Enforcement Report - Week of January 4, 2023

Class II Drugs Event

Event ID:
91272

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
12/09/2022

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
12/28/2022

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

Recalling Firm:
NCH Life Sciences LLC
2730 Carl Rd
Irving TX United States

Distribution Pattern:
Nationwide in United States and Canada.

Associated Products

Product Description:
Alcohol Antiseptic 80% Topical Solution Hand Sanitizer, Non-Sterile Solution, packaged as a a) 2.5 gallon bottle (9,464 ml), NDC 55533-524-02, and b) 55 gallon bottle (208,198 ml), NDC 55533-524-03, Manufactured for: Multi-Mist Products A Division of NCH Corporation 1618 Northgate, Irving, Texas 75062

Product Quantity:
10,930 gallons

Reason for Recall:
CGMP Deviations: Impurities of acetal and acetaldehyde were discovered in the product in excess of allowed limits.

Recall Number:
D-0092-2023

Code Information:
Lots: 12032504, 12014282, 12013501, 12104039, 12013505, 12032523, 12013510, 12014804, 12015401, and 12014113

Class II Drugs Event

Event ID:
91333

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
12/16/2022

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
12/27/2022

Initial Firm Notification of Consignee or Public:

Recalling Firm:
Hikma Pharmaceuticals USA Inc.
2 Esterbrook Ln
Cherry Hill NJ United States

Distribution Pattern:
USA Nationwide

Associated Products

Product Description:
Ganciclovir for Injection, USP, 500mg per vial, packaged in a 10-count carton, Rx Only, Mfd. by: THYMOORGAN PHARMAZIE GmbH, Germany, Distributed by Hikma Berkeley Heights, NJ 07922, NDC 0143-9299-01

Product Quantity:
13,760 vials

Reason for Recall:
Labeling: Label mix-up - one vial was mislabeled as Cladribine Injection 10mg/mL inside a 10-count carton of Ganciclovir 500 mg.

Recall Number:
D-0090-2023

Code Information:
Lot#: BQ0006, Exp 08/2023

Class II Drugs Event

Event ID:
91390

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
12/22/2022

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
12/28/2022

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
AVKARE LLC
615 N 1st St
Pulaski TN United States

Distribution Pattern:
USA Nationwide

Associated Products

Product Description:
Glycopyrrolate Tablets, USP, 1 mg, 50 Tablets (5x10) Unit Dose carton, Rx Only, Manufactured for: AvKARE Pulaski, TN 38478, NDC 50268-363-15

Product Quantity:
1237 cartons

Reason for Recall:
Failed impurities/degradation specifications: Out of specification for unknown impurities.

Recall Number:
D-0091-2023

Code Information:
Lot#: 43313, 43342, Exp 12/2023

Class III Drugs Event

Event ID:
91353

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
12/21/2022

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
12/28/2022

Initial Firm Notification of Consignee or Public:
Letter

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

Distribution Pattern:
USA Nationwide

Associated Products

Product Description:
Timolol Maleate Ophthalmic Solution, USP 0.5%, 2.5 mL, Rx Only, Mfg by: Apotex Inc. Toronto, Ontario Canada M9L 1T9 Mfg for: Apotex Corp. Weston, FL 33326, NDC 60505-1005-4

Product Quantity:
22,027 bottles

Reason for Recall:
Failed Stability Specifications: Out of specification for weight loss at the 18-month stability timepoint and projected weight loss of 21.1% at shelf life.

Recall Number:
D-0093-2023

Code Information:
Lot# TA4844, Exp 03/2023