Enforcement Report - Week of May 18, 2016

Biologics | Cosmetics | Devices | Drugs | Food | Tobacco | Veterinary

Class II Drugs Event

Event ID:
73671
Product Type:
Drugs

Status:
Ongoing
Recalling Firm:
Mylan Pharmaceuticals Inc.
781 Chestnut Ridge Rd
Morgantown WV United States
Recall Initiation Date:
02/12/2016
Center Classification Date:
05/06/2016
Date Terminated:

Voluntary / Mandated:
Voluntary: Firm Initiated
Initial Firm Notification of Consignee or Public:
E-Mail
Distribution Pattern:
Nationwide

Associated Products

Product Description:
Paliperidone Extended-release Tablets, 1.5 mg, 30 count bottles, Rx only, Mylan Pharmaceuticals, Inc., Morgantown, WV --- NDC 0378-3978-93
Product Quantity:
2928 bottles
Code Information:
Lot: 2005441, 01/2017, Code: 0378-3978-93

Reason for Recall:
Failed Dissolution Specifications; three month stability time point.

Recall Number:
D-0840-2016

Class II Drugs Event

Event ID:
73812
Product Type:
Drugs

Status:
Ongoing
Recalling Firm:
Baxter Healthcare Corp.
1 Baxter Pkwy
Deerfield IL United States
Recall Initiation Date:
04/12/2016
Center Classification Date:
05/12/2016
Date Terminated:

Voluntary / Mandated:
Voluntary: Firm Initiated
Initial Firm Notification of Consignee or Public:
Letter
Distribution Pattern:
Nationwide

Associated Products

Product Description:
Brevibloc DOUBLE STRENGTH Premixed Injection, Esmolol Hydrochloride in Sodium Chloride, 2000mg/100mL (20 mg/mL), 100 mL, Rx only, Manufactured by Baxter Healthcare Corporation, Deerfield, Il 60015, NDC 10019-075-87
Product Quantity:
11,630 babs
Code Information:
Lot # C989954, Exp 9/17

Reason for Recall:
Discoloration: presence of atypical yellow discoloration of the solution .

Recall Number:
D-0852-2016

Class II Drugs Event

Event ID:
73822
Product Type:
Drugs

Status:
Ongoing
Recalling Firm:
Dr. Reddy's Laboratories, Inc.

Voluntary / Mandated:
Voluntary: Firm Initiated
Initial Firm Notification of Consignee or Public:
Letter
Distribution Pattern:
Nationwide

107 College Rd E
Princeton NJ United States

Recall Initiation Date:
03/30/2016
Center Classification Date:
05/09/2016
Date Terminated:

Associated Products

Product Description:
Ondansetron Tablets USP, 4 mg, 30 count bottles, Rx only, Manufactured by: Dr. Reddy's Laboratories, Bachupally, India --- NDC 56111-153-30

Product Quantity:
50,280 bottles

Code Information:
Lot number C500691, exp 12/2016

Reason for Recall:
Failed Impurities/Degradation Specifications; 12 month stability time point

Recall Number:
D-0841-2016