: Ibuprofen Oral Suspension USP may have small particles of an inert plastic material introduced during manufacturing.</td>
<td>D-0299-2020</td>
</tr>
</tbody>
</table>

https://www.accessdata.fda.gov/scripts/ires/index.cfm?action=print.getPrintData&ts=1062019104114
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:

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:
Innoxe Pharmaceuticals Inc

https://www.accessdata.fda.gov/scripts/ires/index.cfm?action=print.getPrintData&ts=1062019104114
### Associated Products

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<tr>
<th>Product Description</th>
<th>Reason for Recall</th>
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</tr>
</thead>
<tbody>
<tr>
<td>Lyophilized Chorionic Gonadotropin 11,000 USP Units for Injection, Rx Only, Compounded by: Innoveix Addison, TX 75001 800-370-1910</td>
<td>Lack of Sterility Assurance.</td>
<td>D-0157-2020</td>
<td>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. 3/3/20; INX 565 Exp. 5/18/20; INX 570 Exp. 6/28/20; INX 575 Exp. 7/18/20</td>
</tr>
<tr>
<td>Lyophilized Human Chorionic Gonadotropin 5,000 USP Units For injection, Rx Only, Compounded by: Innoveix Addison, TX 75001 800-370-1910</td>
<td>Lack of Sterility Assurance.</td>
<td>D-0158-2020</td>
<td>Lot #: INX 910 Exp. 2/7/20; INX 915 Exp. 3/12/20</td>
</tr>
<tr>
<td>Lyophilized Sermorelin w/ GHRP2 3 mg For injection, Rx Only, Compounded by: Innoveix Addison, TX 75001 800-370-1910</td>
<td>Lack of Sterility Assurance.</td>
<td>D-0159-2020</td>
<td>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</td>
</tr>
<tr>
<td>Lyophilized Human Chorionic Gonadotropin 5,500 USP Units For injection, Rx Only, Compounded by: Innoveix Addison, TX 75001 800-370-1910</td>
<td>Lack of Sterility Assurance.</td>
<td>D-0160-2020</td>
<td>Lots: INX 50 Exp. 5/1/20</td>
</tr>
</tbody>
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### Class II Drugs Event

https://www.accessdata.fda.gov/scripts/ires/index.cfm?action=printData&ts=1062019104114

3/10
Event ID: 84039
Status: Ongoing
Recall Initiation Date: 10/18/2019
Center Classification Date: 10/28/2019
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
Status: Ongoing
Recall Initiation Date: 10/22/2019
Center Classification Date: 10/28/2019
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, 20180568, May-2020; 20190003, Jun-2020; b) 20180515, 20180543, Apr-2020; 20180597, May-2020

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Class II Drugs Event

<table>
<thead>
<tr>
<th>Event ID:</th>
<th>84081</th>
</tr>
</thead>
<tbody>
<tr>
<td>Status:</td>
<td>Ongoing</td>
</tr>
</tbody>
</table>

Recall Initiation Date:
10/17/2019

Center Classification Date:
10/28/2019

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

Distribution Pattern:
CO, MO

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Associated Products

<table>
<thead>
<tr>
<th>Product Description:</th>
<th>AVKARE Ranitidine Hydrochloride Capsules 150 mg 500 Capsules Rx Only NDC 42291-735-50 UPC 342291735507 Manufactured for: AvKARE, Inc. Pulaski, TN 38478</th>
</tr>
</thead>
<tbody>
<tr>
<td>Product Quantity:</td>
<td>7293 bottles</td>
</tr>
<tr>
<td>Reason for Recall:</td>
<td>CGMP Deviations: Impurity N-nitrosodimethylamine (NDMA) found in API</td>
</tr>
<tr>
<td>Recall Number:</td>
<td>D-0164-2020</td>
</tr>
<tr>
<td>Code Information:</td>
<td>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</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Product Description:</th>
<th>AVKARE Ranitidine Hydrochloride Capsules 300 mg 500 Capsules Rx Only NDC 42291-736-50 UPC 342291736504 Manufactured for: AvKARE, Inc. Pulaski, TN 38478</th>
</tr>
</thead>
<tbody>
<tr>
<td>Product Quantity:</td>
<td>1351 bottles</td>
</tr>
<tr>
<td>Reason for Recall:</td>
<td>CGMP Deviations: Impurity N-nitrosodimethylamine (NDMA) found in API</td>
</tr>
<tr>
<td>Recall Number:</td>
<td>D-0165-2020</td>
</tr>
<tr>
<td>Code Information:</td>
<td>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</td>
</tr>
</tbody>
</table>
Class III Drugs Event
Event ID: 83868
Status: Ongoing
Recall Initiation Date: 09/23/2019
Center Classification Date: 10/29/2019
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: 69966 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
Status: Ongoing
Recall Initiation Date: 09/27/2019
Center Classification Date: 10/30/2019
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-dose vials

**Recall Number:** D-0167-2020

**Code Information:**
lot# 23803,002B, Exp 07/2020; 23803,005A, Exp 01/2021

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### Class III Drugs Event

**Event ID:** 84082

**Status:** Ongoing

**Recall Initiation Date:** 10/17/2019

**Center Classification Date:** 10/28/2019

**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:**

**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

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https://www.accessdata.fda.gov/scripts/ires/index.cfm?action=printgetData&ts=1062019104114
### Class III Drugs Event

**Event ID:**
84106

**Product Type:**
Drugs

**Status:**
Ongoing

**Date Terminated:**

**Voluntary / Mandated:**
Voluntary: Firm initiated

**Recall Initiation Date:**
10/21/2019

**Center Classification Date:**
10/28/2019

**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:**
11/6/2019

Status: Ongoing

Recall Initiation Date: 10/22/2019

Center Classification Date: 10/28/2019

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

Status: Ongoing

Recall Initiation Date: 09/16/2019

Center Classification Date:

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