Enforcement Report - Week of May 10, 2017

Class I Drugs Event

Event ID:
76789

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
03/12/2017

Voluntary / Mandated:
Voluntary: Firm Initiated

Center Classification Date:
04/28/2017

Initial Firm Notification of Consignee or Public:
Press Release

Recalling Firm:
Meridian Medical Technologies a Pfizer Company
2555 Hermelin Dr
Brentwood MO United States

Distribution Pattern:
Nationwide and Puerto Rico, Argentina, Austria, Australia, Belgium, Chile, Croatia, Czech Republic, Denmark, Estonia, Finland, France, Germany, Ireland, Italy, Japan, Latvia, Lithuania, Netherlands, New Zealand, Norway, Polan d, Portugal, Romania, Saudi Arabia, Singapore, Slovakia, Slovenia, Sweden, Switzerland, Taiwan, Thailand, United Kingdom. There has been no U.S. government or military distribution.

Associated Products

Product Description:
EpiPen 2-Pak (Epinephrine) Auto-Injectors 0.3 mg, Rx only, Manufactured for Mylan Specialty L.P., Morgantown WV 26505 by Meridian Medical Technologies, Inc., Columbia, MD 21046, a Pfizer company; NDC 49502-500-02 ---- ALSO LABELED OUTSIDE THE US AS ---- Epipen Auto-Injector 0.3 mg -Bright Stock labeled for multiple countries- manufactured for Mylan by Meridian Medical Technologies, Inc., Columbia, MD 21046, a Pfizer company.

Product Quantity:
373,960 2-paks (U.S.) ; 331,738 auto-injectors (O.U.S.)

Reason for Recall:
Defective Delivery System; reports of the device failing to activate which could result in a patient not receiving medication

Recall Number:
D-0690-2017

Code Information:
US: lot 5GM631, exp. April 2017; lot 5GM640, exp. May 2017; lot 6GM072, exp. Sep 2017; lot 6GM082, exp. Sep 2017; lot 6GM088, exp. Oct 2017; lot 6GM087, exp. Oct 2017; lot 6GM198, exp. Oct 2017; lot 6GM081, exp. Sep 2017; lot 6GM091, exp. Oct 2017; lot 6GM199, exp. Oct 2017: INTERNATIONAL: lot 5FA665, exp. April 2017; lot 5GU763, exp. May 2017; lot 6FA293, exp. Oct 2017; lot 6FA292, exp. Oct 2017; lot 6GH294, exp. Oct 2017.

Product Description:
EpiPen Jr. 2-Pak (Epinephrine) Auto-Injectors 0.15 mg, Rx only, Manufactured for Mylan Specialty L.P., Morgantown WV 26505 by Meridian Medical Technologies, Inc., Columbia, MD 21046, a Pfizer company; NDC 49502-500-02 ---- ALSO LABELED OUTSIDE THE US AS: Epipen Auto-Injector Jr. 0.15 mg -Bright Stock labeled for multiple countries- manufactured for Mylan by Meridian Medical Technologies, Inc., Columbia, MD 21046, a Pfizer company.

Product Quantity:
92,544 2-pak (U.S.); 198,579 syringes (O.U.S.)

Reason for Recall:
Defective Delivery System; reports of the device failing to activate which could result in a patient not receiving medication

Recall Number:
D-0691-2017

Code Information:
US lot 5GN767, expiration April 2017; lot 5GN773, expiration April 2017; lot 6GN215, expiration Sep 2017: INTERNATIONAL lot 5GR765, expiration March 2017; lot 5GK771, expiration April 2017; lot 5ED824, expiration April 20 17; and lot 6ED117, expiration ***

Class II Drugs Event

Event ID:
76627

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
12/12/2016

Voluntary / Mandated:
Voluntary: Firm Initiated

Center Classification Date:
05/02/2017

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Amneal Pharmaceuticals LLC
118 Beaver Trl
Glasgow KY United States

Distribution Pattern:
Nationwide within the US and PR

Associated Products

Product Description:
Rabeprazole Sodium Delayed Release Tablets, 20 mg, a) 30-count bottle (NDC 65162-0724-03), b) 90-count bottle (NDC 65162-0724-09), Rx Only, Manufactured by Amneal Pharmaceuticals Pvt. Ltd., Ahmedabad INDIA 382220, Distributed by Amneal Pharmaceuticals, Bridgewater, NJ 08807

Product Quantity:
105,215 Bottles

Reason for Recall:
Failed Dissolution Specifications

Recall Number:
D-0693-2017

Code Information:
Lot #: a) AR151324, AR151322, AR151325, Exp. 9/2017; AR160730A, AR160731A, AR160732A, Exp. 05/2018. b) AR151324, AR151322, AR151325, Exp. 9/2017; AR160730B, 5/2018.

Class II Drugs Event

Event ID:
76831

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
03/13/2017

Voluntary / Mandated:
Voluntary: Firm Initiated

Center Classification Date:
05/04/2017

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Akorn Inc
1925 W Field Ct
Lake Forest IL United States

Distribution Pattern:
Nationwide

Associated Products

Product Description:
Sulfamethoxazole and Trimethoprim Oral Suspension, USP 200 mg / 40 mg per 5 mL , Grape Flavor, Rx Only, 16 fl oz. (473 mL), HI-TECH PHARMACAL CO., INIC, Amityville, NY 11701, NDC 50383-824-16

Product Quantity:
55,968 bottles

Reason for Recall:
Failed Dissolution Specifications

Recall Number:
D-0696-2017

Code Information:
Lot# 348913, Exp.01/18; Lot# 349552, Exp.03/18; Lot# 349681, Exp. 03/18; Lot# 349683, Exp. 03/18; Lot# 349685, Exp. 03/18; Lot# 349687, Exp. 03/18; Lot# 349689, Exp. 03/18; Lot# 350636, Exp.03/18

Class II Drugs Event

Event ID:
77106

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
01/05/2017

Voluntary / Mandated:
Voluntary: Firm Initiated

Center Classification Date:
04/28/2017

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
The Harvard Drug Group
17177 N Laurel Park Dr Ste 233
Livonia MI United States

Distribution Pattern:
Nationwide within the US

Associated Products

Product Description:
Fluconazole Tablets, USP, 100 mg, 100-count Unit Dose carton, Rx only, Manufactured by Dr. Reddy's Laboratories Limited, Bachupally - 500 090 INDIA, Distributed by MAJOR PHARMACEUTICALS, 31778 Enterprise Dr., Livonia, MI 48150 USA, NDC 0904-6500-61

Product Quantity:
2,341 cartons

Reason for Recall:
Failed Dissolution Specifications

Recall Number:
D-0688-2017

Code Information:
Lot#: T-00520, EXP 02-17, T-00632, T-00699, EXP. 04-17

Product Description:
Fluconazole Tablets, USP, 200 mg, 100-count Unit Dose carton, Rx only, Manufactured by Dr. Reddy's Laboratories Limited, Bachupally - 500 090 INDIA, Distributed by MAJOR PHARMACEUTICALS, 31778 Enterprise Dr., Livonia, MI 48150 USA, NDC 0904-6501-61

Product Quantity:
914 cartons

Reason for Recall:
Failed Dissolution Specifications

Recall Number:
D-0689-2017

Code Information:
Lot #:T-00519, Exp. 01-17

Class III Drugs Event

Event ID:
77007

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
04/17/2017

Center Classification Date:
05/02/2017

Recalling Firm:
P & L Development, LLC
200 Hicks St
Westbury NY United States

Distribution Pattern:
Nationwide

Voluntary / Mandated:
Voluntary: Firm Initiated

Initial Firm Notification of Consignee or Public:
E-Mail

Associated Products

Product Description:
Allergy Relief Diphenhydramine HCl 25 mg, Antihistamine, Dye-Free, 24 Softgels, distributed under the following labels: (a) TopCare Allergy Relief, DISTRIBUTED BY TOPCO ASSOCIATES LLC, ELK GROVE VILLAGE, IL 60007, NDC 36800-483-24, UPC 0-36800-39134-5; (b) Rexall Since 1903 Allergy Relief, PACKAGED FOR DOLGENCORP, LLC, 100 MISSION RIDGE GOODLETTSVILLE, TN 37072, UPC 3-59726-72025-0; (c) HyVee health Allergy Relief, DISTRIBUTED BY HY-VEE, INC. 5820 WESTOWN PARKWAY, WEST DES MOINES, IA 50266, NDC 42507-483-24, UPC 0-75450-12369-2; (d) up & up allergy relief, Distributed by Target Corporation, Minneapolis, MN 55403, NDC 11673-720-24, UPC 3-59726-72025-0; (e) smart sense allergy softgels, Distributed by Kmart Corporation, Hoffman Estates, IL 60179, NDC 49738-483-24, UPC 8-83967-39839-3.

Product Quantity:
369,012 cartons

Reason for Recall:
Subpotent: This product is being recalled due to low out of specification assay results at the 9 month time point.

Recall Number:
D-0694-2017

Code Information:
Lot #: a) A01542, A03660, A04300, A04930, Exp 03/19; A05484, A07951, A12448, Exp 07/19; Y93105, Exp 02/19; b) A04938, Exp 03/19; A08149, A12621, Exp 07/19; c) A06557, A13030, Exp 03/19; d) A00239, Exp 03/19; A05180, A09906, Exp 07/19; Y83246, Y87531, Y87680, Exp 08/18; Y91225, Y92670, Y98200, Y98674, Exp 02/19; A13354, Exp 07/19; e) A07871, A11374, Exp 03/19; A14370, A18467, Exp 07/19.

Class III Drugs Event

Event ID:
77018

Status:
Ongoing

Recall Initiation Date:
04/17/2017

Center Classification Date:
05/03/2017

Recalling Firm:
Fagron, Inc
2400 Pilot Knob Rd
Saint Paul MN United States

Distribution Pattern:
Nationwide within US

Product Type:
Drugs

Date Terminated:

Voluntary / Mandated:
Voluntary: Firm Initiated

Initial Firm Notification of Consignee or Public:
Letter

Associated Products

Product Description:
Zinc Oxide Paste 25%, 500 g, For Prescription Compounding, Fagron Inc.2400 Pilot Knob Rd, St. Paul, MN 55120m NDC 51522-0694-5.

Product Quantity:

Reason for Recall:
Labeling: Error on Declared Strength: Error is due to an incorrect value in the Drug Facts Panel. The correct strength is displayed on the primary container.

Recall Number:
D-0695-2017

Code Information:
Lot #: 17C01-U07-036096, Exp. 5/1/2020

Class III Drugs Event

Event ID:
77105

Status:
Completed

Recall Initiation Date:
12/27/2016

Center Classification Date:
05/02/2017

Recalling Firm:
The Harvard Drug Group
17177 N Laurel Park Dr Ste 233
Livonia MI United States

Distribution Pattern:
Nationwide and PR

Product Type:
Drugs

Date Terminated:

Voluntary / Mandated:
Voluntary: Firm Initiated

Initial Firm Notification of Consignee or Public:
Letter

Associated Products

Product Description:
Aripiprazole Tablets, 2 mg, 30 count unit dose box, Rx only, Manufactured by Apotex Inc., Toronto, Ontario, Canada, Distributed by Major Pharmaceuticals, Livonia, MI NDC 0904-6509-04

Product Quantity:
36,990 tablets