Enforcement Report - Week of January 8, 2020

Class I Drugs Event

Event ID:
84279

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
11/13/2019

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
12/31/2019

Initial Firm Notification of Consignee or Public:
Press Release

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

Distribution Pattern:
Nationwide in the U.S.

Associated Products

Product Description:
Silver Bullet, Get Bigger and Harder, Works in Minutes, Lasts for Days, 10 male enhancement capsules in blister foil package, 725mg per capsule, Distributed by Silver Bullet Ltd, Golden Springs, CO, USA, UPC: 610877392698.

Product Quantity:
2,800 capsules

Reason for Recall:
Marketed Without an Approved NDA/ANDA; Product contains undeclared active ingredient - Sildenafil.

Recall Number:
D-0633-2020

Code Information:
Lot # 01251ZX1, exp. date 11/2022 UPC: 610877392698

Class II Drugs Event

Event ID:
84208

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
11/01/2019

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
12/29/2019

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
American Health Packaging
2550 John Glenn Ave Ste A
Columbus OH United States

Distribution Pattern:
Nationwide USA

Associated Products

Product Description:
Ranitidine Syrup (Ranitidine Oral Solution USP), 15 mg/mL, 150 mg/10 mL per cup, Rx Only, Distributed by: American Health Packaging, Columbus, Ohio. (a) Case of 50 cups (NDC 60687-260-69) (b) Case of 40 cups (NDC 60687-260-23 (c) Unit Dose Cup (NDC 60687-260-69)

Product Quantity:
1,692 cases of 40 and 50 cups

Reason for Recall:
CGMP Deviations: Presence of NDMA impurity detected in product.

Recall Number:
D-0631-2020

Code Information:
[Case of 40] Lots 183723, 184278, exp 10/31/2020; Lot 187652, exp 05/31/2021; [Case of 50] Lot 177874, exp 01/31/ 2020; Lot 178413, exp 02/29/ 2020; Lot 183449, exp 10/31/2020; Lot 184445, exp 12/31/ 2020; Lot 186563, exp 03/31/ 2021; Lot 187691, exp 05/31/2021

Class II Drugs Event

Event ID:
84261

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
11/15/2019

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
01/06/2020

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Akorn, Inc.
1925 W Field Ct Ste 300
Lake Forest IL United States

Distribution Pattern:
Nationwide in the USA and Puerto Rico

Associated Products

Product Description:
MYORISAN (isotretinoin capsules, USP), 20mg, packaged in 30-count Capsules (3 x 10 Prescription Packs) per box, Rx only, Distributed by: VersaPharm Inc. - An Akorn Company, Lake Forset, IL 60045; NDC 61748-302-13.

Product Quantity:
4,206 boxes

Reason for Recall:
Unit Dose Mispackaging: Customer complaint that a carton labeled as Myorisan 20 mg Capsules, USP erroneously contained one 10-count blister card of the 40 mg product in addition to two 10-count blister cards of the 20 mg product.

Recall Number:
D-0647-2020

Code Information:
Lot V20M54A, Exp 01/2021

Class II Drugs Event

Event ID:
84522

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
12/13/2019

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
12/29/2019

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Granules India Limited
Plot No. 160/A, 161/E, 162 and 174/A Gagillapur Village
Qutbullapur Mandal, Ranga Redd India

Distribution Pattern:
OR, NY, NJ

Associated Products

Product Description:
RANITIDINE TABLETS, USP 150mg, 10,000-count bag, Country of Origin: INDIA NDC 62207-773-32

Product Quantity:
23,090,000 tablets

Reason for Recall:
CGMP Deviations: Impurity N-nitrosodimethylamine (NDMA) found in API

Recall Number:
D-0632-2020

Code Information:
7730001A, 7730002A, 7730003A, 7730004A, 7730005A, 7730006A, 7730007A, 7730008A, 7730009A, 7730010A, 7730011A and 7730012A

Class III Drugs Event

Event ID:
84495

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
12/13/2019

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
01/02/2020

Initial Firm Notification of Consignee or Public:
Letter

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

Distribution Pattern:
Nationwide in the U.S.

Associated Products

Product Description:
Bimatoprost Ophthalmic Solution, 0.03%, For Use in the Eyes Only, Sterile, Rx Only, 7.5 mL bottle, Manufactured by: Lupin Limited, Pithampur (M.P.), INDIA, NDC: 68180-429-03.

Product Quantity:
2,130 bottles

Reason for Recall:
Failed Impurities/Degradation Specifications: Out-of-specification result observed in any other individual impurity.

Recall Number:
D-0635-2020

Code Information:
Lot# H801686, Exp. 12/31/2019.

Class III Drugs Event

Event ID:
84561

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
12/20/2019

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
12/31/2019

Initial Firm Notification of Consignee or Public:
Telephone

Recalling Firm:
Island Kinetics, Inc. d.b.a. CoValence Laboratories
460 S Benson Ln Ste 1-3
Chandler AZ United States

Distribution Pattern:
AZ

Associated Products

Product Description:
PCA Skin Blemish Control Bar, 3.2 oz/90g, Salicylic acid 2% - Acne cleanser, For external use only, Distributed by PCA Skin, 6210 E. Thomas Rd., Ste. 200, Scottsdale, AZ 85251; UPC 812025010397.

Product Quantity:
2542 units

Reason for Recall:
Superpotent Drug: Salicylic acid content is above the firm's specification.

Recall Number:
D-0634-2020

Code Information:
Batch number: L041918A, Exp. 04/2021 Lot # F9518B2