Enforcement Report - Week of April 14, 2021

Class I Drugs Event

Event ID:
87533

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
03/17/2021

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
04/07/2021

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Alembic Pharmaceuticals Limited
Near Baska
Tajpura India

Distribution Pattern:
Nationwide within the United States

Associated Products

Product Description:
Telmisartan Tablets, USP 20 mg, 30-count bottles, Rx only, Manufactured by: Alembic Pharmaceuticals Limited (Formulation Division) Panelav 38935, Gujarat, India Manufactured for: Alembic Pharmaceuticals, Inc. 750 Route 202, Bridgewater, NJ 08807, NDC 62332-087-30

Product Quantity:
12288 bottles

Reason for Recall:
Labeling: Label-mixup

Recall Number:
D-0326-2021

Code Information:
Lot #: 1905005661, Exp March 2022

Class II Drugs Event

Event ID:
87304

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
02/01/2021

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
04/02/2021

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Kimberly-Clark Corporation
1400 Holcomb Bridge Rd
Roswell GA United States

Distribution Pattern:
Nationwide in the US. Product also distributed in Canada.

Associated Products

Product Description:
Scott¿ Moisturizing Foam Hand Sanitizer, 1.2 Liters (40.5 fl oz), Distributed in the U.S. by Kimberly-Clark Global Sales, LLC, Roswell, GA 30076-2199 Distributed in Canada by Kimberly-Clark Inc., Mississauga, Ontario L5B 3Y5 UPC 0 36000 91592 1

Product Quantity:
2,982 cases

Reason for Recall:
Labeling; Label Mix-up; some bottles containing Foam Skin Cleanser soap are incorrectly labeled as Moisturizing Foam Hand Sanitizer

Recall Number:
D-0319-2021

Code Information:
Product Code 91590 Lot #WV0280SLA EXP: 2022/09/29

Class II Drugs Event

Event ID:
87500

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
03/19/2021

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
04/08/2021

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
X-Gen Pharmaceuticals Inc.
300 Daniel Zenker Dr
Horseheads NY United States

Distribution Pattern:
Distributed Nationwide in the USA

Associated Products

Product Description:
Neomycin Sulfate Tablets, USP 500mg, Rx Only, 10x10 Unit dose 100 Tablets, Manufactured for: X-GEN Phamaceuticals, Inc. Big Flats, NY 14814. NDC 39822-0310-5

Product Quantity:
720 100-count (10x10 blister strips)

Reason for Recall:
Failed Stability Specifications: Out of Specification (OOS) result reported for microbiological assay and Neomycin C for the 3-month 25¿C/65% RH stability timepoint for the representative 2020 annual stability Lot CFPXF that utilized the same API Lot (CM8254) and was manufactured in the same campaign as Lot CFMBX. The OOS for microbiological assay was reported as 87.0%, outside the stability specifications of 90.0 to 120.0%. Lot CFMBX had a reported microbiological assay value of 93.4% at time of release and, although within specifications, is on the lower end of the specification and is not expected to meet its expiry dating of 24 months.

Recall Number:
D-0328-2021

Code Information:
Lot # CFMBX, EXP 9/2022

Class II Drugs Event

Event ID:
87545

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
03/15/2021

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
04/02/2021

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
SUN PHARMACEUTICAL INDUSTRIES INC

2 Independence Way
Princeton NJ United States

Distribution Pattern:
NJ

Associated Products

Product Description:
Ganirelix Acetate Injection, 250 mcg/0.5 mL, Sterile Prefilled Syringe, Rx only, Distributor: Ferring Pharmaceuticals, Inc., Parsippany, NJ 07054 USA, Manufactured by: Sun Pharmaceutical Industries Ltd, Halol, Gujarat, India Made in India, NDC 55566-1000-1.

Product Quantity:
91,211 syringes

Reason for Recall:
Failed Impurities/Degradation Specifications

Recall Number:
D-0320-2021

Code Information:
Lots JKU1212A, JKU1503A, JKU1504A, JKU1505A, JKU1506A, Exp 03/2021; JKU3313A & JKU3314A, Exp 08/2021.

Class II Drugs Event

Event ID:
87608

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
03/25/2021

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
04/07/2021

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Cosette Pharmaceuticals, Inc.
111 Coolidge St
South Plainfield NJ United States

Distribution Pattern:
Nationwide in the US

Associated Products

Product Description:
Mometasone Furoate Topical Solution, USP, 0.1%, (Lotion), a) 30 mL (NDC 0713-0701-85) and b) 60 mL (NDC 0713-0701-53), Rx Only, Distributed by: Cosette Pharmaceuticals, Inc., South Plainfield, NJ 07080

Product Quantity:
a) 30 mL: 7724 b) 60 mL: 8064 bottles

Reason for Recall:
CGMP Deviaitons

Recall Number:
D-0327-2021

Code Information:
a) 30 mL: 1014611 and 1014612, exp 12/2022 b) 60 mL:1014593, 1014594 and 1014595, exp 10/2022

Class II Drugs Event

Event ID:
87648

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
03/31/2021

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
04/06/2021

Initial Firm Notification of Consignee or Public:
Press Release

Recalling Firm:
Apotex Corp.
2400 N Commerce Pkwy Ste 400
Weston FL United States

Distribution Pattern:
Nationwide within the United States

Associated Products

Product Description:
Guanfacine Extended-Release Tablets 2 mg,100-count bottles, Rx Only, Manufactured by: Apotex Inc. Toronto, Ontario Canada M9L 1T9 Manufactured for: Apotex Corp. Weston, Florida 33326, NDC 60505-3928-1, UPC 3 60505 39281 0

Product Quantity:
55620 bottles

Reason for Recall:
Cross Contamination with Other Product: Product is being recalled due to Trace Amounts of Quetiapine Fumarate

Recall Number:
D-0324-2021

Code Information:
Lot #: RX1662, RX1663, RX1664 Exp. 11/2022

Class III Drugs Event

Event ID:
87547

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
03/18/2021

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
04/05/2021

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Washington Homeopathic Products, Inc.
260 J R Hawvermale Way
Berkeley Springs WV United States

Distribution Pattern:
Product was distributed to MD, CO & TX only

Associated Products

Product Description:
Macula Pellets Homeopathic Medicine, 1 Oz bottles, Rx only, Manufactured for: Natural Ophthalmics Inc. PO Box 1510 Dillon, CO 80435, NDC 58770-190-42

Product Quantity:
1,909 bottles

Reason for Recall:
An error occurred where the product was manufactured with Potassium Chloride instead of Potassium Phosphate.

Recall Number:
D-0321-2021

Code Information:
Lot # 27479, exp. date 11/2022

Product Description:
Sp-4, 100 mL solution bottles, Rx only, Washington Homeopathic Products, Inc.260 J R Hawvermale Way Berkeley Springs West Virginia 25411

Product Quantity:
114 bottles

Reason for Recall:
An error occurred where the product was manufactured with Potassium Chloride instead of Potassium Phosphate.

Recall Number:
D-0322-2021

Code Information:
Lot # 24844, 25500, 26310

Product Description:
LCL-2-0191, 5 gallon carboys, Rx only, Manufactured for: LaCore Labs, LLC, by: Washington Homeopathic Products, Inc.260 J R Hawvermale Way Berkeley Springs West Virginia 25411

Product Quantity:
300 liters

Reason for Recall:
An error occurred where the product was manufactured with Potassium Chloride instead of Potassium Phosphate.

Recall Number:
D-0323-2021

Code Information:
Lot # 28506

Class III Drugs Event

Event ID:
87617

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
03/25/2021

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
04/07/2021

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:
Metformin HCl Extended-Release Tablets, USP, 500 mg, Rx Only, 500-count bottle, Rx only, Distributed by: Sun Pharmaceutical Industries, Inc., Cranbury, NJ 08512; Manufactured by: Sun Pharmaceutical Industries Ltd., Halol-Baroda HIghway, Halol-389 350 Gujarat, India, NDC 62756-142-02.

Product Quantity:
2520 bottles

Reason for Recall:
Failed Moisture Limits: Out of specification for water content

Recall Number:
D-0325-2021

Code Information:
Lot #JKU4639A, Exp 10/2022