Enforcement Report - Week of July 24, 2019

Class I Drugs Event

Event ID:
83234

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
06/28/2019

Voluntary / Mandated:
Voluntary: Firm Initiated

Center Classification Date:
07/17/2019

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Fresenius Kabi USA, LLC
2045 Cornell Ave
Melrose Park IL United States

Distribution Pattern:
Nationwide USA and Puerto Rico

Associated Products

Product Description:
Fluorouracil Injection, USP, 5 g / 100 mL (50 mg / mL), 100 mL fill in a 100 mL vial, Rx Only, Mfd. by: Fresenius Kabi, Lake Zurich, IL 60047. 63323-117-61 [Fresenius Kabi brand] and NDC 63323-117-69 [NOVAPLUS brand]

Product Quantity:
14,016 vials

Reason for Recall:
Presence of Particulate Matter; glass particulates

Recall Number:
D-1489-2019

Code Information:
Lot 6120420 NDC 63323-117-61, Product Code 101761 and Lot 6120341 NDC 63323-117-69, Product Code NP101761

Class II Drugs Event

Event ID:
83267

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
07/09/2019

Voluntary / Mandated:
Voluntary: Firm Initiated

Center Classification Date:
07/12/2019

Initial Firm Notification of Consignee or Public:
Letter

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

Distribution Pattern:
United States, PR, and Guam

Associated Products

Product Description:
Milrinone Lactate Injection 200 mcg (0.2 mg)/mL* in 5% Dextrose Injection 40 mg/200 mL, 200 mL bag, Rx Only, Hospira, Inc., Lake Forest, IL 60045 USA, NDC 0409-2776-02, Barcode (01)00304092776028.

Product Quantity:
58200 bags

Reason for Recall:
Lack of Assurance of Sterility: Bags have the potential to leak.

Recall Number:
D-1486-2019

Code Information:
Lot #s: 86-615-KL, Exp. 1FEB2020; 87-701-KL, Exp. 1MAR2020; 90-114-KL, Exp. 1JUN2020

Product Description:
Milrinone Lactate Injection 200 mcg (0.2 mg)/mL* in 5% Dextrose Injection, 20 mg/100 mL, 100 mL bag, Rx Only, Hospira, Inc., Lake Forest, IL 60045 USA, NDC 0409-2776-23, Barcode (01)00304092776233.

Product Quantity:
280340 bags

Reason for Recall:
Lack of Assurance of Sterility: Bags have the potential to leak.

Recall Number:
D-1487-2019

Code Information:
Lot #s: 85-516-KL; 85-517-KL, Exp. 1JAN2020; 86-601-KL; 86-603-KL; 86-618-KL, Exp. 1FEB2020; 87-707-KL, Exp. 1MAR2020; 91-205-KL, Exp. 1JUL2020; 92-306-KL, Exp. 1AUG2020.

Class III Drugs Event

Event ID:
83333

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
07/11/2019

Voluntary / Mandated:
Voluntary: Firm Initiated

Center Classification Date:
07/17/2019

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Lupin Pharmaceuticals Inc.
111 S Calvert St Fl 21ST
Baltimore MD United States

Distribution Pattern:
Nationwide in the U.S. and PR.

Associated Products

Product Description:
Gatifloxacin Ophthalmic Solution 0.5%, For Use in the Eyes Only, Rx Only, Sterile, 2.5 mL Bottle, Manufactured for: Lupin Pharmaceuticals, Inc. Baltimore, Maryland 21202, United States, Manufactured by: Lupin Limited, Pithampur (M.P.) 454 775, India, NDC 68180-435-01.

Product Quantity:
17,238 bottles

Reason for Recall:
Labeling: Missing label; Product complaints reported missing bottle label.

Recall Number:
D-1490-2019

Code Information:
Lot #: H805157, Exp. 05/2020