Enforcement Report - Week of October 3, 2018

Class II Drugs Event

Event ID:
80961

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
09/04/2018

Voluntary / Mandated:
Voluntary: Firm Initiated

Center Classification Date:
09/27/2018

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Boehringer Ingelheim Pharmaceuticals, Inc.
900 Ridgebury Rd
Ridgefield CT United States

Distribution Pattern:
Nationwide

Associated Products

Product Description:
Synjardy (empagliflozin and metformin hydrochloride) Tablets. 5 mg/1000 mg. Rx only. 180-count bottle. Distributed by: Boehinger Ingelheim (BI) Pharmaceuticals, Inc. Ridgefield, CT 06877. Made in Germany. Marketed by: BI Pharmaceuticals, Inc. Ridgefield, CT 06877 and Eli Lilly and Company Indianapolis IN 46285 NDC 0597-0175-18

Product Quantity:
998 180-count bottles

Reason for Recall:
Cross Contamination With Other Products:

Recall Number:
D-1217-2018

Code Information:
Lot # 603968 EXP 4/2019

Class II Drugs Event

Event ID:
80997

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
09/07/2018

Voluntary / Mandated:
Voluntary: Firm Initiated

Center Classification Date:
09/25/2018

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Noven Pharmaceuticals, Inc.
11960 SW 144th St
Miami FL United States

Distribution Pattern:
Nationwide

Associated Products

Product Description:
Minivelle (estradiol transdermal system) Patches Delivers 0.1 mg/day, a) 2 count and b) 8 count boxes, Rx only, , Mfd. by: Noven Pharmaceuticals, Inc. Miami, Florida 33186 Dist. By: Noven Therapeutics, LLC. Miami, Florida 33186 --- NDC 68968-6610-8

Product Quantity:
213714 boxes of 8 patches and 15927 boxes of 2 patches

Reason for Recall:
Defective Delivery System: out of specification results for shear, an attribute related to the adhesive properties of the transdermal patches.

Recall Number:
D-1207-2018

Code Information:
a) 82200 Exp. 01/2019 b) 81637 Exp. 10/2018; 82200 Exp. 01/2019; 82293 Exp. 02/2019; 82600 Exp. 04/2019; 83027 Exp. 04/2019; 83173 Exp. 06/2019; 83396 Exp. 09/2019

Product Description:
Minivelle (estradiol transdermal system) Patches, Delivers 0.05 mg/day, a) 2 count and 8 count boxes, Rx only, Mfd. by: Noven Pharmaceuticals, Inc. Miami, Florida 33186 Dist. By: Noven Therapeutics, LLC. Miami, Florida 33186 --- NDC 68968-6650-8

Product Quantity:
149631 boxes of 8 patches and 15809 boxes of 2 patches

Reason for Recall:
Defective Delivery System: out of specification results for shear, an attribute related to the adhesive properties of the transdermal patches.

Recall Number:
D-1208-2018

Code Information:
a) 82292 Exp. 02/2019; b) 82139 Exp. 10/2018; 82292 Exp. 02/2019; and 82598 Exp. 04/2019

Product Description:
Minivelle (estradiol transdermal system) Patches, Delivers 0.025 mg/day, 8 count boxes, Rx only, Mfd. by: Noven Pharmaceuticals, Inc. Miami, Florida 33186 Dist. By: Noven Therapeutics, LLC. Miami, Florida 33186 --- NDC 68968-6625-8

Product Quantity:
26217 boxes of 8 patches

Reason for Recall:
Defective Delivery System: out of specification results for shear, an attribute related to the adhesive properties of the transdermal patches.

Recall Number:
D-1209-2018

Code Information:
Lots: 82199 Exp. 12/2018; 83025 Exp. 05/2019

Product Description:
Minivelle (estradiol transdermal system) Patches, Delivers 0.075 mg/day, 8 count boxes, Rx only, Mfd. by: Noven Pharmaceuticals, Inc. Miami, Florida 33186 Dist. By: Noven Therapeutics, LLC. Miami, Florida 33186 --- NDC 68968-6675-8

Product Quantity:
74908 boxes of 8 patches

Reason for Recall:
Defective Delivery System: out of specification results for shear, an attribute related to the adhesive properties of the transdermal patches.

Recall Number:
D-1210-2018

Code Information:
Lots: 82599 Exp. 05/2019; 82660 Exp. 03/2019; 83396 Exp. 09/2019

Class II Drugs Event

Event ID:
81029

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
08/20/2018

Voluntary / Mandated:
Voluntary: Firm Initiated

Center Classification Date:
09/26/2018

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Hetero Labs Limited Unit V
Unit V (SEZ Unit I in APIIC SEZ) Surv. No. 439-441, 458, Polepally Vill.
Jadcherla Mandal, Mahaboob Nagar India

Distribution Pattern:
Nationwide in the USA

Associated Products

Product Description:
Montelukast Sodium Tablets, 10 mg*, 30-count bottles, Rx Only, By: Hetero, Hetero Labs Limited, Unit V, Polepally, Jadcherla, Mahaboob Nagar - 509 301, India, Manufactured for: Camber Pharmaceuticals, Inc., Piscataway, NJ 08854, NDC 31722-726-30.

Product Quantity:
98,016 bottles

Reason for Recall:
Discoloration: A complaint was received from a pharmacist for the presence of blue specks on tablets.

Recall Number:
D-1213-2018

Code Information:
Lot #: MON17355, Exp 12/19

Class III Drugs Event

Event ID:
80987

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
09/25/2018

Voluntary / Mandated:
Voluntary: Firm Initiated

Center Classification Date:
09/27/2018

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Baxter Healthcare Corporation
1 Baxter Pkwy
Deerfield IL United States

Distribution Pattern:
Nationwide USA and Puerto Rico

Associated Products

Product Description:
Levofloxacin Injection in 5% Dextrose, 500 mg (5 mg/mL), 100 mL Container bag, Rx only, Manufactured for: Claris Lifesciences Inc., North Brunswick, NJ 08902; By: Claris Injectables Ltd., Gujarat, India, NDC 36000-047-24.

Product Quantity:
523,896 bags

Reason for Recall:
Superpotent Drug: High out of specification results for levofloxacin resulting in increased concentration of solution.

Recall Number:
D-1215-2018

Code Information:
Lot #: A0A0741, A0A0747, A0A0748, Exp. 6/2019; A0A0814, A0A0815, A0A0823, Exp. 7/2019; A0A0889, A0A0893, Exp. 8/2019; A0A1005, A0A1006, A0A1008, A0A1012, A0A1016, A0A1028, A0A1036, Exp. 10/2019

Product Description:
Levofloxacin Injection in 5% Dextrose, 750 mg (5 mg/mL), 150 mL Container bag, Rx only, Manufactured for: Claris Lifesciences Inc., North Brunswick, NJ 08902; By: Claris Injectables Ltd., Gujarat, India, NDC 36000-048-24.

Product Quantity:
23,712 bags

Reason for Recall:
Superpotent Drug: High out of specification results for levofloxacin resulting in increased concentration of solution.

Recall Number:
D-1216-2018

Code Information:
Lot #: A0A0258, Exp 2/2019

Class III Drugs Event

Event ID:
81017

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
09/12/2018

Voluntary / Mandated:
Voluntary: Firm Initiated

Center Classification Date:
09/25/2018

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Hetero Labs, Ltd. - Unit III
Plot 22-110, Part Ii, Ida Rangareddy, Jeedimetla
Hyderabad India

Distribution Pattern:
Indiana and Louisiana

Associated Products

Product Description:
Fenofibrate Tablets, USP 145 mg, 90-count bottles, Rx only, Manufactured for: Camber Pharmaceuticals, Inc. Piscataway, NJ, 08854, NDC 31722-596-90

Product Quantity:
5,424 bottles

Reason for Recall:
Presence of Foreign Tablet/Capsule: A foreign identified as Valacyclovir tablet 500 mg was co-mingled in a bottle containing Fenofibrate Tablets, USP 145 mg.

Recall Number:
D-1211-2018

Code Information:
Lot #: E181370, Exp. 5/2020

Not Yet Classified Drugs Event

Event ID:
81012

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
09/12/2018

Voluntary / Mandated:
Voluntary: Firm Initiated

Center Classification Date:

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:
Product was distributed to retailers, distributors, physician officers and medical facilities throughout the United States.

Associated Products

Product Description:
Zoledronic Acid Injection, 5mg/100 mL (0.05 mg/mL) 100ml vial, Rx Only. Mfd By: Gland Pharma Limited D.P. Pally - 500 043 India: Mfd. For: Dr. Reddy's Laboratories Limited Bachupally - 500 090 India. NDC 55111-688-52

Product Quantity:
59,468 vials

Reason for Recall:
Out-of-Specification result observed for related substance: unknown impurity.

Recall Number:

Code Information:
Batch Numbers: BS633, EXP 9/2018; BS701, BS702, BS703, EXP 12/2018; BS708, BS709, BS711, BS712, BS713, BS714, BS715, EXP 3/2019; BS726, BS727, EXP 6/2019; BS728, BS729, BS730, EXP 7/2019; BS801, EXP 03/2020..

Product Description:
Zoledronic Acid Injection, 5 mg/100 mL (0.05 mg/mL) One 100ml Single-Dose Bottle, Rx Only. NOVAPLUS Mfd By: Gland Pharma Limited D.P. Pally - 500 043 India: Mfd. For: Dr. Reddy's Laboratories Limited Bachupally - 500 090 India. N+ and NOVAPLUS are registered trademarks of Vizient, Inc. NDC 43598-331-11

Product Quantity:
10,530 vials

Reason for Recall:
Out-of-Specification result observed for related substance: unknown impurity.

Recall Number:

Code Information:
Batch Numbers: BS704, EXP 12/018; BS725, EXP 6/2019; BS745, EXP 11/2019.