Enforcement Report - Week of July 19, 2023

Class I Drugs Event

Event ID:
91621

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
01/30/2023

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
07/14/2023

Initial Firm Notification of Consignee or Public:
E-Mail

Recalling Firm:
Global Pharma Healthcare Private Limited
A - 9 Sidco Pharmaceutical Complex Thiruporur
Chennai India

Distribution Pattern:
Product was distributed to two distributors who further distributed Nationwide in the USA.

Associated Products

Product Description:
Artificial Tears (Carboxymethylcellulose Sodium) Lubricant Eye Drops, 10 MG in 1 ml, 1/2 fl oz (15 ml) bottle, Distributed by. EzriCare, LLC, Lakewood, NJ, NDC 79503-0101-15.

Product Quantity:
400,008 bottles total for all products

Reason for Recall:
Non-Sterility: FDA analysis found unopened products to have bacterial contamination.

Recall Number:
D-0919-2023

Code Information:
Lot #: PCMI005, Exp. date AUG-2024; PCMJ001, PCMJ002, PCMJ004, PCMJ005, PCMJ006, PCMJ008, PCMJ009, PCMJ010, PCMJ011, PCMJ012, PCMJ013, PCMJ014, PCMJ015, PCMJ016, Exp. date MAR-2025

Product Description:
Delsam Pharma's ARTIFICIAL TEARS (Carboxymethylcellulose Sodium) Lubricant Eye Drops, 10 MG in 1 ml, 1%, 1/2 fl oz (15 ml) bottle, Distributed By: Delsam Pharma Llc, Bronx, New York 10467, NDC 72570 121 15.

Product Quantity:
400,008 bottles total for all products

Reason for Recall:
Non-Sterility: FDA analysis found unopened products to have bacterial contamination.

Recall Number:
D-0921-2023

Code Information:
Lot #: PCMH001, PCMH002, PCMH005, PCMH007, Exp. date NOV-2023

Class I Drugs Event

Event ID:
92616

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
06/27/2023

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
07/21/2023

Initial Firm Notification of Consignee or Public:
Letter

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

Distribution Pattern:
Nationwide in the US

Associated Products

Product Description:
Albuterol Sulfate Inhalation Aerosol, 90 mcg, 200 Metered Inhalation, net content 6.7 g canister packaged in a box, Rx only, Manufactured by: Cipla Ltd, Indore SE Z, Pithampur, India, Manufactured for: Cipla USA, Inc., 10 Independence Boulevard, Suite 300, Warren, NJ, 07059, NDC 69097-142-60

Product Quantity:
278,538 canisters

Reason for Recall:
Defective container: empty inhaler and leakage observed through the inhaler valve due to partially missing bottom seat (gasket).

Recall Number:
D-0938-2023

Code Information:
Lot # IB20045, IB20055, IB20056, IB20057, IB20059, IB20072, Exp Nov. 30, 2023

Class II Drugs Event

Event ID:
91621

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
01/30/2023

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
07/14/2023

Initial Firm Notification of Consignee or Public:
E-Mail

Recalling Firm:
Global Pharma Healthcare Private Limited
A - 9 Sidco Pharmaceutical Complex Thiruporur
Chennai India

Distribution Pattern:
Product was distributed to two distributors who further distributed Nationwide in the USA.

Associated Products

Product Description:
Artificial Tears (Carboxymethylcellulose Sodium) Lubricant Eye Drops, 10 MG in 1 ml, 1/2 fl oz (15 ml) bottle, Distributed by. EzriCare, LLC, Lakewood, NJ, NDC 79503-0101-15.

Product Quantity:
400,008 bottles total for all products

Reason for Recall:
CGMP Deviations: All other lots of eye drops are being recalled due to CGMP Deviations because they were manufactured in the same facility under the same conditions as the lots found to be contaminated.

Recall Number:
D-0920-2023

Code Information:
Lot #: PCMH009, PCMH010, PCMH011, PCMH012, PCMH013, PCMH014, PCMH015, PCMH016, exp. date Nov-2023; PCMI001, PCMI002, PCMI003, PCMI004, PCMI006, PCMI 07, PCMI 008, Exp. date AUG-2024; PCMJ003, PCMJ007, Exp. date MAR-2025

Product Description:
Delsam Pharma's ARTIFICIAL TEARS (Carboxymethylcellulose Sodium) Lubricant Eye Drops, 10 MG in 1 ml, 1%, 1/2 fl oz (15 ml) bottle, Distributed By: Delsam Pharma Llc, Bronx, New York 10467, NDC 72570 121 15.

Product Quantity:
400,008 bottles total for all products

Reason for Recall:
CGMP Deviations: All other lots of eye drops are being recalled due to CGMP Deviations because they were manufactured in the same facility under the same conditions as the lots found to be contaminated.

Recall Number:
D-0922-2023

Code Information:
Lot #: PCMH003, PCMH004, PCMH006, PCMH008, Exp. date NOV-2023

Class II Drugs Event

Event ID:
91672

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
02/09/2023

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
07/11/2023

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
L. Perrigo Company
515 Eastern Ave
Allegan MI United States

Distribution Pattern:
Nationwide within the USA

Associated Products

Product Description:
Allergy, Fexofenadine Hydrochloride Tablets, 180 mg, packaged in a) 30-count cartons (NDC 72288-847-39), and b)150-count cartons (NDC 72288-847-47 and 72288-847-37), Distributed By: Amazon.com Services LLC., 410 Terry Avenue N., Seattle, WA 98109.

Product Quantity:
11,904 cartons

Reason for Recall:
Failed Impurities/Degradation Specifications

Recall Number:
D-0900-2023

Code Information:
Lot # a) 2GR0329, Exp. date 04/24 Lot # b) 2DR0472, Exp. date 02/23; 2MR0417, Exp. date 07/24

Product Description:
Non-Drowsy Allergy Relief, Fexofenadine Hydrochloride Tablets, 180 mg, 150-count cartons, Distributed By: BJ's Wholesale Club, 25 Research Drive, Westborough, MA 01581. NDC 68391-847-47

Product Quantity:
23,868 cartons

Reason for Recall:
Failed Impurities/Degradation Specifications

Recall Number:
D-0901-2023

Code Information:
Lot #:2DV1863, 2HV2698, Exp. date 12/23; 2GV1583, Exp. date 02/24; 2GV1950, 2HV2697, Exp. Date 01/24.

Product Description:
Allergy Relief, Fexofenadine Hydrochloride Tablets, 180 mg, 15-count cartons, Distributed By: Adusa Distribution, LLC, Salisbury, NC 28147. NDC 72476-847-22

Product Quantity:
3,240 cartons

Reason for Recall:
Failed Impurities/Degradation Specifications

Recall Number:
D-0902-2023

Code Information:
Lot #: 2JE2185, Exp. date 01/24

Product Description:
Allergy Relief, Fexofenadine Hydrochloride Tablets, 180 mg, 30-count cartons, Distributed By: CVS Pharmacy, Inc., One CVS Drive, Woonsocket, RI 02895. NDC 69842-0914-39

Product Quantity:
16,200 cartons

Reason for Recall:
Failed Impurities/Degradation Specifications

Recall Number:
D-0903-2023

Code Information:
Lot #: 2DV1925, Exp. date 06/23

Product Description:
aller-ease, Fexofenadine Hydrochloride Tablets, 180 mg, 30-count cartons, Packaged For: Your Military Exchanges, By: Perrigo Company, Allegan, MI USA 49010. NDC 55301-847-39

Product Quantity:
1,920 cartons

Reason for Recall:
Failed Impurities/Degradation Specifications

Recall Number:
D-0904-2023

Code Information:
Lot #: 2ER0285,Exp. date 01/24

Product Description:
Allergy ALLER-FEX, Fexofenadine Hydrochloride Tablets, 180 mg, 180-count cartons, Packaged by: Perrigo, 515 Eastern Ave., Allegan, MI 49010 USA. NDC 63981-847-48

Product Quantity:
360,184

Reason for Recall:
Failed Impurities/Degradation Specifications

Recall Number:

D-0905-2023

Code Information:
Lot #: 2DV1487, 2DV1870, 2DV1871, 2DV1873, 2EV1676, 2GV2132, 2HV2679, Exp. date 12/23; 2DV2000, exp. date 11/23; 2LV1573, 2MV1314, Exp. date 04/24; 2FV1764, 2FV1765 2FV1766, 2GV1579, 2GV1937, 2GV1941 , 2GV1942, 2GV2157, 2HV1886, 2HV1997, 2HV2019, 2HV2047, Exp. datev02/24; 2EV1666, 2EV1667, 2EV1668, 2EV1670, 2EV1671, 2EV1672, 2EV1674, 2EV1677, 2EV1678, 2HV2017, Exp. date 01/24.

Product Description:
allergy relief, Fexofenadine Hydrochloride Tablets, 180 mg, packaged in a)15-count cartons (NDC 79481-0847-0), b)30-count cartons (NDC 79481-0847-1), and c) 45-count cartons (NDC 79481-0847-2), Distributed by: MEIJER DISTRIBUTION, INC., GRAND RAPIDS, MI 49544.

Product Quantity:
59,688 cartons

Reason for Recall:
Failed Impurities/Degradation Specifications

Recall Number:
D-0906-2023

Code Information:
Lot #: a) 2JE1882, Exp. date 01/24 b) 2FV1918, 2ER0411, Exp. date 01/24; 2GV1902, Exp. date 04/24; 2CR0652, 2DR0465, Exp. date 12/23; 2GR0329, Exp. date 04/24 c)2CR0653, 2DR0466, Exp. date 12/23; 2ER0287, 2ER0412, Exp. date 01/24

Product Description:
Fexofenadine Hydrochloride Tablets, 180 mg, 100-count cartons, Distributed by: Perrigo, Allegan, MI 49010. NDC 45802-847-78

Product Quantity:
15,504 cartons

Reason for Recall:
Failed Impurities/Degradation Specifications

Recall Number:
D-0907-2023

Code Information:
Lot #: 2DR0351, Exp. date 12/23

Product Description:
Fexofenadine Hydrochloride Tablets, 180 mg, packaged in a) 30-count cartons (NDC 0113-0847-39), and b) 45-count cartons (NDC 0113-0847-95), Distributed by: Perrigo, Allegan, MI 49010.

Product Quantity:
32,376 cartons

Reason for Recall:
Failed Impurities/Degradation Specifications

Recall Number:
D-0908-2023

Code Information:
Lot #: a) 2DV1869, 2EV1613, 2EV1614, Exp. date 12/23; 2EV1820, 2FV1943, Exp. date 01/24; 2GV1893, Exp. date 04/24. Lot #: b) 2CR0653, 2DR0466, Exp. date 12/23, 2ER2087, Exp. date 01/24

Product Description:
allergyrelief, Fexofenadine Hydrochloride Tablets, 180 mg, packaged in a)30-count cartons (NDC 56062-847-39); and b) 45-count cartons (NDC 56062-847-95), Distributed by: Publix Super Markets, Inc., 3300 Publix Corporate Parkway, Lakeland, FL 33811.

Product Quantity:
32,904 cartons

Reason for Recall:
Failed Impurities/Degradation Specifications

Recall Number:
D-0909-2023

Code Information:
Lot #: a) 2CR0652, 2DR0464, 2DR0465,Exp. Date 12/23; 2ER0285, Exp. Date 01/24. b) 2DR0466, Exp. Date 12/23; 2ER0412, Exp. Date 01/24;

2GR0330, Exp. Date 04/24

Product Description:
allergy relief, Fexofenadine Hydrochloride Tablets, 180 mg, packaged in a)15-count cartons (NDC 11673-617-22), b)30-count cartons (NDC 11673-617-39), c)70-count cartons (NDC 11673-617-01), and d)150-count cartons (11673-617-47), Distributed by: Target Corporation, Minneapolis, MN 55403.

Product Quantity:
208,416 cartons

Reason for Recall:
Failed Impurities/Degradation Specifications

Recall Number:
D-0910-2023

Code Information:
Lot #: a) 2HE2032, 2JE1882, 2JE2185 Exp. Date 01/24; b) 2DR0464, 2ER0410, Exp. Date 12/23; 2ER0286, 2ER0411, Exp. Date 01/24 c) 2DR0467, 2DR0468, 2DR0469, 2ER0288, Exp. Date 12/23 d) 2ER0414, Exp. Date 01/24, 2GR0333, Exp. Date 02/24

Product Description:
Picnic, Fexofenadine Hydrochloride Tablets, 180 mg, Antihistamine, 90-count cartons, Distributed by: Thirty Madison, Inc., New York, NY 10001. NDC 45 tablets: 80159-112-03

Product Quantity:
6,216 cartons

Reason for Recall:
Failed Impurities/Degradation Specifications

Recall Number:
D-0911-2023

Code Information:
Lot#: 2DR0471, Exp. Date 12/23

Product Description:
Allergy Relief, Fexofenadine Hydrochloride Tablets, 180 mg, packaged in a) 30-count cartons (NDC 36800-691-39), b)45-count cartons (NDC 36800-691-95), and 90-count cartons (NDC 36800-691-75), Distributed by: Topco Associates LLC, Elk Grove Village, IL 60007.

Product Quantity:
44,280 cartons

Reason for Recall:
Failed Impurities/Degradation Specifications

Recall Number:
D-0912-2023

Code Information:
Lot #: a) 2FV1948, 2ER0285, 2ER0411, Exp. Date 01/24 b)2CR0653, Exp. Date 12/23 c)2GR0331, Exp. Date 04/24

Class II Drugs Event

Event ID:
92533

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
06/13/2023

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
07/07/2023

Initial Firm Notification of Consignee or Public:
E-Mail

Recalling Firm:
K.C. Pharmaceuticals, Inc

3215 Producer Way
Pomona CA United States

Distribution Pattern:
Nationwide in the USA

Associated Products

Product Description:
Original Eye Drops; Redness Reliever; (Tetrahydrozoline HCl), 0.05%, 0.5 FL OZ (15mL); distributed by a) Original Formula Eye Drops, DG health, DISTRIBUTED BY OLD EAST MAIN CO, 100 MISSION RIDGE, GOODLETTSVILLE, TN 37072, UPC 0 95072 00556 5; b) Publix, DISTRIBUTED BY PUBLIX SUPER MARKETS, INC, 3300 PUBLIX CORPORATE PARKWAY, LAKELAND, FL 33811, UPC 0 41415 01076 5; c) sterile eye drops, Original Formula, sunmark, Distributed by McKesson, 6555 State Highway 161, Irving, TX 75039, UPC 0 10939 16733 0, NDC 49348-037-29; d) TopCare health, DISTRIBUTED BY TOPCO ASSOCIATES LLC, ELKGROVE VILLAGE, IL 60007, UPC 0 36800 03639 0; e) Eye Drops, Original Formula, GoodSense, Distributed By: Geiss, Destin & Dunn, Inc., Peachtree City, GA 30269, UPC 1 80410 00015 6, NDC 50804-141-01; f) sterile eye drops, Circle K, Product manufactured for: Lil' Drug Store Products, Inc., 9300 Earhart Lane SW, Cedar Rapids, IA 52404 Proudly distributed by Circle K Stores Inc., UPC 1 94283 65185 8; g) Sterile Eye Drops, Regular Formula, Lil Drug Store, Product manufactured for: Lil' Drug Store Products, Inc., 9300 Earhart Lane SW, Cedar Rapids, IA 52404; UPC 3 66715 68324 3; h) Tetrahydrozoline Ophthalmic Solution, Rugby, Distributed by: Rugby Laboratories, 17177 N Laurel Park Drive, Suite 233, Livonia, MI 48152, UPC 3 05361 21794 5, NDC 0536-1217-94, i) Leader, DISTRIBUTED BY CARDINAL HEALTH, DUBLIN, OHIO 43017, UPC 0 96295 13645 6, NDC 70000-0454-1; j) REDNESS RELIEF EYE DROPS, CAREone, Distributed by: FOODHOLD USA, LLC, LANDOVER, MD 20785; UPC 0 41520 86531 1, NDC 41520-431-05; k) Eye Drops, Original Formula, Good Neighbor Pharmacy, Distributed By AmerisourceBergen, 1300 Morris Drive, Chesterbrook, PA 19087, UPC 0 87701 14975 7, NDC 24385-075-05; l) Eye Drops, ORIGINAL FORMULA, Walgreens, DISTRIBUTED BY: WALGREEN CO., 200 WILMOT RD., DEERFIELD, IL 60015, UPC 3 11917 20076 7; m) CVS Health, Distributed by: CVS Pharmacy, Inc., One CVS Drive, Woonsocket, RI 02895, UPC 0 50428 36131 3; n) H-E-B, MADE WITH PRIDE & CARE FOR H-E-B, SAN ANTONIO, TX 78204, UPC 0 41220 43747 4; o) redness relief, Original Redness Reliever Eye Drops, meijer, DIST. BY MEIJER DISTRIBUTION INC., GRAND RAPIDS, MI 49544, UPC 0 41250 82916 4, NDC 41250-814-01; p) Eye Drops, ORIGINAL, Best Choice, PROUDLY DISTRIBUTED BY: VALU MERCHANDISERS, CO., 5000 KANSAS AVE, KANSAS CITY, KS 66106, UPC 0 70038 47011 3

Product Quantity:
341,568 bottles

Reason for Recall:
CGMP Deviations: good manufacturing deficiencies related to a lack of documentation of the fill line.

Recall Number:
D-0897-2023

Code Information:
Lot #: a) RG21F01, Exp: 6/30/2023; b) RG21F01, Exp: 6/30/2023; c) RG21F01, Exp: 6/30/2023; d) RG21F01, RG21F02, Exp 6/30/2023; e) RG21F02, RG21F03, Exp 6/30/2023; f) RG21F02, Exp 6/30/2023; g) RG21F02, Exp 6/30/2023; h) RG21F02, Exp 6/30/2023; i) RG21F02, Exp 6/30/2023; j) RG21F02, Exp 6/30/2023; k) RG21F02, Exp 6/30/2023; l) RG21F02, Exp 6/30/2023; m) RG21F03, Exp 6/30/2023; n) RG21F03, Exp 6/30/2023; o) RG21F03, Exp 6/30/2023; p) RG21F03, Exp 6/30/2023

Product Description:
Dry Eye Relief Lubricant Eye Drops, (Glycerin 0.2%, Hypromellose 0.2 %, Polyethylene glycol 400 1%), 0.5 FL OZ (15mL) bottle, packaged in a) equate, DISTRIBUTED BY: Walmart Inc., Bentonville, AR 72716, 2-0.5 FL OZ (15 mL) Bottles, 1 FL OZ (30 mL) TOTAL, UPC 6 81131 36701 1, NDC 49035-280-02; b) DG health, DISTRIBUTED BY OLD EAST MAIN CO., 100 MISSION RIDGE, GOODLETTSVILLE, TN 37072, UPC 0 95072 02656 0; c) sunmark, Distributed By McKesson, 6555 State Highway 161, Irving, TX 75039, UPC 0 10939 62144 3, NDC 49348-037-29; d) TopCare health, DISTRIBUTED BY TOPCO ASSOCIATES LLC, ELK GROVE VILLAGE, IL 60007, UPC 0 36800 36100 3; e) HealthMart, Distributed by McKesson, 6555 State Highway 161, Irving, TX 75039, UPC 0 52569 13715 4; f) exchange select Artificial Tears, Manufactured for your Military Exchanges by: KC Pharmaceuticals, Inc., Pomona, CA 91768, UPC 6 14299 05620 6; g) meijer, DIST. BY MEIJER DISTRIBUTION, INC., GRAND RAPIDS, MI 49544, UPC 7 13733 29692 2, NDC 41250-718-01; h) H.E.B, MADE WITH PRIDE AND CARE FOR H.E.B, SAN ANTONIO, TX 78204, UPC 0 41220 43741 2; i) GeriCare, Distributed by: Gericare Pharmaceuticals Corp., 1650 63rd St., Brooklyn, NY 11204, UPC 3 57896 18405 6, NDC 57896-181-05

Product Quantity:
397,430 bottles

Reason for Recall:
CGMP Deviations: good manufacturing deficiencies related to a lack of documentation of the fill line.

Recall Number:
D-0898-2023

Code Information:
Lot #: a) LT21FO2, LT21F03, Exp 6/2023; b) LT21FO2, LT21F03, Exp 6/2023; c) LT21FO2, LT21F03, Exp 6/2023; d) LT21FO2, LT21F03, Exp

6/2023; e) LT21F02, Exp 6/2023; f) LT21F02, Exp 6/2023; g) LT21F03, Exp 6/2023; h) LT21F03, Exp 6/2023; i) LT21F03, Exp 6/2023

Class II Drugs Event

Event ID:
92634

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
07/10/2023

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
07/12/2023

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Tenn South Distillery LLC dba Big Machine Distillery
1800 Abernathy Rd
Lynnville TN United States

Distribution Pattern:
TN

Associated Products

Product Description:
Big Machine Distillery Hand Sanitizer Non-Sterile Solution Alcohol Antiseptic 80% Topical Solution, Produced and Distributed by Big Machine Distillery 1800 Abernathy Road Lynnville, TN 38472 a) 50 mL UPC 8 59105 00452 5; b) 100 mL UPC 8 59105 00453 2; c) 375 mL; d) 1/2 gallon; e) 1 gallon; f) 5 gallon; g) 55 gallon; i) Indianapolis Motor Speedway 50 mL UPC 8 59105 00452 5; j) Indianapolis Motor Speedway 375 mL UPC 8 59105 00454 9; k) Indianapolis Motor Speedway 1 gallon UPC 8 59105 00451 7; l) The Contributor 50 mL; m) Tony Kanaan Last Lap 100 mL; n) Tony Kanaan Last Lap 375 mL; o) Trexis Insurance 50 mL; p) Team Penske 50 mL; q) Middle Tennessee State University Lightning 50 mL.

Product Quantity:
540 gallons

Reason for Recall:
CGMP Deviation: impurities exceed allowable limits.

Recall Number:
D-0915-2023

Code Information:
All lots remaining within expiry.

Class II Drugs Event

Event ID:
92636

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
07/05/2023

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
07/11/2023

Initial Firm Notification of Consignee or Public:
Letter

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

Distribution Pattern:
Product was distributed to 3 wholesalers/distributors who further distributed the product Nationwide in the USA.

Associated Products

Product Description:
Sunitinib Malate Capsules, 12.5 mg, 28-count bottles, Rx only, Manufactured By: Teva Pharmaceuticals USA, Inc., Parsippany, NJ 07054, NDC 0093-8199-28

Product Quantity:
180 bottles

Reason for Recall:
Failed Moisture Limits: Water (moisture) content above the approved product specifications.

Recall Number:
D-0913-2023

Code Information:
Lot # 100037220, Exp 10/2024

Class II Drugs Event

Event ID:
92639

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
07/03/2023

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
07/13/2023

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Accord Healthcare, Inc.
1009 Slater Rd Ste 210B
Durham NC United States

Distribution Pattern:
Nationwide within the United States

Associated Products

Product Description:
Atropine Sulfate Injection, USP 8 mg per 20 mL (0.4 mg per mL), 20 mL Multiple Dose Vials, Rx only, Manufactured for: Accord Healthcare, Inc. Durham, NC 27703 Manufactured by: Intas Pharmaceuticals Limited Ahmedabad-382 210, India, NDC 16729-512-43.

Product Quantity:
2348 vials

Reason for Recall:
Presence of Particulate Matter: Particulate matter identified as fiber.

Recall Number:
D-0917-2023

Code Information:
Lot #: M2210154 Exp. date 06/2025; M2212575 Exp. date 08/2025

Product Description:
Bivalirudin for Injection 250 mg, 10 Single-Dose Vials, Rx Only, Manufactured for: Accord Healthcare, Inc. Durham, NC 27703 Manufactured by: Intas Pharmaceuticals Limited Ahmedabad-382 210, India, NDC 16729-275-67.

Product Quantity:
1680 vials

Reason for Recall:
Presence of Particulate Matter: Particulate matter identified as fiber.

Recall Number:
D-0918-2023

Code Information:
Lot #: M2212070 Exp. date 08/2024

Class II Drugs Event

Event ID:
92640

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
07/05/2023

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
07/13/2023

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
B. Braun Medical Inc.
1845 Mason Ave
Daytona Beach FL United States

Distribution Pattern:
USA Nationwide

Associated Products

Product Description:
0.9% Sodium Chloride Injection USP, 1000 mL Excel Plus Container, Rx only, B. Braun Medical Inc. Bethlehem, PA 18018-3524 USA, NDC 0264-5802-00

Product Quantity:
79,880 bags

Reason for Recall:
Lack of assurance of sterility: bags have the potential to leak.

Recall Number:
D-0916-2023

Code Information:
Lot#: 0061858305, 0061858306 Exp 3/31/2025

Class II Drugs Event

Event ID:
92671

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
07/10/2023

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
07/11/2023

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
SUN PHARMACEUTICAL INDUSTRIES INC
2 Independence Way
Princeton NJ United States

Distribution Pattern:
Distributed nationwide in the USA.

Associated Products

Product Description:
Tiagabine Hydrochloride Tablets, 2 mg, 30-count bottle, Distributed by Sun Pharmaceutical Industries. Inc. Cranbury NJ 08512, Manufactured by: Sun Pharmaceutical Industries Limited Halol-Baroda Highway, Halol-389 350, Gujarat, India. NDC#: 62756-200-83

Product Quantity:
8,880 30-count bottles

Reason for Recall:
Failed Impurities: Out of Specification (OOS) result observed during Related Substances testing

Recall Number:
D-0914-2023

Code Information:
Lot HAC3339A, Expires 07/2023

Class III Drugs Event

Event ID:
92582

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
06/23/2023

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
07/07/2023

Initial Firm Notification of Consignee or Public:

Recalling Firm:
Vivus, Inc.
900 E Hamilton Ave Ste 550
Campbell CA United States

Distribution Pattern:
Nationwide within the United States

Associated Products

Product Description:
PANCREAZE (pancrelipase) Delayed-Release Capsules, 100-count bottles, Rx only, Rx only, Manufactured by VIVUS LLC, Campbell, CA 95008, UPC: N3 62541-401-10 5, NDC 62541-401-10,

Product Quantity:
4240 bottles

Reason for Recall:
Failed Stability Specifications

Recall Number:
D-0896-2023

Code Information:
Lot #: 102101, Exp: 31 July 2024

Class III Drugs Event

Event ID:
92618

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
06/27/2023

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
07/07/2023

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Lupin Pharmaceuticals Inc.
Harborplace Tower 111 S Calvert St Fl 21st
Baltimore MD United States

Distribution Pattern:
Product was distributed directly to three distributors in TN and NJ. Product may have been further distributed throughout the United States.

Associated Products

Product Description:
Amlodipine Besylate Tablets, USP 10 mg, 1000-count bottles, Rx only, Manufactured for: Lupin Pharmaceuticals, Inc. Baltimore, Maryland 21202 U.S, Manufactured by: Lupin Limited, Aurangabad 431 210 India, NDC 68180-721-03

Product Quantity:
3,096 bottles

Reason for Recall:
Subpotent Drug: Out-of-Specification test results observed in assay test at 21-month long term stability study.

Recall Number:
D-0899-2023

Code Information:
Lot #: A102887, Exp. 6/2023