Enforcement Report - Week of April 30, 2025

Class II Drugs Event

Event ID:
96600

Product Type:
Drugs

Status:
Ongoing

Date Terminated:
N/A

Recall Initiation Date:
03/31/2025

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
04/21/2025

Initial Firm Notification of Consignee or Public:
N/A

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

Distribution Pattern:
US Nationwide.

Associated Products

Product Description:
Bimatoprost powder, Bulk Ingredient, a) 5g (NDC 38779-3066-03), b) 1g (NDC 38779-3066-06), c) 1g (NDC 38779-3066-09) drums, Medisca, Plattsburgh, NY

Product Quantity:
161.6 grams

Reason for Recall:
CGMP Deviations

Recall Number:
D-0386-2025

Code Information:
Lot# 201727/A/B/C/D/E & F, exp. date 05/31/2027, product # 3066 Lot# 208475/A/B/D/E/G/H & I, exp. date 09/30/2028, product # 3066

Class II Drugs Event

Event ID:
96601

Product Type:
Drugs

Status:
Ongoing

Date Terminated:
N/A

Recall Initiation Date:
04/09/2025

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
04/18/2025

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Apipharma
Ulica Jeronima Kavanjina 26
Zagreb
Croatia

Distribution Pattern:
AZ

Associated Products

Product Description:
Hemopropin Ointment, Lanolin 17.76% and Petrolatum 71.2%, Net Wt. 0.7 oz (20g) tubes, Manufactured by: Apipharma d.o.o, Croatia, Distributed by: Apipharma, LLC, Tempe, AZ UPC 3 858882 103534 and UPC 3 858882 101318

Product Quantity:
4,218 boxes

Reason for Recall:
CGMP Deviations

Recall Number:
D-0375-2025

Code Information:
Lot #: A00001, Exp.: 2027-12; A00005, Exp.: 2027-01; B00001, Exp.:2028-02

Product Description:
Kapsin Ointment, Camphor 3.16% and Capsaicin 0.03%. Net Wt. 2 oz (60g) tubes, Manufactured by: Apipharma d.o.o, Jeronima Kavanjina 26, 10090 Zagreb, Croatia, Distributed by: Apipharma, LLC, 2331 West Alameda Drive, Tempe, AZ 85282 UPC 3 858882 101363

Product Quantity:
5,095 cartons

Reason for Recall:
CGMP Deviations

Recall Number:
D-0376-2025

Code Information:
Lot #: 153211, Exp.: 2025-04; 210221, Exp.: 2026-05.

Class II Drugs Event

Event ID:
96607

Product Type:
Drugs

Status:
Ongoing

Date Terminated:
N/A

Recall Initiation Date:
03/31/2025

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
04/18/2025

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Denver Solutions, LLC DBA Leiters Health
13796 Compark Blvd
Englewood, CO 80112-7145
United States

Distribution Pattern:
Nationwide in the U.S.A

Associated Products

Product Description:
Glycopyrrolate, 1mg per 5mL, (0.2 mg/mL), Single Dose 5 mL syringe, Rx only, Leiters Health, 13796 Compark Blvd, Englewood, CO 80112. NDC 71449-104-11

Product Quantity:
170 syringes

Reason for Recall:
Lack of Assurance of Sterility: Leaking/damaged syringes.

Recall Number:
D-0370-2025

Code Information:
Lot #: 2431015B, Exp. 4/10/2025.

Product Description:
dexmedeTOMIDine HCl PF, in 0.9% Sodium Chloride, 20 mcg (base) per 5mL, (4 mcg (base) per mL), 5mL Single Dose syringe, Rx only, Leiters Health, 13796 Compark Blvd, Englewood, CO 80112, NDC: 71449-131-11.

Product Quantity:
23,610 syringes

Reason for Recall:
Lack of Assurance of Sterility: Leaking/damaged syringes.

Recall Number:
D-0371-2025

Code Information:
Lot #: 2431276A, Exp.: 4/20/2025

Product Description:
PHENYLephrine HCl in 0.9% Sodium Chloride, 0.5 mg per 5mL (100 mcg/mL), 5 mL Single Dose Syringe, Rx Only, Leiters Health, 13796 Compark Blvd, Englewood, CO 80112. NDC: 71449-001-11,

Product Quantity:
7,290 syringes

Reason for Recall:
Lack of Assurance of Sterility: Leaking/damaged syringes.

Recall Number:
D-0372-2025

Code Information:
Lot #: 2431349A, Exp.: 6/16/2025

Product Description:
Ketamine HCl 50mg per 5mL (10 mg per mL), 5mL Single Dose Syringe, Rx only, Leiters Health, 13796 Compark Blvd, Englewood, CO 80112.NDC: 71449-068-11

Product Quantity:
49,830 syringes

Reason for Recall:
Lack of Assurance of Sterility: Leaking/damaged syringes.

Recall Number:
D-0373-2025

Code Information:
Lot #:2530019, Exp.: 7/10/2025; 2530053, Exp.: 7/19/2025.

Product Description:
Rocuronium Bromide 50 mg per 5mL (10mg per mL), 5mL Single Dose Syringe, Rx only, Leiters Health, 13796 Compark Blvd, Englewood, CO 80112. NDC: 71449-004-11

Product Quantity:
16,655 syringes

Reason for Recall:
Lack of Assurance of Sterility: Leaking/damaged syringes.

Recall Number:
D-0374-2025

Code Information:
Lot #:2530023, Exp.: 7/12/2025

Class II Drugs Event

Event ID:
96627

Product Type:
Drugs

Status:
Ongoing

Date Terminated:
N/A

Recall Initiation Date:
03/24/2025

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
04/18/2025

Initial Firm Notification of Consignee or Public:
Letter

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

Distribution Pattern:
PA

Associated Products

Product Description:
Clindamycin HCl, 300 mg Capsule, QTY: 30 Capsules per bottle, Rx Only, Repackaged by: RemedyRepack Inc., Indiana, PA 15701. NDC; 70518-3772-00

Product Quantity:
1,858 30-count blister cards

Reason for Recall:
CGMP Deviations

Recall Number:
D-0378-2025

Code Information:
Lot J0826722-121624 Exp. 12/31/2025 Lot J0820365-111324 Exp. 11/30/2025 Lot J0814691-101624 Exp. 10/31/2025

Class II Drugs Event

Event ID:
96636

Product Type:
Drugs

Status:
Ongoing

Date Terminated:
N/A

Recall Initiation Date:
04/02/2025

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
04/18/2025

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Amerisource Health Services LLC
2550 John Glenn Ave Ste A
Columbus, OH 43217-1188
United States

Distribution Pattern:
Nationwide in the USA

Associated Products

Product Description:
Haloperidol Decanoate Injection, 50mg/mL* , 1 mL Single-Dose Vial, Rx only, Manufactured by Somerset Therapeutics Limited, 54/1, Boodhihal

Village, Nelamangala, Bangalore - 562123, Karnataka, India, Manufactured for: BluePoint Laboratories, NDC 68001-580-41.

Product Quantity:
2,110 vials

Reason for Recall:
Lack of assurance of sterility. Bacterial contamination detected in some media fill units

Recall Number:
D-0367-2025

Code Information:
A240467B, EXP 07/31/2026

Product Description:
Haloperidol Decanoate Injection, 100 mg/mL*, 1 x 1 mL Single-Dose Vial, Rx only, Manufactured by: Somerset Therapeutics Limited, #54/1, Boodhihal Village, Nelamangala, Bangalore - 562123, Karnataka, India, Manufactured for BluePoint Laboratories, NDC 68001-581-41.

Product Quantity:
14,189 vials

Reason for Recall:
Lack of assurance of sterility. Bacterial contamination detected in some media fill units

Recall Number:
D-0368-2025

Code Information:
A240482A, EXP 08/31/2026

Product Description:
Haloperidol Decanoate Injection, 100mg/mL*, 5 x 1 mL Single-Dose Vials, Rx Only, Manufactured by: Somerset Therapeutics Limited, #54/1 Boodhihal Village, Nelamangala, Bangalore -562123, Karnataka, India, Manufactured for: BluePoint Laboratories, NDC 68001-581-48.

Product Quantity:
143 1x5 vials

Reason for Recall:
Lack of assurance of sterility. Bacterial contamination detected in some media fill units

Recall Number:
D-0369-2025

Code Information:
A240482B, EXP 08/31/2026

Class II Drugs Event

Event ID:
96639

Product Type:
Drugs

Status:
Ongoing

Date Terminated:
N/A

Recall Initiation Date:
04/15/2025

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
04/21/2025

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Pharmadel, LLC
650 Centerpoint Blvd
Historic New Castle, DE 19720-8108
United States

Distribution Pattern:
DE

Associated Products

Product Description:
DoloDent Maximum Strength Toothache Drops, Homeopathic Oral Drops, 0.50 oz fl (15 mL), Distributed by: Pharmadel, New Castle, DE 19720, NDC 55758-400-15

Product Quantity:
9504 bottles

Reason for Recall:
cGMP deviations

Recall Number:
D-0379-2025

Code Information:
Lot EDD-01

Product Description:
DoloEar Earache Drops, Homeopathic, 0.50 oz fl (15 mL), Distributed by: Pharmadel, New Castle, DE 19720, NDC 55758-401-15

Product Quantity:
27,648 bottles

Reason for Recall:
cGMP deviations

Recall Number:
D-0380-2025

Code Information:
Lot, expiry: DEE-01, EXP: OCT 26; DEE-02 EXP: FEB 27

Product Description:
Kingskin, Elimina Las Verrugas, For the removal of common warts, 0.50 oz fl (15 mL), Distributed by: Pharmadel, New Castle, DE 19720, NDC 55758-409-15

Product Quantity:
20,048 bottles

Reason for Recall:
cGMP deviations

Recall Number:
D-0381-2025

Code Information:
Lot, expiry: KSE-01, EXP: OCT 26; KSE-02, EXP: FEB 27

Product Description:
Rapidol Arnica Gel, Topical Gel, Homeopathic Medicine, 2 oz (57 g), Distributed by: Pharmadel, New Castle, DE 19720, NDC 55758-403-02

Product Quantity:
6,048 bottles

Reason for Recall:
cGMP deviations

Recall Number:
D-0382-2025

Code Information:
Lot, expiry: EAG-01, EXP: MAR 27

Product Description:
Rapidol Arnica Tablets, Homeopathic Medicine, 100-count bottle, Distributed by: Pharmadel, New Castle, DE 19720, NDC 55758-405-99

Product Quantity:
6,048 bottles

Reason for Recall:
cGMP deviations

Recall Number:
D-0383-2025

Code Information:
Lot, expiry: EAT-01, EXP: MAR 27

Product Description:
Urodel, Urinary Tract Infection Symptoms Relief, Homeopathic, 30 chewable tablets per bottle, Distributed by: Pharmadel, New Castle, DE 19720, NDC 55758-406-30

Product Quantity:
10,752 bottles

Reason for Recall:
cGMP deviations

Recall Number:
D-0384-2025

Code Information:
Lot, expiry: UDE-01, EXP: OCT 26

Class II Drugs Event

Event ID:
96681

Product Type:
Drugs

Status:
Ongoing

Date Terminated:
N/A

Recall Initiation Date:
04/10/2025

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
04/18/2025

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Lupin Pharmaceuticals Inc.
5801 Pelican Bay Blvd Suite 500
Naples, FL 34108-2755
United States

Distribution Pattern:
USA nationwide

Associated Products

Product Description:
clomiPRAMINE hydrochloride Capsules USP, 25 mg, 100-count bottle, Rx only, Manufactured For: Lupin Pharmaceuticals, Inc., Baltimore, MD 21202, United States, Manufactured By: Lupin Limited, Nagpur, 441 108 INDIA, NDC 68180-492-01

Product Quantity:
2724 bottles

Reason for Recall:
Failed Impurities/Degradation Specifications: an out of specification result observed in degradation product test (any unspecified degradation product) during 18-month long term stability study.

Recall Number:
D-0377-2025

Code Information:
Lot #: M300442, Exp Date: 6/30/2025

Class II Drugs Event

Event ID:
96707

Product Type:
Drugs

Status:
Ongoing

Date Terminated:
N/A

Recall Initiation Date:
04/14/2025

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
04/22/2025

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Breckenridge Pharmaceutical, Inc
15 Massirio Dr Ste 201
Berlin, CT 06037-2352
United States

Distribution Pattern:
US Nationwide.

Associated Products

Product Description:
Duloxetine Delayed-Release Capsules USP, 60 mg, 1000-count bottles, Rx Only, Manufactured by Towa Pharmaceutical Europe, S.L., Distributed by Breckenridge Pharmaceutical, Inc. Berkeley Heights, NJ 07922, NDC# 51991-748-10

Product Quantity:
16,473 bottles

Reason for Recall:
CGMP Deviations: Presence of Nitrosamine Drug Substance Related Impurity above the proposed interim limit.

Recall Number:
D-0387-2025

Code Information:
Lot # 240987C, exp. date 04/2027 241014C, exp. date 04/2027

Product Description:
Duloxetine Delayed-Release Capsules USP, 30 mg, a.) 90-count bottles (NDC# 51991-747-90), b.) 1000-count bottles (NDC 51991-747-10), Rx Only, Manufactured by Towa Pharmaceutical Europe, S.L. Distributed by Breckenridge Pharmaceutical, Inc. Berkeley Heights, NJ 07922

Product Quantity:
343,344 bottles

Reason for Recall:
CGMP Deviations: Presence of Nitrosamine Drug Substance Related Impurity above the proposed interim limit.

Recall Number:
D-0388-2025

Code Information:
Lot # 230201C, exp. date 01/2026 230471C, exp. date 01/2026 230288C, exp. date 01/2026

Class III Drugs Event

Event ID:
96706

Product Type:
Drugs

Status:
Ongoing

Date Terminated:
N/A

Recall Initiation Date:
04/15/2025

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
04/21/2025

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
OurPharma LLC
2512 S City Lake Rd
Fayetteville, AR 72701-5013
United States

Distribution Pattern:
Nationwide in the USA

Associated Products

Product Description:
HYDROmorphone Hydrochloride 50mg/50mL (1mg/mL), packaged in a 50 mL Cassette, Rx Only, OurPharma, LLC, 2512 S. City Lake Rd., Fayetteville, AR 72701, NDC 73013-1040-01.

Product Quantity:
1,375 cassettes

Reason for Recall:
Superpotent Drug: Assay/potency result for hydromorphone HCl in the compounded stability lot was higher than specification..

Recall Number:
D-0385-2025

Code Information:
104024120001, Exp Date 06/01/2025; 104024120002, Exp Date 06/21/2025; 104025010001, Exp Date 07/13/2025; 104025010002, Exp Date 07/28/2025