# Enforcement Report - Week of June 14, 2023

## Class II Drugs Event

**Event ID:**
92366

**Product Type:**
Drugs

**Status:**
Ongoing

**Date Terminated:**

**Recall Initiation Date:**
05/25/2023

**Voluntary / Mandated:**
Voluntary: Firm initiated

**Center Classification Date:**
06/05/2023

**Initial Firm Notification of Consignee or Public:**
Letter

**Recalling Firm:**
Viatris Inc
1000 Mylan Blvd
Canonsburg PA United States

**Distribution Pattern:**
Product was distributed to 10 distributors who may have further distribute the product to the retail level.

## Associated Products

**Product Description:**
Levsin injection (hyoscyamine sulfate injection, USP), 0.5 mg per ml in water for Injection, 1 ml Ampule (Box of 5 ampules), Rx Only, Distributed by: Meda pharmaceuticals Inc. (a Viatris company) Somerset New Jersey 00873-4120, NDC #0037-9001-05

**Product Quantity:**
2,736 boxes

**Reason for Recall:**
CGMP Deviations: Discontinuation of the Quality program by manufacturer that would assure product meet the identity, strength, quality, and purity characteristics that they are purported or represented to possess.

**Recall Number:**
D-0866-2023

**Code Information:**
Lot #: 101241A, Exp 10/23

## Class II Drugs Event

**Event ID:**
92367

**Product Type:**
Drugs

**Status:**
Ongoing

**Date Terminated:**

**Recall Initiation Date:**
05/12/2023

**Voluntary / Mandated:**
Voluntary: Firm initiated

**Center Classification Date:**
06/05/2023

**Initial Firm Notification of Consignee or Public:**
E-Mail

**Recalling Firm:**
Empower Clinic Services LLC dba Empower Pharmacy
5980 W Sam Houston Pkwy N Ste 300
Houston TX United States

**Distribution Pattern:**
Distributed Nationwide in the USA

## Associated Products

**Product Description:**
ASCORBIC ACID PRESERVED INJECTION SOLUTION, 500 mg/mL, 30 mL Sterile Multiple-Dose Vial, RX ONLY, Compounded by: Empower Pharmacy, 5980 W Sam Houston Pkwy N Ste 300 Houston, TX 77041, NDC 72627-2405-1

**Product Quantity:**
504 vials

**Reason for Recall:**
Mislabeling: preservative free product labeled as preserved.

**Recall Number:**
D-0865-2023

**Code Information:**
Lot: 606775 BUD: 09/25/2023

## Class II Drugs Event

**Event ID:**
92402

**Product Type:**
Drugs

**Status:**
Ongoing

**Date Terminated:**

**Recall Initiation Date:**
05/25/2023

**Voluntary / Mandated:**
Voluntary: Firm initiated

**Center Classification Date:**
06/06/2023

**Initial Firm Notification of Consignee or Public:**
Letter

**Recalling Firm:**
Golden State Medical Supply Inc.
5187 Camino Ruiz
Camarillo CA United States

**Distribution Pattern:**
Nationwide in the USA

## Associated Products

**Product Description:**
Travoprost Ophthalmic Solution, USP (Ionic Buffered Solution), 0.004%, Rx only, Manufactured by Apotex Inc., Manufactured by: GSMS Incorporated, Camarillo, CA 93012, a) NDC 51407-731-25 (2.5 mL bottle), b) NDC 51407-731-05 (5 mL bottle).

**Product Quantity:**
1,920 bottles

**Reason for Recall:**
Lack of Assurance of Sterility: Tamper Evidence Seal is missing on secondary container.

**Recall Number:**
D-0867-2023

**Code Information:**
Lot #s: a) GS049666, GS049807, Exp: 03/31/2024; b) GS049667, GS051447, Exp: 09/30/2024.

## Class III Drugs Event

**Event ID:**
92468

**Product Type:**
Drugs

**Status:**
Ongoing

**Date Terminated:**

**Recall Initiation Date:**
06/06/2023

**Voluntary / Mandated:**
Voluntary: Firm initiated

**Center Classification Date:**
06/08/2023

**Initial Firm Notification of Consignee or Public:**
Letter

**Recalling Firm:**
HF Acquisition Co LLC
11629 49th Pl W
Mukilteo WA United States

**Distribution Pattern:**
Distributed in TX, AZ and CA only

## Associated Products

**Product Description:**
GLYCOPYRROLATE INJECTION, USP 0.2MG/ML, 1mL VIAL, manufactured by HF Acquisition Co. LLC, Mukilteo, WA 98275, NDC 51662-1487-3

**Product Quantity:**
9 boxes of 25 vials

**Reason for Recall:**
Labeling: Label Mix-up

**Recall Number:**
D-0870-2023

**Code Information:**
Lot #: 2205095.1, Exp. Date 7/31/2024