Enforcement Report - Week of July 14, 2021

Class II Drugs Event

Event ID:
87372

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
02/26/2021

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
07/02/2021

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Alvogen, Inc
44 Whippany Rd Ste 107
Morristown NJ United States

Distribution Pattern:
USA nationwide.

Associated Products

Product Description:
Buprenorphine and Naloxone Sublingual Film 2mg/0.5mg, 30 pouches each containing 1 sublingual film, Distributed by: Alvogen, Inc. Pine Brook, NJ 07058 USA, NDC 47781-355-11

Product Quantity:
9,696 cartons

Reason for Recall:
Subpotent drug: Out of specification for assay of naloxone and buprenorphine (low)

Recall Number:
D-0649-2021

Code Information:
Lot #: 36924, Exp 6/2021

Class II Drugs Event

Event ID:
88100

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
06/09/2021

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
07/06/2021

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Genentech Inc
1 Dna Way
South San Francisco CA United States

Distribution Pattern:
Product was distributed nationwide

Associated Products

Product Description:
Xolair (omalizumab) Injection, 150 mg/1 mL, 1 prefilled syringe, Rx Only, For Subcutaneous Use. Single-Dose Prefilled Syringe. Product of France, Manufactured by: Genentech, Inc. A Member of the Roche Group, South San Francisco, CA 9480-4990. NDC: 50242-215-01

Product Quantity:
88,620 prefilled syringes

Reason for Recall:
Failed Stability Specifications: Out of Specification results of Polysorbate 20 (PS20) content were detected at the 12 month testing time point.

Recall Number:
D-0650-2021

Code Information:
Lot No.: 3352758, Exp. Date Aug 2021; Lot No.: 3352759, Exp. Date Aug 2021

Class II Drugs Event

Event ID:
88194

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
06/25/2021

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
07/07/2021

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Fresenius Kabi USA LLC
2020 N Ruby St
Melrose Park IL United States

Distribution Pattern:
Distributed Nationwide in the USA

Associated Products

Product Description:
Xylocaine-MPF with Epinephrine 1:200,000, (Lidocaine HCl and Epinephrine Injection, USP), 1%, 300 mg/30 mL, (10 mg/mL), 30 mL Single Dose Vial, 25 Vials per Tray, Rx only, Fresenius Kabi USA, LLC, Lake Zurich, IL 60047. Vial NDC 63323-487-07, Tray NDC 63323-487-37

Product Quantity:
234,800 vials

Reason for Recall:
Low out of specification results for epinephrine assay.

Recall Number:
D-0651-2021

Code Information:
Batch, expiry: Batch 6123435, exp 01/2022; 6124730, 6124731, exp 07/2022

Not Yet Classified Drugs Event

Event ID:
88154

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
06/18/2021

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:

Initial Firm Notification of Consignee or Public:
Letter

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

Distribution Pattern:
Distributed Nationwide in the USA

Associated Products

Product Description:
Topotecan Injection 4 mg/4mL (1 mg/mL), Single-Dose vial, Teva Pharmaceuticals USA, Inc. North Whales, PA 19454, Carton NDC# 0703-4714-01, Vial NDC# 0703-4714-71

Product Quantity:
10,425 vials

Reason for Recall:
Presence of Particulate Matter: Complaint received of a glass particle observed inside the vial. The vial was returned to Teva for further analysis where two other particulates were found and identified as one (1) grey silicone particle and one (1) translucent, colorless cotton fiber.

Recall Number:

Code Information:
Lot # 31328962B, exp. date 04/2022