

# Enforcement Report - Week of February 16, 2022

## Class I Drugs Event

**Event ID:**  
89457

**Product Type:**  
Drugs

**Status:**  
Ongoing

**Date Terminated:**

**Recall Initiation Date:**  
01/26/2022

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

**Center Classification Date:**  
02/10/2022

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

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

**Distribution Pattern:**  
Nationwide in the US

## Associated Products

### Product Description:

Polymyxin B for Injection USP, 500,000 Units per Vial, 10 mL vials, packaged in 10 vials per carton, Sterile, Rx Only, Distributed by: AuroMedics Pharma LLC, E. Windsor, NJ 08520, NDC 55150-234-10

**Product Quantity:**  
35,520 vials

**Reason for Recall:**  
Presence of Particulate Matter; product complaint of hair discovered in a vial within the lot

**Recall Number:**  
D-0556-2022

**Code Information:**  
Lot CPB200013, exp 9/2022

## Class I Drugs Event

**Event ID:**  
89501

**Product Type:**  
Drugs

**Status:**  
Ongoing

**Date Terminated:**

**Recall Initiation Date:**  
01/28/2022

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

**Center Classification Date:**  
02/15/2022

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

**Recalling Firm:**  
Esupplementsales, LLC  
1670 Saturno Heights Dr  
Reno NV United States

**Distribution Pattern:**  
Nationwide in the USA via Amazon at www.amazon.com

## Associated Products

### Product Description:

HARD DAWN, Rise and Shine capsules, 500 mg, packaged in 10-count blisters per carton, Made in Malaysia, UPC 680044 364926, ASIN:

B077XCCL59

**Product Quantity:**

500 cartons

**Reason for Recall:**

Marketed Without an Approved NDA/ANDA: Firm was informed by Amazon that analytical testing showed the presence of tadalafil. Tadalafil is a FDA approved drug, making this product an unapproved drug.

**Recall Number:**

D-0561-2022

**Code Information:**

Lot: 2107, Exp July 2024

## Class I Drugs Event

**Event ID:**

89543

**Status:**

Ongoing

**Recall Initiation Date:**

02/04/2022

**Center Classification Date:**

02/11/2022

**Recalling Firm:**

Junp Hydration LLC  
1013 Mcdonald Ave  
Brooklyn NY United States

**Distribution Pattern:**

Product was distributed nationwide in the USA via Amazon Marketplace

**Product Type:**

Drugs

**Date Terminated:****Voluntary / Mandated:**

Voluntary: Firm initiated

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

Press Release

## Associated Products

**Product Description:**

MegMan Performance Booster, 800 mg capsules, packaged in 10-count blisters packaged in a carton, UPC 8 48998 00091 2, ASIN B08Z74KS88

**Product Quantity:**

750 cartons

**Reason for Recall:**

Marketed Without An Approved NDA/ANDA: product was found to contain undeclared tadalafil, an ingredient found in FDA approved products for the treatment of male sexual enhancement, making this an unapproved drug.

**Recall Number:**

D-0557-2022

**Code Information:**

Lot # 2010291, Exp 01/07/2024

## Class II Drugs Event

**Event ID:**

89334

**Status:**

Ongoing

**Recall Initiation Date:**

01/26/2022

**Center Classification Date:**

02/09/2022

**Product Type:**

Drugs

**Date Terminated:****Voluntary / Mandated:**

Voluntary: Firm initiated

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

Letter

**Recalling Firm:**

ULTRAtab Laboratories, Inc.  
50 Toc Dr  
Highland NY United States

**Distribution Pattern:**

Bulk product was distributed to 3 distributors who may have distributed finished product.

## Associated Products

**Product Description:**

3-Component Cold Tabs (Acetaminophen 325 mg, Guaifenesin 200 mg, Phenylephrine HCl 5mg) Bulk Container, ULTRAtab Laboratories, Inc., Highland, NY NDC 62959-106-00

**Product Quantity:**

33,758,436 tablets

**Reason for Recall:**

CGMP Deviations

**Recall Number:**

D-0523-2022

**Code Information:**

Product Code C106L; Bulk lots: 18J080, 18L029, 19A103, 19B063, 19D019, 19F065, Product Code C106LA; Bulk lots: 18K045, 18K046, 18L008, 18L105, 19A068, 19A094, 19A106, 19B009, 19C031, 19C032, 19C033, 19G085, 19H070, 19D018, 19H071, 19H082, 19J027

**Product Description:**

4-Component Cold Tabs (Acetaminophen 325 mg, Guaifenesin 200 mg, Dextromethorphan HBr 15mg, Phenylephrine HCL 5mg) Bulk Container, ULTRAtab Laboratories, Inc., Highland, NY NDC 62959-107-00

**Product Quantity:**

19,103,287 tablets

**Reason for Recall:**

CGMP Deviations

**Recall Number:**

D-0524-2022

**Code Information:**

Product Code: C107L Bulk Lots: 18G085, 19B061, 19F066, 19J068 Product Code: C107LB Bulk Lots: 18J051, 18M079, 18M080, 19B017, 19B018, 19C001, 19C081, 19D056, 19D057 Product C107LA: Bulk lots: 19F067

**Product Description:**

Zee Cold Tabs (Acetaminophen 325 mg, Guaifenesin 100 mg, Phenylephrine HCl 5 mg Bulk Container, ULTRAtab Laboratories, Inc., Highland, NY NDC 62959-111-xx

**Product Quantity:**

1,798,048 tablets

**Reason for Recall:**

CGMP Deviations

**Recall Number:**

D-0525-2022

**Code Information:**

Product Codes: C111L Bulk Lot: 18L028

**Product Description:**

Kramer Novis Tusicoof Caplet (Guaifenesin 400 mg, Dextromethorphan HBr 20 mg, Phenylephrine HCl 10 mg) Bulk Container, ULTRAtab Laboratories, Inc., Highland, NY NDC 62959-124-00

**Product Quantity:**

639,729 tablets

**Reason for Recall:**

CGMP Deviations

**Recall Number:**

D-0526-2022

**Code Information:**

Product Codes: C119L Bulk Lots: 18K028

**Product Description:**

Dologen 325 Caplet (Acetaminophen 325 mg, Dexbrompheniramine Maleate 1.0 mg) Bulk Container, ULTRAtab Laboratories, Inc., Highland, NY NDC 62959-121-00

**Product Quantity:**

917,304 tablets

**Reason for Recall:**

CGMP Deviations

**Recall Number:**

D-0527-2022

**Code Information:**

Product Codes: C121L Bulk Lots: 19G074, 19G075

**Product Description:**

Coated APAP 325 mg Phenyl HCl 5 mg tablet (Acetaminophen 325 mg, Phenylephrine HCl 5mg) Bulk Container, ULTRAtab Laboratories, Inc., Highland, NY NDC 62959-134-00

**Product Quantity:**

14,566,510 tablets

**Reason for Recall:**

CGMP Deviations

**Recall Number:**

D-0528-2022

**Code Information:**

Product Codes: C134LC Bulk Lots: 18K055 18M081 19A097 19B024 19C054 19E092 19G094 19J042

**Product Description:**

APAP 325 mg/Phenylephrine HCl, 5mg Tablets Bulk Container, ULTRAtab Laboratories, Inc., Highland, NY NDC 62959-135-00

**Product Quantity:**

451,123 tablets

**Reason for Recall:**

CGMP Deviations

**Recall Number:**

D-0529-2022

**Code Information:**

Product Codes: C135LA Bulk Lots: 19F077

**Product Description:**

APAP 500 mg Phenyl HCl 5mg tablet (Acetaminophen 500mg, Phenylephrine HCl 5mg), Bulk Container, ULTRAtab Laboratories, Inc., Highland, NY NDC 62959-140-00

**Product Quantity:**

14,349,148 tablets

**Reason for Recall:**

CGMP Deviations

**Recall Number:**

D-0530-2022

**Code Information:**

Product Codes: C140L Bulk Lots: 18K017, 18L002, 19C064, 19E067, 19F064, 19H053, 19J023, 19J051

**Product Description:**

APAP 325 mg (Acetaminophen 325 mg) Bulk Container, ULTRAtab Laboratories, Inc., Highland, NY NDC 62959-200-00

**Product Quantity:**

3,677,483 tablets

**Reason for Recall:**

CGMP Deviations

**Recall Number:**

D-0531-2022

**Code Information:**

Product Codes: L200L Bulk Lots: 18K072, 19C049

**Product Description:**

Coated APAP 325mg (Acetaminophen 325 mg) Bulk Container, ULTRAtab Laboratories, Inc., Highland, NY NDC 62959-202-00

**Product Quantity:**

16,429,211 tablets

**Reason for Recall:**

CGMP Deviations

**Recall Number:**

D-0532-2022

**Code Information:**

Product Codes: L202L Bulk Lots: 18K013, 18K014, 18K015, 19A040, 18M076, 19A041, 19H072, 19H073, 19H074

**Product Description:**

Normed APAP 325 mg (Acetaminophen 325 mg) Bulk Container, ULTRAtab Laboratories, Inc., Highland, NY NDC 62959-203-00

**Product Quantity:**

3,667,885 tablets

**Reason for Recall:**

CGMP Deviations

**Recall Number:**

D-0533-2022

**Code Information:**

Product Codes: L203L Bulk Lots: 18K012, 19E091

**Product Description:**

Coated APAP 500 mg caplet (Acetaminophen 500 mg) Bulk Container, ULTRAtab Laboratories, Inc., Highland, NY NDC 62959-206-00

**Product Quantity:**

2,048,941 tablets

**Reason for Recall:**

CGMP Deviations

**Recall Number:**

D-0534-2022

**Code Information:**

Product Codes: L206L Bulk Lots: 19B002

**Product Description:**

Extra-Strength Unaspirin caplet (Acetaminophen 500 mg) Bulk Container, ULTRAtab Laboratories, Inc., Highland, NY NDC 62959-207-00

**Product Quantity:**

6,215,512 tablets

**Reason for Recall:**

CGMP Deviations

**Recall Number:**

D-0535-2022

**Code Information:**

Product Codes: L207L Bulk Lots: 18K111, 19E104, 19F050

**Product Description:**

APAP 500 mg tablet (Acetaminophen 500 mg) Bulk Container, ULTRAtab Laboratories, Inc., Highland, NY NDC 62959-210-00

**Product Quantity:**

6,249,082 tablets

**Reason for Recall:**

CGMP Deviations

**Recall Number:**

D-0536-2022

**Code Information:**

Product Codes: L210L Bulk Lots: 18L120, 19B044, 19E082

**Product Description:**

APAP 500 mg SRC Coated (Acetaminophen 500 mg) Bulk Container, ULTRAtab Laboratories, Inc., Highland, NY NDC 62959-211-00

**Product Quantity:**

18,772,640 tablets

**Reason for Recall:**

CGMP Deviations

**Recall Number:**

D-0537-2022

**Code Information:**

Product Codes: L211L Bulk Lots: 18M043, 18M044, 18M045, 19B032, 19B033, 19B034, 19F008, 19F009, 19F010

**Product Description:**

HPC Tablet (Acetaminophen 110 mg, Aspirin 162 mg, Caffeine 32.4 mg, Salicylamide 152 mg) Bulk Container, ULTRAtab Laboratories, Inc., Highland, NY NDC 62969-242-00

**Product Quantity:**

50,585,623 tablets

**Reason for Recall:**

CGMP Deviations

**Recall Number:**

D-0538-2022

**Code Information:**

Product Codes: L242SRC Bulk Lot: 18K086, 18L009, 18L050, 18L083, 18M025, 18M073, 18M098, 19A010, 19A084, 19A105, 19A107; Product Code: L242L Bulk Lot: 19H014; Product Code: L242PA Bulk Lot: 18F072, 18L119, 19A067, 19G043; Product Code: L242N Bulk Lot: 19H040

**Product Description:**

Peppermint Antacid tablet (Calcium Carbonate 420 mg) Bulk Container, ULTRAtab Laboratories, Inc., Highland, NY NDC 62959-303-00

**Product Quantity:**

3,349,387 tablets

**Reason for Recall:**

CGMP Deviations

**Recall Number:**

D-0539-2022

**Code Information:**

Product Code: M303 Bulk lots: 19C042, 19C043, 19F083; Product Code: M303A Bulk Lot: 19E105

**Product Description:**

Cherry Antacid Tablet (Calcium Carbonate 420 mg) Bulk Container, ULTRAtab Laboratories, Inc., Highland, NY NDC 62959-304-00

**Product Quantity:**

3,052,313 tablets

**Reason for Recall:**

CGMP Deviations

**Recall Number:**

D-0540-2022

**Code Information:**

Product Codes: M304 Bulk Lots: 18K059, 18L106, 18L117, 18M067, 18M068

**Product Description:**

Trial Antacid Tablet (Calcium Carbonate 420 mg) Bulk Container, ULTRAtab Laboratories, Inc., Highland, NY NDC 62959-310-00

**Product Quantity:**

3,050,308 tablets

**Reason for Recall:**

CGMP Deviations

**Recall Number:**

D-0541-2022

**Code Information:**

Product Codes: M310 Bulk Lots: 19C044, 19H015

**Product Description:**

Spearmint Antacid Tablet (Calcium Carbonate 420 mg) Bulk Container, ULTRAtab Laboratories, Inc., Highland, NY NDC 62959-311-00

**Product Quantity:**

1,527,203 tablets

**Reason for Recall:**

CGMP Deviations

**Recall Number:**

D-0542-2022

**Code Information:**

Product Codes: M311 Bulk Lots: 19A069

**Product Description:**

Nutralox Peppermint Antacid (Calcium Carbonate 420 mg) Bulk Container, ULTRAtab Laboratories, Inc., Highland, NY NDC 62959-312-00

**Product Quantity:**

5,923,518 tablets

**Reason for Recall:**

CGMP Deviations

**Recall Number:**

D-0543-2022

**Code Information:**

Product Codes: M312 Bulk Lots: 18J004, 18J005, 18C045, 19C046

**Product Description:**

Ephedrine 25 Guaifenesin 200 Tablet (Ephedrine HCl 25 mg, Guaifenesin 200 mg) Bulk Container, ULTRAtab Laboratories, Inc., Highland, NY NDC 62959-320-00

**Product Quantity:**

7,297,709 tablets

**Reason for Recall:**

CGMP Deviations

**Recall Number:**

D-0544-2022

**Code Information:**

Product Codes: M320L Bulk Lots: 18M063, 19G076

**Product Description:**

Phenylephrine HCl 5 mg Tablet (Phenylephrine HCl 5mg) Bulk Container, ULTRAtab Laboratories, Inc., Highland, NY NDC 62959-333-00

**Product Quantity:**

4,531,580 tablets

**Reason for Recall:**

CGMP Deviations

**Recall Number:**

D-0545-2022

**Code Information:**

Product Codes: M333 Bulk Lots: 18M065, 19J078

**Product Description:**

Coated Phenylephrine HCl 5mg Tablet (Phenylephrine HCl 5mg ) Bulk Container, ULTRAtab Laboratories, Inc., Highland, NY NDC 62959-338-00

**Product Quantity:**

7,983,360 tablets

**Reason for Recall:**

CGMP Deviations

**Recall Number:**

D-0546-2022

**Code Information:**

Product Codes: M338 Bulk Lots: 19A070, 19B080, 19J043

**Product Description:**

Migrenol Caplet (Acetaminophen 500 mg, Caffeine 65 mg) Bulk Container, ULTRAtab Laboratories, Inc., Highland, NY NDC 62959-565-00

**Product Quantity:**

990,197 tablets

**Reason for Recall:**

CGMP Deviations

**Recall Number:**

D-0547-2022

**Code Information:**

Product Codes: M565L Bulk Lots: 19F014

**Product Description:**

APAP 325 mg (Acetaminophen 325 mg, Pamabrom 25 mg tablet) Bulk Container, ULTRAtab Laboratories, Inc., Highland, NY NDC 62959-700-00

**Product Quantity:**

6,380,282 tablets

**Reason for Recall:**

CGMP Deviations

**Recall Number:**

D-0548-2022

**Code Information:**

Product Codes: M700LA Bulk Lots: 18K037, 18L093, 18M006, 19A121, 19G044, 19G045, 19G046

**Product Description:**

Normed Fem Tablet (Acetaminophen 325 mg, Pamabrom 25 mg) Bulk Container, ULTRAtab Laboratories, Inc., Highland, NY NDC 62959-701-00

**Product Quantity:**

452,038 tablets

**Reason for Recall:**

CGMP Deviations

**Recall Number:**

D-0549-2022

**Code Information:**

Product Codes: M701L Bulk Lots: 19G077

**Product Description:**

Pain Aid PMF Caplet (Acetaminophen 500 mg, Pamabrom 25 mg) Bulk Container, ULTRAtab Laboratories, Inc., Highland, NY NDC 62959-710-00

**Product Quantity:**

1,585,375 tablets

**Reason for Recall:**

CGMP Deviations

**Recall Number:**

D-0550-2022

**Code Information:**

Product Codes: M710L Bulk Lots: 19A071

**Product Description:**



Back Relief II (Acetaminophen 200 mg, Magnesium Salicylate 200 mg) Bulk Container, ULTRAtab Laboratories, Inc., Highland, NY NDC 62959-740-00

**Product Quantity:**

1,477,641 tablets

**Reason for Recall:**

CGMP Deviations

**Recall Number:**

D-0551-2022

**Code Information:**

Product Codes: M740LA Bulk Lots: 19C022, 19C023

**Product Description:**

Legatrin (Acetaminophen 500 mg, Diphenhydramine HCl 50 mg) Bulk Container, ULTRAtab Laboratories, Inc., Highland, NY NDC 62959-785-00

**Product Quantity:**

14,066,434 tablets

**Reason for Recall:**

CGMP Deviations

**Recall Number:**

D-0552-2022

**Code Information:**

Product Codes: M785L Bulk Lots: 18K029, 18L059, 18M100, 19B013, 19D024, 19D059, 19E029, 19J050

**Product Description:**

Coated Back Relief Tablet (Acetaminophen 250 mg, Magnesium Salicylate 290 mg, Caffeine 50 mg) Bulk Container, ULTRAtab Laboratories, Inc., Highland, NY NDC 62959-800-00

**Product Quantity:**

25,769,495 tablets

**Reason for Recall:**

CGMP Deviations

**Recall Number:**

D-0553-2022

**Code Information:**

Product Codes: M800L Bulk Lots: 18K005, 18K075, 18K098, 18M064, 19C021, 19C050, 19G081, 19G082, 19H012, 19H013, 19J036, 19J037

**Product Description:**

DBI Magnums Tablet (Caffeine 200 mg) 100 and 500 count & 3 and 36 count packets & Bulk Container, ULTRAtab Laboratories, Inc., Highland, NY NDC 62959-941-00

**Product Quantity:**

8,727,657 tablets

**Reason for Recall:**

CGMP Deviations

**Recall Number:**

D-0554-2022

**Code Information:**

Product Codes: M941L M940LA Bulk Lots: 19C065, 19F081, 19H083, 17D088

**Product Description:**

Cystex Tablet (Sodium Salicylate 162.5 mg, Methenamine 162 mg) Bulk Container, ULTRAtab Laboratories, Inc., Highland, NY 62959-945-00

**Product Quantity:**

37,464,418 tablets

**Reason for Recall:**

CGMP Deviations

**Recall Number:**

D-0555-2022

**Code Information:**

Product Codes: M945 Bulk Lots: 18J072, 18K030, 18L123, 19A043, 19A093, 19B062, 19C079, 19C080, 19D041, 19E035, 19E087, 19G084, 19H098