# Enforcement Report - Week of October 12, 2022

## Class I Drugs Event

**Event ID:**
90874

**Product Type:**
Drugs

**Status:**
Ongoing

**Date Terminated:**

**Recall Initiation Date:**
09/14/2022

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

**Center Classification Date:**
10/04/2022

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

**Recalling Firm:**
Salon Technologies International Inc
8810 Commodity Cir Ste 20
Orlando FL United States

**Distribution Pattern:**
FL and WA only

### Associated Products

**Product Description:**
Antica Farmacista Hand Sanitizer Ocean Citron (ethyl alcohol, denatured 65%) packaged in 473 mL/16 fl. oz. bottles, Dist. By Antica Farmacista Seattle, WA 98122 UPC 8 47005 00450 9

**Product Quantity:**
512 bottles

**Reason for Recall:**
Chemical Contamination: product found to contain benzene

**Recall Number:**
D-0002-2023

**Code Information:**
Lot #: 1166A Exp. 6/18/2023

## Class II Drugs Event

**Product Description:**
Sanitizing Hand Spray 80% (alcohol 80% v/v) Packaged in 2 FL OZ (60 mL) bottles, Salon Technologies International 8810 Commodity Circle STE 22-23, Orlando, FL 32819, UPC 6 96952 12904 5

**Product Quantity:**
1656 bottles

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

**Recall Number:**
D-0001-2023

**Code Information:**
Lot #: 20-018 Exp. 4/3/2023

## Class II Drugs Event

**Event ID:**
90903

**Product Type:**
Drugs

**Status:**
Ongoing

**Date Terminated:**

**Recall Initiation Date:**
09/27/2022

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

**Center Classification Date:**
10/04/2022

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

**Recalling Firm:**
Pfizer Inc.
235 East 42nd Street
New York NY United States

**Distribution Pattern:**
Distributed in the United States and Puerto Rico.

## Associated Products

**Product Description:**
Aminophylline Injection, USP 250 mg/10 mL (25 mg/mL) 25x10 mL Single-dose vial, Rx only, Distributed by Hospira, Inc. Lake Forest, IL 60045 USA. NDC 0409-5921-16 (vial) 0409-5921-01 (carton)

**Product Quantity:**
103,150 10 mL vials

**Reason for Recall:**
Presence of Particulate Matter: A complaint was received for the presence of a hair in one vial.

**Recall Number:**
D-0003-2023

**Code Information:**
Lot: 30-137-DK Exp. 1 DEC. 2022

## Class II Drugs Event

**Event ID:**
90920

**Product Type:**
Drugs

**Status:**
Ongoing

**Date Terminated:**

**Recall Initiation Date:**
09/29/2022

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

**Center Classification Date:**
09/30/2022

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

**Recalling Firm:**
CIPLA
10 Independence Blvd
Warren NJ United States

**Distribution Pattern:**
Product was distributed nationwide to distributors/wholesalers who may have further distributed the product.

## Associated Products

**Product Description:**
Arformoterol Tartrate Inhalation Solution, 15 mcg/2mL, 2 mL Sterile Unit-Dose Vial packaged in 5 x 2 mL Sterile Unit-Dose Vials per pouch, NDC 69097-168-48; 60 (12 x 5) x 2 mL Sterile Unit-Dose Vials per carton, NDC 69097-168-64, Rx Only, Manufactured by: Cipla Ltd., Indore SEZ, Pithampur, India; Manufactured for: Cipla USA, Inc., 10 Independence Boulevard, Suite 300, Warren, NJ 07059.

**Product Quantity:**
9041 cartons

**Reason for Recall:**
Lack of Assurance of Sterility: environmental monitoring failure.

**Recall Number:**
D-1550-2022

**Code Information:**
Batch No: IA10082, IA10083, IA10084, IA10085, IA10086, exp. date 01/2023; IA10122, IA10123, IA10124, IA10125, IA10126, IA10127, IA10128, IA10129, IA10130, exp. date 02/2023

## Class III Drugs Event

**Event ID:**
90846

**Product Type:**
Drugs

**Status:**
Ongoing

**Date Terminated:**

**Recall Initiation Date:**
08/30/2022

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

**Center Classification Date:**
10/06/2022

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

**Recalling Firm:**
Woodbine Products Co Inc
915 W Smith Rd
Medina OH United States

**Distribution Pattern:**
NC

## Associated Products

**Product Description:**
Antibacterial Foaming Wash with Hydria Moisturizing Formula, Cucumber-Melon Scent, 1250 mL (42 fl oz.), Manufactured for: Triple S, 800-323-2251, Made in USA, NDC 11429-1010-8

**Product Quantity:**
595 cases (4 bottles per case)

**Reason for Recall:**
Labeling: Not Elsewhere Classified - Incorrect label-incorrect scent listed on label.

**Recall Number:**
D-0006-2023

**Code Information:**
Lot #: VDAF017, Exp 4/24; VDAF018, Exp 5/24

## Class III Drugs Event

**Event ID:**
90868

**Product Type:**
Drugs

**Status:**
Ongoing

**Date Terminated:**

**Recall Initiation Date:**
09/14/2022

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

**Center Classification Date:**
10/06/2022

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

**Recalling Firm:**
Dr. Reddy's Laboratories, Inc.
107 College Rd E
Princeton NJ United States

**Distribution Pattern:**
USA nationwide

## Associated Products

**Product Description:**
Phytonadione Injectable Emulsion USP, 10 mg/mL, 25x 1 mL single dose ampules per carton, Rx only, Distributed by: Dr. Reddy's Laboratories Inc., Princeton, NJ 08540, NDC 43598-405-16

**Product Quantity:**
2,838 ampules

**Reason for Recall:**
Failed Stability Specifications: Out of specification results reported at 12-month stability testing for aluminum content.

**Recall Number:**
D-0007-2023

**Code Information:**
Lot # ACB101, Exp 03/2023

## Class III Drugs Event

**Event ID:**
90897

**Product Type:**
Drugs

**Status:**
Ongoing

**Date Terminated:**

**Recall Initiation Date:**
09/26/2022

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

**Center Classification Date:**
09/30/2022

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

**Recalling Firm:**
AuroMedics Pharma LLC
279 Princeton Hightstown Rd
East Windsor NJ United States

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

## Associated Products

**Product Description:**
Tranexamic Acid Injection, USP, 1000mg per 10 mL (100mg / 10mL), 10mL single-dose vial, Rx Only, Distributed by: AuroMedics Pharma LLC E. Windsor, NJ 08520, Made in India, NDC 55150-188-10

**Product Quantity:**
88080 vials

**Reason for Recall:**
Presence of Particulate Matter: Piece of metal found in a vial

**Recall Number:**
D-1551-2022

**Code Information:**
Lot: CTA210006, Exp. 02/2024