Enforcement Report - Week of October 18, 2017

Class II Drugs Event

Event ID:
78183

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
09/27/2017

Voluntary / Mandated:
Voluntary: Firm Initiated

Center Classification Date:
10/10/2017

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
United Pharmacy
3951 Haverhill Rd N
West Palm Beach FL United States

Distribution Pattern:
Nationwide.

Associated Products

Product Description:
Glutamine, Arginine and Carnitine, 10/100/200mg/mL, 30 mL (Multi Dose Vial), Rx Only, For Injection, United Pharmacy Compounded, 13951 N. Haverhill Rd Ste. 120-121 West Palm Beach, FL 33417

Product Quantity:
268 vials

Reason for Recall:
CGMP Deviations; FDA analysis deterrmined that the product does not contain glutamine and two unknown impurities were observed

Recall Number:
D-0008-2018

Code Information:
Lot: GAC-12 BUD 11/10/17; Lot: GAC-13 BUD: 01/14/18

Class III Drugs Event

Event ID:
78172

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
09/22/2017

Voluntary / Mandated:
Voluntary: Firm Initiated

Center Classification Date:
10/06/2017

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Boehringer Ingelheim Pharmaceuticals, Inc.
39 Briar Ridge Rd.
Danbury CT United States

Distribution Pattern:
CO, OH

Associated Products

Product Description:
Mobic (meloxicam) tablets, 15 mg, package in 100-count bottle, Rx only, Dist. by: Boehringer Ingelheim (BI) Pharmaceuticals, Inc., Ridgefield, CT 06877 USA, Lic. from: BI Int'l GmbH, Made in Italy, NDC 0597-0030-01

Product Quantity:
128 bottles

Reason for Recall:
Labeling: Incorrect or missing package insert. One lot of Mobic Tablets is packaged with an incorrect insert.

Recall Number:
D-0007-2018

Code Information:
Lot 754037

Class III Drugs Event

Event ID:
78220

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
10/03/2017

Voluntary / Mandated:
Voluntary: Firm Initiated

Center Classification Date:
10/11/2017

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Dr. Reddy's Laboratories, Inc.
107 College Rd E
Princeton NJ United States

Distribution Pattern:
Nationwide

Associated Products

Product Description:
Famotidine tablets, 10 mg, packaged in 30-count bottle, OTC, labeled as a) CVS Pharmacy Acid Controller, NDC 55111-118-30, Distributed by: CVS Pharmacy, Inc., One CVS Drive, Woonsocket, RI 02895, Made in India, b) Equate Famotidine, NDC 49035-118-30, Distributed by: Wal-Mart Stores, Inc. Bentonville, AR 72716, Made in India

Product Quantity:
569376 bottles

Reason for Recall:
Failed impurities/degradation specifications: Famotodine has an out of specification result for an individual related substance observed during routine stability testing of a batch for related substances -impurity 8 at 24 month stability interval.

Recall Number:
D-0009-2018

Code Information:
Lot #: a) 79C408882B, 79C408884C, 79C408886B, Exp 10/17; 79C501523B, Exp 01/18; 79C501524B, Exp 01/18; 79C502318B, Exp 3/18; b) 79C408885B, 79C408886A, Exp 10/17; 79C500967, 79C501523C, 79C501525A, 79C501525B, 79C501525C, 79C501526B, Exp 01/18; 79C502317A, Exp 3/18; 79C504087B, 79C504088A, Exp 5/18; 79C505926A, Exp 7/18.