Enforcement Report - Week of October 2, 2019

Class I Drugs Event

Event ID:
83792

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
09/12/2019

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
10/01/2019

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Shire Human Genetic Therapies, Inc.
300 Shire Way
Lexington MA United States

Distribution Pattern:
Product was distributed throughout the United States.

Associated Products

Product Description:
Natpara (parathyroid hormone) for Injection, 25 mcg/dose, 2 pack cartridges, Rx only, For subcutaneous use only, Manufactured for: Shire-NPS Pharmaceuticals, Inc., Lexington, MA NDC 68875-0202-02

Product Quantity:
1,556

Reason for Recall:
Defective Delivery System: potential risk of rubber stopper particles clogging the needle and leading to underdosing

Recall Number:
D-0035-2020

Code Information:
08569357, exp 4/30/2020; 07983652, 08544833, exp 6/30/2021

Product Description:
Natpara (parathyroid hormone) for Injection, 50 mcg, 2 pack medication cartridges, Rx only, For subcutaneous use only, Manufactured for: Shire-NPS Pharmaceuticals, Inc., Lexington, MA NDC 68875-0203-02

Product Quantity:
13,897

Reason for Recall:
Defective Delivery System: potential risk of rubber stopper particles clogging the needle and leading to underdosing

Recall Number:
D-0036-2020

Code Information:
06628461, exp 8/31/2020 06661658, 07110136, 7164106, 07761970 exp 10/31/2020 07630717, 08689119, exp 12/31/2020 07769458, exp 4/30/2021 07983643, 08003758, exp 6/30/2021 08214790, exp 8/31/2020 NY17002DA, NY17002DB, exp 6/30/2020

Product Description:
Natpara (parathyroid hormone) for Injection, 75 mcg, 2 pack medication cartridges, Rx only, For subcutaneous use only, Manufactured for: Shire-NPS Pharmaceuticals, Inc., Lexington, MA NDC 68875-0204-02

Product Quantity:
15,075

Reason for Recall:
Defective Delivery System: potential risk of rubber stopper particles clogging the needle and leading to underdosing

Recall Number:
D-0037-2020

Code Information:
06628462, exp 5/31/2020 06651000, exp 9/30/2020 06661659, exp 6/30/2020 07110125, 07301073, exp 10/31/2020 07200435, 7/31/2020 07482211, exp 12/31/2020 07630714, exp 3/31/2021 NX170002DA, exp 12/31/2019 NX17004DA, exp 3/31/2020 NX17007DA, NX17007DB, NX17008DA exp 4/30/2020 NX17010DA, NX17012DA, exp 6/30/2020

Product Description:
Natpara (parathyroid hormone) for Injection, 100 mcg, 2 pack medication cartridges, Rx only, For subcutaneous use only, Manufactured for: Shire-NPS Pharmaceuticals, Inc., Lexington, MA

Product Quantity:
8,003

Reason for Recall:
Defective Delivery System: potential risk of rubber stopper particles clogging the needle and leading to underdosing

Recall Number:
D-0038-2020

Code Information:
06828752, exp 12/31/2019 07110118, exp 4/30/2021 07164107, exp 12/31/2019 07200436, 07301074, exp 4/30/2021 07482212, 07630715, exp 6/30/2021 07769460, exp 4/30/2021

Class II Drugs Event

Event ID:
83457

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
08/29/2019

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
09/25/2019

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Johnson Matthey Inc.
2003 Nolte Dr
West Deptford NJ United States

Distribution Pattern:
Nationwide within the United States

Associated Products

Product Description:
Fentanyl Citrate Active Pharmaceutical Ingredient, Johnson Matthey Pharmaceutical Materials 2003 Nolte Drive, West Deptford, NJ 08066-1742 (856) 384-7001.

Product Quantity:
52882.23 grams

Reason for Recall:
cGMP Deviations: Potential glass contamination

Recall Number:
D-1880-2019

Code Information:
Lot #: B0030-180101, B0030-180102, Exp. Feb 2023

Product Description:
Cisplatin Active Pharmaceutical Ingredient, Johnson Matthey Pharmaceutical Materials 2003 Nolte Drive, West Deptford, NJ 08066-1742 (856) 384-7001

Product Quantity:
26625 grams

Reason for Recall:
cGMP Deviations: Potential glass contamination

Recall Number:
D-1881-2019

Code Information:
Lot #: B0101-161102, Exp. Dec 2021

Product Description:
Oxaliplatin Active Pharmaceutical Ingredient, Johnson Matthey Pharmaceutical Materials 2003 Nolte Drive, West Deptford, NJ 08066-1742 (856) 384-7001 NDC 49821-0075

Product Quantity:
316703.32

Reason for Recall:
cGMP Deviations: Potential glass contamination

Recall Number:
D-1882-2019

Code Information:
Lot #: B0126-170701; B0126-170802; Exp. Sep 2022; B0126-180401, Exp. May 2023; B0126-180702, B0126-180803, Exp. Oct 2023

Class II Drugs Event

Event ID:
83711

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
08/29/2019

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
09/24/2019

Initial Firm Notification of Consignee or Public:
Telephone

Recalling Firm:
Preferred Pharmaceuticals, Inc
1250 N Lakeview Ave Ste O
Anaheim CA United States

Distribution Pattern:
Product was distributed to 1 physician in Gainesville Florida.

Associated Products

Product Description:
Fexofenadine HCl Tablets, 180 mg, Pkg Size 90, Mfg: Aurohealth LLC, Repackaged by Preferred Pharmaceuticals, Inc., Anaheim, CA, NDC #: 68788-6848-09

Product Quantity:
79 (90 ct.) bottles

Reason for Recall:
Failed Impurities/Degradation Specifications

Recall Number:
D-1877-2019

Code Information:
Lot #: G0219K, Exp 3/2021; C1419E, Exp 3/2021

Class II Drugs Event

Event ID:
83721

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
09/17/2019

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
09/24/2019

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Akorn, Inc.
1925 W Field Ct Ste 300
Lake Forest IL United States

Distribution Pattern:
Nationwide within the United States and Puerto Rico

Associated Products

Product Description:
Lidocaine Hydroclhoride Jelly USP, 2%, 30 mL tubes, Rx Only, Sterile, Manufactured by: Akorn, Inc., Lake Forest, IL 60045. NDC 17478-711-30

Product Quantity:
10,543 tubes

Reason for Recall:
cGMP Deviations: firm reported finding metal particulate matter in the filling room near the tube feeder during the filling operation of the product. No particulates were identified in the product, but rather were identified on the filling line.

Recall Number:
D-1878-2019

Code Information:
Lot #: 9B21A, Exp. 1/2022

Class II Drugs Event

Event ID:
83731

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
09/06/2019

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
09/20/2019

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Cardinal Health dba Specialty Pharmaceutical Services
15 Ingram Blvd
La Vergne TN United States

Distribution Pattern:
Nationwide in the U.S.

Associated Products

Product Description:
Nucala (mepolizumab) Injection, 100 mg/mL Prefilled Syringe, Single-Dose, For subcutaneous use only, Rx Only, Manufactured by GlaxoSmithKline LLC, Philadelphia, PA 19112, Distributed by GlaxoSmithKline, Research Triangle Park, NC 27709, NDC 0173-0892-42.

Product Quantity:
38 syringes

Reason for Recall:
Temperature Abuse; Product stored and shipped outside of labeled storage requirements.

Recall Number:
D-1876-2019

Code Information:
Lot #: S25X, Exp. 03/31/21

Class III Drugs Event

Event ID:
83788

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
09/12/2019

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
10/01/2019

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Pfizer Inc.
235 E 42nd St
New York NY United States

Distribution Pattern:
Nationwide in the USA

Associated Products

Product Description:
ethosuximide capsules, USP, 250 mg, 100-count bottle, Rx Only, Distributed by: Greenstone LLC Peapack, NJ 07977 Made in Netherlands. NDC 59762-2250-2

Product Quantity:
7,824 100-count bottles

Reason for Recall:
Labeling: Incorrect or Missing Lot and/or Exp Date. The expiry date on the product label is incorrect. The label states an expiry date of 09/2021 when it should be 09/2020.

Recall Number:
D-0001-2020

Code Information:
Lot #3267079A, Exp 09/2021

Product Description:
Zarontin (ethosuximide capsules, USP) 250 mg, 100-count bottle, Rx Onl,y Made in Netherlands Distributed by Parke-Davis Division of Pfizer In NY, NY 10017, NDC 0071-0237-24

Product Quantity:
7,686 100-count bottles

Reason for Recall:
Labeling: Incorrect or Missing Lot and/or Exp Date. The expiry date on the product label is incorrect. The label states an expiry date of 09/2021 when it should be 09/2020.

Recall Number:
D-0002-2020

Code Information:
Lot #3267079, Exp 09/2021

Not Yet Classified Drugs Event

Event ID:
83734

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
09/06/2019

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Darmerica, LLC
198 Wilshire Blvd
Casselberry FL United States

Distribution Pattern:
U.S.A. Nationwide

Associated Products

Product Description:
Quinacrine Dihydrochloride (98.25%), bulk API product, packaged in a) 500 g NDC# 71052-530-05; b) 50 g NDC# 71052-530-55, c) 25g NDC# 71052-530-25, Darmerica LLC 198 Wilshire Blvd Casselberry, FL 32707

Product Quantity:
1.8 kilograms

Reason for Recall:
Label Mix-Up: Product labeled as Quinacrine Dihydrochloride; however, after testing, identified as Artemisinin.

Recall Number:

Code Information:
Lot#: a) DL4654A, Exp. 04/27/21; b) DR4654, Exp. 04/27/21 c) DR4654, Exp. 04/27/21

Not Yet Classified Drugs Event

Event ID:
83809

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
08/26/2019

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:

Initial Firm Notification of Consignee or Public:
E-Mail

Recalling Firm:
EPI Health, LLC
134 Columbus St
Charleston SC United States

Distribution Pattern:
Firm recalling only from EPI Field Representatives.

Associated Products

Product Description:
minolira (minocycline hydrochloride) extended-release tablets 135 mg* Physician Sample Not for Sale 5 Tablets, Rx Only, Mfg by: Dr. Reddy's Laboratories Limited, FTO-SEZ, Process Unit-01 Devunipalavalasa Village Srikakulam (District) Andhra Pradesh, INDIA. Manufactured for: EPI Health, LLC 134 Columbus St. Charleston, SC 29403 USA. NDC 71403-102-05.

Product Quantity:
1,626 5-count bottles

Reason for Recall:
Failed Dissolution Specifications:

Recall Number:

Code Information:
Lot# T900093, Exp 11/2020