Enforcement Report - Week of July 6, 2022

Class I Drugs Event

Event ID:
90245

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
05/23/2022

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
06/27/2022

Initial Firm Notification of Consignee or Public:
E-Mail

Recalling Firm:
Akcea Therapeutics, Inc.
2855 Gazelle Ct
Carlsbad CA United States

Distribution Pattern:
KY, USA

Associated Products

Product Description:
Tegsedi (inotersen) Injection 284 mg/1.5 mL, Rx Only, Sterile solution for Subcutaneous Use, 4 prefilled syringes, each containing 284 mg of inotersen, (equivalent to 300 mg inotersen sodium in 1.5 ml of solution), Distributed by Sobi, Inc. Inc Waltham MA 02451, NDC: 72126-007-01

Product Quantity:
450 cartons

Reason for Recall:
Superpotent: High Out of specification (OOS) test result for percent label claim (%LC).

Recall Number:
D-1166-2022

Code Information:
Lots: 028C21AB, 028C21AC, Exp. 05/2025

Class I Drugs Event

Event ID:
90382

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
06/08/2022

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
06/24/2022

Initial Firm Notification of Consignee or Public:
Press Release

Recalling Firm:
Buzzagogo, LLC
85 Lakeview Dr
Nottingham NH United States

Distribution Pattern:
Product was distributed via the internet to consumers, retailers and to distributors who may have further distributed the product.

Associated Products

Product Description:
Allergy Bee Gone for Kids Nasal Swab Remedy 0.33 FL OZ (10 mL) tubes, UPC Code 860002022116

Product Quantity:
28,328 tubes

Reason for Recall:
Microbial Contamination of Non-Sterile Product

Recall Number:
D-1160-2022

Code Information:
Lot #: 2006491, Exp. Date 08/24

Class I Drugs Event

Event ID:
90384

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
06/09/2022

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
06/27/2022

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

Recalling Firm:
Green Pharmaceuticals, Inc.
591 Constitution Ave Ste A
Camarillo CA United States

Distribution Pattern:
Nationwide within the United States

Associated Products

Product Description:
SnoreStop NasoSpray, 0.3 FL OZ (9 mL), Green Pharmaceuticals Inc. Camarillo, CA 93012 NDC 61152-199-99, UPC 69682 29101

Product Quantity:
1074 units

Reason for Recall:
Microbial Contamination of Non-Sterile Product. Microbial contamination identified as Providencia rettgeri.

Recall Number:
D-1165-2022

Code Information:
Lot #: 2373/21222

Class II Drugs Event

Event ID:
90383

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
06/06/2022

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
06/27/2022

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
PD-Rx Pharmaceuticals, Inc.
727 N Ann Arbor Ave
Oklahoma City OK United States

Distribution Pattern:
Nationwide

Associated Products

Product Description:
Losartan Potassium Tablets, USP 25 mg, 90 Tablets bottles, Rx Only Marketed and Packaged By: PD-Rx Pharmaceuticals, Inc. Oklahoma City, OK 73127 Manufactured by: Vivimed Life Sciences Private Limited, Plot No. 101, 102, 107 & 108 SIDCO Pharmaceutical Complex, Alathur, Kanchipuram-603 110, Tamilnadu, India NDC 72789-163-90 UPC 3 72789 16390 1

Product Quantity:
1441 bottles

Reason for Recall:
CGMP Deviations- AZIDO Impurity levels observed to be above acceptable limits

Recall Number:
D-1161-2022

Code Information:
Lots: D21C18 Exp. 09/30/22; E21A28 Exp. 09/30/22; E21C04 Exp. 09/30/22; E21D59 Exp. 09/30/22; G21B65 Exp. 09/30/22; H21A12 Exp. 09/30/22; H21D42 Exp. 09/30/22; K21D19 Exp. 10/31/22; A22A73 Exp. 10/31/22

Product Description:
Losartan Potassium Tablets, USP 50 mg, 90 Tablets bottles, Rx Only Marketed and Packaged By: PD-Rx Pharmaceuticals, Inc. Oklahoma City, OK 73127 Manufactured by: Vivimed Life Sciences Private Limited, Plot No. 101, 102, 107 & 108 SIDCO Pharmaceutical Complex, Alathur, Kanchipuram-603 110, Tamilnadu, India NDC 72789-164-90 UPC 3 72789 16490 8

Product Quantity:
687 bottles

Reason for Recall:
CGMP Deviations- AZIDO Impurity levels observed to be above acceptable limits

Recall Number:
D-1162-2022

Code Information:
Lots: D21D63 Exp. 11/30/22; E21A73 Exp. 11/30/22; E21D35 Exp. 11/30/22; F21A28 Exp. 11/30/22; F21D04 Exp. 09/30/22; G21B03 Exp. 11/30/22; G21E23 Exp. 11/30/22; H21B46 Exp. 11/30/22; H21D46 Exp. 08/31/23; H21D46 Exp. 08/31/23; I21B67 Exp. 01/31/23; J21A26 Exp. 01/31/23; J21C44 Exp. 01/31/23

Product Description:
Losartan Potassium Tablets, USP 100 mg, 90 Tablets bottles, Rx Only, Marketed and Packaged By: PD-Rx Pharmaceuticals, Inc. Oklahoma City, OK 73127 Manufactured by: Vivimed Life Sciences Private Limited, Plot No. 101, 102, 107 & 108 SIDCO Pharmaceutical Complex, Alathur, Kanchipuram-603 110, Tamilnadu, India NDC 72789-165-90 UPC 3 72789 16590 5

Product Quantity:
1320 bottles

Reason for Recall:
CGMP Deviations- AZIDO Impurity levels observed to be above acceptable limits

Recall Number:
D-1163-2022

Code Information:
Lots: G21C26 Exp. 07/31/22; H21B96 Exp. 07/31/22; I21B39 Exp. 07/31/22; I21C44 Exp. 07/31/22; D21F35 Exp. 10/31/22; E21A66 Exp. 10/31/22; E21C72 Exp. 10/31/22; E21F01 Exp. 10/31/22; F21C15 Exp. 10/31/22; F21E19 Exp. 10/31/22; G21B14 Exp. 10/31/22; K21A61 Exp. 11/30/22; L21A45 Exp. 11/30/22

Class II Drugs Event

Event ID:
90405

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
06/13/2022

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
06/30/2022

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 USA

Associated Products

Product Description:
Fluticasone Propionate Nasal Spray, USP, 50 mcg, 16 g net fill weight per amber glass bottle, Rx only, Manufactured by: HI-TECH PHARMACAL CO., INC., Amityville, NY 11701. NDC 50383-700-16

Product Quantity:
44,400 bottles

Reason for Recall:
Defective container: defect prevents product from dispensing as intended.

Recall Number:
D-1172-2022

Code Information:
Lot #: 379073, 379079, Exp 9/30/2023

Class II Drugs Event

Event ID:
90426

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
06/10/2022

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
06/27/2022

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Macleods Pharma Usa Inc
666 Plainsboro Rd Bldg 200 Ste 230
Plainsboro NJ United States

Distribution Pattern:
Product was distributed nationwide.

Associated Products

Product Description:
Losartan potassium & Hydrochlorothiazide Tablets 100 mg/25 mg, 30, 90 & 1000 count NDC # 33342-052-07, NDC #33342-052-10 & NDC # 33342-052-44, Rx Only, MFR: Macleods Pharma USA, Inc. Plainsboro, NJ 08536

Product Quantity:
84/1000 count bottles

Reason for Recall:
CGMP Deviations- AZIDO Impurity levels observed to be above acceptable limits

Recall Number:
D-1164-2022

Code Information:
Lot # BLM2114A, exp. date 07/2023

Class II Drugs Event

Event ID:
90431

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
06/29/2022

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
06/30/2022

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Glenmark Pharmaceuticals Inc., USA
750 Corporate Dr
Mahwah NJ United States

Distribution Pattern:
One sole distributor in TX

Associated Products

Product Description:
Desmopressin Acetate Tablets, 0.2 mg, 100-count bottles, Rx Only, Manufactured for: Northstar Rx LLC, Memphis, TN 38141, Manufactured by: Glenmark Pharmaceuticals Ltd., Colvale-Bardez, Goa 403513, India, NDC 16714-884-01

Product Quantity:
36 bottles

Reason for Recall:
CGMP Deviations

Recall Number:
D-1171-2022

Code Information:
Lot #: 20020121, Exp 01/2024

Class II Drugs Event

Event ID:
90442

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
06/10/2022

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
06/29/2022

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 U.S.

Associated Products

Product Description:
Calcipotriene Topical Solution, 0.005% (Scalp Solution), Rx only, 60 mL (2 fl. oz.) bottle, Manufactured by: HI-TECH PHARMACAL CO., INC., Amityville, N.Y. 11701. NDC: 50383-732-02

Product Quantity:
2,736 Bottles

Reason for Recall:
Defective Delivery System: Potential defect that could prevent the product from dispensing as intended.

Recall Number:
D-1170-2022

Code Information:
Lot #: 378440, Exp. 07/31/2023

Class II Drugs Event

Event ID:
90506

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
06/24/2022

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
06/29/2022

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Noven Pharmaceuticals Inc
11960 Sw 144th St
Miami FL United States

Distribution Pattern:
Distributed Nationwide in the USA

Associated Products

Product Description:
Daytrana (methylphenidate transdermal system) Delivers 10 mg over 9 hours (1.1 mg/hr) Contains: 30 Patches, Rx only, Manufactured for Noven Therapeutics, LLC, Miami, FL 33186 By Noven Pharmaceuticals, Inc., Miami, FL 33186. NDC 68968-5552-3

Product Quantity:
8,559 cartons

Reason for Recall:
Defective Delivery System: Customer complaints received for ripping patches and tight release/adhesive transfer.

Recall Number:
D-1169-2022

Code Information:
Lot: 91272 Exp. 12/22.

Class III Drugs Event

Event ID:
90344

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
06/03/2022

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
06/29/2022

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 USA

Associated Products

Product Description:
Olopatadine HCl, Ophthalmic Solution, USP, 0.2%, 2.5 mL per dropper bottle, Rx Only, Manufactured by: Akorn, Inc., Lake Forest, IL 60045, NDC 17478-305-12

Product Quantity:
111,304 bottles

Reason for Recall:
Failed impurity/degradation specifications: Out of specification for 2-HMP (a product leachable) measured in retention samples

Recall Number:

Code Information:
Lot#: 1D90A, 1D92A, Exp 3/2023; 1E30A, Exp 4/2023