Enforcement Report - Week of April 16, 2025

Class II Drugs Event

Event ID:
96434

Product Type:
Drugs

Status:
Ongoing

Date Terminated:
N/A

Recall Initiation Date:
03/07/2025

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
04/07/2025

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
ASEGUA THERAPEUTICS LLC
333 Lakeside Dr
Foster City, CA 94404-1147
United States

Distribution Pattern:
US Nationwide

Associated Products

Product Description:
Sofosbuvir and Velpatasvir, 400 mg/100 mg tablets, 28 tablets: 2x14 blister cards, Rx Only, Manufactured for: Asegua Therapeutics LLC an affiliate of Gilead Sciences, Inc., Foster City, CA 94404, Made in Ireland, NDC# 72626-2701-1

Product Quantity:
18,541 cartons.

Reason for Recall:
Defective Container: blister packs not properly sealed resulting in tablets being loose in the carton.

Recall Number:
D-0313-2025

Code Information:
Lot# 24ASV002UA, Exp Date: 6/30/2028

Class II Drugs Event

Event ID:
96474

Product Type:
Drugs

Status:
Ongoing

Date Terminated:
N/A

Recall Initiation Date:
03/13/2025

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
04/08/2025

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:
U.S. Nationwide

Associated Products

Product Description:
Fenofibrate Capsules 67 mg, USP, 100-count bottle, Rx Only, Manufactured by: Glenmark Pharmaceuticals Limited, Pithampur, Madhya Pradesh 454775, India, Manufactured for: Glenmark Pharmaceuticals Inc. USA, Mahwah, NJ 07430. NDC# 68462-580-01

Product Quantity:
N/A

Reason for Recall:
CGMP Deviations

Recall Number:
D-0314-2025

Code Information:
Lot # 17230834, exp. date Mar-25 17230835, exp. date Mar-25

Product Description:
Propafenone Hydrochloride Extended-Release Capsules 225mg, 60-count bottle, Rx Only, Manufactured by: Glenmark Pharmaceuticals Limited, Pithampur, Madhya Pradesh 454775, India, Manufactured for: Glenmark Pharmaceuticals Inc. USA, Mahwah, NJ 07430.NDC# 68462-408-60

Product Quantity:
N/A

Reason for Recall:
CGMP Deviations

Recall Number:
D-0315-2025

Code Information:
Lot # 17230819, exp. date Mar-25

Product Description:
Propafenone Hydrochloride Extended-Release Capsules 325mg, 60-count bottle, Rx Only Manufactured by: Glenmark Pharmaceuticals Limited, Pithampur, Madhya Pradesh 454775, India, Manufactured for: Glenmark Pharmaceuticals Inc. USA, Mahwah, NJ 07430. NDC# 68462-409-60

Product Quantity:
N/A

Reason for Recall:
CGMP Deviations

Recall Number:
D-0316-2025

Code Information:
Lot # 17230767, exp. date Mar-25

Product Description:
Solifenacin Succinate Tablets 10MG, a. 30-count bottle (NDC# 68462-387-30), b. 90-Count Bottle (NDC 68462-387-90),Rx Only, Manufactured by: Glenmark Pharmaceuticals Limited, Pithampur, Madhya Pradesh 454775, India, Manufactured for: Glenmark Pharmaceuticals Inc. USA, Mahwah, NJ 07430.

Product Quantity:
N/A

Reason for Recall:
CGMP Deviations

Recall Number:
D-0317-2025

Code Information:
Lot # 17230762, exp. date Mar-25

Product Description:
Voriconazole Tablets 200 mg, 30-count bottle, Rx Only, Manufactured by: Glenmark Pharmaceuticals Limited, Pithampur, Madhya Pradesh 454775, India, Manufactured for: Glenmark Pharmaceuticals Inc. USA, Mahwah, NJ 07430. NDC# 68462-573-30

Product Quantity:
N/A

Reason for Recall:
CGMP Deviations

Recall Number:
D-0318-2025

Code Information:
Lot # 17230853, exp. date Mar-25 17231271, exp. date May-25 17231300, exp. date May-25 17242050, exp. date Oct-26 17231046, exp. date Apr-25 17241156, exp. date Jun-26 17241388, exp. date Jul-26 17241800, exp. date Sep-26

Product Description:
Voriconazole Tablets 50mg, 30-count bottle, Rx Only, Manufactured by: Glenmark Pharmaceuticals Limited, Pithampur, Madhya Pradesh 454775, India, Manufactured for: Glenmark Pharmaceuticals Inc. USA, Mahwah, NJ 07430. NDC# 68462-572-30.

Product Quantity:
N/A

Reason for Recall:
CGMP Deviations

Recall Number:
D-0319-2025

Code Information:
Lot # 17231045, exp. date Apr-25

Product Description:
Gabapentin Tablets 600mg, 500-count bottles, Rx Only, Manufactured by: Glenmark Pharmaceuticals Limited, Pithampur, Madhya Pradesh 454775, India, Manufactured for: Glenmark Pharmaceuticals Inc. USA, Mahwah, NJ 07430. NDC# 68462-126-05.

Product Quantity:
N/A

Reason for Recall:
CGMP Deviations

Recall Number:
D-0320-2025

Code Information:
Lot # 17231015, exp. date Apr-25 17231128, exp. date Apr-25 17231138, exp. date Apr-25 17231139, exp. date Apr-25 17231143, exp. date Apr-25 17231144, exp. date Apr-25 17231848, exp. date Aug-25 17231898, exp. date Aug-25 17231977, exp. date Aug-25 17231978, exp. date Aug-25 17232015, exp. date Aug-25 17232016, exp. date Aug-25 17232017, exp. date Aug-25 17232034, exp. date Aug-25 17232041, exp. date Aug-25 17232396, exp. date Nov-25 17232406, exp. date Nov-25 17232410, exp. date Nov-25 17232490, exp. date Nov-25 17240326, exp. date Jan-26 17240327, exp. date Jan-26 17240383, exp. date Feb-26 17240395, exp. date Feb-26 17241863, exp. date Oct-26 17241869, exp. date Oct-26 17241870, exp. date Oct-26 17231256, exp. date May-25 17231386, exp. date May-25 17231387, exp. date May-25 17231407, exp. date May-25 17231417, exp. date May-25 17231418, exp. date May-25 17231754, exp. date Jul-25 17240085, exp. date Dec-25 17240117, exp. date Dec-25 17240131, exp. date Dec-25

Product Description:
Lacosamide Tablets 200mg, 60-count bottle, Rx Only, Manufactured by: Glenmark Pharmaceuticals Limited, Pithampur, Madhya Pradesh 454775, India, Manufactured for: Glenmark Pharmaceuticals Inc. USA, Mahwah, NJ 07430. NDC# 68462-681-60.

Product Quantity:
N/A

Reason for Recall:
CGMP Deviations

Recall Number:
D-0321-2025

Code Information:
Lot # 17230982, exp. date Apr-25 17230986, exp. date, Apr-25 17231001, exp. date, Apr-25 17240197, exp. date Jan-26 17240198, exp. date Jan-26 17240215, exp. date Jan-26 17240846, exp. date Apr-26 17240847, exp. date Apr-26

Product Description:
Frovatriptan Succinate Tablets 2.5mg, 9-count bottle, Rx Only, Manufactured by: Glenmark Pharmaceuticals Limited, Pithampur, Madhya Pradesh

454775, India, Manufactured for: Glenmark Pharmaceuticals Inc. USA, Mahwah, NJ 07430. NDC# 68462-694-97

Product Quantity:
N/A

Reason for Recall:
CGMP Deviations

Recall Number:
D-0322-2025

Code Information:
Lot # 17231352, exp. date Jun-25 17231649, exp. date Jul-25

Product Description:
Rufinamide Tablets 200mg, 120-count bottle, Rx Only, Manufactured by: Glenmark Pharmaceuticals Limited, Pithampur, Madhya Pradesh 454775, India, Manufactured for: Glenmark Pharmaceuticals Inc. USA, Mahwah, NJ 07430. NDC# 68462-713-08

Product Quantity:
N/A

Reason for Recall:
CGMP Deviations

Recall Number:
D-0323-2025

Code Information:
Lot # 17231643, exp. date Jul-25 17231644, exp. date Jul-25

Product Description:
Nitroglycerin Sublingual Tablets 0.4MG 100-count carton, Rx Only, Manufactured by: Glenmark Pharmaceuticals Limited, Pithampur, Madhya Pradesh 454775, India, Manufactured for: Glenmark Pharmaceuticals Inc. USA, Mahwah, NJ 07430. NDC# 68462-639-45.

Product Quantity:
N/A

Reason for Recall:
CGMP Deviations

Recall Number:
D-0324-2025

Code Information:
Lot # 17232024, exp. date Aug-25 17232071, exp. date Sep-25 17232072, exp. date Sep-25

Product Description:
Pravastatin Sodium Tablets 80mg, 90-count bottle, Rx Only, Manufactured by: Glenmark Pharmaceuticals Limited, Pithampur, Madhya Pradesh 454775, India, Manufactured for: Glenmark Pharmaceuticals Inc. USA, Mahwah, NJ 07430. NDC# 68462-198-90.

Product Quantity:
N/A

Reason for Recall:
CGMP Deviations

Recall Number:
D-0325-2025

Code Information:
Lot # 17221771, exp. date Aug-25 17230930, exp. date Apr-26 17230931, exp. date Apr-26 17231252, exp. date May-26 17231274, exp. date May-26 17231855, exp. date Aug-26 17231916, exp. date Aug-26 17231917, exp. date Aug-26 17231945, exp. date Aug-26

Product Description:
Fluphenazine Hydrochloride Tablets, 10mg, 100-Count Bottle, Rx Only, Manufactured by: Glenmark Pharmaceuticals Limited, Pithampur, Madhya Pradesh 454775, India, Manufactured for: Glenmark Pharmaceuticals Inc. USA, Mahwah, NJ 07430. NDC# 68462-338-01

Product Quantity:
N/A

Reason for Recall:

CGMP Deviations

Recall Number:
D-0326-2025

Code Information:
Lot # 17232206, exp. date Sep-25

Product Description:
Fluphenazine Hydrochloride Tablets 2.5mg, 100-count bottle, Rx Only, Manufactured by: Glenmark Pharmaceuticals Limited, Pithampur, Madhya Pradesh 454775, India, Manufactured for: Glenmark Pharmaceuticals Inc. USA, Mahwah, NJ 07430. NDC# 68462-336-01

Product Quantity:
N/A

Reason for Recall:
CGMP Deviations

Recall Number:
D-0327-2025

Code Information:
Lot # 17232214, exp. date Sep-25

Product Description:
Metformin Hydrochloride Extended-Release Tablets 1000mg, 90-count bottle. Manufactured by: Glenmark Pharmaceuticals Limited, Pithampur, Madhya Pradesh 454775, India, Manufactured for: Glenmark Pharmaceuticals Inc. USA, Mahwah, NJ 07430. NDC 68462-521-90.

Product Quantity:
N/A

Reason for Recall:
CGMP Deviations

Recall Number:
D-0328-2025

Code Information:
Lot # 17232088, exp. date Sep-25 17232093, exp. date Sep-25

Product Description:
Indomethacin Extended-Release Capsules, 75mg, 60-count bottles, Manufactured by: Glenmark Pharmaceuticals Limited, Pithampur, Madhya Pradesh 454775, India, Manufactured for: Glenmark Pharmaceuticals Inc. USA, Mahwah, NJ 07430. NDC# 68462-325-60

Product Quantity:
N/A

Reason for Recall:
CGMP Deviations

Recall Number:
D-0329-2025

Code Information:
Lot # 17232323, exp. date Oct-25 17232335, exp. date Oct-25 17232323, exp. date Oct-25

Product Description:
Lacosamide Tablets, 100mg , 60-count bottle, Rx Only, Manufactured by: Glenmark Pharmaceuticals Limited, Pithampur, Madhya Pradesh 454775, India, Manufactured for: Glenmark Pharmaceuticals Inc. USA, Mahwah, NJ 07430. NDC# 68462-679-60

Product Quantity:
N/A

Reason for Recall:
CGMP Deviations

Recall Number:
D-0330-2025

Code Information:
Lot # 17232533, exp. date Nov-25 17232534, exp. date Nov-25 17240606, exp. date Mar-26 17240619, exp. date Mar-26 17240911, exp. date May-26 17240912, exp. date May-26 17241121, exp. date Jun-26 17241124, exp. date Jun-26

Product Description:
Nitroglycerin Sublingual Tablets 0.3MG, 100-count bottles, Manufactured by: Glenmark Pharmaceuticals Limited, Pithampur, Madhya Pradesh 454775, India, Manufactured for: Glenmark Pharmaceuticals Inc. USA, Mahwah, NJ 07430.NDC# 68462-638-01

Product Quantity:
N/A

Reason for Recall:
CGMP Deviations

Recall Number:
D-0331-2025

Code Information:
Lot # 17232361, exp. date Nov-25 17232367, exp. date Nov-25

Product Description:
Saxagliptin Tablets 5mg, a). 30-count bottle (NDC# 68462-727-30) b.) 90-count bottle (68462-727-90), Rx Only, Manufactured by: Glenmark Pharmaceuticals Limited, Pithampur, Madhya Pradesh 454775, India, Manufactured for: Glenmark Pharmaceuticals Inc. USA, Mahwah, NJ 07430.

Product Quantity:
N/A

Reason for Recall:
CGMP Deviations

Recall Number:
D-0332-2025

Code Information:
Lot # 17232460, exp. date Nov-25 17232460, exp. date Nov-25 17241194, exp. date Jun-26 17241194, exp. date Jun-26

Product Description:
Solifenacin Succinate Tablets 5mg, a.) 30-count bottle (NDC# 68462-386-30) b.) 90-count bottle (NDC# 68462-386-90), Rx Only. Manufactured by: Glenmark Pharmaceuticals Limited, Pithampur, Madhya Pradesh 454775, India, Manufactured for: Glenmark Pharmaceuticals Inc. USA, Mahwah, NJ 07430.

Product Quantity:
N/A

Reason for Recall:
CGMP Deviations

Recall Number:
D-0333-2025

Code Information:
Lot # 17232395, exp. date Nov-25 17232400, exp. date Nov-25 17232395, exp. date Nov-25

Product Description:
Teriflunomide Tablets, 14mg, 30-count bottle, Rx Only, Manufactured by: Glenmark Pharmaceuticals Limited, Pithampur, Madhya Pradesh 454775, India, Manufactured for: Glenmark Pharmaceuticals Inc. USA, Mahwah, NJ 07430. NDC# 68462-424-30

Product Quantity:
N/A

Reason for Recall:
CGMP Deviations

Recall Number:
D-0334-2025

Code Information:
Lot # 17232462, exp. date Nov-25

Product Description:
Ranolazine Extended-Release Tablets 1000mg, 60-count bottle, Rx Only, Manufactured by: Glenmark Pharmaceuticals Limited, Pithampur, Madhya Pradesh 454775, India, Manufactured for: Glenmark Pharmaceuticals Inc. USA, Mahwah, NJ 07430. NDC# 68462-320-60

Product Quantity:

N/A

Reason for Recall:
CGMP Deviations

Recall Number:
D-0335-2025

Code Information:
Lot # 17240040, exp. date Dec-25

Product Description:
Carvedilol Tablets, USP 12.5 mg, 500-count bottle, Rx Only, Manufactured by: Glenmark Pharmaceuticals Limited, Pithampur, Madhya Pradesh 454775, India, Manufactured for: Glenmark Pharmaceuticals Inc. USA, Mahwah, NJ 07430 NDC# 68462-164-05.

Product Quantity:
N/A

Reason for Recall:
CGMP Deviations

Recall Number:
D-0336-2025

Code Information:
Lot # 17240238, exp. date Jan-26 17240243, exp. date Jan-26 17240245, exp. date Jan-26 17240248, exp. date Jan-26

Product Description:
Lacosamide Tablets, 50mg, 60-count bottles, Rx Only, Manufactured by: Glenmark Pharmaceuticals Limited, Pithampur, Madhya Pradesh 454775, India, Manufactured for: Glenmark Pharmaceuticals Inc. USA, Mahwah, NJ 07430.NDC# 68462-678-60

Product Quantity:
N/A

Reason for Recall:
CGMP Deviations

Recall Number:
D-0337-2025

Code Information:
Lot # 17240221, exp. date Jan-26 17240222, exp. date Jan-26

Product Description:
Prochlorperazine Maleate Tablets, 10mg, 100-count bottles, Rx Only, Manufactured by: Glenmark Pharmaceuticals Limited, Pithampur, Madhya Pradesh 454775, India, Manufactured for: Glenmark Pharmaceuticals Inc. USA, Mahwah, NJ 07430. NDC# 68462-890-01

Product Quantity:
N/A

Reason for Recall:
CGMP Deviations

Recall Number:
D-0338-2025

Code Information:
Lot # 17240254, exp. date Jan-26 17240257, exp. date Jan-26

Product Description:
Rosuvastatin Tablets 40mg, 30-count bottle, Rx Only, Manufactured by: Glenmark Pharmaceuticals Limited, Pithampur, Madhya Pradesh 454775, India, Manufactured for: Glenmark Pharmaceuticals Inc. USA, Mahwah, NJ 07430. NDC# 68462-264-30

Product Quantity:
N/A

Reason for Recall:
CGMP Deviations

Recall Number:
D-0339-2025

Code Information:
Lot # 17240389, exp. date Feb-26 17240390, exp. date Feb-26 17240426, exp. date Feb-26 17240427, exp. date Feb-26 17240428, exp. date Feb-26 17240778, exp. date Apr-26 17241055, exp. date May-26 17241074, exp. date Jun-26 17241075, exp. date Jun-26 17241091, exp. date Jun-26 17241100, exp. date Jun-26

Product Description:
Colesvelam Hydrocholoride Tablets 625mg, 180-count bottle, Rx Only, Manufactured by: Glenmark Pharmaceuticals Limited, Pithampur, Madhya Pradesh 454775, India, Manufactured for: Glenmark Pharmaceuticals Inc. USA, Mahwah, NJ 07430. NDC# 68462-433-18

Product Quantity:
N/A

Reason for Recall:
CGMP Deviations

Recall Number:
D-0340-2025

Code Information:
Lot # 17240669, exp. date Mar-26 17240876, exp. date Apr-26 17240883, exp. date May-26 17240909, exp. date May-26 17240914, exp. date May-26 17240927, exp. date May-26

Product Description:
Pravastatin Sodium Tablets, 20mg, a).500-count bottle (NDC# 68462-196-05), b). 90-count bottle (NDC# 68462-196-90), Rx only, Manufactured by: Glenmark Pharmaceuticals Limited, Pithampur, Madhya Pradesh 454775, India, Manufactured for: Glenmark Pharmaceuticals Inc. USA, Mahwah, NJ 07430.

Product Quantity:
N/A

Reason for Recall:
CGMP Deviations

Recall Number:
D-0341-2025

Code Information:
Lot # 17230810, exp. date Mar-26 17230811, exp. date Mar-26 17230810, exp. date Mar-26 17232501, exp. date Nov-26 17232502, exp. date Nov-26

Product Description:
Diltiazem Hydrochloride Extended-Release Capsules 12HR 120mg, 100-count bottle, Rx, Only. Manufactured by: Glenmark Pharmaceuticals Limited, Pithampur, Madhya Pradesh 454775, India, Manufactured for: Glenmark Pharmaceuticals Inc. USA, Mahwah, NJ 07430. NDC# 68462-562-01

Product Quantity:
N/A

Reason for Recall:
CGMP Deviations

Recall Number:
D-0342-2025

Code Information:
Lot # 17241067, exp. date May-26 17241628, exp. date Aug-26

Product Description:
Lacosamide Tablets 150mg, 60-count bottle, Rx Only, Manufactured by: Glenmark Pharmaceuticals Limited, Pithampur, Madhya Pradesh 454775, India, Manufactured for: Glenmark Pharmaceuticals Inc. USA, Mahwah, NJ 07430.NDC# 68462-680-60.

Product Quantity:
N/A

Reason for Recall:
CGMP Deviations

Recall Number:
D-0343-2025

Code Information:
Lot # 17241125, exp. date Jun-26 17242202, exp. date Nov-26 17242204, exp. date Dec-26

Product Description:
Clindamycin Hydrochloride Capsules, USP, 300mg, 100-count bottles, Manufactured by: Glenmark Pharmaceuticals Limited, Pithampur, Madhya Pradesh 454775, India, Manufactured for: Glenmark Pharmaceuticals Inc. USA, Mahwah, NJ 07430.NDC# 68462-144-01

Product Quantity:
N/A

Reason for Recall:
CGMP Deviations

Recall Number:
D-0344-2025

Code Information:
Lot # 17241278, exp. date Jul-26 17241297, exp. date Jul-26 17241304, exp. date Jul-26 17241315, exp. date Jul-26 17241327, exp. date Jul-26

Product Description:
Saxagliptin Tablets, USP, 2.5mg, a). 30-count bottle (NDC# 68462-726-30), b).90-count bottle(NDC# 68462-726-90), Manufactured by: Glenmark Pharmaceuticals Limited, Pithampur, Madhya Pradesh 454775, India, Manufactured for: Glenmark Pharmaceuticals Inc. USA, Mahwah, NJ 07430.

Product Quantity:
N/A

Reason for Recall:
CGMP Deviations

Recall Number:
D-0345-2025

Code Information:
Lot # 17241788, exp. date Sep-26 17241821, exp. date Sep-26 17241822, exp. date Sep-26

Product Description:
Naproxen Sodium Tablets, USP, 550mg, 100-count bottles, Rx Only, Manufactured by: Glenmark Pharmaceuticals Limited, Pithampur, Madhya Pradesh 454775, India, Manufactured for: Glenmark Pharmaceuticals Inc. USA, Mahwah, NJ 07430. NDC# 68462-179-01

Product Quantity:
N/A

Reason for Recall:
CGMP Deviations

Recall Number:
D-0346-2025

Code Information:
Lot # 17231956, exp. date Aug-25

Product Description:
Acetaminophen and Ibuprofen (NSAID) Tablets, 250 mg/125 mg a). 144-count packets (NDC# 72657-157-74), b). 216-count packets(72657-157-76),Distributed by: Glenmark Therapeutics Inc., USA, Mahwah, NJ 07430, Product of India

Product Quantity:
N/A

Reason for Recall:
CGMP Deviations

Recall Number:
D-0347-2025

Code Information:
Lot # 17241302, exp. date Jul-26 Amazon & Walmart 17241140, exp. date Jul-26 Amazon & Walmart 17241141, exp. date Jul-26 Amazon & Walmart

Product Description:
Cetirizine Hydrochloride Tablets, USP, 10mg, 365-count packs, Rx Only, Manufactured for: Glenmark Therapeutics Inc., Distributed by: Amazon. NDC# 72657-129-35

Product Quantity:
N/A

Reason for Recall:
CGMP Deviations

Recall Number:
D-0348-2025

Code Information:
Lot # 17231980, ep.. date Aug-25 Amazon 17232044, ep.. date Aug-25 Walmart 17241436, ep.. date Jul-26 Amazon 17241437, ep.. date Jul-26 Amazon 17241455, ep.. date Jul-26 Amazon 17241456, ep.. date Aug-26 Amazon 17241457, ep.. date Aug-26 Amazon 17241892, ep.. date Oct-26 Amazon 17241893, ep.. date Oct-26 Amazon

Product Description:
Pravastatin Sodium Tablets, USP, 20mg, a).90-count bottle, Rx Only, Mfd for: Northstar Rx LLC, Memphis, TN 38141, Mfd by: Glenmark Pharmaceuticals Limited, Pithampur, Madhya Pradesh 454775, India. NDC# 16714-559-01

Product Quantity:
N/A

Reason for Recall:
CGMP Deviations

Recall Number:
D-0349-2025

Code Information:
Lot # 17230810, exp. date Mar-26

Product Description:
Pravastatin Sodium Tablets, USP, 80mg, a).90-count bottle (16714-570-01), b). 500-count bottle (NDC 16714-570-02), Rx Only, Mfd for: Northstar Rx LLC, Memphis, TN 38141, Mfd by: Glenmark Pharmaceuticals Limited, Pithampur, Madhya Pradesh 454775, India

Product Quantity:
N/A

Reason for Recall:
CGMP Deviations

Recall Number:
D-0350-2025

Code Information:
Lot # 17221770, exp. date Aug-25 17221774, exp. date Aug-25 17231251, exp. date May-26 17231262, exp. date May-26 17232112, exp. date Sep-26 17232133, exp. date Sep-26

Product Description:
Propafenone Hydrochloride Extended-Release Capsules USP, 225mg 60-count bottles, Rx Only, Mfd by: Glenmark Pharmaceuticals Limited, Pithampur, Madhya Pradesh 454775, India. NDC# 16714-825-01.

Product Quantity:
N/A

Reason for Recall:
CGMP Deviations

Recall Number:
D-0351-2025

Code Information:
Lot # 17230819, exp. date Mar-25

Product Description:
Propafenone Hydrochloride Extended-Release Capsules, USP 325mg,60-count bottles, Rx Only, Mfd for: Northstar Rx LLC, Memphis, TN 38141, Mfd by: Glenmark Pharmaceuticals Limited, Pithampur, Madhya Pradesh 454775, India. NDC# 16714-826-01

Product Quantity:
N/A

Reason for Recall:
CGMP Deviations

Recall Number:
D-0352-2025

Code Information:
Lot # 17230767, exp. date Mar-25

Class II Drugs Event

Event ID:
96508

Product Type:
Drugs

Status:
Ongoing

Date Terminated:
N/A

Recall Initiation Date:
03/12/2025

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
04/09/2025

Initial Firm Notification of Consignee or Public:
E-Mail

Recalling Firm:
Alchemee, LLC
3 Skyline Dr
Hawthorne, NY 10532-2174
United States

Distribution Pattern:
Nationwide in the USA

Associated Products

Product Description:
Proactiv Emergency Blemish Relief (Benzoyl Peroxide 5%), 0.33 oz. (9.45 g), Distributed by Alchemee LLC, Santa Monica, CA 90401, Made in the USA, UPC 7 35786 01921 1, UPC 8 42944 10223 1, and also packaged as a twin pack UPC 8 42944 10241 5,

Product Quantity:
38,237 bottles

Reason for Recall:
Chemical contamination: Presence of benzene

Recall Number:
D-0359-2025

Code Information:
Lots V3304A, V3305A, Exp 10/31/2025

Product Description:
Proactiv Skin Smoothing Exfoliator (Benzoyl Peroxide 2.5%), Packaged as a) 6 fl. oz. (177.4 mL), UPC 7 35786 01528 2; b) 0.33 OZ (9.45g), UPC 8 42944 10223 1; Distributed by Alchemee, LLC, Santa Monica, CA 90401,

Product Quantity:
3,500 bottles

Reason for Recall:
Chemical contamination: Presence of benzene

Recall Number:
D-0360-2025

Code Information:
Lot, V4204A, Exp 07/31/2025

Class II Drugs Event

Event ID:
96553

Product Type:
Drugs

Status:
Ongoing

Date Terminated:
N/A

Recall Initiation Date:
03/21/2025

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
04/04/2025

Initial Firm Notification of Consignee or Public:
E-Mail

Recalling Firm:
Zydus Pharmaceuticals (USA) Inc
73 Route 31 N
Pennington, NJ 08534-3601
United States

Distribution Pattern:
US Nationwide.

Associated Products

Product Description:
Venlafaxine Tablets, USP, 75 mg, 100 Tablets, Rx only, Mfg. by: Zydus Lifesciences Ltd, Ahmedabad, India, Dist. by: Zydus Pharmaceuticals (USA) Inc., Pennington, NJ 08534, NDC 68382-021-01.

Product Quantity:
13,128 100-Count Bottles

Reason for Recall:
Presence of Foreign Substance: Product complaint received for the presence of foreign material embedded resembling a metal shaving in one tablet.

Recall Number:
D-0310-2025

Code Information:
Lot #: M314265, Exp.: 31 October 2025.

Class II Drugs Event

Event ID:
96569

Product Type:
Drugs

Status:
Ongoing

Date Terminated:
N/A

Recall Initiation Date:
03/21/2025

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
04/08/2025

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Somerset Therapeutics Private Limited
54/1 Budihal Village
Bengaluru
India

Distribution Pattern:
U.S. Nationwide

Associated Products

Product Description:
Methocarbamol Injection USP 100mg/mL (10mL), Single-dose vial, Rx Only, Manufactured for: Somerset Therapeutics, LLC, Somerset, NJ 08873, NDC# 70069-101-25

Product Quantity:
506,080 vials

Reason for Recall:
Lack of Assurance of Sterility: Media fill with bacterial contamination

Recall Number:
D-0354-2025

Code Information:
A240304, exp. date 05/2026 A240305, exp. date 05/2026 A240320, exp. date 05/2026 A240322, exp. date 05/2026 A240334, exp. date 05/2026 A240335, exp. date 05/2026 A240340, exp. date 05/2026 A240342, exp. date 06/2026 A240347, exp. date 06/2026 A240385, exp. date 06/2026 A240391, exp. date 06/2026 A240326, exp. date 05/2026

Product Description:
Haloperidol Decanoate Injection 50mg/mL (1mL), Single-dose vial, Rx Only, Manufactured for: Somerset Therapeutics, LLC, Somerset, NJ 08873, NDC# 70069-381-01

Product Quantity:
997 vials

Reason for Recall:
Lack of Assurance of Sterility: Media fill with bacterial contamination

Recall Number:
D-0355-2025

Code Information:
A240467A, exp. date 07/2026 A240467C, exp. date 07/2026

Product Description:
Haloperidol Decanoate Injection 50mg/mL (1mL), Single-dose vial, Rx Only, Manufactured for: Somerset Therapeutics, LLC, Somerset, NJ 08873, NDC# 68001-580-41.

Product Quantity:
4956 vials

Reason for Recall:
Lack of Assurance of Sterility: Media fill with bacterial contamination

Recall Number:
D-0356-2025

Code Information:
A240467B, exp. date 07/2026

Product Description:
Haloperidol Decanoate Injection 100mg/mL (1mL), Single-dose vial, Rx Only, Manufactured for: Somerset Therapeutics, LLC, Somerset, NJ 08873, NDC# 68001-581-41 & 68001-581-48

Product Quantity:
23,960 vials

Reason for Recall:
Lack of Assurance of Sterility: Media fill with bacterial contamination

Recall Number:
D-0357-2025

Code Information:
A240482A, exp. date 08/2026 A240482B, exp. date 08/2026

Product Description:
Haloperidol Decanoate Injection ,100mg/mL (1mL), Single-dose vial, Rx Only, Manufactured for: Somerset Therapeutics, LLC, Somerset, NJ 08873, NDC# 70069-383-10

Product Quantity:
240 vials

Reason for Recall:
Lack of Assurance of Sterility: Media fill with bacterial contamination

Recall Number:
D-0358-2025

Code Information:
A240482D, exp. date 08/2026

Class II Drugs Event

Event ID:
96605

Product Type:
Drugs

Status:
Ongoing

Date Terminated:
N/A

Recall Initiation Date:
03/31/2025

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
04/08/2025

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
B. Braun Medical Inc
2525 Mcgaw Ave
Irvine, CA 92614-5841
United States

Distribution Pattern:
Product was distributed to 12 distributors who may have further distributed the product nationwide.

Associated Products

Product Description:
0.9% Sodium chloride Irrigation USP, Isotonic Solution for Irrigation, 500 mL Plastic Irrigation Container (PIC), B. Braun Medical, Inc., Bethlehem, PA 18018-3524 USA, NDC 0264-2201-10

Product Quantity:
32,256 Bottles

Reason for Recall:
Presence of Particulate Matter

Recall Number:
D-0353-2025

Code Information:
Lot # J4K936, Exp 7/31/2027

Class II Drugs Event

Event ID:
96626

Product Type:
Drugs

Status:
Ongoing

Date Terminated:
N/A

Recall Initiation Date:
04/03/2025

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
04/10/2025

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:
Nationwide within U.S - MS, AL, TN, VT, OH, ND, MN, WI, SC, AR, FL, IN, LA, NJ, AZ, TX, KY and PA

Associated Products

Product Description:
chlorproMAZINE Hydrochloride Tablets, USP 10 mg, Rx Only, 100 Tablets bottles, Manufactured by: Zydus Lifesciences Ltd., Baddi, India, Distributed by: Zydus Pharmaceuticals (USA) Inc., Pennington, NJ 08534, NDC 70710-1129-1

Product Quantity:
3144 bottles, pack size: 100's Count

Reason for Recall:
CGMP deviations: presence of N-Nitroso-Desmethyl Chlorpromazine impurity above the recommended interim limit

Recall Number:
D-0361-2025

Code Information:
Lot #: Z400069, Exp.: 12/31/2025

Class III Drugs Event

Event ID:
96415

Product Type:
Drugs

Status:
Ongoing

Date Terminated:
N/A

Recall Initiation Date:
03/04/2025

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
04/04/2025

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
SUN PHARMACEUTICAL INDUSTRIES INC
2 Independence Way
Princeton, NJ 08540-6620
United States

Distribution Pattern:
Nationwide in the USA

Associated Products

Product Description:
Gabapentin Capsules, USP 300 mg, Rx Only, Packaged in a) 500-count bottles, NDC 62756-138-05; b) 1000-count bottles, NDC 62756-138-04, Distributed by: Sun Pharmaceutical Industries, Inc. Cranbury, NJ 08512, Manufactured by: Sun Pharmaceutical Industries Ltd. Halol-Baroda Highway, Halol-389 350, Gujarat, India.

Product Quantity:
12,876 bottles

Reason for Recall:
Cross Contamination

Recall Number:
D-0311-2025

Code Information:
Lot # a) HAD1458A, Exp. date 04/2025, HAD2718A, Exp. date 07/2025, b) HAD3432A, exp. date 08/2025

Product Description:
Gabapentin Capsules, USP 400 mg, Rx Only, Packaged in a) 500-count bottles, NDC 62756-139-05; b) 1000-count bottles, NDC 62756-139-04; Distributed by: Sun Pharmaceutical Industries, Inc. Cranbury, NJ 08512, Manufactured by: Sun Pharmaceutical Industries Ltd. Halol-Baroda Highway, Halol-389 350, Gujarat, India.

Product Quantity:
852 bottles

Reason for Recall:
Cross Contamination

Recall Number:
D-0312-2025

Code Information:
Lot # a) HAD1712B, Exp. date 03/2025 b) HAD1712C, exp. date 03/2025