Enforcement Report - Week of May 14, 2025

Class I Drugs Event

Event ID:
96648

Product Type:
Drugs

Status:
Ongoing

Date Terminated:
N/A

Recall Initiation Date:
04/17/2025

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
05/05/2025

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Amneal Pharmaceuticals, LLC
400 Crossing Blvd Fl 3
Bridgewater, NJ 08807-2863
United States

Distribution Pattern:
Nationwide in the US

Associated Products

Product Description:
Ropivacaine Hydrochloride Injection, USP, 0.5%, 500 mg per 100 mL (5mg/mL), Manufactured by: Amneal Pharmaceuticals Pvt. Ltd., Mehsana, India, , Distributed by: Amneal Pharmaceuticals LLC, Bridgewater, NJ 08807 NDC 70121-1734-1 (bag); NDC 70121-1734-3 (box)

Product Quantity:
62 (12x100mL) bags

Reason for Recall:
Presence of Particulate Matter

Recall Number:
D-0402-2025

Code Information:
Lot #'s: AL240003, AL240004, Exp.: 01/31/2026

Class II Drugs Event

Event ID:
96740

Product Type:
Drugs

Status:
Ongoing

Date Terminated:
N/A

Recall Initiation Date:
04/18/2025

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
05/05/2025

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
FDC Limited
B-8 MIDC Industrial Area Waluj District
Aurangabad, Maharashtra State
India

Distribution Pattern:
U.S. Nationwide

Associated Products

Product Description:
Timolol Maleate Ophthalmic Solution USP, 0.5%, Sterile, 10mL bottles, Rx only, Manufactured by: FDC Limited, Waluj, Aurangabad, Maharashtra, India, Distributed by: Rising Pharmaceuticals Inc, New Jersey, NDC 64980-514-01.

Product Quantity:
60428 bottles

Reason for Recall:
Defective Container: Unable to get the solution out of the bottle as the spike of the cap was lodged in the nozzle of the product bottle.

Recall Number:
D-0403-2025

Code Information:
Lot #: 083I098, Exp. Date 08/31/2025

Class II Drugs Event

Event ID:
96741

Product Type:
Drugs

Status:
Ongoing

Date Terminated:
N/A

Recall Initiation Date:
04/23/2025

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
05/06/2025

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
BRS Analytical Services, LLC
11697 Lakeside Crossing Ct
Saint Louis, MO 63146-8606
United States

Distribution Pattern:
Nationwide in the USA

Associated Products

Product Description:
Artificial Tears Ophthalmic Solution, Dextran 70.01%/Glycerin 0.2%/Hypromellose 0.3% (Eye Lubricants) Lubricant Eye Drops, STERILE, 0.5 FL OZ (15 mL) per dropper bottle, Distributed by: AvKARE, Pulaski, TN 38478, NDC: 50268-043-15.

Product Quantity:
13,872 cases (24 cartons per case)

Reason for Recall:
cGMP deviations and lack of assurance of sterility.

Recall Number:
D-0404-2025

Code Information:
Lot, expiry: Lot 126, exp 10/26/25; Lot 127, exp 10/30/25; Lot 128, exp 11/02/25; Lot 129, exp 11/06/25; Lot 162, exp 5/09/26; Lot 163, exp 5/14/26; Lot 164, exp 5/20/26; Lot 165, exp 5/23/26; Lot 166, exp 5/29/26; Lot 167, exp 6/03/26; Lot 168, exp 6/06/26; Lot 169, exp 6/10/26; Lot 170, exp 6/13/26; Lot 193, exp 10/07/26; Lot 194, exp 10/10/26; Lot 195, exp 10/14/26; Lot 196, exp 10/17/26; Lot 197, exp 10/21/26; Lot 198, exp 10/24/26; Lot 199, exp 10/30/26.

Product Description:
Carboxymethylcellulose Sodium Ophthalmic Gel 1%, Carboxymethlycellulose Sodium 1% Eye Lubricant, Lubricant Eye Gel, Soothing Gel, Sterile, 0.5 FL OZ (15mL) per bottle, Distributed by: AvKARE, Pulaski, TN 38478, NDC: 50268-066-15.

Product Quantity:
1,610 cases (24 cartons per case)

Reason for Recall:
cGMP deviations and lack of assurance of sterility.

Recall Number:
D-0405-2025

Code Information:
Lot, expiry: Lot 114, exp 9/04/25; Lot 115, exp 9/06/25; Lot 116, exp 9/10/25; Lot 207, exp 12/05/26

Product Description:
Carboxymethylcellulose Sodium Ophthalmic Solution 0.5%, Carboxymethlycellulose Sodium 0.5% Eye Lubricant, Lubricating Eye Drops, Moisturizing, Sterile, 0.5 FL OZ (15mL) per dropper bottle, Distributed by: AvKARE, Pulaski, TN 38478, NDC: 50268-068-15.

Product Quantity:
32,876 cases (24 cartons per case)

Reason for Recall:
cGMP deviations and lack of assurance of sterility.

Recall Number:
D-0406-2025

Code Information:
Lot, expiry: Lot 103, exp 4/26/25; Lot 104, exp 5/03/25; Lot 108, exp 6/29/25; Lot 109, exp 7/18/25; Lot 110, exp 8/17/25; Lot 111, exp 8/22/25; Lot 112, exp 8/27/25; Lot 113, exp 9/18/25; Lot 125, exp 10/23/25; Lot 130, exp 11/09/25; Lot 131, exp 11/14/25; Lot 132, exp 11/27/25; Lot 133, exp 11/30/25; Lot 134, exp 12/05/25; Lot 135, exp 12/11/25; Lot 136, exp 12/14/25; Lot 137, exp 1/02/26; Lot 139, exp 1/15/26; Lot 140, exp 1/19/26; Lot 141, exp 1/25/26; Lot 151, exp 3/18/26; Lot 152, exp 3/21/26; Lot 153, exp 3/25/26; Lot 154, exp 3/28/26; Lot 155, exp 4/01/26; Lot 156, exp 4/08/26; Lot 157, exp 4/11/26; Lot 160, exp 4/26/26; Lot 180, exp 8/08/26; Lot 181, exp 8/12/26; Lot 182, exp 8/18/26; Lot 183, exp 8/21/26; Lot 184, exp 8/26/26; Lot 185, exp 9/04/26; Lot 186, exp 9/09/26; Lot 187, exp 9/16/26; Lot 188, exp 9/18/26; Lot 189, exp 9/21/26; Lot 190, exp 9/25/26; Lot 191, exp 9/28/26; Lot 192, exp 10/02/26; Lot 208, exp 12/11/26; Lot 209, exp 12/16/26; Lot 212, exp 1/15/27; Lot 213, exp 1/21/27; Lot 214, exp 1/24/27; Lot 215, exp 2/02/27; Lot 216, exp 2/04/27; Lot 224, exp 3/27/27.

Product Description:
Lubricant Eye Drops Solution, Polyethylene Glycol 400 0.4% Eye Lubricant, Propylene Glycol 0.3% Eye Lubricant, Lubricant Eye Drops, Moisturizing, Sterile, 0.5 FL OZ (15mL) per dropper bottle, Distributed by: AvKARE, Pulaski, TN 38478, NDC: 50268-126-15.

Product Quantity:
13,104 cases (24 cartons per case)

Reason for Recall:
cGMP deviations and lack of assurance of sterility.

Recall Number:
D-0407-2025

Code Information:
Lot, expiry: Lot 117, exp 9/20/25; Lot 118, exp 9/25/25; Lot 119, exp 9/27/25; Lot 121, exp 10/05/25; Lot 161, exp 5/01/26; Lot 171, exp 6/18/26; Lot 172, exp 6/24/26; Lot 174, exp 7/01/26; Lot 175, exp 7/08/26; Lot 200, exp 11/05/26; Lot 201, exp 11/10/26; Lot 202, exp 11/13/26; Lot 203, exp 11/18/26; Lot 204, exp 11/21/26; Lot 205, exp 11/25/26; Lot 206, exp 12/02/26; Lot 219, exp 2/24/27; Lot 221, exp 3/02/27; Lot 222, exp 3/05/27.

Product Description:
Polyvinyl Alcohol Ophthalmic Solution 1.4%, Lubricant Eye Drops, Moisturizing, Sterile, 0.5 FL OZ (15mL) per dropper bottle, Distributed by: AvKARE, Pulaski, TN 38478, NDC: 50268-678-15.

Product Quantity:
14,333 cases (24 cartons per case)

Reason for Recall:
cGMP deviations and lack of assurance of sterility.

Recall Number:
D-0408-2025

Code Information:
Lot, expiry: Lot 120, exp 10/02/25; Lot 122, exp 10/09/25; Lot 123, exp 10/12/25; Lot 124, exp 10/16/25; Lot 138, exp 1/08/26; Lot 142, exp 1/29/26; Lot 143, exp 2/01/26; Lot 144, exp 2/07/26; Lot 145, exp 2/12/26; Lot 146, exp 2/15/26; Lot 147, exp 2/21/26; Lot 148, exp 2/27/26; Lot 149, exp 3/04/26; Lot 150, exp 3/11/26; Lot 158, exp 4/15/26; Lot 159, exp 4/22/26; Lot 176, exp 7/24/26; Lot 177, exp 7/28/26; Lot 178, exp 7/31/26; Lot 179, exp 8/05/26.

Class II Drugs Event

Event ID:

Product Type:

96754

Status:
Ongoing

Recall Initiation Date:
04/15/2025

Center Classification Date:
05/06/2025

Recalling Firm:
Apollo Care, LLC
3801 Mojave Ct Ste 101
Columbia, MO 65202-4042
United States

Distribution Pattern:
MO

Product Type:
Drugs

Date Terminated:
N/A

Voluntary / Mandated:
Voluntary: Firm initiated

Initial Firm Notification of Consignee or Public:
Letter

Associated Products

Product Description:
FentaNYL 500mcg (2mcg/mL) and Ropivacaine HCl 250mg (0.1%) added to 250 mL, 0.9% Sodium Chloride Injection (For Epidural Use Only), Sterile, Single-Use Container, Rx Only, Apollocare, 3801 Mojave Ct, Ste 101, Columbia, MO 65202, NDC 71170-950-25

Product Quantity:
440 bags

Reason for Recall:
Lack of Assurance of Sterility

Recall Number:
D-0409-2025

Code Information:
Lot AC-016878, exp date 6/16/2025

Class II Drugs Event

Event ID:
96763

Status:
Ongoing

Recall Initiation Date:
04/28/2025

Center Classification Date:
05/06/2025

Recalling Firm:
Siddha Flower Essences, LLC.
2350 Eastman Ave Ste 107
Oxnard, CA 93030-7265
United States

Distribution Pattern:
US Nationwide.

Product Type:
Drugs

Date Terminated:
N/A

Voluntary / Mandated:
Voluntary: Firm initiated

Initial Firm Notification of Consignee or Public:
Two or more of the following: Email, Fax, Letter, Press Release, Telephone, Visit

Associated Products

Product Description:
temper tamer, 1 US fl oz. (29.6 mL), Homeopathic Oral Spray, Manufactured by: Siddha Flower Essences, Oxnard, CA, 93030 NDC 69779-020-01.

Product Quantity:
N/A

Reason for Recall:
CGMP Deviations

Recall Number:
D-0410-2025

Code Information:
Lot# S22-26424D; Exp 9/27/2027

Class II Drugs Event

Event ID:
96764

Product Type:
Drugs

Status:
Ongoing

Date Terminated:
N/A

Recall Initiation Date:
04/22/2025

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
05/06/2025

Initial Firm Notification of Consignee or Public:
E-Mail

Recalling Firm:
RemedyRePack Inc.
625 Kolter Dr Ste 4
Indiana, PA 15701-3571
United States

Distribution Pattern:
Within U.S - PA, VA, FL.

Associated Products

Product Description:
Clindamycin HCl Capsule, 300 mg, QTY: 30 Capsules per bottle, Rx Only, Repackaged by: RemedyRepack Inc., Indiana, PA 15701. NDC#: 70518-3772-02

Product Quantity:
23 bottles/30 count- 690 capsules

Reason for Recall:
CGMP Deviations

Recall Number:
D-0411-2025

Code Information:
Lot#: B3698036-033125, B3688703-032625, Exp.: 07/31/2026.

Class II Drugs Event

Event ID:
96792

Product Type:
Drugs

Status:
Ongoing

Date Terminated:
N/A

Recall Initiation Date:
04/28/2025

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
05/06/2025

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
BSO LLC
12860 W Cedar Dr Ste 211
Lakewood, CO 80228-1971
United States

Distribution Pattern:
Nationwide in the USA

Associated Products

Product Description:
TESTOSTERONE PELLET 100 mg (with Cholesterol
Product Quantity:
2,762 vials

Reason for Recall:
Presence of Particulate Matter: Glass particles were found in pellet vials.

Recall Number:
D-0412-2025

Code Information:
Lot 20250102@6, exp 12/11/2025; Lot 20250130@4, exp 1/22/2026

Product Description:
TESTOSTERONE PELLET 200 mg (with Cholesterol
Product Quantity:
1,974 vials

Reason for Recall:
Presence of Particulate Matter: Glass particles were found in pellet vials.

Recall Number:
D-0413-2025

Code Information:
Lot 20250207@1, exp 1/31/2026; Lot 20250228@1, exp 1/31/2026

Product Description:
TESTOSTERONE PELLET 200 mg BLUNT (with Cholesterol
Product Quantity:
355 vials

Reason for Recall:
Presence of Particulate Matter: Glass particles were found in pellet vials.

Recall Number:
D-0414-2025

Code Information:
Lot 20250217@7, exp 1/31/2026

Product Description:
TESTOSTERONE PELLET 200 mg (with Cholesterol
Product Quantity:
1,447 vials

Reason for Recall:
Presence of Particulate Matter: Glass particles were found in pellet vials.

Recall Number:
D-0415-2025

Code Information:
Lot 20250205@6, exp 1/30/2026

Product Description:
TESTOSTERONE PELLET 200 mg BLUNT, 1 Pellet for Subcutaneous Use, This is a Compounded Drug, Not for Resale, RX or Office Use Only, Belmar Select Outsources, 12860 W. Cedar Drive #211, Lakewood, CO 80228, NDC: 70168-0121-01

Product Quantity:
1,964 vials

Reason for Recall:
Presence of Particulate Matter: Glass particles were found in pellet vials.

Recall Number:
D-0416-2025

Code Information:
Lot 20250129@1, exp 1/17/2026; Lot 20250218@4, exp 1/25/2026