Enforcement Report - Week of March 15, 2017

Class II Drugs Event

Event ID:
76467

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
01/19/2017

Voluntary / Mandated:
Voluntary: Firm Initiated

Center Classification Date:
03/03/2017

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
LEO PHARMA INC
7 Giralda Farms
Madison NJ United States

Distribution Pattern:
U.S. Nationwide

Associated Products

Product Description:
Calcipotriene Cream 0.0005%, packaged in a) 60g tube, (NDC 66993-877-61), b) 120g tube (NDC 66993-877-78), Rx Only, Manufactured by: LEO Pharma Inc., Dublin, Ireland, Manufactured for: Prasco Laboratories, Mason, OH, 45040

Product Quantity:
272,062 tubes

Reason for Recall:
Incorrect/Undeclared excipients: inadvertent omission of a drug excipient from the the Authorized Generic label and also a warning regarding contact dermatitis from the brand product labeling not being incorporated into the Authorized Generic labeling.

Recall Number:
D-0510-2017

Code Information:
Lot #: a) EK8760, Exp 2/17; EK1115, Exp 3/17; EK2358, Exp 4/17; EK6143, Exp 7/17; EM0837, Exp 10/17; EM2088, 12/17; A20899, Exp 5/18; A24492, Exp 6/18; b) EK8764, Exp 2/17; EL6145, Exp 7/17; EM2091, Exp 2/17; A2 5206, Exp 6/18.

Class II Drugs Event

Event ID:
76515

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
02/10/2017

Voluntary / Mandated:
Voluntary: Firm Initiated

Center Classification Date:
03/09/2017

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Sandoz Inc
100 College Rd W
Princeton NJ United States

Distribution Pattern:
Nationwide

Associated Products

Product Description:
Pioglitazone and Glimepiride Tablets, USP, 30 mg/4 mg, 30 count bottles, Rx only, Manufactured by Lek Pharmaceuticals d.d., Verovskova Ulica 57, Ljubljana, - SI-1526, Slovenia --- NDC 0781-5635-31

Product Quantity:

Reason for Recall:
Failed Dissolution Specifications

Recall Number:
D-0515-2017

Code Information:
Lot FY3669 with expiry 11/2017

Class II Drugs Event

Event ID:
76542

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
02/22/2017

Voluntary / Mandated:
Voluntary: Firm Initiated

Center Classification Date:
03/03/2017

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Endo Pharmaceuticals, Inc.
1400 Atwater Drive
Malvern PA United States

Distribution Pattern:
Nationwide within the United States

Associated Products

Product Description:
Edex (alprostadil for injection) 10mcg, packaged in a 2 pack carton, Rx only, Manufactured in Germany for: Actient Pharmaceuticals, LLC, Lake Forest, Illinois 60045; NDC 52244-010-02.

Product Quantity:
5,086 cartridges

Reason for Recall:
Lack of Assurance of Sterility: Defective container resulting in the lack of sterility assurance. ok thanks

Recall Number:
D-0512-2017

Code Information:
Lot #: 207386, Exp. May 2019

Class II Drugs Event

Event ID:
76631

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
02/23/2017

Voluntary / Mandated:
Voluntary: Firm Initiated

Center Classification Date:
03/07/2017

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 USA

Associated Products

Product Description:
Aspirin Chewable Tablets, 81 mg, (NSAID*), packaged in UD 750 Tablets (25 x 30) tablets in blisters per carton, Dist. By: McKesson Packaging Services, a business unit of McKesson Corporation, 7101 Weddington Rd., Concord, NC 28027, NDC 63739-434-01.

Product Quantity:
6,717 cartons

Reason for Recall:
Presence of Foreign Substance: foreign material found in the bulk inventory.

Recall Number:
D-0513-2017

Code Information:
Lot numbers: 0113784, 0113786, 0113834, 0113887, Exp. 07/18

Class III Drugs Event

Event ID:
76421

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
02/07/2017

Voluntary / Mandated:
Voluntary: Firm Initiated

Center Classification Date:
03/09/2017

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Actavis Inc
400 Interpace Pkwy
Parsippany NJ United States

Distribution Pattern:
Nationwide

Associated Products

Product Description:
Levofloxacin Ophthalmic Solution, 0.5%, Sterile, packaged in 5mL bottles, Rx Only, Manufactured by Hi-Tech Pharmacal Co., Inc., Amityville, NY 11707, NDC 50383-283-05

Product Quantity:
14280 bottles

Reason for Recall:
Failed Impurities/ Degradation Specifications: OOS for related compound (levofloxacin n-oxide) at the 18 month stability time point.

Recall Number:
D-0514-2017

Code Information:
Lot # 348748, Exp 11/30/2017; 350578, Exp 3/31/2018; 633467, Exp 3/31/2017

Class III Drugs Event