Enforcement Report - Week of September 4, 2019

Class II Drugs Event

Event ID:
83511

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
08/08/2019

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
08/29/2019

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Alkermes Inc
265 Olinger Cir
Wilmington OH United States

Distribution Pattern:
Distributed Nationwide in the USA

Associated Products

Product Description:
Vivitrol (naltrexone for extended-release injectable suspension) 380 mg/vial. Each Carton Contains: 1) One vial of 380 mg of Vivitrol, 2) One vial containing 4 mL of diluent, 3) One 5-mL prepackaged syringe, 4) One 20-gauge 1-inch needle, 5) Two 20-gauge 1.5-inch safety needles, 6) Two 20-gauge 2-inch safety needles. Rx Only. Manufactured and marketed by: Alkermes, Inc. Kit NDC: 65757-300-01

Product Quantity:
6,514 kits

Reason for Recall:
Labeling: Not Elsewhere Classified. Drug product kit recalled due to 1 inch needles being placed in the 1 1/2 inch needle cardboard sleeve labelled as administration needles. The product vial is not impacted.

Recall Number:
D-1846-2019

Code Information:
Lot 2018-3010T Exp 8/2021

Class II Drugs Event

Event ID:
83533

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
08/14/2019

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
08/28/2019

Initial Firm Notification of Consignee or Public:
Press Release

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

Distribution Pattern:
Nationwide in the USA and Puerto Rico.

Associated Products

Product Description:
RELPAX (eletriptan HBr) tablets, 40 mg, packaged in a) 6-count (1 card x 6 tablets) per carton, NDC 0049-2340-45; b) 12-count (2 cards x 6 tablets) per carton, NDC 0049-2340-05, Rx only, Made in Ireland, Distributed by Pfizer Roerig, Division of Pfizer Inc., NY, NY 10017.

Product Quantity:
a) 20,117 cartons; b) 2,502 cartons

Reason for Recall:
Microbial Contamination of Non-Sterile Products: contamination with Burkholderia and Pseudomonas.

Recall Number:
D-1845-2019

Code Information:
Lot #: a) AR5407, Exp 2022 FEB; b) CD4565, Exp 2022 FEB

Class III Drugs Event

Event ID:
83436

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
07/29/2019

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
08/26/2019

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:
Product was distributed nationwide by three major distributors who may have further distributed the product.

Associated Products

Product Description:
Simvastatin Tablets, USP 40 mg. Rx Only 1000 Count Bottles Manufactured by: Aurolife Pharma LLC Dayton NJ 08810 Manufactured for: Aurobindo Pharma USA, Inc. Dayton, NJ 08810 NDC 65862-053-99

Product Quantity:
2,352/1000 count bottles

Reason for Recall:
Labeling; Incorrect or Missing Lot and/or Exp Date; some bottles labeled with lot number 05318054B instead of 05318034B

Recall Number:
D-1842-2019

Code Information:
05318054B, exp 3/2021

Class III Drugs Event

Event ID:
83497

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
08/06/2019

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
08/23/2019

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 in the U.S.

Associated Products

Product Description:
Eptifibatide Injection, 75 mg/100 mL (0.75 mg/mL), 100 mL Single-use Vial, For Intravenous Use Only, Rx Only, Manufactured by: Akorn, Inc., Lake Forest, IL 60045, NDC 17478-903-90.

Product Quantity:
4085 vials

Reason for Recall:
Failed Impurities/Degradation Specifications: Out of Specification (OOS) for known impurity, D-aspartic acid.

Recall Number:
D-1839-2019

Code Information:
Lot #s: 091287A, 091377A, Exp. 9/19.

Product Description:
Eptifibatide Injection, 75 mg/100 mL (0.75 mg/mL), 100 mL Single-use Vial, For Intravenous Use Only, Rx Only, Manufactured by: Akorn Inc., Lake Forest, IL 60045, NDC 17478-903-90.

Product Quantity:
648 vials

Reason for Recall:
Short Fill: fill volume was out of specification at 94 mL (specification: no less than 100 mL) and Failed Impurities/Degradation Specifications: Out of Specification (OOS) for known impurity, D-aspartic acid.

Recall Number:
D-1840-2019

Code Information:
Lot #: 101107A, Exp. 10/19.

Product Description:
Eptifibatide Injection, a) 20 mg/10 mL (2 mg/mL),10 mL Single Use Vial, NDC 17478-902-10, b) 200 mg/100 mL (2 mg/mL), 100 mL Single-use Vial, NDC 17478-902-90, For Intravenous Use Only, Rx Only, Manufactured by: Akorn Inc., Lake Forest, IL 60045.

Product Quantity:
8187 vials

Reason for Recall:
Failed Impurities/Degradation Specifications: Out of Specification (OOS) for known impurity, D-aspartic acid.

Recall Number:
D-1841-2019

Code Information:
Lot #s: a) 091307A, Exp. 9/19; 101097A, Exp. 10/19; b) 091277A, Exp. 9/19.