Enforcement Report - Week of December 11, 2024

Class I Drugs Event

Event ID:
95714

Product Type:
Drugs

Status:
Ongoing

Date Terminated:
N/A

Recall Initiation Date:
11/04/2024

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
12/02/2024

Initial Firm Notification of Consignee or Public:
E-Mail

Recalling Firm:
Boulla LLC
2108 N ST #7929
Sacramento, CA 95816
United States

Distribution Pattern:
Nationwide within the United States

Associated Products

Product Description:
VitalityXtra Capsules, 500 mg, packaged in 10 count blisters in cartons, Distributed by: VitalityXtra, San Francisco, CA www.vitalityxtra.com

Product Quantity:
Unknown

Reason for Recall:
Marketed without an approved NDA/ANDA: Products found to contain undeclared sildenafil and diclofenac.

Recall Number:
D-0083-2025

Code Information:
Lot #: 230811, Exp: 08/11/2025

Product Description:
PeakMax Capsules, 500 mg, packaged in 10 count blisters in cartons, Distributed by: PeakMax, San Francisco, CA, www.PeakMax.com

Product Quantity:
Unknown

Reason for Recall:
Marketed without an approved NDA/ANDA: Products found to contain undeclared sildenafil and diclofenac.

Recall Number:
D-0084-2025

Code Information:
Lot #: 230811, Exp: 08/11/2025

Product Description:
ZoomMax Capsules, 500 mg, 10 count blisters in cartons, Distributed by: ZoomMax, 2108 N St. Sacramento, CA 95816, www.zoommax.com

Product Quantity:
Unknown

Reason for Recall:
Marketed without an approved NDA/ANDA: Products found to contain undeclared sildenafil and diclofenac.

Recall Number:
D-0085-2025

Code Information:
Lot #: YZM240406, Exp: 04/05/2027

Product Description:
ZapMax Capsules, 500 mg, 10 count blisters in cartons, Distributed by: ZapMax, 2108 N St. Sacramento, CA 95816, www.zapmax.com

Product Quantity:
Unknown

Reason for Recall:
Marketed without an approved NDA/ANDA: Products found to contain undeclared sildenafil and diclofenac.

Recall Number:
D-0086-2025

Code Information:
Lot #: YZM240406, Exp: 04/05/2027

Class II Drugs Event

Event ID:
95596

Product Type:
Drugs

Status:
Ongoing

Date Terminated:
N/A

Recall Initiation Date:
10/18/2024

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
12/04/2024

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
AvKARE
615 N 1st St
Pulaski, TN 38478-2403
United States

Distribution Pattern:
Nationwide within the United States

Associated Products

Product Description:
Sunitinib Malate Capsules, 12.5 mg, 28-count bottles, Rx Only, Manufactured for: AvKARE, Pulaski, TN 38478. NDC 42291-901-28

Product Quantity:
40 bottles

Reason for Recall:
Labeling: Label Mix-Up

Recall Number:
D-0103-2025

Code Information:
Lot #: 100049371, Exp. Date 07/31/2026

Product Description:
Sunitinib Malate Capsules, 25 mg, 28-count bottles, Rx Only, Manufactured for: AvKARE, Pulaski, TN 38478. NDC 42291-902-28

Product Quantity:
20 bottles

Reason for Recall:
Labeling: Label Mix-Up

Recall Number:
D-0104-2025

Code Information:
Lot #: 100049501, Exp. Date 07/31/2026

Class II Drugs Event

Event ID:
95630

Product Type:
Drugs

Status:
Ongoing

Date Terminated:
N/A

Recall Initiation Date:
10/25/2024

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
12/05/2024

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Lannett Company Inc.
1101 C Ave W
Seymour, IN 47274-3342
United States

Distribution Pattern:
Nationwide in the USA

Associated Products

Product Description:
Lisdexamfetamine Dimesylate Capsules, 10 mg, 100 Capsules per bottle, Rx only, Distributed by: Lannet Company, Philadelphia, PA 19136, NDC: 0527-4661-37

Product Quantity:
1608 bottles

Reason for Recall:
Failed Content Uniformity Specifications: Product failed to meet the action limits for stratified content uniformity.

Recall Number:
D-0112-2025

Code Information:
Lot: 23274856A, Exp 04/30/2025

Class II Drugs Event

Event ID:
95660

Product Type:
Drugs

Status:
Ongoing

Date Terminated:
N/A

Recall Initiation Date:
11/01/2024

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
12/03/2024

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:
Nationwide in the USA

Associated Products

Product Description:
Diltiazem Hydrochloride Extended-Release Capsules, USP 60 mg, Twice-a-Day Dosage, Rx Only, 100 Capsules per bottle, Manufactured for: Glenmark Pharmaceuticals Inc., USA Mahwah, NJ 07430, Product of India, NDC 68462-850-01.

Product Quantity:
34848 bottles

Reason for Recall:
cGMP Deviations: Presence of N-nitroso-Desmethyl-Diltiazem impurity above FDA recommended interim limit.

Recall Number:
D-0093-2025

Code Information:
Lot #s: 17222544, Exp. Date 11/30/2024 ; 17230784, Exp Date 03/31/2025; 17231080, Exp. Date 04/30/2025

Product Description:
Diltiazem Hydrochloride Extended-Release Capsules, USP 90 mg, Rx Only, 100 Capsules, Manufactured for : Glenmark Pharmaceuticals Inc., USA Mahwah, NJ 07430, Product of India, NDC 68462-851-01.

Product Quantity:
12,864 bottles

Reason for Recall:
cGMP Deviations: Presence of N-nitroso-Desmethyl-Diltiazem impurity above FDA recommended interim limit.

Recall Number:
D-0094-2025

Code Information:
Lot #s 17222452, Exp. Date, 11/30/2024; 17230607, Exp. Date 02/28/2025

Product Description:
Diltiazem Hydrochloride Extended-Release Capsules, USP 120 mg, Rx Only, 100 Capsules, Manufactured for: Glenmark Pharmaceuticals Inc., USA, Mahwah, NJ 07430, Product of India, NDC 68462-562-01.

Product Quantity:
25584 bottles

Reason for Recall:
cGMP Deviations: Presence of N-nitroso-Desmethyl-Diltiazem impurity above FDA recommended interim limit.

Recall Number:
D-0095-2025

Code Information:
Lot #: 17222470, 17230680, 17222547, Exp. Date 11/30/2024; 17230304, Exp. Date, 12/31/2024; 17230598, Exp. Date, 02/2025.

Product Description:
Diltiazem Hydrochloride Extended-Release Capsules, USP 60 mg, Twice-a-Day Dosage, Rx Only, 100 Capsules per bottle, Mfd for: Northstar Rx LLC, Memphis, TN, Mfd by: Glenmark Pharmaceuticals Limited, Pithampur, Madhya Pradesh India, NDC 16714-553-01.

Product Quantity:
5232 bottles

Reason for Recall:
cGMP Deviations: Presence of N-nitroso-Desmethyl-Diltiazem impurity above FDA recommended interim limit.

Recall Number:
D-0096-2025

Code Information:
Lot #: 17222544, Exp 11/30/2024.

Product Description:
Diltiazem Hydrochloride Extended-Release Capsules, USP 90mg, Twice-a-Day Dosage, Rx Only, 100 Capsules per bottle, Mfd for: Northstar Rx LLC, Memphis, TN, Mfd by: Glenmark Pharmaceuticals Limited, Pithampur, Madhya Pradesh India, NDC 16714-554-01.

Product Quantity:
4704 bottles

Reason for Recall:
cGMP Deviations: Presence of N-nitroso-Desmethyl-Diltiazem impurity above FDA recommended interim limit.

Recall Number:
D-0097-2025

Code Information:
Lot #: 17222452, Exp Date 11/30/2024; 17230607, Exp Date 02/28/2025.

Product Description:
Diltiazem Hydrochloride Extended-Release Capsules, USP 120mg, Twice-a-Day Dosage, Rx Only, 100 Capsules per bottle, Mfd for: Northstar Rx LLC, Memphis, TN, Mfd by: Glenmark Pharmaceuticals Limited, Pithampur, Madhya Pradesh India, NDC 16714-555-01.

Product Quantity:
7296 bottles

Reason for Recall:
cGMP Deviations: Presence of N-nitroso-Desmethyl-Diltiazem impurity above FDA recommended interim limit.

Recall Number:
D-0098-2025

Code Information:
Lot #:17222547, Exp. Date, 11/30/2024; 17230598, Exp. Date 02/28/2025

Class II Drugs Event

Event ID:
95711

Product Type:
Drugs

Status:
Ongoing

Date Terminated:
N/A

Recall Initiation Date:
11/11/2024

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
11/29/2024

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
American Regent, Inc.
5 Ramsey Rd
Shirley, NY 11967-4701
United States

Distribution Pattern:
Nationwide in the USA

Associated Products

Product Description:
Venofer (iron sucrose) Injection, USP 100 mg Elemental Iron per 5 mL (20 mg/mL), 5 mL Single-Dose Vials, Rx Only, For Intravenous Use Only, Distributed by: Fresenius Medical Care NA, Waltham, MA 02451, NDC: 49230-534-01 (vial), NDC: 49230-534-25 (25 x 5 mL/vial cartons).

Product Quantity:
N/A

Reason for Recall:
Presence of Particulate Matter: Potential for glass delamination from the vials.

Recall Number:
D-0080-2025

Code Information:
Lot#s: 4196, Exp 05/31/2026

Product Description:
Venofer (iron sucrose) Injection, USP 50 mg Elemental Iron per 2.5 mL (20 mg/mL), 2.5 mL Single-Dose Vials, Rx Only, For Intravenous Use Only, Distributed by: Fresenius Medical Care NA, Waltham, MA 02451, NDC: 49230-530-01 (vial), NDC: 49230-530-10 (10 x 2.5mL/vial cartons), NDC: 49230-530-25 (25 x 2.5mL/vial cartons).

Product Quantity:
N/A

Reason for Recall:
Presence of Particulate Matter: Potential for glass delamination from the vials.

Recall Number:
D-0081-2025

Code Information:
Lot #s: 4206, 4210, Exp 05/31/2026; 4223, Exp 06/30/2026; 24231, 24237, Exp 07/31/2026.

Product Description:
Venofer (iron sucrose) Injection, USP 100 mg Elemental Iron per 5 mL (20 mg/mL), 5 mL Single-Dose Vials, Rx Only, For Intravenous Use Only, American Regent, Inc. Shirley, NY 11967, NDC: 0517-2340-01 (vial), NDC: 0517-2340-10 (10 x 5 mL/vial cartons), NDC: 0517-2340-25 (25 x 5 mL/vial cartons).

Product Quantity:
N/A

Reason for Recall:
Presence of Particulate Matter: Potential for glass delamination from the vials.

Recall Number:
D-0082-2025

Code Information:
Lot #s: 4205, Exp 05/31/2026; 24229, 24233, 24239, Exp 07/31/2026.

Class II Drugs Event

Event ID:
95730

Product Type:
Drugs

Status:
Ongoing

Date Terminated:
N/A

Recall Initiation Date:
11/07/2024

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
11/29/2024

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Aurobindo Pharma USA Inc
279 Princeton Hightstown Rd
East Windsor, NJ 08520-1401
United States

Distribution Pattern:
USA Nationwide

Associated Products

Product Description:
Cinacalcet Tablets, 30 mg, packaged in: a) 30-count HDPE bottle (NDC 65862-831-30); b) 500-count HDPE bottle (NDC 65862-831-05), Rx Only, Distributed by: Aurobindo Pharma USA, Inc. 279 Princeton-Hightstown Road, East Windsor, NJ 08520, Made in India.

Product Quantity:
102576 bottles

Reason for Recall:
cGMP Deviations: Presence of N-nitroso Cinacalcet impurity above FDA recommended interim limit

Recall Number:
D-0077-2025

Code Information:
Lot #: a) CFSA23001A, CFSA23002A, CFSA23003A, Exp 03/31/2025; CFSA23004A, Exp 07/31/2025; CFSA23005A, Exp 10/31/2025; b) P2300191, P2300192, P2300193, P2300194, Exp 12/31/2024

Product Description:
Cinacalcet Tablets, 60mg, packaged in: a) 30-count HDPE bottle (NDC 65862-832-30), b) 500-count HDPE bottle (NDC 65862-832-05), Rx Only, Distributed by: Aurobindo Pharma USA, Inc. 279 Princeton-Hightstown Road, East Windsor, NJ 08520, Made in India.

Product Quantity:
3336 bottles

Reason for Recall:
cGMP Deviations: Presence of N-nitroso Cinacalcet impurity above FDA recommended interim limit

Recall Number:
D-0078-2025

Code Information:
Lot #: a) CFSB23001A, Exp 03/31/2025, CFSB23002A, Exp 07/31/2025; CFSB23003A, Exp 10/31/2025; CFSB23004A, Exp 10/31/2025; b) P2300196, 12/31/2024

Product Description:
Cinacalcet Tablets, 90 mg, packaged in: a) 30-count HDPE bottle (NDC 65862-833-30), b) 500-count HDPE bottle (NDC 65862-833-05), Rx Only, Distributed by: Aurobindo Pharma USA, Inc. 279 Princeton-Hightstown Road, East Windsor, NJ 08520, Made in India. 90 mg - 30 Tablets - NDC 65862-833-30 90 mg - 500 Tablets - NDC 65862-833-05

Product Quantity:
N/A

Reason for Recall:
cGMP Deviations: Presence of N-nitroso Cinacalcet impurity above FDA recommended interim limit

Recall Number:
D-0079-2025

Code Information:
Lot #: a) CFSC23001A, CFSC23001B, Exp 03/31/2025; b) P2300195, Exp 12/31/2024

Class II Drugs Event

Event ID:
95747

Product Type:
Drugs

Status:
Ongoing

Date Terminated:
N/A

Recall Initiation Date:
11/08/2024

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
11/29/2024

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
ACCORD HEALTHCARE, INC.
8041 Arco Corporate Dr Ste 200
Raleigh, NC 27617-2010
United States

Distribution Pattern:
USA Nationwide

Associated Products

Product Description:
Levothyroxine Sodium Tablets, USP, 75 mcg (0.075 mg), 1000-count bottle, Rx Only, Manufactured for: Accord Healthcare, Inc., Durham, NC 27703, Manufactured by: Intas Pharmaceuticals Limited, Camp Road, Selaqui, Dehradun-248 197, INDIA, NDC 16729-449-17

Product Quantity:
N/A

Reason for Recall:
Subpotent drug

Recall Number:
D-0076-2025

Code Information:
Lot #: D2300191, Exp 12/31/2025

Class II Drugs Event

Event ID:
95756

Product Type:
Drugs

Status:
Ongoing

Date Terminated:
N/A

Recall Initiation Date:
11/19/2024

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
12/05/2024

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Rising Pharma Holding, Inc.
2 Tower Center Blvd Ste 1401
East Brunswick, NJ 08816-1149
United States

Distribution Pattern:
Nationwide.

Associated Products

Product Description:
Duloxetine Delayed-Release Capsules USP, 20 mg, 60 count bottles, Rx only, Distributed by: Rising Pharma Holdings, Inc., East Brunswick, NJ NDC 57237-017-60

Product Quantity:
209,376 bottles

Reason for Recall:
CGMP Deviations: Presence of N-nitroso-duloxetine impurity above recommended interim limit

Recall Number:
D-0105-2025

Code Information:
a) Lot # DT2022023A, DT2022024A, DT2022025A, DT2022026A, DT2022027A, exp. date Nov-24 DT2023001B, DT2023004A, DT2023005A, DT2023006A, exp. date Jan-25

Product Description:
Duloxetine Delayed-Release Capsules USP, 30 mg, a) 30 count (NDC 57237-018-30), b) 90 count (NDC 57237-018-90) and c) 1000 count (NDC 57237-018-99) bottles, Rx only, Distributed by: Rising Pharma Holdings, Inc., East Brunswick, NJ

Product Quantity:
122,925 bottles

Reason for Recall:
CGMP Deviations: Presence of N-nitroso-duloxetine impurity above recommended interim limit

Recall Number:
D-0106-2025

Code Information:
a) 30s; DT3023019A, exp. date Jan-25 DT3023050A, exp. date Apr-25; b) 90s; DT3023022A, exp. date Jan-25; c) 1000s; DT3022108A,

DT3022107A, DT3022106A, DT3022111A, DT3022109A, exp. date Nov-24, DT3023001A, DT3023003A, exp. date Dec-24, DT3023024A, DT3023020B, exp. date Jan-25 DT3023027A, DT3023028A, exp. date Feb-25, DT3023034A, exp. date Mar-25, DT3023049A, exp. date Apr-25, DT3023095A, exp. date Jul-25

Product Description:
Duloxetine DR Capsules USP 60 mg, a) 30 count (NDC 57237-019-30), b) 90 count NDC 57237-019-90 and c) 1000 count (NDC 57237-019-99) bottles, Distributed by: Rising Pharmaceuticals, Inc., East Brunswick, NJ

Product Quantity:
233,003 bottles

Reason for Recall:
CGMP Deviations: Presence of N-nitroso-duloxetine impurity above recommended interim limit

Recall Number:
D-0107-2025

Code Information:
a) 30s; DT6023059A, DT6023060A, DT6023065A, DT6023069A, DT6023070A, exp. date Jan-25, DT6023080A, exp. date Feb-25, DT6023093A, exp. date Mar-25, DTC24012A, exp. date Dec-25; b) 90s; DT6023108A, exp. date Apr-25, DTC23201A, exp. date Aug-25; c) 1000s; DT6022160A, DT6022165A, DT6022162A, DT6022164A, DT6022163A, DT6022171A, DT6022169A, DT6022170A, DT6022173A, exp. date Nov-24, DT6023009A, DT6023007A, DT6023008A, DT6023011A, DT6023034B, exp. date Dec-24, DT6023067C, exp. date Jan-25, DT6023114A, exp. date Apr-25, DTC23243A, exp. date Oct-25, DTC24040A, exp. date Dec-25

Class II Drugs Event

Event ID:
95819

Product Type:
Drugs

Status:
Ongoing

Date Terminated:
N/A

Recall Initiation Date:
11/22/2024

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
12/05/2024

Initial Firm Notification of Consignee or Public:
E-Mail

Recalling Firm:
Generitech Corporation
4967 E Lansing Way
Fresno, CA 93727-7408
United States

Distribution Pattern:
CA

Associated Products

Product Description:
10 Irregular Pigmentation, Accelerator, Pigment Fading Activator, Only Your Rx, Nature + Science, 1 fl. oz., 30 mL Bottle, For Professional Use Only, Only YourRx Inc., Chatsworth, CA 91311, Made in USA, Onlyyourrx.com.

Product Quantity:
77.5lbs

Reason for Recall:
CGMP Deviations: Inconsistency in the water systems.

Recall Number:
D-0111-2025

Code Information:
Lot #: 2400017, Exp: 4/30/2026

Class II Drugs Event

Event ID:
95826

Product Type:
Drugs

Status:
Ongoing

Date Terminated:
N/A

Recall Initiation Date:
11/06/2024

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
12/02/2024

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Midlab Incorporated
140 Private Brand Way
Athens, TN 37303-1401
United States

Distribution Pattern:
Nationwide in the USA

Associated Products

Product Description:
MAXIM Assure Antibacterial, Chloroxylenol 0.1%, Net Contents: One U.S. Gallon (3.78 L), For Industrial and Institutional Use Only, MIDLAB 140 Private Brand Way, Athens, TN 37303

Product Quantity:
N/A

Reason for Recall:
cGMP Deviations: Out of specification results for micro in hand soap products.

Recall Number:
D-0087-2025

Code Information:
Lot 0711241

Product Description:
boardwalk ANTIBACTERIAL HANDSOAP REFILL, Chloroxylenol 0.1%, 1 gal. (3.78 L), Manufactured for Essendant Co., One Parkway North, Deerfield, IL 60015

Product Quantity:
N/A

Reason for Recall:
cGMP Deviations: Out of specification results for micro in hand soap products.

Recall Number:
D-0088-2025

Code Information:
Lot 0711241

Product Description:
Array Liquid Antiseptic Handwash, Chloroxylenol 0.1%, NET CONTENTS: 128 FL OZ (1 GAL) 3.785 L, FOR DISTRIBUTION EXCLUSIVELY BY GORDON FOOD SERVICE, WYOMING, MI 49509

Product Quantity:
N/A

Reason for Recall:
cGMP Deviations: Out of specification results for micro in hand soap products.

Recall Number:
D-0089-2025

Code Information:
Lot 0711241

Product Description:
ROYALAB Germ Away Antibacterial Hand Soap, Chloroxylenol 0.1%, NET CONTENTS: ONE U.S. GALLON (3.78 L), Royal Papers, 2701 Hereford St., St. Louis, MO 63139

Product Quantity:
N/A

Reason for Recall:
cGMP Deviations: Out of specification results for micro in hand soap products.

Recall Number:
D-0090-2025

Code Information:
Lot 0711241

Product Description:
Genuine Joe Antibacterial Lotion Soap , Chloroxylenol 0.1%, 1 GALLON (3.78L), Manufactured in the U.S.A. for S.P. Richards Co., Atlanta, GA 30339

Product Quantity:
N/A

Reason for Recall:
cGMP Deviations: Out of specification results for micro in hand soap products.

Recall Number:
D-0091-2025

Code Information:
Lot 0711241

Product Description:
Compliance Dishwashing Liquid & Antibacterial Soap, PCMX 0.1%, Net Contents: 1 Gallon, 128 Ounces, 3.785 Liters, Royal Corporation, 10232 Palm Drive, Santa Fe Springs, CA 90670

Product Quantity:
N/A

Reason for Recall:
cGMP Deviations: Out of specification results for micro in hand soap products.

Recall Number:
D-0092-2025

Code Information:
Lot 0711241

Class II Drugs Event

Event ID:
95849

Product Type:
Drugs

Status:
Ongoing

Date Terminated:
N/A

Recall Initiation Date:
11/14/2024

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
12/03/2024

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:
PA, OH, PR

Associated Products

Product Description:
Duloxetine Delayed-Release Capsules, USP, 20 mg, Rx only, 60 count bottles, Manufactured by: Aurobindo Pharma Limited, Hyderabad-500 090, India, For BluePoint Laboratories NDC 68001-413-06

Product Quantity:
37,916 bottles

Reason for Recall:
CGMP Deviations: Presence of N-nitroso-duloxetine impurity above the recommended interim limit

Recall Number:
D-0099-2025

Code Information:
Lots: DT2023001A, DT2023009A, exp date Jan 31, 2025

Product Description:
Duloxetine Delayed-Release Capsules, USP, 30 mg, Rx only, a) 30 count (NDC 68001-414-04) and b) 1,000 count (NDC 68001-414-08) bottles, Manufactured by: Aurobindo Pharma Limited, Hyderabad-500 090, India, For BluePoint Laboratories

Product Quantity:
23,490 bottles

Reason for Recall:
CGMP Deviations: Presence of N-nitroso-duloxetine impurity above the recommended interim limit

Recall Number:
D-0100-2025

Code Information:
a) 30 count; Lot, expiry: DT3023019B, DT3023020A, exp 01/31/2025 b) 1000 count; Lot, expiry: DTB23098A, exp 08/31/2025

Product Description:
Duloxetine Delayed-Release Capsules, USP, 60 mg, Rx only, 1,000 count bottle, Manufactured by: Aurobindo Pharma Limited, Hyderabad-500 090, India, For BluePoint Laboratories NDC 68001-415-08

Product Quantity:
8,561 bottles

Reason for Recall:
CGMP Deviations: Presence of N-nitroso-duloxetine impurity above the recommended interim limit

Recall Number:
D-0101-2025

Code Information:
Lot, expiry: DT6022159A, DT6022167A, DT6022168A, exp 11/30/2024; Lot DT6023034A, 12/31/2024; Lots DT6023050A, DT6023051A, DT6023063A, DT6023067A, exp 01/31/2025; Lots DT6023073A, DT6023072A, exp 02/28/2025

Class II Drugs Event

Event ID:
95897

Product Type:
Drugs

Status:
Ongoing

Date Terminated:
N/A

Recall Initiation Date:
11/27/2024

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
12/05/2024

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
AvKARE
615 N 1st St

Pulaski, TN 38478-2403
United States

Distribution Pattern:
USA Nationwide

Associated Products

Product Description:
Cinacalcet Tablets, 30 mg, 30-count bottle, Rx only, Manufactured for: AvKARE, Pulaski, TN 38478, NDC 42291-459-30

Product Quantity:
50,304 bottles

Reason for Recall:
CGMP deviations: Presence of Nitrosamine Drug Substance Related Impurity (NDSRI), N-Nitroso-Cinacalcet above acceptable intake limit.

Recall Number:
D-0108-2025

Code Information:
Lot#: 44378, 44597, 45804, Exp 12/31/2024

Product Description:
Cinacalcet Tablets, 60 mg, 30-count bottle, Rx only, Manufactured for: AvKARE, Pulaski, TN 38478, NDC 42291-460-30

Product Quantity:
2,396 bottles

Reason for Recall:
CGMP deviations: Presence of Nitrosamine Drug Substance Related Impurity (NDSRI), N-Nitroso-Cinacalcet above acceptable intake limit.

Recall Number:
D-0109-2025

Code Information:
Lot # 44550, Exp 12/31/2024

Product Description:
Cinacalcet Tablets, 90 mg, 30-count bottle, Rx only, Manufactured for: AvKARE, Pulaski, TN 38478, NDC 42291-461-30

Product Quantity:
2,796 bottles

Reason for Recall:
CGMP deviations: Presence of Nitrosamine Drug Substance Related Impurity (NDSRI), N-Nitroso-Cinacalcet above acceptable intake limit.

Recall Number:
D-0110-2025

Code Information:
Lot #: 44405, Exp 12/31/2024

Class III Drugs Event

Event ID:
95767

Product Type:
Drugs

Status:
Ongoing

Date Terminated:
N/A

Recall Initiation Date:
11/14/2024

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
12/04/2024

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Zydus Pharmaceuticals (USA) Inc
73 Route 31 N

Pennington, NJ 08534-3601
United States

Distribution Pattern:
USA Nationwide.

Associated Products

Product Description:
Esomeprazole Magnesium for Delayed-Release Oral Suspension 40 mg, 30 Single-Dose Packets, Rx Only, Manufactured by: Zydus Lifesciences Ltd. Ahmedabad, India, Distributed by: Zydus Pharmaceuticals (USA) Inc., Pennington, NJ 08534, NDC 68382-849-94. Packaged in sachets

Product Quantity:
4404 packs

Reason for Recall:
Labeling: Not Elsewhere Classified - Wrong NDC number

Recall Number:
D-0102-2025

Code Information:
Lot#: M408002, Exp 05/31/2026