Enforcement Report - Week of February 15, 2023

Class II Drugs Event

Event ID:
91576

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
01/17/2023

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
02/08/2023

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Urban Electric Power
401 N Middletown Rd Bldg 155
Pearl River NY United States

Distribution Pattern:
Nationwide within the United States

Associated Products

Product Description:
Ohm Hand Sanitizer (alcohol (ethanol) 70 % v/v), packaged in a) 2 FL OZ (60 ML), b) 3 FL OZ (88 ML) bottles, c) 10 FL OZ (295 ML) bottles, d)12 FL OZ (355 ML) bottles, e)16 FL OZ (473 ML) bottles, f) 64 FL OZ (1892 ML) bottles, g) 128 FL OZ (3785 ML) bottles

Product Quantity:
a) 239 bottles, b) 6,352 bottles, c)14,963 bottles, d) 8,117 bottles, e)22 bottles, f)856 bottles, g) 707 bottles

Reason for Recall:
CGMP Deviations: FDA analysis found product to contain acetaldehyde and acetal above specification limits.

Recall Number:
D-0263-2023

Code Information:
All lots within expiry

Product Description:
Ohm Sanitizer Spray (alcohol (ethyl alcohol) 80% v/v, 8 FL OZ (237 ML) bottles.

Product Quantity:
609 bottles

Reason for Recall:
CGMP Deviations: FDA analysis found product to contain acetaldehyde and acetal above specification limits.

Recall Number:
D-0264-2023

Code Information:
All lots within expiry

Class II Drugs Event

Event ID:
91577

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:

Voluntary / Mandated:

01/31/2023

Center Classification Date:
02/14/2023

Recalling Firm:
BIOCON PHARMA INC
485 HWY 1 (S)
ISELIN NJ United States

Distribution Pattern:
Nationwide in the USA

Voluntary / Mandated:
Voluntary: Firm initiated

Initial Firm Notification of Consignee or Public:
E-Mail

Associated Products

Product Description:
Posaconazole Delayed-Release Tablets, 100 mg, 60-count bottle, Rx Only, Manufactured for: Biocon Pharma Inc., Iselin, NJ 08830-3009; Manufactured by: Biocon Pharma Limited, Bengaluru, India - 560 099, NDC 70377-038-11.

Product Quantity:
3665 bottles

Reason for Recall:
Failed Impurities/Degradation Specifications: High Out Of Specification degradation results.

Recall Number:
D-0268-2023

Code Information:
Lot #: BF21003163, BF21003246, BF21003161, Exp. Sep-2023; BF21004742, Exp. Dec-2023; BF22003359, Exp. Sep-2025

Class III Drugs Event

Event ID:
91580

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
01/30/2023

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
02/08/2023

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Akorn, Inc.
5605 Centerpoint Ct Ste A
Gurnee IL United States

Distribution Pattern:
Nationwide in the USA and Puerto Rico

Associated Products

Product Description:
Atropine Sulfate Ophthalmic Solution, USP 1%, For Topical Application To The Eye, 2 mL bottle, Sterile, Rx only, Distributed by: Akorn Operating Company LLC, Gurnee, IL 60031. NDC: 17478-215-02

Product Quantity:
45,117 Bottles

Reason for Recall:
Failed Stability Specifications: Out of specification test results for viscosity was identified at the 12M stability timepoint.

Recall Number:
D-0265-2023

Code Information:
Lot: 081031A, Exp 2/28/2023