Enforcement Report - Week of April 15, 2026

Class II Drugs Event

Event ID:
98275

Product Type:
Drugs

Status:
Ongoing

Date Terminated:
N/A

Recall Initiation Date:
01/12/2026

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
04/08/2026

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Teva Pharmaceuticals USA, Inc
400 Interpace Pkwy Bldg A
Parsippany, NJ 07054-1120
United States

Distribution Pattern:
FL, OH, PR & MS

Associated Products

Product Description:
Isotretinoin Capsules, USP, 30 mg, Rx Only, 10 count Prescription Pack, Manufactured for: Teva Pharmaceuticals USA, Inc., Parsippany, NJ 07054, NDC 0591-2435-15 (carton), NDC 0591-2435-45 (blister pack).

Product Quantity:
21984 packages

Reason for Recall:
Superpotent and Subpotent

Recall Number:
D-0445-2026

Code Information:
Lots 100055426, Exp. date 02/2026, 100071518, Exp. date 04/2027 & 100072450, Exp. Date 07/2027

Product Description:
Isotretinoin Capsules, USP, 40 mg, 10 count Prescription Pacs, Rx only, Manufactured for: Teva Pharmaceuticals USA, Inc., Parsippany, NJ 07054, NDC 0591-2436-15 (carton), NDC 0591-2436-45 (blister pack).

Product Quantity:
8376 packages

Reason for Recall:
Superpotent and Subpotent

Recall Number:
D-0446-2026

Code Information:
Lots 100075305 Exp date 06/2027, 100075512, Exp date 07/2027 & 100076103, Exp date 07/2027 .

Class II Drugs Event

Event ID:
98575

Product Type:
Drugs

Status:
Ongoing

Date Terminated:
N/A

Recall Initiation Date:
03/13/2026

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
04/03/2026

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Cipla USA, Inc.
10 Independence Blvd
Warren, NJ 07059-2730
United States

Distribution Pattern:
Nationwide in the USA

Associated Products

Product Description:
Lanreotide Injection, 120 mg*/0.5 mL, Box contains 1 Pre-filled syringe and 1 safety needle, Single dose only, Rx Only, Manufactured by: Pharmathen International, S.A., Rodopi, Greece. Manufactured for: Cipla USA, Inc., 10 Independence Boulevard, Suite 300, Warren, NJ 07059. NDC: 69097-870-67

Product Quantity:
54,583 syringes

Reason for Recall:
Lack of Assurance of Sterility: Due to an FDA observation at the contract manufacturing site for deficiencies in their visual inspection procedure.

Recall Number:
D-0422-2026

Code Information:
Lot, expiry: 4401666IR1, Exp 8/31/2027; 4401703IR1, Exp 9/30/2027; 4401703IR2, EXP 9/30/2027; 4401704IR1, Exp 9/30/2027; 4401705IR1, Exp 9/30/2027; 4401706IR1, Exp 9/30/2027; 4401720IR1, Exp 9/30/2027; 4401721IR1, Exp 9/30/2027; 4401733IR1, Exp 9/30/2027; 4401770IR1, Exp 9/30/2027; 4401777IR1, Exp 9/30/2027; 4401788IR1, Exp 10/31/2027; 4401804IR1, Exp 10/31/2027; 4401805IR1, Exp 10/31/2027; 4401824IR1, Exp 10/31/2027; 4401860IR1, Exp 10/31/2027; 4500019IR1, Exp 11/30/2027; 4500035IR1, Exp 11/30/2027; 4500036IR1, Exp 11/30/2027; 4500078IR1, Exp 11/30/2027; 4500079IR1, Exp 11/30/2027; 4500102IR1, Exp 12/31/2027; 4500119IR1, Exp 12/31/2027; 4500120IR1, Exp 12/31/2027; 4500121IR1, Exp 12/31/2027; 4500268IR1, Exp 1/31/2028; 4500269IR1, Exp 1/31/2028; 4500272IR1, Exp 1/31/2028; 4500314IR2, EXP 1/31/2028; 4500314RIR, EXP 1/31/2028; 4500315IR1, Exp 2/28/2028; 4500352IR1, Exp 2/28/2028; 4500353IR1, Exp 2/28/2028; 4500354IR1, Exp 2/28/2028; 4500355IR1, Exp 2/28/2028; 4500408IR1, Exp 2/28/2028; 4500409IR1, Exp 3/31/2028; 4500410IR1, Exp 3/31/2028; 4500480IR1, Exp 3/31/2028; 4500481IR1, Exp 3/31/2028; 4500545IR1, Exp 3/31/2028; 4500546IR1, Exp 3/31/2028; 4500588IR1, Exp 4/30/2028; 4500589IR1, Exp 4/30/2028; 4500635IR1, Exp 4/30/2028; 4500636IR1, Exp 4/30/2028; 4500687IR1, Exp 4/30/2028; 4500688IR1, Exp 4/30/2028; 4500758IR1, Exp 4/30/2028; 4500759IR1, Exp 5/31/2028; 4500788IR1, Exp 5/31/2028; 4500789IR1, Exp 5/31/2028; 4500819IR1, Exp 5/31/2028; 4500846IR1, Exp 5/31/2028; 4500849IR1, Exp 6/30/2028; 4500850IR1, Exp 7/31/2028; 4500907IR1, Exp 7/31/2028; 4501108IR1, Exp 7/31/2028; 4501109IR1, Exp 7/31/2028; 4501110IR1, Exp 7/31/2028; 4501111IR1, Exp 7/31/2028; 4501166IR1, Exp 7/31/2028; 4501386IR1, Exp 8/31/2028; 4501387IR1, Exp 8/31/2028;

Product Description:
Lanreotide Injection, 120 mg/0.5 mL, Box contains 1 Pre-filled syringe, Single dose only, Rx Only, Manufactured by: Pharmathen International, S.A., Rodopi, Greece. Manufactured for: Cipla USA, Inc., 10 Independence Boulevard, Suite 300, Warren, NJ 07059. NDC 69097-906-67

Product Quantity:
N/A

Reason for Recall:
Lack of Assurance of Sterility: Due to an FDA observation at the contract manufacturing site for deficiencies in their visual inspection procedure.

Recall Number:
D-0423-2026

Code Information:
Lot, expiry: 4401699IR1, Exp. 5/31/2026; 4401699IR2, Exp. 5/31/2026; 4401700IR1, Exp. 5/31/2026; 4401701IR1, Exp. 5/31/2026; 4401702IR1, Exp. 5/31/2026; 4401722IR1, Exp. 5/31/2026; 4401723IR1, Exp. 5/31/2026; 4401724IR1, Exp. 5/31/2026; 4401725IR1, Exp. 5/31/2026; 4401732IR1, Exp. 5/31/2026; 4401768IR1, Exp. 6/30/2026 4401769IR1, Exp. 11/30/2026; 4401787IR1, Exp. 11/30/2026; 4401815IR1, Exp. 11/30/2026; 4401816IR1, Exp. 11/30/2026; 4401834IR1, Exp. 11/30/2026; 4401835IR1, Exp. 11/30/2026; 4401846IR1, Exp. 11/30/2026; 4401851IR1, Exp. 11/30/2026; 4500017IR1, Exp. 12/31/2026; 4500031IR1, Exp. 12/31/2026; 4500032IR1, Exp. 12/31/2026; 4500033IR1, Exp. 12/31/2026; 4500076IR1, Exp. 1/31/2027; 4500117IR1, Exp. 2/28/2027; 4500118IR1, Exp. 2/28/2027; 4500173IR1, Exp. 4/31/2027; 4500270IR1, Exp. 2/28/2027; 4500271IR1, Exp. 2/28/2027; 4500273IR1, Exp. 2/28/2027; 4500312IR1, Exp. 2/28/2027; 4500313IR1, Exp. 3/31/2027;

4500350IR1, Exp. 3/31/2027; 4500351IR1, Exp. 3/31/2027; 4500383IR1, Exp. 3/31/2027; 4500404IR1, Exp. 3/31/2027; 4500436RI1, Exp. 3/31/2027; 4500482IR1, Exp. 4/30/2027; 4500543IR1, Exp. 4/30/2027; 4500544IR1, Exp. 4/30/2027; 4500586IR1, Exp. 5/31/2027; 4500587IR1, Exp. 5/31/2027; 4500633IR1, Exp. 5/31/2027; 4500634IR1, Exp. 5/31/2027; 4500686IR1, Exp. 5/31/2027; 4500695IR1, Exp. 5/31/2027; 4500696IR1, Exp. 5/31/2027; 4500756IR1, Exp. 6/30/2027; 4500757IR1, Exp. 6/30/2027; 4500790IR1, Exp. 6/30/2027; 4500820IR1, Exp. 6/30/2027; 4500843IR1, Exp. 6/30/2027; 4500845IR1, Exp. 6/30/2027; 4500854IR1, Exp. 6/30/2027; 4500898IR1, Exp. 6/30/2027; 4500899IR1, Exp. 6/30/2027; 4500900IR1, Exp. 7/31/2027; 4500941IR1, Exp. 6/30/2027; 4500942IR1, Exp. 6/30/2027; 4500954IR1, Exp. 6/30/2027; 4500955IR1, Exp. 8/31/2027; 4500956IR1, Exp. 8/31/2027; 4500960IR1, Exp. 7/31/2027; 4501104IR1, Exp. 8/31/2027; 4501105IR1, Exp. 8/31/2027; 4501107IR1, Exp. 8/31/2027; 4501163IR1, Exp. 8/31/2027; 4501168IR1, Exp. 8/31/2027; 4501169IR1, Exp. 8/31/2027; 4501216IR1, Exp. 8/31/2027; 4501280IR1, Exp. 9/30/2027; 4501493IR1, Exp. 9/30/2027; 4501381IR1, Exp. 9/30/2027; 4501279IR1, Exp. 9/30/2027; 4501380IR1, Exp. 9/30/2027;

Class II Drugs Event

Event ID:
98581

Product Type:
Drugs

Status:
Ongoing

Date Terminated:
N/A

Recall Initiation Date:
03/11/2026

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
04/03/2026

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Fresenius Kabi USA, LLC
3 Corporate Dr
Lake Zurich, IL 60047-8930
United States

Distribution Pattern:
US Nationwide , Alaska, and Puerto Rico.

Associated Products

Product Description:
0.45% Sodium Chloride Injection, USP, 1.125 grams per 250 mL (4.5 mg per mL), 250 mL in a 250 mL freeflex bag, Rx only, Fresenius Kabi USA, LLC ("Fresenius Kabi"), Lake Zurich, IL 60047, Unit of Use NDC: 63323-626-03, Unit of Sale NDC Number: 63323-626-25 (30 bags in 1 case).

Product Quantity:
N/A

Reason for Recall:
Lack of Assurance of Sterility

Recall Number:
D-0424-2026

Code Information:
Batch # 6402413, Exp Date: 02/29/2028

Product Description:
0.9% Sodium Chloride Injection, USP 0.9% (450 mg per 50 mL) (9 mg per mL) 50 mL, Rx only, Fresenius Kabi USA, LLC ("Fresenius Kabi"), Lake Zurich, IL 60047, Unit of Use NDC: 65219-466-05, Unit of Sale NDC Number: 65219-466-60.

Product Quantity:
N/A

Reason for Recall:
Lack of Assurance of Sterility

Recall Number:
D-0425-2026

Code Information:
Batch# 6402372, 6402374, Exp Date: 08/31/2026; Batch# 6402437, Exp Date: 10/31/2026.

Product Description:
0.9% Sodium Chloride Injection, USP, 0.9% (900 mg per 100 mL) (9 mg per mL) 100 mL in a 100 mL freeflex bag, Rx only, Fresenius Kabi USA, LLC ("Fresenius Kabi"), Lake Zurich, IL 600047, Unit of Use NDC: 65219-468-05, Unit of Sale NDC Number: 65219-468-50.

Product Quantity:
N/A

Reason for Recall:
Lack of Assurance of Sterility

Recall Number:
D-0426-2026

Code Information:
Batch# 6402299, 6402300, 6402301, 6402302, 6402303, Exp Date: 01/31/2027; Batch# 6402305, 6402398, Exp Date: 02/28/2027; Batch# 6402467, Exp Date: 04/30/2027; Batch# 6402577, 6402578, Exp Date: 06/30/2027.

Product Description:
0.9% Sodium Chloride Injection, USP, (2,250 mg per 250 mL) (9 mg per mL) 250 mL in a 250 mL freeflex bag, Rx only, Fresenius Kabi USA, LLC ("Fresenius Kabi"), Lake Zurich, IL 60047, Unit of Use NDC: 65219-470-05, Unit of Sale NDC Number: 65219-470-30.

Product Quantity:
N/A

Reason for Recall:
Lack of Assurance of Sterility

Recall Number:
D-0427-2026

Code Information:
Batch# 23SU10008, Exp Date: 12/31/2026; Batch# 24JU10003, Exp Date: 07/31/2027; Batch# 24LU10011, 24LU10012, Exp Date: 9/30/2027; Batch# 6402273, 6402275, Exp Date: 01/31/2028; Batch# 6402420, 6402421, 6402422, 6402423, Exp Date: 03/31/2028; Batch# 6402473, 6402474, 6402475, 6402476, 6402485, Exp Date: 04/30/2028; Batch# 6402516, Exp Date: 05/31/2028.

Product Description:
0.9% Sodium Chloride Injection, USP, (4,500 mg per 500 mL) (9 mg per mL) 500 mL in a 500 mL freeflex bag, Rx only, Fresenius Kabi USA, LLC ("Fresenius Kabi"), Lake Zurich, IL 60047, Unit of Use NDC: 65219-472-05, Unit of Sale NDC Number: 65219-472-20.

Product Quantity:
N/A

Reason for Recall:
Lack of Assurance of Sterility

Recall Number:
D-0428-2026

Code Information:
Batch# 24LU10013, 24LU10014, Exp Date: 09/30/2027; Batch# 24NU10001, 24NU10002, Exp Date: 10/31/2027.

Product Description:
0.9% Sodium Chloride Injection, USP, 50 mL x60, Becton, Dickson and Company, 1 Beckton Drive, Franklin Lakes, NJ 07417 USA, Distributed by BD, Manufactured by Fresenius Kabi USA, LLC ("Fresenius Kabi"), Unit of Sale NDC Number: 17271-701-02.

Product Quantity:
N/A

Reason for Recall:
Lack of Assurance of Sterility

Recall Number:
D-0429-2026

Code Information:
Batch# 6402428, Exp Date: 10/31/2026; Batch# 6402481, 6402482, Exp Date: 11/30/2026.

Product Description:
0.9% Sodium Chloride Injection, USP, 900 mg per 100 mL (9 mg per mL) 100 mL in a Single Dose freeflex bag, Rx only, BD Beckton, Dickson and

Company, 1 Beckton Drive, Franklin Lakes, NJ 07417 USA, Distributed by BD, Manufactured by: Fresenius Kabi USA, LLC ("Fresenius Kabi"), Unit of Sale NDC Number: 17271-701-03.

Product Quantity:
N/A

Reason for Recall:
Lack of Assurance of Sterility

Recall Number:
D-0430-2026

Code Information:
Batch# 6402153, Exp Date: 11/30/2026; Batch# 6402297, 6402298, Exp Date: 01/31/2027; Batch# 6402377, 6402378, 6402379, Exp Date: 02/28/2027; Batch # 6402429, 6402430, 6402431, 6402432, 6402433, Exp Date: 03/31/2027; Batch# 6402434, Exp Date: 04/30/2027; Batch# 6402512, Exp Date: 05/2027; Batch# 6402574, 6402576, Exp Date: 06/30/2027.

Product Description:
0.9% Sodium Chloride Injection, USP, 900 mg per 100 mL (9 mg per mL) 250 mL in a Single Dose freeflex bag, Rx only, BD Becton, Dickson and Company, 1 Beckton Drive, Franklin Lakes, NJ 07417, Distributed by BD, Manufactured by: Fresenius Kabi USA, LLC ("Fresenius Kabi"), Unit of Sale NDC Number: 17271-701-05.

Product Quantity:
N/A

Reason for Recall:
Lack of Assurance of Sterility

Recall Number:
D-0431-2026

Code Information:
Batch# 6402290, 6402291, Exp Date: 01/31/2028; Batch# 6402411, Exp Date: 02/29/2028; Batch# 6402412, 6402419, 6402424, 6402425, 6402426, 6402427, Exp Date: 03/31/2028; Batch# 6402479, 6402480, 6402517, 6402571, Exp Date: 05/31/2028; Batch# 6402518, Exp Date: 06/30/2028.

Product Description:
0.9% Sodium Chloride Injection, USP 900 mg per 100 mL (9 mg per mL) 500 mL in a Single Dose freeflex bag, 500 mL x 20, Manufactured for: Fresenius Kabi USA, LLC ("Fresenius Kabi"), IL 60047, Unit of Use NDC: 65219-432-20, Unit of Sale NDC Number: 65219-432-85.

Product Quantity:
N/A

Reason for Recall:
Lack of Assurance of Sterility

Recall Number:
D-0432-2026

Code Information:
Batch# 23DU10004, Exp Date: 04/30/2026; Batch# 23HU10006, Exp Date: 06/30/2026.

Product Description:
0.9% Sodium Chloride Injection, USP, 900 mg per 100 mL (9 mg per mL) 1,000 mL in a Single Dose freeflex bag, 1,000 mLx10, Fresenius Medical Care, Waltham, MA 02451, Distributed by: Fresenius Medical Care RTG, LLC, Manufactured by: Fresenius Kabi, Unit of Use NDC: 65219-282-01, Unit of Sale NDC Number: 65219-282-10.

Product Quantity:
N/A

Reason for Recall:
Lack of Assurance of Sterility

Recall Number:
D-0433-2026

Code Information:
Batch# 23SU10001, Exp Date: 12/31/2026; Batch# 24AU10003, 24AU10004, 24AU10005, 24AU10008, Exp Date: 01/31/2027; Batch # 24EU10001, 24EU10002, Exp Date: 05/31/2027; Batch# 24PU10002, Exp Date: 11/30/2027; Batch# 25BU10003, Exp Date: 02/29/2028; Batch# 25EU10005, Exp Date: 05/31/2028.

Product Description:
0.9% Sodium Chloride Injection, USP 900 mg per 100 mL (9 mg per mL), 1,000 mL in a Single Dose freeflex bag, Rx only, BD Becton, Dickson and Company, 1 Becton Drive, Franklin Lakes, NJ 07417, Distributed by BD, Manufactured by Fresenius Kabi, Unit of Sale NDC Number: 17271-701-07.

Product Quantity:
N/A

Reason for Recall:
Lack of Assurance of Sterility

Recall Number:
D-0434-2026

Code Information:
Batch# 24EU10010, Exp Date: 05/31/2027.

Product Description:
5% Dextrose Injection, USP 2.5 g per 50 mL (50 mg per mL) 50 mL in a 100 mL freeflex bag, Fresenius Kabi USA, LLC ("Fresenius Kabi"), Unit of Use NDC: 65219-456-05, Unit of Sale NDC Number: 65219-456-60.

Product Quantity:
N/A

Reason for Recall:
Lack of Assurance of Sterility

Recall Number:
D-0435-2026

Code Information:
Batch# 6402296, Exp Date: 07/31/2026.

Product Description:
5% Dextrose Injection, USP 5 g per 100 mL (50 mg per mL) 100 mL in a 100 mL freeflex bag, Fresenius Kabi USA, LLC ("Fresenius Kabi"), Unit of Use NDC: 65219-464-05, Unit of Sale NDC Number: 65219-464-50.

Product Quantity:
N/A

Reason for Recall:
Lack of Assurance of Sterility

Recall Number:
D-0436-2026

Code Information:
Batch# 6402399, 6402400, 6402401, Exp Date: 02/28/2027.

Product Description:
5% Dextrose Injection, USP 12.5 g per 250 mL (50 mg per mL) 250 mL in a 250 mL freeflex bag, Fresenius Kabi USA, LLC ("Fresenius Kabi"), Unit of Use NDC: 65219-458-05, Unit of Sale NDC Number: 65219-458-30.

Product Quantity:
N/A

Reason for Recall:
Lack of Assurance of Sterility

Recall Number:
D-0437-2026

Code Information:
Batch# 6402165, Exp Date: 05/30/2028.

Class II Drugs Event

Event ID:
98613

Product Type:
Drugs

Status:
Ongoing

Date Terminated:
N/A

Recall Initiation Date:
03/17/2026

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
04/08/2026

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Viatris, Inc.
1000 Mylan Blvd
Canonsburg, PA 15317-5853
United States

Distribution Pattern:
US Nationwide.

Associated Products

Product Description:
Xanax XR, alprazolam, extended-release tablets, 3 mg, 60 Tablets bottles, Rx only, Distributed by: Viatris Specialty LLC, Morgantown, WV 06506, U.S.A, Made in Ireland, NDC 58151-506-91

Product Quantity:
N/A

Reason for Recall:
Failed Dissolution Specifications

Recall Number:
D-0444-2026

Code Information:
Lot# 8177156, Exp Date: 02/28/2027

Class II Drugs Event

Event ID:
98614

Product Type:
Drugs

Status:
Ongoing

Date Terminated:
N/A

Recall Initiation Date:
03/19/2026

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
04/13/2026

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Teva Pharmaceuticals USA, Inc
400 Interpace Pkwy Bldg A
Parsippany, NJ 07054-1120
United States

Distribution Pattern:
Within U.S

Associated Products

Product Description:
Clonidine Transdermal System, USP, 0.1 mg/day, supplied in cartons of 4 Systems and 4 Adhesive Covers, Rx Only, Manufactured by: Actavis Laboratories UT Inc., Salt Lake City, UT 84108, Distributed by: Actavis Pharma, Inc, Parsippany, NJ, NDC 0591-3508-04 carton, NDC 0591-3508-54 pouch

Product Quantity:
124,054 Cartons

Reason for Recall:
CGMP Deviations: use of an unapproved raw material

Recall Number:
D-0472-2026

Code Information:
Lot: 100060315, Exp.: 04/2026; 100068644, Exp.: 01/2027.

Product Description:
Clonidine Transdermal System, USP, 0.2 mg/day, supplied in cartons of 4 Systems and 4 Adhesive Covers, Rx only, Manufactured by: Actavis Laboratories UT Inc., Salt Lake City, UT 84108, Distributed by: Actavis Pharma, Inc, Parsippany, NJ, NDC 0591-3509-04 carton, NDC 0591-3509-54 pouch

Product Quantity:
62,136 Cartons

Reason for Recall:
CGMP Deviations: use of an unapproved raw material

Recall Number:
D-0473-2026

Code Information:
Lot: 100060002, Exp.: 07/2026; 100066802, Exp.: 05/2027

Product Description:
Clonidine Transdermal System, USP, 0.3 mg/day, supplied in cartons of 4 Systems and 4 Adhesive Covers, Rx only, Manufactured by: Actavis Laboratories UT Inc., Salt Lake City, UT 84108, Distributed by: Actavis Pharma, Inc, Parsippany, NJ, NDC 0591-3510-04 carton, NDC 0591-3510-54 pouch

Product Quantity:
113,943 Cartons

Reason for Recall:
CGMP Deviations: use of an unapproved raw material

Recall Number:
D-0474-2026

Code Information:
Lot: 100053892, Exp.: 04/2026; 100057899, Exp.: 05/2026; 100062704, Exp.: 02/2027.

Class II Drugs Event

Event ID:
98636

Product Type:
Drugs

Status:
Ongoing

Date Terminated:
N/A

Recall Initiation Date:
03/20/2026

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
04/07/2026

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Fagron Compounding Services
8710 E 34th St N
Wichita, KS 67226-2636
United States

Distribution Pattern:
Nationwide in the U.S.A.

Associated Products

Product Description:
norepinephrine Bitartrate,16mg per 250mL 0.9% Sodium Chloride Injection USP, Fagron Sterile Services, 8710 34th St. N. Wichita, KS 67226, NDC

71266-5026-02

Product Quantity:
25,260 bags

Reason for Recall:
Lack of Assurance of Sterility; blue Break-Off-Part could detach from the administration port

Recall Number:
D-0438-2026

Code Information:
Lot: C274-000049934, Exp.: 4/23/2026; C274-000049963, Exp.:4/24/2026; C274-000050074, Exp.: 4/30/2026; C274-000050123, Exp.:5/1/2026; C274-000050296, Exp.: 5/9/2026; C274-000050420, Exp.: 5/16/2026; C274-000050774, Exp.:6/5/2026; C274-000050924, 6/7/2026; C274-000050961, Exp.: 6/11/2026; C274-000050991, Exp.: 6/12/2026; C274-000051139, Exp.:6/19/2026; C274-000051166, Exp.:6/20/2026; C274-000051198, Exp.:6/21/2026; C274-000051343, Exp.:6/28/2026.

Product Description:
norepinephrine Bitartrate, 32mg per 250mL 0.9% Sodium Chloride Injection USP, Fagron Sterile Services, 8710 34th St. N. Wichita, KS 67226, NDC 71266-5027-02

Product Quantity:
5140 bags

Reason for Recall:
Lack of Assurance of Sterility; blue Break-Off-Part could detach from the administration port

Recall Number:
D-0439-2026

Code Information:
Lot: C274-000050004, Exp.: 4/24/2026; C274-000050295, Exp.:5/8/2026; C274-000050773, Exp.: 6/4/2026; C274-000051219, Exp.: 6/21/2026; C274-000051318, Exp.: 6/27/2026; C274-000051602, Exp.: 7/12/2026.

Product Description:
Vancomycin HCl, 1.25 grams added to 250 mL, 0.9% Sodium Chloride Injection USP, Fagron Sterile Services, 8710 34th St. N. Wichita, KS 67226, NDC 71266-5083-01

Product Quantity:
34,260 bags

Reason for Recall:
Lack of Assurance of Sterility; blue Break-Off-Part could detach from the administration port

Recall Number:
D-0440-2026

Code Information:
Lot: C274-000050857, Exp.:7/6/2026; C274-000049316, Exp.: 4/26/2026; C274-000049367, Exp.: 4/28/2026; C274-000049496, Exp.: 5/3/2026; C274-000049518, Exp.: 5/4/2026; C274-000049535, Exp.: 5/5/2026; C274-000049653, Exp.: 5/11/2026; C274-000049654, Exp.: 5/11/2026; C274-000049745, Exp.: 5/16/2026; C274-000050128, Exp.: 5/31/2026; C274-000050151, Exp.: 6/1/2026; C274-000050184, Exp.: 6/6/2026; C274-000050504, Exp.: 6/15/2026; C274-000050662, Exp.: 6/21/2026; C274-000050836, Exp.: 7/5/2026; C274-000051014, Exp.: 7/13/2026; C274-000051057, Exp.: 7/18/2026; C274-000051240, Exp.: 7/25/2026.

Product Description:
Vancomycin HCl, 1.5 grams added to 250 mL, 0.9% Sodium Chloride Injection USP, Fagron Sterile Services, 8710 34th St. N. Wichita, KS 67226, NDC 71266-5085-01

Product Quantity:
16,130 bags

Reason for Recall:
Lack of Assurance of Sterility; blue Break-Off-Part could detach from the administration port

Recall Number:
D-0441-2026

Code Information:
Lot: C274-000050858, Exp.:7/6/2026; C274-000051018, Exp.: 7/13/2026; C274-000049194, Exp.: 4/20/2026; C274-000049591, Exp.: 5/9/2026;

C274-000049592, Exp.: 5/9/2026; C274-000049823, Exp.: 5/18/2026; C274-000050301, Exp.: 6/8/2026; C274-000050411, Exp.: 6/13/2026; C274-000051056, Exp.:7/18/2026.

Product Description:
Vancomycin HCL, 1 gram added to 250 mL, 0.9% Sodium Chloride Injection USP, Fagron Sterile Services, 8710 34th St. N. Wichita, KS 67226, NDC 71266-5082-01

Product Quantity:
11,680 bags

Reason for Recall:
Lack of Assurance of Sterility; blue Break-Off-Part could detach from the administration port

Recall Number:
D-0442-2026

Code Information:
Lot: C274-000050987, Exp.:7/12/2026; C274-000049425, Exp.: 5/2/2026; C274-000050069, Exp.: 5/30/2026; C274-000050346, Exp.: 6/10/2026; C274-000050698, Exp.: 6/27/2026; C274-000050699, Exp.:6/27/2026; C274-000050775, Exp.:7/4/2026.

Class II Drugs Event

Event ID:
98656

Product Type:
Drugs

Status:
Ongoing

Date Terminated:
N/A

Recall Initiation Date:
03/24/2026

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
04/09/2026

Initial Firm Notification of Consignee or Public:
N/A

Recalling Firm:
GE Healthcare Ireland Limited
Ida Business Park
Carrigtwohill
Ireland

Distribution Pattern:
U.S. Nationwide.

Associated Products

Product Description:
GE Healthcare Omnipaque (iohexol) Injection, 300 mg/mL (64.7%), Rx Only, Distributed by: GE Healthcare Inc., Marlborough, MA 01752 USA, NDC 0407-1413-63.

Product Quantity:
866,570 vials

Reason for Recall:
Presence of particulate matter

Recall Number:
D-0447-2026

Code Information:
Lot# 17225029; Exp. September 3, 2028 Lot# 17265376; Exp. October 3, 2028 Lot# 17270885; Exp. September 10, 2028 Lot# 17292246; Exp. October 4, 2028 Lot# 17301805; Exp. October 18, 2028 Lot# 17301807; Exp. September 7, 2028 Lot# 17301810; Exp. October 20, 2028 Lot# 17304992; Exp. October 5, 2028 Lot# 17304993; Exp. October 19, 2028 Lot# 17304996; Exp. November 25, 2028 Lot# 17321225; Exp. September 8, 2028 Lot# 17333589; Exp. November 24, 2028 Lot# 17333611; Exp. November 26. 2028 Lot# 17333613; Exp. November 23. 2028 Lot# 17357000; Exp. December 5, 2028 Lot# 17366399; Exp. December 14, 2028 Lot# 17376486; Exp. December 14, 2028 Lot# 17404114; Exp. December 6, 2028

Product Description:
GE Healthcare Omnipaque (iohexol) Injection, 350 mg/mL (64.7%), Rx Only, Distributed by: GE Healthcare Inc., Marlborough, MA 01752 USA, NDC

0407-1414-91.

Product Quantity:
306,810 vials

Reason for Recall:
Presence of particulate matter

Recall Number:
D-0448-2026

Code Information:
Lot# 17333197; Exp. December 10, 2028 Lot# 17333198; Exp. November 17, 2028 Lot# 17396945; Exp. December 18, 2028 Lot# 17396948; Exp. December 22, 2028 Lot# 17396953; Exp. January 11, 2029 Lot# 17396956; Exp. January 9, 2029 Lot# 17423503; Exp. January 1, 2029 Lot# 17423525; Exp. January 3, 2029 Lot# 17426429; Exp. January 1, 2029 Lot# 17426440; Exp. January 4, 2029 Lot# 17431310; Exp. January 11, 2029

Class II Drugs Event

Event ID:
98687

Product Type:
Drugs

Status:
Ongoing

Date Terminated:
N/A

Recall Initiation Date:
03/25/2026

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
04/07/2026

Initial Firm Notification of Consignee or Public:
N/A

Recalling Firm:
Preferred Pharmaceuticals, Inc.
1250 N Lakeview Ave Ste O
Anaheim, CA 92807-1801
United States

Distribution Pattern:
Nationwide within the United States

Associated Products

Product Description:
Artificial Tears Lubricant Eye Drops (glycerin 0.2%, hypromellose 0.2%, polyethylene glycol 400 1%), 0.5 oz bottles, Mfg: Geri-Care; Brooklyn, New York NDC 68788-7266-0

Product Quantity:
720 bottles

Reason for Recall:
Lack of Assurance of Sterility

Recall Number:
D-0443-2026

Code Information:
Lot #: F1924R, F2024G, F2424E, G2424M, G2624P, J2424M