Enforcement Report - Week of May 6, 2026

Class II Drugs Event

Event ID:
98694

Product Type:
Drugs

Status:
Ongoing

Date Terminated:
N/A

Recall Initiation Date:
04/01/2026

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
04/28/2026

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Wells Pharma of Houston LLC
9265 Kirby Dr
Houston, TX 77054-2520
United States

Distribution Pattern:
U.S. Nationwide.

Associated Products

Product Description:
Phenylephrine Hydrochloride Injectable Solution, 40mg, 250*mL Bag, wells pharma of Houston, NDC 73702-122-03

Product Quantity:
13,070 IV Bags

Reason for Recall:
cGMP deviations.

Recall Number:
D-0502-2026

Code Information:
120325122032719, Exp Date 04/03/2026, 120425122032734 Exp Date 04/04/2026, 120425122032735, Exp Date 04/04/2026, 120925122032781, Exp Date 04/10/2026, 010626122030010, Exp Date, 05/08/2026, 010626122030009, Exp Date 05/08/2026, 010826122030031, Exp Date 05/13/2026, 010826122030032, Exp Date 05/13/2026, 011326122030072, Exp Date 05/15/2026, 011326122030071, Exp Date 05/15/2026, 011626122030107, Exp Date 05/20/2026, 011626122030106, Exp Date 05/20/2026, 011926122030118, Exp. Date, 05/21/2026, 011926122030119, Exp Date, 05/21/2026, 012726122030171, Exp Date, 05/29/2026, 012726122030170, Exp Date 05/29/2026, 012826122030181, Exp Date 05/30/2026, 012826122030182, Exp Date 05/30/2026, 020226122030201, Exp Date 06/04/2026, 020326122030217, Exp Date 06/05/2026, 020426122030235, Exp Date 06/06/2026, 020426122030242, Exp Date 06/06/2026, 020426122030241, Exp Date 06/06/2026, 020626122030260, Exp Date 06/09/2026, 020626122030256, Exp Date 06/09/2026, 020926122030303, Exp Date 06/11/2026, 021026122030308, Exp Date, 06/12/2026, 021126122030321, Exp Date 06/13/2026, 021126122030316, Exp Date 06/13/2026, 021226122030326, Exp Date 06/16/2026, 021326122030341, Exp Date 06/17/2026, 021726122030366, Exp Date 06/19/2026, 021726122030369, Exp Date 06/19/2026, 021826122030388, Exp Date 06/20/2026, 022026122030421, Exp Date 06/24/2026, 022026122030420, Exp Date 06/24/2026, 022326122030435, Exp Date, 06/25/2026, 031026122030552, Exp Date 07/10/2026, 031026122030553, Exp Date 07/10/2026

Product Description:
fentaNYL Citrate Injectable Solution, NARCOTIC, Cii, 1000 mcg/100 mL (10 mcg per mL), 100 mL bag, Wells Pharma in Houston, NDC 73702-202-02.

Product Quantity:
4,030 IV Bags

Reason for Recall:
cGMP deviations.

Recall Number:
D-0503-2026

Code Information:
120925202022769, Expiration Date 04/09/2026, 123125202022883, Expiration Date 05/05/2026, 123125202022884, Expiration Date 05/05/2026 011226202020057, Expiration Date 05/14/2026, 011226202020058, Expiration Date 05/14/2026, 011626202020110, Expiration Date 05/20/2026 012726202020156, Expiration Date 05/28/2026. 012726202020161, Expiration Date 05/28/2026 020226202020195, Expiration Date 06/04/2026 021826202020386, Expiration Date 06/20/2026 022026202020417, Expiration Date 06/24/2026 022026202020424 Expiration Date 06/24/2026

Product Description:
fentaNYL Citrate injectable Solution in 0.9% Sodium Chloride, Narcotic, (2500 mcg/ 250 mL) (10 mcg per mL), 250 mL bag, wells pharma of Houston, NDC 73702-202-03.

Product Quantity:
2940 IV Bags

Reason for Recall:
cGMP deviations.

Recall Number:
D-0504-2026

Code Information:
120125202032701, Exp Date 04/01/2026; 122625202032857, Exp Date 04/25/2026; 122625202032862, Exp Date 04/28/2026, 122625202032863. Exp Date 04/28/2026; 122625202032864, Exp Date 04/28/2026; 122625202032865, Exp Date 04/28/2026, 011226202030062, Exp Date 05/14/2026, 011326202030776, Exp Date 05/15/2026; 011326202030077, Exp Date 05/15/2026, 011626202030111, Exp Date 05/20/2026, 011926202030122, Exp Date 05/21/2026; 011926202030123, Exp Date 05/21/2026, 012726202030159, Exp Date 05/28/2026, 020226202030200, Exp Date 06/04/2026, 020326202030216, Exp Date 06/05/2026, 020426202030234, Exp Date 06/06/2026, 02182202030398, Exp Date 06/20/2026.

Product Description:
fentaNYL Citrate Injectable Solution, Narcotic, CII, 1250 mcg/25mL (50 mcg per mL), 25 mL, wells pharma of Houston, NDC 73702-204-25.

Product Quantity:
50 syringes

Reason for Recall:
cGMP deviations.

Recall Number:
D-0505-2026

Code Information:
Lot 011226204250063, Exp Date 05/14/2026

Product Description:
fentaNYL Citrate Injectable Solution in 0.9% Sodium Chloride, 1000 mcg/50mL (20 mcg per mL), well pharma of Houston, NDC 73702-203-65.

Product Quantity:
150 syringes

Reason for Recall:
cGMP deviations.

Recall Number:
D-0506-2026

Code Information:
Lot 022326203650432; Exp Date 06/25/2026

Product Description:
Ketamine Hydrochloride Injectable Solution, 50mg/ml, (50 mg per mL) Volume: 1 mL, 5265 Kitty Drive, Houston, TX 77054, NDC 73702-302-31.

Product Quantity:
4975 syringes

Reason for Recall:
cGMP deviations.

Recall Number:
D-0507-2026

Code Information:
120925302312764, Exp Date 04/09/2026, 123125302312879 Exp Date, 05/05/2026, 123125302312880, Exp Date 05/05/2026, 010226302310003,

Exp Date 05/06/2026, 010626302310007, Exp Date 05/08/2026, 010626302310008, Exp Date 05/08/2026 020426302310243, Exp Date 06/06/2026.

Product Description:
fentaNYL Citrate Injectable Solution in 0.9% Sodium Chloride, 50 mcg/5mL)(10 mcg per mL), wells pharma, NDC 73702-202-15.

Product Quantity:
50 syringes

Reason for Recall:
cGMP deviations.

Recall Number:
D-0508-2026

Code Information:
Lot 020226202150202, Exp Date 05/05/2026.

Class II Drugs Event

Event ID:
98792

Product Type:
Drugs

Status:
Ongoing

Date Terminated:
N/A

Recall Initiation Date:
04/23/2026

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
04/28/2026

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Thea Pharma, Inc.
303 Wyman St
Waltham, MA 02451-1208
United States

Distribution Pattern:
Nationwide within the United States

Associated Products

Product Description:
iVIZIA, Sterile Lubricant Eye Drops (Povidone 0.5%), 0.33 Fl oz (10 mL), Made in France, Distributed by: Thea Pharma Inc., Waltham, MA 02451, NDC 82584-700-11

Product Quantity:
N/A

Reason for Recall:
Lack of Assurance of Sterility: This recall has been initiated due to CGMP deviations found by the FDA during an inspection of the manufacturer.

Recall Number:
D-0500-2026

Code Information:
Lot#: 3T36B, Exp. Date October 31, 2026.

Product Description:
Similasan, iVIZIA, Sterile Lubricant Eye Drops (Povidone 0.5%), 0.33 Fl oz (10 mL), Made in France, Distributed by: Thea Pharma Inc., Waltham, MA 02451, NDC 59262-700-11

Product Quantity:
N/A

Reason for Recall:
Lack of Assurance of Sterility: This recall has been initiated due to CGMP deviations found by the FDA during an inspection of the manufacturer.

Recall Number:
D-0501-2026

Code Information:
Lot# 5S30B, 5S30C, Exp Date: April 30, 2026; Lot# 5S31B, 6S57B, Exp Date: May 31, 2026.

Class II Drugs Event

Event ID:
98802

Product Type:
Drugs

Status:
Ongoing

Date Terminated:
N/A

Recall Initiation Date:
04/20/2026

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
04/28/2026

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
SCOPE HEALTH
79 Madison Avenue 27 E 28th St
New York, NY 10016-7921
United States

Distribution Pattern:
Nationwide within the United States

Associated Products

Product Description:
Optase Dry Eye Intense Drops (Glycerin 0.2%), packaged in 0.33 fl oz, Sterile, Manufactured for Scope Health Inc., 79 Madison Ave., 8th Floor, New York, NY 10016, USA, NDC 72972-002-01.

Product Quantity:
N/A

Reason for Recall:
Lack of Assurance of Sterility

Recall Number:
D-0499-2026

Code Information:
Lot#: 8T98, 9T31, 9T32, Exp. Date: 30/04/26; 2V13, 2V14, 2V15, Exp. Date 30/06/26; 3V35, Exp. Date 31/08/26;3V36, 3V37, Exp. Date 30/09/26; 5V45, 5V46, 9V12, Exp. Date 31/03/27; 1X57, 1X70, 1X84, Exp. Date 31/05/27.

Class II Drugs Event

Event ID:
98815

Product Type:
Drugs

Status:
Ongoing

Date Terminated:
N/A

Recall Initiation Date:
04/21/2026

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
04/24/2026

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Alcon Research LLC
6201 South Fwy
Fort Worth, TX 76134-2099
United States

Distribution Pattern:
Nationwide within the United States

Associated Products

Product Description:
Systane, Lubricant Eye Gel, Night Gel, Sterile, 10g (0.35 oz), Processed in France for: Alcon Laboratiroes, Inc., Fort Worth, TX 76134, USA, NDC 0065-0474-01

Product Quantity:
N/A

Reason for Recall:
Lack of Assurance of Sterility: Due to FDA inspection observations that it believes may impact product quality.

Recall Number:
D-0491-2026

Code Information:
Lot#: 9T21, Exp Date: 4/30/2026; Lot# 1U63, 2U47, Exp Date: 5/31/2026; Lot# 6V00, 6V12, 8V54, Exp Date: 1/31/2027; Lot# 9V55, 8V58, 9V39, 9V97, Exp Date: 2/28/2027; Lot# 1W39, 1W40, Exp Date: 3/31/2027; Lot# 1X76, Exp Date: 4/30/2027.

Product Description:
GenTeal Tears, Lubricant Eye Gel, Sterile, 10g (0.34 Fl oz), Distributed by: Alcon Laboratories, Inc., Fort Worth, Texas 76134, USA, NDC: 0065-8064-01.

Product Quantity:
N/A

Reason for Recall:
Lack of Assurance of Sterility: Due to FDA inspection observations that it believes may impact product quality.

Recall Number:
D-0492-2026

Code Information:
Lot #: 9T20, 9T50, 9T59, 1U30, 1U48, Exp Date: 4/30/2026; 4V15, Exp Date: 8/31/2026; 7V61, Exp Date: 12/31/2026; 1W47, 1W49, 1X14, Exp Date: 3/31/2027.

Class III Drugs Event

Event ID:
98737

Product Type:
Drugs

Status:
Ongoing

Date Terminated:
N/A

Recall Initiation Date:
04/07/2026

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
04/30/2026

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Water-Jel Technologies, LLC
13359 Reese Blvd East
Huntersville, NC 28078
United States

Distribution Pattern:
Nationwide in the USA

Associated Products

Product Description:
Lidocaine Wound Gel (Benzalkonium Chloride, 0.13% and Lidocaine Hydrochloride, 2%), NET WT 0.5 OZ (14 g), Distributed by: CVS PHarmacy, INc., One CVS Drive, Woonsocket, RI 02895. NDC 59898-950

Product Quantity:
31,488 tubes

Reason for Recall:
Failed PH Specifications

Recall Number:
D-0509-2026

Code Information:
Lots: A5014, A5018, A5019

Class III Drugs Event

Event ID:
98787

Product Type:
Drugs

Status:
Ongoing

Date Terminated:
N/A

Recall Initiation Date:
04/16/2026

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
04/28/2026

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
American Regent, Inc.
6610 New Albany Rd E
New Albany, OH 43054-8730
United States

Distribution Pattern:
U.S. Nationwide

Associated Products

Product Description:
Levocarnitine Injection, USP, 1 g/5 mL (200 mg/mL), 5 mL Single-Dose Vial, For intravenous use, Rx Only, American Regent, Inc., Shirley, NY 11967. NDC: 0517-1045-01

Product Quantity:
74,040 Single Dose Vials

Reason for Recall:
Labeling: Missing Label

Recall Number:
D-0494-2026

Code Information:
Lot 24159N0C0, Exp. June 30, 2026 Lot 25193N0C0, Exp. July 31, 2027

Not Yet Classified Drugs Event

Event ID:
98744

Product Type:
Drugs

Status:
Ongoing

Date Terminated:
N/A

Recall Initiation Date:
04/07/2026

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
N/A

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Hikma Pharmaceuticals USA INC
1809 Wilson Rd
Columbus, OH 43228-9579
United States

Distribution Pattern:
US Nationwide.

Associated Products

Product Description:
Alendronate Sodium Oral Solution, 70 mg/75 mL, 75 mL, Rx only, 4 x 75 mL Single Dose Bottles, Distr. by: Hikma Pharmaceuticals USA Inc., Berkeley Heights, NJ 07922, NDC 0054-0282-59.

Product Quantity:
N/A

Reason for Recall:
This recall is being conducted due to out of specification assay results in a limited number of bottles that were stored on side.

Recall Number:
N/A

Code Information:
Lot # AC2040A, Exp Date: 04/2026