Enforcement Report - Week of September 13, 2017

Class II Drugs Event

Event ID:
77647

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
06/23/2017

Voluntary / Mandated:
Voluntary: Firm Initiated

Center Classification Date:
09/07/2017

Initial Firm Notification of Consignee or Public:
Two or more of the following: Email, Fax, Letter, Press Release, Telephone, Visit

Recalling Firm:
ImprimisRx CA, Inc., dba ImprimisRx
9257 Research Dr
Irvine CA United States

Distribution Pattern:
Nationwide

Associated Products

Product Description:
Curcumin Emulsion 10mg/ml Injection, Sterile 10 mL Multiple Dose Vial, For Slow IV Administration, Compounded for a licensed professional or patient use by ImprimisRx, Irvine, CA

Product Quantity:
2608 vials

Reason for Recall:
Incorrect/Undeclared Excipient; non-pharmaceutical grade PEG 40 Castor Oil was used due to a mislabeling by the supplier

Recall Number:
D-1130-2017

Code Information:
03212017@21B Exp:6/19/2017; 03232017@19B Exp:6/21/2017; 03292017@27B Exp:6/27/2017; 03292017@9B Exp:6/27/2017; 04042017@21B Exp:7/3/2017; 04122017@22B Exp:7/11/2017; 04132017@14B Exp:7/12/2017; 04192017@37B Exp:7/18/2017; 04192017@17B Exp:7/18/2017; 04242017@18B Exp:7/23/2017

Product Description:
Latanoprost PF Solution, 0.005%, Ophthalmic Drops in Sterile 5ml Bottles, Compounded for a licensed professional or patient use, imprimisRx, Irvine, CA

Product Quantity:
19 bottles

Reason for Recall:
Incorrect/Undeclared Excipient; non-pharmaceutical grade PEG 40 Castor Oil was used due to a mislabeling by the supplier

Recall Number:
D-1131-2017

Code Information:
0404017@32B, 10/01/2017

Product Description:
Timolol-Latanoprost PF Solution (0.5-0.005)%, Ophthalmic Drops, Sterile 5ml Bottle, Compounded for a licensed professional or patient use, imprimisRx, Irvine, CA

Product Quantity:
16 bottles

Reason for Recall:
Incorrect/Undeclared Excipient; non-pharmaceutical grade PEG 40 Castor Oil was used due to a mislabeling by the supplier

Recall Number:
D-1132-2017

Code Information:
04042017@34B, 10/01/2017

Product Description:
Timolol-Brimonidine-Dorzolamide-Latanoprost (0.5/0.15/2/0.005)% Ophthalmic Drops, Sterile 5ml Bottle, Compounded for a licensed professional or patient use, imprimisRx, Irvine, CA

Product Quantity:
2 bottles

Reason for Recall:
Incorrect/Undeclared Excipient; non-pharmaceutical grade PEG 40 Castor Oil was used due to a mislabeling by the supplier

Recall Number:
D-1133-2017

Code Information:
05092017@2B, 11/5/2017

Class II Drugs Event

Event ID:
78034

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
08/04/2017

Voluntary / Mandated:
Voluntary: Firm Initiated

Center Classification Date:
09/07/2017

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Degasa Sa De Cv
Calle Centenario 15 Col. DEPORTIVA
Jiutepec Mexico

Distribution Pattern:
CA, IL.

Associated Products

Product Description:
Povidone Iodine, USP Prep Solution, 10%, packaged in 1 gallon bottle, OTC, Manufactured for PSS World Medical, Inc. Southpoint Blvd. Jacksonville, FL Made in Mexico, NDC 68345-350-09

Product Quantity:
720 bottles

Reason for Recall:
Labeling: Label mix-up. Finished product Povidone iodine 7.5% was labeled as Povidone iodine 10% , the outer box had the correct label.

Recall Number:
D-1129-2017

Code Information:
Lot #: 3A176011, Exp 10/18

Class III Drugs Event

Event ID:
78020

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
08/28/2017

Voluntary / Mandated:
Voluntary: Firm Initiated

Center Classification Date:
09/06/2017

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Mckesson Packaging Services
7101 Weddington Rd NW
Concord NC United States

Distribution Pattern:
PA, OH, IL, CO, LA

Associated Products

Product Description:
Propafenone Hydrochloride tablets, 150 mg, packaged in 10 x 10 unit dose cards (100-count box), Rx only, Manufactured By: Watson Pharmaceuticals 311 Bonnie Circle Corona, CA 92880, NDC 63739-509-10

Product Quantity:
3966 unit-dose boxes

Reason for Recall:
Failed moisture limits: Out of specification for moisture content.

Recall Number:
D-1128-2017

Code Information:
Lot#: 0112313 Exp. 12/2017; 0113376 Exp. 06/2018; 0113645 Exp. 02/2019.

Class III Drugs Event

Event ID:
78032

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
05/02/2017

Voluntary / Mandated:
Voluntary: Firm Initiated

Center Classification Date:
09/01/2017

Initial Firm Notification of Consignee or Public:
E-Mail

Recalling Firm:
Lupin Pharmaceuticals Inc.
111 S Calvert St Fl 21ST
Baltimore MD United States

Distribution Pattern:
Nationwide in the USA

Associated Products

Product Description:
Famotidine for Oral Suspension USP, 40 mg/5 mL, 50 mL bottle, Rx only, Manufactured for: Lupin Pharmaceuticals, Inc., Baltimore, Maryland 21202; Manufactured by: Lupin Limited, Goa 403 722 INDIA, NDC 68180-150-01

Product Quantity:
12,888 bottles

Reason for Recall:
CGMP Deviations

Recall Number:
D-1127-2017

Code Information:
Lot #: G606950, Exp 07/18