Enforcement Report - Week of February 13, 2019

Class II Drugs Event

Event ID:
81784

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
12/07/2018

Voluntary / Mandated:
Voluntary: Firm Initiated

Center Classification Date:
02/04/2019

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
US Pharmaceuticals Inc.
681 Main St Ste 27
Belleville NJ United States

Distribution Pattern:
Nationwide within the United States

Associated Products

Product Description:
Soothe & Cool Protect Moisture Guard Skin Protectant (petrolatum 59%),3.5 oz tubes, Manufactured in USA for: Medline Industries, Inc., Mundelein, IL 60060 USA NDC 53329-303-22

Product Quantity:
19752 units

Reason for Recall:
GMP Deviations: Out of specification results for Total Aerobic Microbial count in excipient purified water sample

Recall Number:
D-0425-2019

Code Information:
Lot #: 50G17, Exp. 5/2019; 76J17, Exp. 7/2019

Product Description:
Hydrocortisone Cream 1% MS Anti itch Cream with Intensive Healing 2 oz tubes, Distributed by: Walgreen Co. 200 Wilmot Rd. Deerfield, IL 60015, NDC 0363-0237-03

Product Quantity:
67848 units

Reason for Recall:
GMP Deviations: Out of specification results for Total Aerobic Microbial count in excipient purified water sample

Recall Number:
D-0426-2019

Code Information:
Lot #: 36G17, 47G17, Exp. 5/2019; 84J17, Exp. 7/2019

Product Description:
Medline Remedy Essential Barrier Skin Protectant Ointment (petrolatum 59%) packaged in a) 2 oz tubes (NDC 53329-302-14) and b) 6 oz tubes (NDC 53329-302-41), Medline Industries Inc., Manufactured for Medline Industries Inc., Mundelien, IL 60060.

Product Quantity:
7020 units

Reason for Recall:
GMP Deviations: Out of specification results for Total Aerobic Microbial count in excipient purified water sample

Recall Number:
D-0427-2019

Code Information:
Lot # a) and b): 44G17, Exp. 05/2019

Class II Drugs Event

Event ID:
81980

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
02/01/2019

Voluntary / Mandated:
Voluntary: Firm Initiated

Center Classification Date:
02/04/2019

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Mylan Pharmaceuticals Inc.
781 Chestnut Ridge Rd
Morgantown WV United States

Distribution Pattern:
Nationwide in the USA.

Associated Products

Product Description:
Dymista (azelastine hydrochloride and fluticasone propionate) Nasal Spray, 137 mcg/50 mcg per spray, 120 Metered Sprays, 23 g net fill weight bottle, Rx Only, Manufactured by: Cipla Ltd., Goa, India, M.L. No. 546; For: Meda Pharmaceuticals Inc., Somerset, New Jersey 08873-4120, NDC 0037-0245-23.

Product Quantity:
10,390 bottles

Reason for Recall:
Defective Container: Potential for broken glass in the neck area of the glass bottles.

Recall Number:
D-0424-2019

Code Information:
Lot: GA70535, Exp. April 2019

Class III Drugs Event

Event ID:
82022

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
01/28/2019

Voluntary / Mandated:
Voluntary: Firm Initiated

Center Classification Date:
02/05/2019

Initial Firm Notification of Consignee or Public:
Letter

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

Distribution Pattern:
Nationwide within the United States.

Associated Products

Product Description:
Bimatoprost Ophthalmic Solution 0.03%, packaged in a) 5 mL (NDC 68180-429-02) and b) 7.5 mL (NDC 68180-429-03) bottles, Rx only, Manufactured by: Lupin Limited Pithampur (M.P.) 454 775, INDIA.

Product Quantity:
9,930 bottles

Reason for Recall:
Failed Impurities/Degradation Specifications: OOS results observed in any other individual impurity and total impurities.

Recall Number:
D-0429-2019

Code Information:
a) H804506 Exp. 06/2020; 803555 Exp. 04/2020; H805394, Exp. 08/2020 b) H804112 Exp. 05/2020; H803220 Exp. 03/2020

Not Yet Classified Drugs Event

Event ID:
81999

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
01/25/2019

Voluntary / Mandated:
Voluntary: Firm Initiated

Center Classification Date:

Initial Firm Notification of Consignee or Public:
E-Mail

Recalling Firm:
Natures Rx
310 N Indian Hill Blvd Ste 600
Claremont CA United States

Distribution Pattern:
eBay sales

Associated Products

Product Description:
the silver bullet 10x Capsules, 725 mg each (proprietary blend of: Mucuna Pruriens Extract, Horny Goat Weed, Ginger Root Extract, Icariin, Wolf Berry (fruit) Lactase, Tribulus Terrestris Extract, Piperine), 10 count mylar package, Nature's Rx, Claremont, CA

Product Quantity:
211

Reason for Recall:
Marketed without an Approved NDA/ANDA; FDA analysis found product to be tainted with undeclared sildenafil and tadalafil

Recall Number:

Code Information:
All lots within expiry