Enforcement Report - Week of December 30, 2020

Class II Drugs Event

Event ID:
86904

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
12/09/2020

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
12/23/2020

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Morton Grove Pharmaceuticals, Inc.
6451 Main St
Morton Grove IL United States

Distribution Pattern:
Nationwide USA and Puerto Rico

Associated Products

Product Description:
Hydroxyzine Hydrochloride Oral Solution, USP (Syrup), 10 mg/5 mL, packaged in a) 4 fl oz (118 mL) bottle, NDC 60432-150-04, b) 1 pint (473 mL), NDC 60432-150-16, Rx Only, Manufactured By: Morton Grove Pharmaceuticals, Inc., Morton Grove, IL 60053

Product Quantity:
127,392 bottles

Reason for Recall:
Failed Impurities/Degradation Specification: OOS for the following - unknown degradant/impurity, 4-chorobenzophenone, and for total impurities.

Recall Number:
D-0174-2021

Code Information:
Lot#: a) UU1328, Exp 10/21; b) UU1207, Exp 07/21; UU1326, Exp 09/21; UU1327, Exp 10/21.

Class II Drugs Event

Event ID:
86955

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
12/09/2020

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
12/18/2020

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Akebia Therapeutics dba Keryx Biopharmaceutials, Inc
245 1st St
Cambridge MA United States

Distribution Pattern:
The product was distributed by two major distributors who further distributed the product nationwide and one specialty pharmacy.

Associated Products

Product Description:
Auryxia (ferric citrate) tablets, 210 mg, 200-count bottles, Rx only, Manufactured for and distributed by: KERYX BIOPHARMACEUTICALS, INC., One Marina Park Drive, 12th Floor, Boston, MA 02210, NDC 59922-631-01

Product Quantity:
2,170 bottles

Reason for Recall:
CGMP Deviations

Recall Number:
D-0170-2021

Code Information:
Lot Number: 9062, exp. date Feb 2021

Class II Drugs Event

Event ID:
86964

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
12/10/2020

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
12/22/2020

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Fresenius Kabi USA, LLC
3 Corporate Dr
Lake Zurich IL United States

Distribution Pattern:
Nationwide in the USA

Associated Products

Product Description:
Sensorcaine-MPF (Bupivacaine HCl and Epinephrine Injection, USP), 0.5%, 150 mg per 30 mL (5 mg per mL), 30 mL Single Dose Vial (NDC 63323-462-01), packaged as 25 Single Dose Vials per tray (NDC 63323-462-37), Rx only, Fresenius Kabi, Lake Zurich, IL 60047.

Product Quantity:
4411 trays

Reason for Recall:
Subpotent Drug: Low out-of-specification assay results for the epinephrine component.

Recall Number:
D-0172-2021

Code Information:
Batch # 6123760, Exp 02/2022

Class II Drugs Event

Event ID:
86982

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
12/14/2020

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
12/21/2020

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
SCA Pharmaceuticals, Inc.
8821 Knoedl Ct
Little Rock AR United States

Distribution Pattern:
Distributed Nationwide in the USA

Associated Products

Product Description:
Vasopressin 20 Units added to 0.9% Sodium Chloride 100 mL Rx Only, Single Dose Container, SCA Pharmaceuticals 8821 Knoedl Ct. Little Rock, AR 72205 Bar Code 70004093232

Product Quantity:
654 bags

Reason for Recall:
Subpotent drug.

Recall Number:
D-0171-2021

Code Information:
Lots: 1120025012 BUD: 01/13/2021, 1120025015 BUD: 01/15/2021, 1120025272 BUD: 01/28/2021