

# Enforcement Report - Week of May 12, 2021

## Class I Drugs Event

**Event ID:**  
87436

**Product Type:**  
Drugs

**Status:**  
Ongoing

**Date Terminated:**

**Recall Initiation Date:**  
03/02/2021

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

**Center Classification Date:**  
04/30/2021

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

**Recalling Firm:**  
A-S Medication Solutions LLC.  
2401 Commerce Dr  
Libertyville IL United States

**Distribution Pattern:**  
Nationwide in the USA

## Associated Products

### Product Description:

Acetaminophen, Extra Strength, Aspirin Free, 500 MG Tablets, 100-count bottles, Mfr: Major Pharmaceuticals, Livonia, MI 48152; Packaged Exclusively By: A-S Medication Solutions LLC, Libertyville, IL 60048, Product # 6967-0; NDC: 50090-5350-0; contained within Health Essentials Kit, Kit Contains: 1 bottle hand sanitizer, 1 reusable face mask, 1 bottle Acetaminophen 500 mg, 1 bag cough drops, 1 digital thermometer, 50 disposable gloves.

**Product Quantity:**  
201,600 kits

### Reason for Recall:

Labeling: Label Mix-up; The bottle of over-the-counter Acetaminophen 500mg Extra Strength, 100 count, included in Health Essential Kits, labeled incorrectly with a prescription drug label instead of an OTC drug label.

**Recall Number:**  
D-0358-2021

### Code Information:

Lots 323206, 323207, 323208, 335353, 335354, 335355, 335356, 335358, 335359, 335360, 335361, 335362, 335395, 352116, Expiry 7/31/2022; 323209, 323210, 323211, 323212, 323213, 323214, 323215, 323216, 323218, 323219, 323220, 323222, 323223, 323224, 323238, 335363, 335364, 335365, 335366, 335367, 335368, 335369, 335370, 335371, 335372, 335373, 335374, 335375, 335376, 335377, Expiry 8/31/2022

## Class I Drugs Event

**Event ID:**  
87531

**Product Type:**  
Drugs

**Status:**  
Ongoing

**Date Terminated:**

**Recall Initiation Date:**  
03/10/2021

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

**Center Classification Date:**  
04/30/2021

**Initial Firm Notification of Consignee or Public:**  
Press Release

**Recalling Firm:**  
PNHC, LLC.  
1105 Baslow Brook Ct  
Raleigh NC United States

**Distribution Pattern:**  
FL, CA

## Associated Products

**Product Description:**

heal the world, moisturizing original hand sanitizer, Non-Sterile Solution, Alcohol Antiseptic, 70% Topical Solution, 9.6 FL OZ. (285 mL) bottle, Heal The World, LLC, Draper, UT 84020, UPC 6 19988 44038 0.

**Product Quantity:**

139,806 bottles

**Reason for Recall:**

Labeling Not Elsewhere Classified: Hand sanitizer packaged in containers resembling drinking water bottles.

**Recall Number:**

D-0365-2021

**Code Information:**

Lots: SAA21, SAA24, SAA27, SAA22, SAA23, SAA29, SAA26, SAA28, SAA25, SAA32, SAA55, SAA56, SAA44, SAA60, expiration 5/2022

## Class II Drugs Event

**Event ID:**

87627

**Product Type:**

Drugs

**Status:**

Ongoing

**Date Terminated:**
**Recall Initiation Date:**

03/26/2021

**Voluntary / Mandated:**

Voluntary: Firm initiated

**Center Classification Date:**

05/04/2021

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

Press Release

**Recalling Firm:**

Antoto-K  
7686 Chadds Landing Way  
Manassas VA United States

**Distribution Pattern:**

Nationwide

## Associated Products

**Product Description:**

Thumbs Up 7 Red 70K, 10 count blister pack cartons, Distributed by Ummzy LLC., Made in USA, UPC 6 17135 89467 3.

**Product Quantity:**

200 cartons

**Reason for Recall:**

Marketed without Approved NDA/ANDA: FDA analysis results obtained the presence of sildenafil and tadalafil.

**Recall Number:**

D-0366-2021

**Code Information:**

All lots within expiry.

## Class II Drugs Event

**Event ID:**

87751

**Product Type:**

Drugs

**Status:**

Ongoing

**Date Terminated:**
**Recall Initiation Date:**

03/31/2021

**Voluntary / Mandated:**

Voluntary: Firm initiated

**Center Classification Date:**

05/06/2021

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

Press Release

**Recalling Firm:**

QMart

495 Mola Blvd  
 Elmwood Park NJ United States

**Distribution Pattern:**

USA Nationwide

## Associated Products

**Product Description:**

IMPERIAL GOLD 2000, Male Sexual Performance Enhancement, 1 Capsule, UPC 718122040702

**Product Quantity:**

200 boxes

**Reason for Recall:**

Marketed without Approved NDA/ANDA: FDA analysis results obtained the presence of tadalafil and/or sildenafil.

**Recall Number:**

D-0368-2021

**Code Information:**

All

**Product Description:**

PremierZen Extreme 3000, Male Sexual Performance Enhancement, 1 Capsule, UPC 728175421887

**Product Quantity:**

500 boxes

**Reason for Recall:**

Marketed without Approved NDA/ANDA: FDA analysis results obtained the presence of tadalafil and/or sildenafil.

**Recall Number:**

D-0369-2021

**Code Information:**

All

**Product Description:**

Burro en Primavera, 2 capsules, UPC 638632431055

**Product Quantity:**

500 boxes

**Reason for Recall:**

Marketed without Approved NDA/ANDA: FDA analysis results obtained the presence of tadalafil and/or sildenafil.

**Recall Number:**

D-0370-2021

**Code Information:**

All

**Product Description:**

Imperial Platinum 2000, 1 capsule, UPC 718122040702

**Product Quantity:**

200 boxes

**Reason for Recall:**

Marketed without Approved NDA/ANDA: FDA analysis results obtained the presence of tadalafil and/or sildenafil.

**Recall Number:**

D-0371-2021

**Code Information:**

All

## Class III Drugs Event

**Event ID:**

87762

**Product Type:**

Drugs

**Status:**

Ongoing

**Date Terminated:**

**Recall Initiation Date:**  
04/21/2021

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

**Center Classification Date:**  
05/06/2021

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

**Recalling Firm:**  
Heritage Pharmaceuticals Inc  
1 Tower Center Blvd Ste 1700  
East Brunswick NJ United States

**Distribution Pattern:**  
OH

### Associated Products

<p><b>Product Description:</b> Acyclovir Tablets, USP, 400 mg, 100 Tablets, Rx Only, Distributed by: Avet Pharmaceuticals Inc., East Brunswick, NJ 08816, NDC 23155-227-01. Packaged in 150 cc white HDPE bottle</p> <p><b>Product Quantity:</b> 408 bottles</p> <p><b>Reason for Recall:</b> Labeling: Incorrect or Missing Lot and/or Exp Date</p> <p><b>Recall Number:</b> D-0367-2021</p> <p><b>Code Information:</b> Lot A120036, Exp DEC 2023</p>
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