# Enforcement Report - Week of July 10, 2024

## Class I Drugs Event

**Event ID:**
94366

**Product Type:**
Drugs

**Status:**
Ongoing

**Date Terminated:**
N/A

**Recall Initiation Date:**
02/01/2024

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

**Center Classification Date:**
07/03/2024

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

**Recalling Firm:**
Integrity Products
5613 Park Road Suite 2
High Ridge, MO 63049
United States

**Distribution Pattern:**
Nationwide in the USA

### Associated Products

**Product Description:**
RAM IT, Horny Goat Weed, dietary supplement capsules, 1000 mg, packaged in a box containing a 10-count blister card, Distributed By: Integrity Products, 1710 Fenpark Dr., Fenton, MO 63026

**Product Quantity:**
2500 boxes

**Reason for Recall:**
Marketed Without an Approved NDA/ANDA: Products contain undeclared sildenafil.

**Recall Number:**
D-0585-2024

**Code Information:**
Lot HGW221116 (Batch 020123-1), Exp 5/31/2025

**Product Description:**
To the Moon Capsules, Horny Goat Weed, 1000 mg, packaged in a box containing a 10-count blister card, Distributed By: Integrity Products, 1710 Fenpark Dr., Fenton, MO 63026

**Product Quantity:**
2500 boxes

**Reason for Recall:**
Marketed Without an Approved NDA/ANDA: Products contain undeclared sildenafil.

**Recall Number:**
D-0586-2024

**Code Information:**
Lot HGW221116 (Batch 022123-1), Exp 5/31/2025

## Class II Drugs Event

**Event ID:**
94781

**Product Type:**
Drugs

**Status:**
Ongoing

**Date Terminated:**
N/A

**Recall Initiation Date:**
06/07/2024

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

**Center Classification Date:**
07/03/2024

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

**Recalling Firm:**
Dr. Reddy's Laboratories, Inc.
107 College Rd E
Princeton, NJ 08540-6623
United States

**Distribution Pattern:**
IL, MS, OH

## Associated Products

**Product Description:**
Allopurinol Tablets, USP 300mg, 100 Tablets per bottle, Rx only, Manufactured By: Dr. Reddy's Laboratories LA LLC, Shreveport, LA 71106 USA, NDC 55111-730-01.

**Product Quantity:**
20,520 units

**Reason for Recall:**
Presence of foreign substance.

**Recall Number:**
D-0583-2024

**Code Information:**
L2300594

## Class II Drugs Event

**Event ID:**
94788

**Product Type:**
Drugs

**Status:**
Ongoing

**Date Terminated:**
N/A

**Recall Initiation Date:**
06/20/2024

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

**Center Classification Date:**
07/02/2024

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

**Recalling Firm:**
Little Moon Essentials LLC
501 Old Griffin Rd
Dania Beach, FL 33004-2774
United States

**Distribution Pattern:**
Nationwide USA and Ontario, Canada (2 retailers)

## Associated Products

**Product Description:**
Little Moon Essentials, Magical Muscle Oil, (Camphor 1.95%, Menthol 3.75%) packaged as: a) 2 FL OZ (59ML) glass jar, UPC Code 6 73673 88202 2, NDC 70722-246-02; b) 4 FL OZ (118ML) jar, UPC Code 6 73673 88233 6, NDC 70722-246-04; Little Moon Essentials LLC Dania Beach, Fl 33004

**Product Quantity:**
1654 glass jars

**Reason for Recall:**
CGMP deviations

**Recall Number:**
D-0571-2024

**Code Information:**
lot code No expiration date on product: a) 325240, 320260, 329011, 324021, 328221, 421110, 422120, 423120, 421220, 426220, 428220, b) 329230, 328140, 320290, 328011.

**Product Description:**
Little Moon Essentials, Crampy Belly Rub (Camphor 1.1%), Packaged as a) 4 FL OZ (118ML) glass jar, UPC Code 6 73673 88260 2, NDC 70722-260-04; b) 2 FL OZ (59ML) glass jar, UPC Code 6 73673 88204 6, NDC 70722-260-02, Little Moon Essentials LLC Dania Beach, Fl 33004

**Product Quantity:**
788 glass jars

**Reason for Recall:**
CGMP deviations

**Recall Number:**
D-0572-2024

**Code Information:**
lot code No Expiration Date on product: a) 224010, b) 321260, 322260, 320280, 328080, 325021, 321121, 423010, 427110, 429120, 420220, 422140

**Product Description:**
Little Moon Essentials, Aching Head Rub (Camphor 3.09%, Menthol 2.55%) , a) 0.5OZ (14G), metal tin, UPC Code 67367388226 8, NDC 70722-203-05; b)1OZ (28G) glass jar, UPC Code 6 73673 88203 9, NDC 70722-203-01; Little Moon Essentials LLC Dania Beach, Fl 33004

**Product Quantity:**
6,312 tin and glass jars

**Reason for Recall:**
CGMP deviations

**Recall Number:**
D-0573-2024

**Code Information:**
lot code No expiration date on product: a) 326070, 420140, b) 322030, 321230, 329230, 321240, 329170, 328280, 326090, 322290, 327021, 323121, 327221, 429210, 424130, 427050

**Product Description:**
Little Moon Essentials, Dream Cream (Camphor 0.45%, Menthol 5%), Packaged as a) 2OZ (57G) glass jar, UPC Code 6 73673 88214 5, NDC 70722-232-02; b) 4OZ (113G) glass jar, UPC Code 6 73673 88804 8, NDC 70722-232-04; Little Moon Essentials LLC Dania Beach, Fl 33004

**Product Quantity:**
1264 glass jars

**Reason for Recall:**
CGMP deviations

**Recall Number:**
D-0574-2024

**Code Information:**
lot code no expiration dates on product: a) 328260, 321221, 425120, 427230, b) 327150, 326260, 320270, 321301, 422020

**Product Description:**
Little Moon Essentials, Vital Vapor Balm, (Camphor 0.6%, Menthol 5.2%) Packaged as a) 0.5OZ (14G) metal tin, UPC Code 6 73673 88231 2, NDC 70722-229-05) b) 2OZ (57G) glass jar, UPC Code 6 73673 88220 6, NDC 70722-229-02; c) 4OZ (113G) glass jar, UPC Code 6 73673 88218 3, NDC 70722-229-04; Little Moon Essentials LLC Dania Beach, Fl 33004

**Product Quantity:**
1041

**Reason for Recall:**
CGMP deviations

**Recall Number:**
D-0575-2024

**Code Information:**
lot code no expiration date on product: a) 324280, b) 328230, 321170, 321290, 326021, 420220, 422140, c) 326040, 328170

**Product Description:**
Little Moon Essentials, Ass Kisser, Packaged as a) 0.5 OZ (14G) metal tin, UPC Code 6 73673 88228 2, NDC 70722-208-05; b) 3 OZ (85.05G) metal tin, UPC Code 6 73673 88208 4, NDC 70722-208-03; Little Moon Essentials LLC Dania Beach, Fl 33004

**Product Quantity:**
165 metal tins

**Reason for Recall:**
CGMP deviations

**Recall Number:**
D-0576-2024

**Code Information:**
lot code no expiration date on product: a) 327140, b) 322170, 325040, 325250

**Product Description:**
Little Moon Essentials, Asana Kisser, (Camphor 1.35%, Menthol 2.86%), Packaged as a) 0.5 OZ (14G) metal tin, UPC Code 6 73673 88227 5, NDC 70722-216-05; b) 3 OZ (85-05G) metal tin UPC Code 6 73673 88216 9, NDC 70722-216-03; Little Moon Essentials LLC Dania Beach, Fl 33004

**Product Quantity:**
320 metal tins

**Reason for Recall:**
CGMP deviations

**Recall Number:**
D-0577-2024

**Code Information:**
lot code no expiration date on product: a) 322230, 424040, b) 322230, 325070, 324080, 325180, 325280, 328290, 426110, 423210, 426120, 422220, 423130, 428230, 325040

**Product Description:**
Little Moon Essentials, Clear Breeze Plus, Hand Sanitizer (Alcohol 65% v/v) Packaged as a) 2 FL OZ (60ML) spray bottle, UPC Code 6 73673 88797 3, NDC 70722-319-02; b) 4 FL OZ (118ML) spray bottle, UPC Code 6 73673 88798 0, NDC 70722-319-04; Little Moon Essentials LLC Dania Beach, Fl 33004

**Product Quantity:**
20 spray bottles

**Reason for Recall:**
CGMP deviations

**Recall Number:**
D-0578-2024

**Code Information:**
lot code expiration dates are not on products: a) 023170, b) 023170

## Class II Drugs Event

**Event ID:**
94818

**Product Type:**
Drugs

**Status:**
Ongoing

**Date Terminated:**
N/A

**Recall Initiation Date:**
06/17/2024

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

**Center Classification Date:**
07/02/2024

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

**Recalling Firm:**
Trigen Laboratories
1880 Mcfarland Pkwy ste 110

Alpharetta, GA 30005-1794
United States

**Distribution Pattern:**
Nationwide in the USA

## Associated Products

**Product Description:**
Methylphenidate Hydrochloride, Extended-release Tablets, USP, 36mg, 100-count Bottle, Rx Only, Manufactured for: Trigen Laboratories, LLC, Alpharetta, GA 30005, NDC 13811-708-10

**Product Quantity:**
10,448 100-count bottles

**Reason for Recall:**
Failed dissolution specifications: this product is being recalled due to this batch not meeting dissolution specifications.

**Recall Number:**
D-0579-2024

**Code Information:**
Lot 230159M, Exp Date 2/28/2026

## Class II Drugs Event

**Event ID:**
94835

**Product Type:**
Drugs

**Status:**
Ongoing

**Date Terminated:**
N/A

**Recall Initiation Date:**
06/18/2024

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

**Center Classification Date:**
07/03/2024

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

**Recalling Firm:**
The Harvard Drug Group LLC dba Major Pharmaceuticals and Rugby Laboratories
341 Mason Rd
La Vergne, TN 37086-3606
United States

**Distribution Pattern:**
Nationwide. No foreign consignees.

## Associated Products

**Product Description:**
Venlafaxine Hydrochloride, extended-release capsules, USP, 37.5mg, 10 x 10 blister card in one carton, Rx only, Mfg by: Cadila Healthcare Ltd., Ahmedabad, India, Distributed by: Major Pharmaceutical 17177 N Laurel Park Dr., Suite 233, Livonia, MI 48152, USA, NDC 0904-7075-61, UPC code: 309047075614

**Product Quantity:**
864 cartons

**Reason for Recall:**
Failed dissolution specifications: out of specification result obtained during routine stability testing for high dissolution.

**Recall Number:**
D-0584-2024

**Code Information:**
Lot code: M04614, Exp 09/30/2024

## Class II Drugs Event

**Event ID:**
94868

**Product Type:**
Drugs

**Status:**
Ongoing

**Date Terminated:**
N/A

**Recall Initiation Date:**
06/26/2024

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

**Center Classification Date:**
06/28/2024

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

**Recalling Firm:**
Medisca Inc.
6641 N Belt Line Rd Ste 130
Irving, TX 75063-6001
United States

**Distribution Pattern:**
Nationwide in the USA and Canada

## Associated Products

**Product Description:**
Budesonide, USP (Micronized), 500 mg, White to off-white odorless, crystalline powder, Medisca Inc., Plattsburgh, NY, 12901, USA, NDC: 38779-3097-00.

**Product Quantity:**
113 bottles

**Reason for Recall:**
CGMP Deviations and Presence of Particulate Matter: Glass

**Recall Number:**
D-0570-2024

**Code Information:**
Lot #s: 202323/G, 202323/H, Exp. 07/31/2026

## Class II Drugs Event

**Event ID:**
94913

**Product Type:**
Drugs

**Status:**
Ongoing

**Date Terminated:**
N/A

**Recall Initiation Date:**
07/02/2024

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

**Center Classification Date:**
07/03/2024

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

**Recalling Firm:**
SUN PHARMACEUTICAL INDUSTRIES INC
2 Independence Way
Princeton, NJ 08540-6620
United States

**Distribution Pattern:**
Nationwide in the USA

## Associated Products

**Product Description:**
Decitabine for Injection 50mg per vial, For intravenous infusion only Cytotoxic Agent, Sterile, Rx Only, Single-Dose Vial, Distributed by: Sun Pharmaceutical Industries, Inc., Cranbury, NJ 08512, Manufactured by: Sun Pharmaceutical Ind. Ltd., Halol-Baroda Highway, Halol-389 350, Gujarat, India, NDC 47335-361-40.

**Product Quantity:**
2088 vials

**Reason for Recall:**
CGMP Deviations: Out of Specification for Total Aerobic Microbial Count (TAMC) test for unfiltered bulk for decitabine for injection.

**Recall Number:**
D-0582-2024

**Code Information:**
HAD2964A, Exp 7/31/2024

## Class III Drugs Event

**Event ID:**
94754

**Product Type:**
Drugs

**Status:**
Ongoing

**Date Terminated:**
N/A

**Recall Initiation Date:**
06/04/2024

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

**Center Classification Date:**
07/02/2024

**Initial Firm Notification of Consignee or Public:**
N/A

**Recalling Firm:**
Dr. Reddy's Laboratories, Inc.
107 College Rd E
Princeton, NJ 08540-6623
United States

**Distribution Pattern:**
OH, MS

## Associated Products

**Product Description:**
Eszopiclone Tablets, USP 1mg CIV, 30-count bottle, Rx only, Mfd. By: Dr. Reddy's Laboratories Limited, Bachupally - 500 090 INDIA, NDC 55111-629-30

**Product Quantity:**
13,752 bottles

**Reason for Recall:**
Failed Impurities/Degradation Specifications: Related Substances

**Recall Number:**
D-0581-2024

**Code Information:**
Lot#: C2302598, Exp 2/29/2025

## Class III Drugs Event

**Event ID:**
94842

**Product Type:**
Drugs

**Status:**
Ongoing

**Date Terminated:**
N/A

**Recall Initiation Date:**
06/18/2024

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

**Center Classification Date:**
07/02/2024

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

**Recalling Firm:**
Accord Healthcare, Inc.
1009 Slater Rd Ste 210B
Durham, NC 27703-8446
United States

**Distribution Pattern:**
USA Nationwide

## Associated Products

**Product Description:**
Dodex Injectable (Cyanocobalamin Injection) USP, 1,000mcg/mL, 1mL multiple dose vial, Rx only, Manufactured for: Accord Healthcare, Inc., Durham, NC 27703, Manufactured by: Intas Pharmaceuticals Limited, Ahmedabad-382 210, India, NDC 16729-533-08, UPC Code: 031672953308

**Product Quantity:**
52,998

**Reason for Recall:**
Subpotent drug: out of specification results

**Recall Number:**
D-0580-2024

**Code Information:**
Lot# R2200834, R2200835, R2200841, R2200958, Exp 06/30/2024; R2201044 R2201045 R2201046, R2201047, R2201095, R2201142, R2201143, R2201144, Exp 07/31/2024; M2215870, M2215918, Exp 10/2024