Enforcement Report - Week of January 31, 2024

Class I Drugs Event

Event ID:
93693

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
12/21/2023

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
01/25/2024

Initial Firm Notification of Consignee or Public:
Press Release

Recalling Firm:
PFIZER
66 Hudson St
New York NY United States

Distribution Pattern:
Nationwide in the USA, Netherlands and Libya

Associated Products

Product Description:
Bleomycin for Injection, USP, 15 units per vial, 1 single dose glass fliptop vial, Rx Only, Distributed by: Hospira, Inc., Lake Forest, IL 68045, NDC 61703-332-18

Product Quantity:
3,546 vials

Reason for Recall:
Presence of particulate matter: glass

Recall Number:
D-0261-2024

Code Information:
Lot #: BL12206A, Exp date 06/30/2024

Class II Drugs Event

Event ID:
93703

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
12/29/2023

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
01/24/2024

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Strides Pharma Inc.
2 Tower Center Blvd Ste 1102
East Brunswick NJ United States

Distribution Pattern:
Nationwide in the USA

Associated Products

Product Description:
Methoxsalen Capsules, USP 10mg, 50-count bottle, Rx Only, Manufactured by: Strides Pharma Science Ltd. Bengaluru - 562106, India. Distributed by:Strides Pharma Inc. East Brunswick, NJ 08816, NDC 64380-752-16

Product Quantity:
396 50-count bottles

Reason for Recall:
Failed Dissolution Specifications

Recall Number:
D-0260-2024

Code Information:
Lot #: 7253092B, Exp Date 09/30/2025

Class II Drugs Event

Event ID:
93719

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
01/04/2024

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
01/22/2024

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Glenmark Pharmaceuticals Inc., USA
750 Corporate Dr
Mahwah NJ United States

Distribution Pattern:
USA Nationwide

Associated Products

Product Description:
Fluocinolone Acetonide Oil, 0.01% (Ear Drops), package in 1 Oz. (20 mL fill volume) bottle, Rx only, Manufactured by: Glenmark Pharmaceuticals Ltd., Village: Kishanpura, Baddi Nalagarh Road, District: Solan, Himachal Pradesh - 173205, India, Manufactured for: Glenmark Pharmaceuticals Inc., USA, Mahwah, NJ 07430, NDC 68462-185-56

Product Quantity:
38,496 bottles

Reason for Recall:
Failed Excipient Specifications: OOS for assay of Isopropyl Alcohol

Recall Number:
D-0259-2024

Code Information:
Lot #: 05220346, 05220369 Exp 1/31/ 2024; 05220582, Exp 2/29/2024; 05220861 Exp 3/31/2024

Class II Drugs Event

Event ID:
93747

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
01/10/2024

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
01/25/2024

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
BE PHARMACEUTICALS AG
Bundesstrasse 3
Zug Switzerland

Distribution Pattern:
Nationwide in the USA

Associated Products

Product Description:
Fosaprepitant for Injection 150 mg per vial, Sterile lyophilized powder for Intravenous use only after reconstitution and dilution, Single Dose Vial, Rx Only, Distributed by BE Pharmaceuticals Inc. 203 New Edition Court Cary, NC 27511, Made in India, NDC 71839-104-01.

Product Quantity:
22,176 Vials

Reason for Recall:
Lack of Sterility Assurance: Aseptic process simulation failure.

Recall Number:
D-0262-2024

Code Information:
lot #13D012AA, Exp: 08/31/2025

Class II Drugs Event

Event ID:
93820

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
01/18/2024

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
01/25/2024

Initial Firm Notification of Consignee or Public:
Letter

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

Distribution Pattern:
Nationwide in the USA

Associated Products

Product Description:
Cinacalcet Tablets 60mg, Rx Only, 30 Tablets per bottle, Distributed by: Sun Pharmaceutical Industries, Inc., Cranbury, NJ 08512, Manufactured by: Sun Pharmaceutical Industries Limited Survey No. 259/15, Dadra-396 191 (U.T. of D & NH), India, NDC 47335-380-83.

Product Quantity:
1,728 bottles

Reason for Recall:
CGMP Deviations: Microbial contamination was reported in stagnant water in the duct of the manufacturing equipment.

Recall Number:
D-0263-2024

Code Information:
Lot #: DNE0702A, Exp. 06/30/2026

Product Description:
Febuxostat Tablets 40mg, Rx Only, 30 Tablets per bottle, Distributed by: Sun Pharmaceutical Industries, Inc., Cranbury, NJ 08512, Manufactured by: Sun Pharmaceutical Industries Ltd., Survey No. 259/15, Dadra-396 191 (U.T. of D & NH), INDIA, NDC 47335-721-83.

Product Quantity:
55,272 bottles

Reason for Recall:
CGMP Deviations: Microbial contamination was reported in stagnant water in the duct of the manufacturing equipment.

Recall Number:
D-0264-2024

Code Information:
Lot #s: DNE0866B Exp. 06/30/2025, DNE1045A, DNE1046B Exp. 08/31/2025

Product Description:
Febuxostat Tablets 80 mg, Rx Only, 30 Tablets per bottle, Distributed by: Sun Pharmaceutical Industries, Inc., Cranbury, NJ 08512, Manufactured by: Sun Pharmaceutical Industries Ltd., Survey No. 259/15, Dadra-396 191, (U.T. of D & NH), INDIA, NDC 47335-722-83.

Product Quantity:
19,992 bottles

Reason for Recall:
CGMP Deviations: Microbial contamination was reported in stagnant water in the duct of the manufacturing equipment.

Recall Number:
D-0265-2024

Code Information:
Lot #s: DNE0867A Exp. 06/30/2025, DNE0894B Exp. 07/31/2025

Product Description:
Lurasidone Hydrochloride Tablets 60mg, Rx Only, 30 Tablets per bottle, Distributed by: Sun Pharmaceutical Industries, Inc., Cranbury, NJ 08512, Manufactured by: Sun Pharmaceutical Industries Ltd., Survey No. 259/15, Dadra-396 191(U.T. of D & NH), INDIA, NDC 47335-639-83.

Product Quantity:
11,400 bottles

Reason for Recall:
CGMP Deviations: Microbial contamination was reported in stagnant water in the duct of the manufacturing equipment.

Recall Number:
D-0266-2024

Code Information:
Lot #: DNE0620A Exp. 05/31/2025

Product Description:
Lurasidone Hydrochloride Tablets 120mg, Rx Only, 30 Tablets per bottle, Distributed by: Sun Pharmaceutical Industries, Inc., Cranbury, NJ 08512, Manufactured by: Sun Pharmaceutical Industries Ltd., Survey No. 259/15, Dadra-396 191(U.T. of D & NH), INDIA, NDC 47335-579-83.

Product Quantity:
9,408 bottles

Reason for Recall:
CGMP Deviations: Microbial contamination was reported in stagnant water in the duct of the manufacturing equipment.

Recall Number:
D-0267-2024

Code Information:
Lot #s: DNE0621A Exp. 11/30/2024, DNE0815A Exp. 12/31/2024

Product Description:
Mesalamine Delayed-Release Tablets, USP 1.2 g per tablet, Rx Only, 120 Tablets per bottle, Once Daily, Distributed by: Sun Pharmaceutical Industries, Inc., Cranbury, NJ 08512, Manufactured by: Sun Pharmaceutical Industries Limited Survey No. 259/15, Dadra-396 191 (U.T. of D & NH), INDIA, NDC 63304-175-13.

Product Quantity:
10,690 bottles

Reason for Recall:
CGMP Deviations: Microbial contamination was reported in stagnant water in the duct of the manufacturing equipment.

Recall Number:
D-0268-2024

Code Information:
Lot #s: DNE0875A Exp. 01/31/2025; DNE0876A, DNE0877A, DNE1080A, DNE1081A Exp. 02/28/2025; DNE1147A, DNE1148A Exp. 03/31/2025.

Product Description:
Niacin Extended-Release Tablets, USP 1000mg, Rx Only, 90 Tablets per bottle, Distributed by: Sun Pharmaceutical Industries, Inc., Cranbury, NJ 08512, Manufactured by: Sun Pharmaceutical Industries Limited, Survey No. 259/15, Dadra-396 191(U.T. of D & NH), INDIA, NDC 47335-613-81.

Product Quantity:
6552 bottles

Reason for Recall:
CGMP Deviations: Microbial contamination was reported in stagnant water in the duct of the manufacturing equipment.

Recall Number:
D-0269-2024

Code Information:
Lot #: DNE0788A Exp. 07/31/2025

Product Description:
Niacin Extended-Release Tablets, USP 500mg, Rx Only, 90 Tablets per bottle, Distributed by: Sun Pharmaceutical Industries, Inc., Cranbury, NJ 08512, Manufactured by: Sun Pharmaceutical Industries Limited, Survey No. 259/15, Dadra-396 191(U.T. of D & NH), INDIA, NDC 47335-539-81.

Product Quantity:
15,768 bottles

Reason for Recall:
CGMP Deviations: Microbial contamination was reported in stagnant water in the duct of the manufacturing equipment.

Recall Number:
D-0270-2024

Code Information:
Lot #s: DNE0771A Exp. 06/30/2025; DNE0857A, DNE0959A Exp. 07/31/2025.

Product Description:
Zolpidem Tartrate Extended-Release Tablets, USP 6.25 mg, Rx Only, 100 Tablets per bottle, Distributed by: Sun Pharmaceutical Industries, Inc., Cranbury, NJ 08512, Manufactured by: Sun Pharmaceutical Industries Limited, Survey No. 259/15, Dadra-396 191, (U.T. of D & NH), INDIA, NDC 47335-307-88.

Product Quantity:
1220 bottles

Reason for Recall:
CGMP Deviations: Microbial contamination was reported in stagnant water in the duct of the manufacturing equipment.

Recall Number:
D-0271-2024

Code Information:
Lot #: DNE0892A Exp. 07/31/2026

Product Description:
Zolpidem Tartrate Extended-Release Tablets, USP 12.5mg, Rx Only, 100 Tablets per bottle, Distributed by: Sun Pharmaceutical Industries, Inc., Cranbury, NJ 08512, Manufactured by: Sun Pharmaceutical Industries Limited, Survey No. 259/15, Dadra-396 191, (U.T. of D & NH), INDIA, NDC 47335-308-88.

Product Quantity:
14,568 bottles

Reason for Recall:
CGMP Deviations: Microbial contamination was reported in stagnant water in the duct of the manufacturing equipment.

Recall Number:
D-0272-2024

Code Information:
Lot #: DNE0893A Expires 07/31/2026

Product Description:
Fexofenadine Hydrochloride Tablets, USP 180mg, Antihistamine, Allergy, 24 hour, a) 30 Tablets per bottle, NDC 51660-998-30; Distributed by: Ohm Laboratories Inc., New Brunswick, NJ 08901, Made in India, b) 45 Tablets per bottle, NDC 51316-800-45; Distributed by: CVS Pharmacy, Inc., Woonsocket, RI 02895, Made in India, c) 150 Tablets per bottle, NDC 51660-998-55, Distributed by: Ohm Laboratories Inc., New Brunswick, NJ 08901, Made in India.

Product Quantity:
54,504 bottles

Reason for Recall:
CGMP Deviations: Microbial contamination was reported in stagnant water in the duct of the manufacturing equipment.

Recall Number:
D-0273-2024

Code Information:
Lot #s: a) DNE0792A Exp. 06/31/2025; DNE1027A Exp. 08/31/2025. b) DNE0793A Exp. 06/31/2025. c) DNE0789A, DNE0790A, DNE0791A Exp. 06/2025, DNE1026A Exp. 08/31/025.

Class III Drugs Event

Event ID:
93778

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
12/26/2023

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
01/19/2024

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Amerisource Health Services LLC
2550 John Glenn Ave Ste A
Columbus OH United States

Distribution Pattern:
Nationwide in the USA

Associated Products

Product Description:
Benzonatate Capsules, USP, 100 mg, 100 Capsules (10 capsules x 10 unit dose cards), Rx only, Distributed by: American Health Packaging, Columbus, Ohio 43217. Carton NDC 68084-214-01; Individual Dose NDC 68084-214-11

Product Quantity:
6,344 cartons

Reason for Recall:
Superpotent drug: Assay results were slightly above specification at the time zero point.

Recall Number:
D-0257-2024

Code Information:
Lot # 1014208, Exp Mar/31/2025

Not Yet Classified Drugs Event

Event ID:
93702

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
12/26/2023

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Haleon US Holdings LLC
184 Liberty Corner Rd
Warren NJ United States

Distribution Pattern:
USA nationwide

Associated Products

Product Description:
Robitussin Honey CF Max Non-Drowsy Adult (Acetaminophen 650mg, Dextromethorphan HBr 20 mg), a) 4 FL OZ (118mL), NDC 0031-8771-12, SKU: F00031877112 and b) 8 FL OZ (237 mL), NDC 0031-8771-18, SKU: F00031877118 bottles, Distributed by: GSK Consumer Healthcare, Warren, NJ 07059

Product Quantity:

Reason for Recall:
Microbial Contamination of Non-Sterile Products

Recall Number:

Code Information:
a) Lot#: T10810, Exp 10/31/2025 b) Lot#: T08730, T08731, T08732, T08733, Exp 05/31/2025; T10808, Exp 09/30/2025

Product Description:
Robitussin Honey CF Max Nighttime Adult (Acetaminophen 650 mg, Diphenhydramine HCl 25mg), 8 FL OZ (237 mL) bottle, Distributed by: GSK Consumer Healthcare, Warren, NJ 07059, NDC 0031-8770-18, SKU: F00031877018

Product Quantity:

Reason for Recall:
Microbial Contamination of Non-Sterile Products

Recall Number:

Code Information:
Lot#: T08740, T08742, Exp 06/30/2026