Enforcement Report - Week of August 3, 2022

Class I Drugs Event

Event ID:
90539

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
06/27/2022

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
07/22/2022

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

Recalling Firm:
Valor Compounding Pharmacy, Inc DBA Valor Compounding Pharmacy
2461 Shattuck Ave
Berkeley CA United States

Distribution Pattern:
CA only

Associated Products

Product Description:
Nifedipine WSP 0.2% Ointment, 60 gram tubes, Rx only, Valor Compounding Pharmacy, 2461 Shattuck Ave., Berkeley, CA 94704

Product Quantity:
5 (60 gram) tubes

Reason for Recall:
Subpotent and Superpotent Drug

Recall Number:
D-1286-2022

Code Information:
Lot #: 06162022@30, BUD 12/13/2022

Class I Drugs Event

Event ID:
90545

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
07/05/2022

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
07/26/2022

Initial Firm Notification of Consignee or Public:
Press Release

Recalling Firm:
Mylan Pharmaceuticals Inc
5005 Greenbag Rd
Morgantown WV United States

Distribution Pattern:
Product was distributed nationwide within the United States

Associated Products

Product Description:
Insulin Glargine (Insulin glargine-yfgn) Injection, 100 units/mL (U-100), 3 mL prefilled pens (NDC 49502-394-71), packaged in cartons of 5 prefilled pens (NDC 49502-394-75), Rx only, Manufactured by: Mylan Pharmaceuticals Inc., Morgantown, WV 15317, Manufactured for: Mylan Specialty L.P., Morgantown, WV

Product Quantity:
253,200 pens (50,650/5 per packs)

Reason for Recall:
Labeling: Missing label: Label missing from some prefilled pens.

Recall Number:
D-1292-2022

Code Information:
Lot #: BF21002895, Exp. Date Aug 2023

Class I Drugs Event

Event ID:
90581

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
07/13/2022

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
08/03/2022

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

Recalling Firm:
Pfizer Inc.
235 East 42nd Street
New York NY United States

Distribution Pattern:
USA Nationwide

Associated Products

Product Description:
Propofol Injectable Emulsion, 1 g/100 mL (10 mg/mL), packaged in 100 mL per glass fliptop vial (NDC 0409-4699-54) further packaged in a tray of 10 vials (NDC Carton: 0409-4699-24), Rx only, Distributed by Hospira, Inc., Lake Forest, IL 60045 USA

Product Quantity:
54,000 vials

Reason for Recall:
Presence of particulate matter: particulate identified as a beetle.

Recall Number:
D-1301-2022

Code Information:
Lot #: DX9067, Exp 5/1/2023

Class II Drugs Event

Event ID:
90495

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
06/27/2022

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
07/26/2022

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
SUN PHARMACEUTICAL INDUSTRIES INC
2 Independence Way
Princeton NJ United States

Distribution Pattern:
Nationwide in the USA

Associated Products

Product Description:
Divalproex Sodium Delayed-Release Tablets, USP 500mg, Rx Only, 100 Tablets, Distributed by: Sun Pharmaceutical Industries, Inc., Cranbury, NJ 08512, Manufactured by: Sun Pharmaceutical Industries, Ltd., Halol-Baroda Highway, Halol- 389 350, Gujarat, India, NDC 62756-798-88.

Product Quantity:
9552 bottles

Reason for Recall:
Failed Dissolution Specifications: Failure occurred during routine stability testing of dissolution test.

Recall Number:
D-1291-2022

Code Information:
Lot: HAC1312A, EXP. 05/2024

Class II Drugs Event

Event ID:
90534

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
06/29/2022

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
07/25/2022

Initial Firm Notification of Consignee or Public:

Recalling Firm:
Teva Pharmaceuticals USA Inc
400 Interpace Pkwy Bldg A
Parsippany NJ United States

Distribution Pattern:
Nationwide in the USA

Associated Products

Product Description:
Testosterone Gel 1% (25mg testosterone/2.5g of gel) 2.5 g per unit dose, Rx Only, 30 unit-dose packets per box. Manufactured by: Actavis Laboratories UT, Inc., Salt Lake City, US 84108, USA, Distributed by: Actavis Pharma, Inc., Parsippany, NJ 07054, USA, Sachet NDC 0591-3216-17, Carton NDC 0591-3216-30

Product Quantity:
12354 cartons

Reason for Recall:
Superpotent Drug: Out of specification assay result was obtained during stability testing.

Recall Number:
D-1289-2022

Code Information:
Lot: 1403180, EXP. 10/2022

Class II Drugs Event

Event ID:
90601

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
07/13/2022

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
07/22/2022

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Dr. Reddy's Laboratories, Inc.
107 College Rd E
Princeton NJ United States

Distribution Pattern:
Nationwide in the USA

Associated Products

Product Description:
Lansoprazole Delayed-Release Orally Disintegrating Tablets, 15 mg, 100-count blisters per carton, 10 Packs of 10 Tablets Each, Rx Only, Distributed by: Dr. Reddy's Laboratories, Inc., Princeton, NJ 08540, Made in India, blister barcode 4359856079, NDC 43598-560-78

Product Quantity:
2,892 cartons

Reason for Recall:
FAILED DISSOLUTION SPECIFICATIONS

Recall Number:
D-1287-2022

Code Information:
Lot T2100514, Exp 01/2023

Product Description:
Lansoprazole Delayed-Release Orally Disintegrating Tablets, 35 mg, 100-count blisters per carton, 10 Packs of 10 Tablets Each, Rx Only, Distributed by: Dr. Reddy's Laboratories, Inc., Princeton, NJ 08540, Made in India, blister barcode 4359856179, NDC 43598-561-78

Product Quantity:
2,639 cartons

Reason for Recall:
FAILED DISSOLUTION SPECIFICATIONS

Recall Number:
D-1288-2022

Code Information:
Lot T2100515, Exp 01/2023

Class II Drugs Event

Event ID:
90610

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
07/18/2022

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
07/26/2022

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Jubilant Cadista Pharmaceuticals, Inc.
207 Kiley Dr
Salisbury MD United States

Distribution Pattern:
Nationwide within the United States

Associated Products

Product Description:
Irbesartan Tablets, USP, 150mg, 90- count bottles, Rx only, Manufactured by: Jubilant Generics Ltd. Roorkee- 247661, India, Marketed by: Jubilant Cadista Pharmaceuticals Inc. Salisbury, MD 21801, USA, NDC 59746-448-90

Product Quantity:
9,600 bottles

Reason for Recall:
Failed dissolution specifications.

Recall Number:
D-1293-2022

Code Information:
Lot #: IB220023A, exp. date 08/2022

Product Description:
Irbesartan Tablets, USP, 75 mg, 90- count bottle, Rx only, Manufactured by: Jubilant Generics Ltd. Roorkee- 247661, India, Marketed by: Jubilant Cadista Pharmaceuticals Inc. Salisbury, MD 21801, USA, NDC 59746-447-90

Product Quantity:
28,560 bottles

Reason for Recall:
Failed Dissolution Specifications

Recall Number:
D-1294-2022

Code Information:
Lot #: IB120012A, IB120013A, IB120014A Exp. date 08/2022

Class III Drugs Event

Event ID:
90560

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
06/29/2022

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
07/27/2022

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Eco Lips, Inc
6000 Huntington Ct Ne
Cedar Rapids IA United States

Distribution Pattern:
CA

Associated Products

Product Description:
Juice Beauty, The Organic Solution, SPF 8, Joyful Lip Moisturizer, Hydratant pour les Levres, NET WT 0.15 oz (4.25 g) per tube, Active Ingredient: Zinc oxide 4%, Manufactured for Juice Beauty, Inc., 709 Fifth Ave., San Rafael, California 94901-3566

Product Quantity:
15,313 tubes

Reason for Recall:
Failed Dissolution Specifications

Recall Number:
D-1298-2022

Code Information:
Lot#: 90121-20321 Exp: 11/2023

Product Description:
Juice Beauty, The Organic Solution, SPF 8, Naturally Clear Lip Moisturizer, Hydratant pour les Levres, NET WT 0.15 oz (4.25 g) per tube, Active Ingredient: Zinc oxide 4%, Manufactured for Juice Beauty, Inc., 709 Fifth Ave., San Rafael, California 94901-3566

Product Quantity:
35,313 tubes

Reason for Recall:
Failed Dissolution Specifications

Recall Number:
D-1299-2022

Code Information:
Lot #: 90122-21015, Exp: 01/24; Lot#: 90122-20356, Exp: 12/23

Class III Drugs Event

Event ID:
90586

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
07/08/2022

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
07/26/2022

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
The Procter & Gamble Company
1 Procter And Gamble Plz
Cincinnati OH United States

Distribution Pattern:
Washington State

Associated Products

Product Description:
Crest 3D White Fluoride Anticavity Toothpaste, Advanced Triple Whitening, 0.243% sodium fluoride, Net Wt. 5.6 oz (158 g) a) Individual carton, UPC 0 37000 598534; b) 5-count Bundle, UPC 037000171867, Distributed. By Procter & Gamble, Cincinnati, OH 45202.

Product Quantity:
1,128 tubes

Reason for Recall:
Labeling: Missing label: the product tube was missing a label and contained a different formulation.

Recall Number:
D-1290-2022

Code Information:
Lot: a) 13191707B4, Exp. 10/31/2023; b)13511707Y1, Exp. 10/31/2023.