Enforcement Report - Week of September 18, 2019

Class II Drugs Event

Event ID:
83699

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
09/06/2019

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
09/12/2019

Initial Firm Notification of Consignee or Public:
Two or more of the following: Email, Fax, Letter, Press Release, Telephone, Visit

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

Distribution Pattern:
Nationwide US and Puerto Rico

Associated Products

Product Description:
Bacteriostatic Water for Injection, USP, 30 mL vials, Rx only, Mfd. for: Hospira, Inc., Lake Forest, IL 60045 USA. NDC Vial: 0409-3977-01; NDC Carton: 0409-3977-03

Product Quantity:
185,700 vials

Reason for Recall:
Lack of Assurance of Sterility

Recall Number:
D-1852-2019

Code Information:
Lot #: W20308, Exp. Dec 1, 2019

Class II Drugs Event

Event ID:
83702

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
08/30/2019

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
09/10/2019

Initial Firm Notification of Consignee or Public:
Press Release

Recalling Firm:
Pacifico National, Inc. dba AmEx Pharmacy
1515 Elizabeth St Ste J
Melbourne FL United States

Distribution Pattern:
Continental U.S. and Puerto Rico

Associated Products

Product Description:
Bevacizumab, 2.5 mg/0.1 mL, Norm-Ject Syringe Intravitreal Injection, Single use only, Rx only, Repackaged by AmEx Pharmacy 1515 Elizabeth St. Suite J Melbourne, FL 32901

Product Quantity:

Reason for Recall:
Lack of assurance of sterility.

Recall Number:
D-1849-2019

Code Information:
All lots remaining within expiry.

Product Description:
Bevacizumab, 1.25 mg/0.05 mL, 31G MJ Syringe Intravitreal Injection, Single use only, Rx only, Repackaged by AmEx Pharmacy 1515 Elizabeth St. Suite J Melbourne, FL 32901

Product Quantity:

Reason for Recall:
Lack of assurance of sterility.

Recall Number:
D-1850-2019

Code Information:
All lots remaining within expiry.

Class II Drugs Event

Event ID:
83722

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
09/03/2019

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
09/12/2019

Initial Firm Notification of Consignee or Public:
Telephone

Recalling Firm:
Compounded Solutions in Pharmacy
810 Main St
Monroe CT United States

Distribution Pattern:
Product was dispensed to patients

Associated Products

Product Description:
20% Acetyl-L-Cysteine Ophthalmic Solutions, dispensed in 3ml dropper bottle.

Product Quantity:
3x3 ml dropper bottles

Reason for Recall:
Lack of Processing Controls:

Recall Number:
D-1853-2019

Code Information:
Lots: 07172019@39 exp: 8/31/19, Rx # 215042 06192019@28 exp: 7/03/19, Rx # 219335 06052019@8 exp: 6/19/19; Rx # 222826

Product Description:
10% Acetyl-L-Cysteine Ophthalmic Solutions, dispensed in a) 5ml, b) 10ml c) 15 ml, dropper bottles

Product Quantity:
a) 6x5ml b) 4x10 c) 1x15 ml bottles,

Reason for Recall:
Lack of Processing Controls:

Recall Number:
D-1854-2019

Code Information:
Lots: a) 08012019@33 exp: 8/15/19, 07182019@66 exp: 8/01/19, 07182019@15 exp: 8/01/19, 07012019@46 exp. 08/31/19, 07082019@27 exp: 8/31/19, b) 07082019@55 exp: 8/31/19; 07182019@55 exp: 08/31/19; 06242019@55 exp: 8/31/19; 06202019@16 exp: 8/31/19 c) 08052019@11 exp: 11/3/19

Product Description:
5% Acetyl-L-Cysteine Ophthalmic Solutions, dispensed in a) 5ml , b) 10ml dropper bottles

Product Quantity:
a) 4x5 ml, b) 1x10 ml bottles

Reason for Recall:
Lack of Processing Controls:

Recall Number:
D-1855-2019

Code Information:
Lots a) 07182019@29 exp: 8/31/19, 07082019@2 exp: 8/31/19, 06052019@21 exp:08/31/19 06062019@52 exp: 6/25/19; b) 07022019@28 exp: 8/31/19

Class III Drugs Event

Event ID:
83597

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
08/21/2019

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
09/11/2019

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Macleods Pharma Usa Inc
666 Plainsboro Rd Bldg 200 Ste 230
Plainsboro NJ United States

Distribution Pattern:
Distributed Nationwide in the USA

Associated Products

Product Description:
Pramipexole Dihydrochloride Tablets 0.125 mg,90-count bottle, Rx Only, Manufactured for: Macleods Pharma USA, Inc. Plainsboro, NJ 08536, Manufactured by: Macleods Phamaceuticals Ltd. Baddi Himachal Pradesh, India. NDC 33342-031-10

Product Quantity:
1837 90-count bottles

Reason for Recall:
Subpotent Drug: Out of specification result during stability study in Pramipexole Dihydrochloride Tablets 0.125 mg

Recall Number:
D-1851-2019

Code Information:
Lot #BPA801A, EXP 12/2020

Class III Drugs Event

Event ID:
83672

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
08/27/2019

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
09/06/2019

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
American Health Packaging
2550 John Glenn Ave Ste A
Columbus OH United States

Distribution Pattern:
Nationwide

Associated Products

Product Description:
Lamivudine Tablets, USP, 150 mg, 30 (3x10) count Unit Dose Blisters Carton, NDC 60687-362-21 (Individual Dose NDC: 60687-362-11), Distributed by American Health Packaging, Columbus, OH

Product Quantity:
60 cartons

Reason for Recall:
Labeling: Incorrect or Missing Package Insert; an error in the Dosage Forms and Strengths section of the insert that incorrectly lists the tablet description coding for the tablets.

Recall Number:
D-1847-2019

Code Information:
Lots 186509 and 186982, exp 6/30/2021

Class III Drugs Event

Event ID:
83673

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
09/06/2019

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
09/09/2019

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Mylan Pharmaceuticals Inc.
781 Chestnut Ridge Rd
Morgantown WV United States

Distribution Pattern:
Nationwide in the USA

Associated Products

Product Description:
Gatifloxacin Ophthalmic Solution 0.5%, 2.5 mL per bottle, Rx Only, Mfd. for: Mylan Pharmaceuticals Inc., Morgantown, WV 26505. Made in India.

NDC: 0378-5431-35

Product Quantity:
13,157 5 mL bottles

Reason for Recall:
Failed Impurities/Degradation Specifications:OOS for unknown impurity.

Recall Number:
D-1848-2019

Code Information:
Lot GABH0003, EXP 7/2020

Not Yet Classified Drugs Event

Event ID:
83693

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
08/30/2019

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Plastikon Healthcare LLC
3780 Greenway Cir
Lawrence KS United States

Distribution Pattern:
One distributor who further distributed Nationwide in the USA.

Associated Products

Product Description:
Milk of Magnesia USP, 2400 mg/30 mL, Magnesium Hydroxide 2400 mg, 30 mL unit dose cups, For Institutional Use Only, packaged in 100-count cartons of 10 trays x 10 unit dose cups, Major Pharmaceuticals, Livonia, MI 48152, NDC 0904-6846-73.

Product Quantity:
1,433 cases

Reason for Recall:
Microbial Contamination of Non-Sterile Products: product failed bioburden testing for Total Aerobic Microbial Count.

Recall Number:

Code Information:
Lots: 19027D, 19027E, Exp 07/21

Not Yet Classified Drugs Event

Event ID:
83700

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
08/28/2019

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
AVKARE Inc.
615 N 1st St
Pulaski TN United States

Distribution Pattern:
Nationwide.

Associated Products

Product Description:
AVKARE Fexofenadine Hydrochloride Tablets USP Antihistamine 180 mg, 500 Tablets per bottle, NDC 42291-297-50.

Product Quantity:
5953 bottles

Reason for Recall:
Failed Stability Specifications.

Recall Number:

Code Information:
Lot #s: 067180011A; 067180012A, Exp. 04/2021; 06718027B1 Exp. 09/2021