Enforcement Report - Week of July 5, 2017

- Biologics
- Cosmetics
- Devices
- Drugs
- Food
- Tobacco
- Veterinary

Class II Drugs Event
Event ID:
77143
Product Type:
Drugs
Status:
Ongoing
Date Terminated:
Recall Initiation Date:
05/01/2017
Voluntary / Mandated:
Voluntary: Firm Initiated
Center Classification Date:
06/29/2017
Initial Firm Notification of Consignee or Public:
Letter
Recalling Firm:
Allergan Sales, LLC
8301 Mars Dr
Waco TX United States
Distribution Pattern:
Nationwide in the US

Associated Products

Product Description:
Blephamide (sulfacetamide sodium and prednisolone acetate ophthalmic ointment, USP) 10%/0.2% sterile, 3.5 g tube, RX only, Manufactured by Allergan, Irvine, California, 92612, U.S.A., NDC: 0023-0313-04.
Product Quantity:
648 units
Reason for Recall:
Failed Impurities/Degradation Specifications: stability testing results did not meet the specification for impurities.
Recall Number:
D-0929-2017
Code Information:
Lot: 93802, EXP NOV 2019

Class II Drugs Event

Event ID:
77525
Product Type:
Drugs
Status:
Ongoing
Date Terminated:
Recall Initiation Date:
06/01/2017
Voluntary / Mandated:
Voluntary: Firm Initiated
Center Classification Date:
06/29/2017
Initial Firm Notification of Consignee or Public:
Telephone
Recalling Firm:
American Pharmaceutical Ingredients LLC
6650 Highland Rd Ste 302
Waterford MI United States
Distribution Pattern:
Nationwide in the US

Associated Products

Product Description:
Doxycycline Hyclate USP, active pharmaceutical ingredient, a) 25 g packaged in a 500 cc container (NDC: 58597-8082-4), b) 100 g packaged in 16 oz container (NDC: 58597-8082-6), c) 500 g packaged in a 2500 cc container (NDC: 58597-8082-7) and a 1,000 g packaged in 1 gallon container (NDC: 58597-8082-8). For Prescription Compounding RX Only. Packed under cGMP conditions by American Pharmaceutical Ingredients, LLC 6650 Highland Road, Waterford, MI 48327
Product Quantity:
23.5kg
Reason for Recall:
Labeling: Not Elsewhere Classified. Manufacturer and product were discovered to be on FDA Import Alert 66-66 for misbranding of active pharmaceutical ingredient.
Recall Number:
D-0927-2017
Code Information:
Lot: 082815-1, EXP 06/04/2019

Class II Drugs Event

Event ID:
77615
Product Type:
Drugs

Status:
Ongoing
Date Terminated:
Recall Initiation Date:
06/05/2017
Voluntary / Mandated:
Voluntary: Firm Initiated
Center Classification Date:
06/28/2017
Initial Firm Notification of Consignee or Public:
Telephone
Recalling Firm:
Apothecary By Design
141 Preble St
Portland ME United States
Distribution Pattern:
Nationwide in the USA

Associated Products

Product Description:
Progesterone Injection in Olive Oil With Benzyl Alcohol 10%, 50mg/mL, 10mL Multi-Dose Vial, Rx only, Apothecary by Design, 141 Preble Street, Portland, ME.
Product Quantity:
25 vials
Reason for Recall:
CGMP Deviations: The metal container closure adheres to the rubber stopper on some of the units of the batch which can impact the integrity of the container closure.
Recall Number:
D-0924-2017
Code Information:
Lot #: 04192017@1, Exp 09/30/2017

Class III Drugs Event

Event ID:
77411
Product Type:
Drugs
Status:
Ongoing
Date Terminated:
Recall Initiation Date:
05/30/2017
Voluntary / Mandated:
Voluntary: Firm Initiated
Center Classification Date:
06/29/2017
Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Mckesson Packaging Services
7101 Weddington Rd NW
Concord NC United States
Distribution Pattern:
Nationwide in the US

Associated Products

Product Description:
BuPROPion HCL Tablets, USP, 75 mg, packaged as UD 100 tablets (10x10), Rx Only, Mfg by: Sandoz Inc., 508 Carnegie Center, Suite 400, Princeton, NJ 08805, NDC: 63739-706-10
Product Quantity:
942 cartons
Reason for Recall:
Failed Moisture Limits: Product tested out-of-specification for moisture content.
Recall Number:
D-0928-2017
Code Information:
Lot # 0113148, 0113149, 0113150, Exp: 04/18; 0113636, Exp: 06/18; 0114513, Exp: 10/18

Class III Drugs Event
Event ID:
77450
Product Type:
Drugs
Status:
Ongoing
Date Terminated:
Recall Initiation Date:
06/05/2017
Voluntary / Mandated:
Voluntary: Firm Initiated
Center Classification Date:
06/28/2017
Initial Firm Notification of Consignee or Public:
Letter
Recalling Firm:
L. Perrigo Company
515 Eastern Ave
Allegan MI United States
Distribution Pattern:
IL

Associated Products

Product Description:
Walgreens Daytime and Nighttime Cold & Flu, packaged in combo pack of two plastic 12FL OZ (355 mL) bottles connected by one paper sleeve, TOTAL 24 FL OZ (1.5 pt)(710 mL), OTC, Distributed by: Walgreen CO., 200 Wilmot Rd., Deerfield, IL 60015

Product Quantity:
1,998 combo packs
Reason for Recall:
Labeling: Label Mix-Up - This product is being recalled due to an incorrect product sleeve on the product twin pack. The incorrect product sleeve is for Day-Night Cold and Fluwhereas the batch contains Day-Night Cough Liquid.
Recall Number:
D-0925-2017
Code Information:
Lot #: 6MV0944, Exp 10/18

Class III Drugs Event

Event ID:
77466
Product Type:
Drugs
Status:
Ongoing
Date Terminated:
Recall Initiation Date:
04/27/2017
Voluntary / Mandated:
Voluntary: Firm Initiated
Center Classification Date:
06/23/2017
Initial Firm Notification of Consignee or Public:
Letter
Recalling Firm:
Noven Pharmaceuticals, Inc.
11960 SW 144th St
Miami FL United States
Distribution Pattern:
Nationwide within US

Associated Products

Product Description:
Minivelle (estradiol Transdermal System) 0.1 mg per day, pack of 8 systems per carton, Rx only, Dist. by: Noven Therapeutics, LLC. Miami, Florida 33186. NDC: 68968-6610-8
Product Quantity:
14434 cartons
Reason for Recall:
Defective Delivery System: Out of specification for peel force from the release liner specification during stability testing at 18M 25C/60%RH.
Recall Number:
D-0923-2017
Code Information:
Lot #:: 78618, Exp. 05/2017

Class III Drugs Event

Event ID:
77478
Product Type:
Drugs
Status:
Ongoing
Date Terminated:
Recall Initiation Date:
06/12/2017
Voluntary / Mandated:
Voluntary: Firm Initiated
Center Classification Date:
06/29/2017
Initial Firm Notification of Consignee or Public:
Letter
Recalling Firm:
Sanofi-Aventis U.S. LLC
55 Corporate Dr
Bridgewater NJ United States
Distribution Pattern:
Nationwide in the USA, Puerto Rico, and the United Kingdom.

Associated Products

Product Description:
Gaviscon (Alumina & Magnesium Trisilicate) Regular Strength Original Flavor Chewable Tablets, 80 mg & 14.2 mg, 100-count bottles, Distributed by: GlaxoSmithKline Consumer Healthcare, L.P., Moon Twp, PA 15108, UPC 3 0088-1175-47 8.
Product Quantity:
2980 bottles
Reason for Recall:
Superpotent Drug: high out-of-specification result for magnesium.
Recall Number:
D-0926-2017
Code Information:
Lot #: 5J69A, Exp 02/19; 6GF2A, 6GF3A, Exp 08/19