

# Enforcement Report - Week of October 2, 2024

## Class II Drugs Event

**Event ID:**

94893

**Product Type:**

Drugs

**Status:**

Ongoing

**Date Terminated:**

N/A

**Recall Initiation Date:**

06/26/2024

**Voluntary / Mandated:**

Voluntary: Firm initiated

**Center Classification Date:**

09/23/2024

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

N/A

**Recalling Firm:**

Guru Inc.  
4370 Lawrenceville Hwy NW # 2204  
Lilburn, GA 30047-1100  
United States

**Distribution Pattern:**

Retail: South Carolina, North Carolina, Ohio; Consumer level: Nationwide within USA

## Associated Products

**Product Description:**

Infla-650 Herbal Dietary Supplement, 700mg, packaged in pouches containing 60 capsules, Distributed by: Guru Inc., 4370 Lawrenceville Hwy NW, P.O. Box 2204, Lilburn, GA 30047-1100, USA. Ph.: 872 216 1566, <http://www.dalayurevda.com>, Made in India, UPC: 042535355019

**Product Quantity:**

N/A

**Reason for Recall:**

Marketed without an approved NDA/ANDA: FDA analysis found product to be tainted with undeclared acetaminophen, diclofenac, and phenylbutazone.

**Recall Number:**

D-0666-2024

**Code Information:**

Batch # IN-032, Exp 11/30/2027

## Class II Drugs Event

**Event ID:**

95275

**Product Type:**

Drugs

**Status:**

Ongoing

**Date Terminated:**

N/A

**Recall Initiation Date:**

09/03/2024

**Voluntary / Mandated:**

Voluntary: Firm initiated

**Center Classification Date:**

09/24/2024

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

Letter

**Recalling Firm:**

Ascend Laboratories, LLC  
339 Jefferson Rd Ste 101  
Parsippany, NJ 07054-3707  
United States

**Distribution Pattern:**

Nationwide in the USA and PR

## Associated Products

**Product Description:**

Mycophenolic Acid Delayed-Release Tablets USP, 360 mg, Rx Only, 120 Tablets per bottle, Manufactured by Alkem Laboratories, LTD, INDIA; Distributed by Ascend Laboratories, LLC, Parsippany, NJ 07054, NDC 67877-427-12.

**Product Quantity:**

117,493 bottles

**Reason for Recall:**

Failed Dissolution Specifications

**Recall Number:**

D-0668-2024

**Code Information:**

Lots 22123437, 22123438, 22123535, Exp Date 9/30/24; 22123536, 22123537, 22123538, 22123646, 22123647, Exp Date 10/31/24; 23120529, 23120530, Exp Date 1/31/25; 23120703, 23120705, Exp Date 2/28/25; 23121429, 23121726, 23122049, 23122097, Exp Date, 4/30/25; 23121984, 23121985, 23121986, Exp Date 5/31/25; 23122325, 23122329, 23122330, 23122331, Exp Date 6/30/26; 23122776, 23122852, 23122853, 23123154, 23123155, Exp Date 8/31/26; 23123458, Exp Date 9/30/26.

## Class II Drugs Event

**Event ID:**

95279

**Product Type:**

Drugs

**Status:**

Ongoing

**Date Terminated:**

N/A

**Recall Initiation Date:**

08/30/2024

**Voluntary / Mandated:**

Voluntary: Firm initiated

**Center Classification Date:**

09/20/2024

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

Letter

**Recalling Firm:**

Glenmark Pharmaceuticals Inc., USA

750 Corporate Dr

Mahwah, NJ 07430-2009

United States

**Distribution Pattern:**

Product was distributed nationwide within the United States.

## Associated Products

**Product Description:**

Mupirocin Ointment, USP, 2%, 22 g, Rx only, Manufactured by: Glenmark Pharmaceuticals, Ltd., Colvale-Bardez, Goa 403513, India. Manufactured for: Glenmark Pharmaceuticals Inc., USA, Mahwah, NJ, 07430, NDC 68462-180-22.

**Product Quantity:**

2,031,480 ointments

**Reason for Recall:**

Subpotent Drug

**Recall Number:**

D-0660-2024

**Code Information:**

Lot #: 19223615, 19223537, 19223544, 19223568, 19223593, 19223641, Exp. Date 08/2024; 19224055, 19224281, 19224307, 19224321, 19224341, 19224467, Exp. Date 09/2024; 19224525, 19224542, 19224560, 19224580, Exp. Date 10/2024; 19224990, 19224998, 19225014, 19225033, 19225293, 19225304, 19225320, 19225349, 19225367, 19225379, 19225401, Exp. Date 11/2024; 19230115, 19230123, 19230132, 19230137, 19230167, 19230170, Exp. Date 12/2024; 19230572, 19230607, 19230614, 19230628, 19230631, Exp. Date 1/2025; 19230874, 19230925, 19230941, 19230957, 19230976, 19231232, 19231238, 19231282, 19231285, Exp. Date 02/2025.

## Class II Drugs Event

**Event ID:**  
95304

**Status:**  
Ongoing

**Recall Initiation Date:**  
09/05/2024

**Center Classification Date:**  
09/20/2024

**Recalling Firm:**  
Empower Pharmacy  
5980 W Sam Houston Pkwy N Ste 300  
Houston, TX 77041-5254  
United States

**Distribution Pattern:**  
Nationwide

**Product Type:**  
Drugs

**Date Terminated:**  
N/A

**Voluntary / Mandated:**  
N/A

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

## Associated Products

**Product Description:**  
Pyridoxine HCL (B6) Injection Solution, 100mg/mL, 30 mL Sterile Multiple-Dose Vial, For IM or IV use only, RX Only, Compounded by: Empower Pharmacy 5980 W Sam Houston Pkwy N Ste 300, Houston, TX 77041 NDC 72627-2424-1.

**Product Quantity:**  
450

**Reason for Recall:**  
Lack of Assurance of Sterility

**Recall Number:**  
D-0663-2024

**Code Information:**  
Product lot number: 609763 Beyond Use Date: 04/18/2025

## Class II Drugs Event

**Event ID:**  
95332

**Status:**  
Ongoing

**Recall Initiation Date:**  
09/16/2024

**Center Classification Date:**  
09/23/2024

**Recalling Firm:**  
AbbVie Inc.  
1 N Waukegan Rd  
North Chicago, IL 60064-1802  
United States

**Distribution Pattern:**  
Nationwide in the USA, Foreign Consignees (Australia, Canada, Great Britain)

**Product Type:**  
Drugs

**Date Terminated:**  
N/A

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

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

## Associated Products

**Product Description:**

Refresh P.M., (Mineral Oil 42.5%, White Petrolatum 57.3%) Lubricant Eye Ointment, Net wt, 0.12 oz (3.5g) Tube, Distributed by: Allergen, an AbbVie company, Madison, NJ 07940, UPC code: 300230667043,

**Product Quantity:**

2,473,563 tubes

**Reason for Recall:**

Lack of Assurance of Sterility: The impacted lots may contain a breach in the tube seal.

**Recall Number:**

D-0664-2024

**Code Information:**

Lot: 387392, 387393, 387394, Exp. Feb 25; 387395, 388729, 388730, 388731, 388732, 390391, 390404, Exp. Apr 25; 391688, 391734, Exp. Oct 25; 392616, 392620, Exp. Dec 25; 392987, 393560, Exp. Jan 26; 394816, 394821, Exp. Nov 25; 394927, 394929, Exp. Feb 26; 395713, 395992, 396815, Exp. Mar 26; 396816, 397248, 397315, Exp. Apr 26; 397316, 397774, 397775, 397776, 398436, 398437, Exp. May 26; 398621, 398643, 398739, 398944, 399001, 399255, 399270, 399271, Exp. Jun 26; 399798, 399806, 400003, Exp. Jul 26; 408668, 408723, 408737, 408853, 408895, Exp. Apr 27; 409121, 409142, Exp. May 27; 409261, Exp. Apr 27; T4534, T4535, T4591, T4592, Exp. Dec 24; T4660, T4661, T4696, T4697, T4709, T4772, T4773, Exp. Jan 25; T4844, T4845, Feb 25

**Product Description:**

Refresh LACRI-LUBE, (42.5% Mineral Oil, 57.3% White Petrolatum) Lubricant Eye Ointment, Net wt, 0.12 oz (3.5g) Tube, Distributed by: Allergen, an AbbVie company, Madison, NJ 07940, UPC code: 300230312042

**Product Quantity:**

763,426 tubes

**Reason for Recall:**

Lack of Assurance of Sterility: The impacted lots may contain a breach in the tube seal.

**Recall Number:**

D-0665-2024

**Code Information:**

Lot: 387489, Exp. Oct 24; 387490, Exp. Jun 25; 390422, Exp. Nov 24; 390424, Exp. Oct 24; 391692, Exp. Jun 25; 391893, Exp. Nov 25; 394822, Exp. Feb 26; 395991, Exp. Mar 26; 397905, 397973, 397974, Exp. May 26; 399019, 399254, Exp. Jun 26; 399922, Exp. Jul 26; 408738, Exp. Mar 27; T3911, Exp. Sep 24; T4015, T4031, T4032, T4033, T4108, Exp. Oct 24.

## Class II Drugs Event

**Event ID:**

95333

**Product Type:**

Drugs

**Status:**

Ongoing

**Date Terminated:**

N/A

**Recall Initiation Date:**

09/11/2024

**Voluntary / Mandated:**

Voluntary: Firm initiated

**Center Classification Date:**

09/20/2024

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

Letter

**Recalling Firm:**

Mckesson Medical-Surgical Inc. Corporate Office  
9954 Maryland Drive Deep Run Iii Ste. 4000  
Richmond, VA 23233  
United States

**Distribution Pattern:**

Product was distributed to two medical facilities in MD and VA.

## Associated Products

**Product Description:**

Proparacaine Hydrochloride Ophthalmic Solution, USP 0.5% (sterile), 15 mL bottle, Rx only, MFG: Bausch & Lomb, NDC 24208-730-06

**Product Quantity:**

27 bottles

**Reason for Recall:**

Temperature abuse: Products exposed to improper temperature above drug label specifications.

**Recall Number:**

D-0661-2024

**Code Information:**

Lot # 476261, 479751, 479741, Exp 3/31/2026

## Class II Drugs Event

**Event ID:**

95339

**Product Type:**

Drugs

**Status:**

Ongoing

**Date Terminated:**

N/A

**Recall Initiation Date:**

09/03/2024

**Voluntary / Mandated:**

Voluntary: Firm initiated

**Center Classification Date:**

09/20/2024

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

Letter

**Recalling Firm:**

Vivier Pharma, Inc.  
288 Adrien-Patenaude St  
Vaudreuil-Dorion  
Canada

**Distribution Pattern:**

Nationwide within the United States

## Associated Products

**Product Description:**

Vivier Sheer SPF 30 Mineral With Antioxidants (titanium dioxide 10% and zinc oxide 8%) packaged in 60 ml/2 fl oz, Vivier Canada Inc. / Mfd. for Vivier Pharma, Vaudreuil-Dorion OC Canada, J7V 5V5, Champlain, NY USA 12919, Made in Canada, NDC 67226-2232-6. SKU 10-160-ZZ-80059-R

**Product Quantity:**

3476 units

**Reason for Recall:**

Microbial Contamination of Non-Sterile Product

**Recall Number:**

D-0662-2024

**Code Information:**

Lot #: 91771, Exp. Date 09/2025

## Class II Drugs Event

**Event ID:**

95390

**Product Type:**

Drugs

**Status:**

Ongoing

**Date Terminated:**

N/A

**Recall Initiation Date:**

09/18/2024

**Voluntary / Mandated:**

Voluntary: Firm initiated

**Center Classification Date:**

09/24/2024

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

N/A

**Recalling Firm:**

EnviroServe Chemicals Inc.  
603 S Wilson Ave  
Dunn, NC 28334-5832  
United States

**Distribution Pattern:**

Product was sent to one distributor in North Carolina.

**Associated Products**

**Product Description:**

EnviroClean Hand Sanitizer Gel (isopropyl alcohol 70% v/v), 473 mL (16 fl. oz.) bottles, EnviroServe Chemicals Inc., 603 South Wilson Avenue, Dunn NC, 28334, NDC 76563-3010-1

**Product Quantity:**

120 bottles

**Reason for Recall:**

CGMP deviations

**Recall Number:**

D-0667-2024

**Code Information:**

Lot #: 042224-L1, Exp. Date 04/22/2025