Enforcement Report - Week of June 26, 2024

Class II Drugs Event

Event ID:
94611

Product Type:
Drugs

Status:
Ongoing

Date Terminated:
N/A

Recall Initiation Date:
05/17/2024

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
06/20/2024

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Breckenridge Pharmaceutical, Inc
15 Massirio Dr Ste 201
Berlin, CT 06037-2352
United States

Distribution Pattern:
Nationwide in the USA

Associated Products

Product Description:
Duloxetine Delayed-Release Capsules, USP, 60mg, 90-count bottle, Rx Only, Mfr. by: Towa Pharmaceutical Europe, S.L. Martorelles, (Barcelona), Spain, Dist. by: Breckenridge Pharmaceuticals, Inc., Berkeley Heights, NJ 07922. NDC 51991-748-90

Product Quantity:
165,678, 90-count bottles

Reason for Recall:
CGMP Deviations: Presence of Nitrosamine Drug Substance Related Impurity (NDSRI), N-nitroso-duloxetine, above the proposed interim limit.

Recall Number:
D-0562-2024

Code Information:
Lot #: 230035C, Exp. date 11/30/2025; 230101C, Exp. date 12/31/2025

Class II Drugs Event

Event ID:
94685

Product Type:
Drugs

Status:
Ongoing

Date Terminated:
N/A

Recall Initiation Date:
05/23/2024

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
06/14/2024

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Eugia US LLC
279 Princeton Hightstown Rd
East Windsor, NJ 08520-1401
United States

Distribution Pattern:
USA Nationwide

Associated Products

Product Description:
Dexamethasone Sodium Phosphate injection USP, 120mg per 30mL (4mg/mL), 30 mL Multiple-Dose Vial, Rx only, Distributed by: AuroMedics Pharma LLC, 279 Princeton-Hightstown Rd. E. Windsor, NJ 08520, Made in India, NDC 55150-239-30

Product Quantity:
70,125 vials

Reason for Recall:
Failed Impurities/Degradation Specifications: impurity sulfonic acid adduct of dexamethasone phosphate results were above spec.

Recall Number:
D-0555-2024

Code Information:
Lot#: 3DS23001, 3DS23004, Exp 6/30/2024; 3DS23009, 3DS23011, Exp 7/31/2024

Class II Drugs Event

Event ID:
94710

Product Type:
Drugs

Status:
Ongoing

Date Terminated:
N/A

Recall Initiation Date:
05/28/2024

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
06/18/2024

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Consumer Product Partners, LLC
1 Swan Dr
Smyrna, TN 37167-2099
United States

Distribution Pattern:
Nationwide.

Associated Products

Product Description:
Petroleum Jelly, White Petrolatum USP, NET WT 13 OZ (368g), sold under the following brands - Rite Aid, with UPC 0-11822-51349-4; Kroger, with UPC 0-41260-35275-1; Harris Teeter, with UPC 0-72036-75051-8; CVS, with UPC 0-50428-31702-0

Product Quantity:
1015 cases

Reason for Recall:
Labeling: Label Mix up; product labeled as pure white petroleum jelly actually contains petroleum jelly with Lavendar and Chamomile

Recall Number:
D-0560-2024

Code Information:
Rite Aid - lot # 0607983, expiration date: 07/2026, NDC # 11822-3135-2 Kroger- lot # 0607983, expiration date: 07/2026, NDC# 30142-069-27 Harris Teeter - lot # 0607983, expiration date: 07/2026, NDC# 72036-069-37 CVS- lot # 0607983, expiration date: 07/2026, NDC # 59779-069-27

Class II Drugs Event

Event ID:
94712

Product Type:
Drugs

Status:
Ongoing

Date Terminated:
N/A

Recall Initiation Date:
05/28/2024

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
06/17/2024

Initial Firm Notification of Consignee or Public:
N/A

Recalling Firm:
Denison Pharmaceuticals, LLC
1 Powder Hill Rd
Lincoln, RI 02865-4407
United States

Distribution Pattern:
Recalled units were distributed to one customer. 100% recovered (113,544 units) and controlled at Denison Pharmaceuticals.

Associated Products

Product Description:
Little Remedies Gas Relief Drops (Simethicone/Antigas), packaged in 1 fl. oz. (30 mL) bottle with dropper, Dist by Medtech Products Inc., Tarrytown, NY 10591, NDC 63029-103-02

Product Quantity:
113,544 bottles

Reason for Recall:
cGMP deviations: Test results confirmed aypical Burkholderia Cepacia were a result of personnel error.

Recall Number:
D-0557-2024

Code Information:
Lot #: 0855, Exp. 8/31/ 2025

Class II Drugs Event

Event ID:
94714

Product Type:
Drugs

Status:
Ongoing

Date Terminated:
N/A

Recall Initiation Date:
05/22/2024

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
06/17/2024

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
MexHealth LLC
4628 Denwood Rd
La Mesa, CA 91942-8803
United States

Distribution Pattern:
US Nationwide

Associated Products

Product Description:
OSSOS-SANS Reforzado con: Glucosamina Curcuma Ortiga tablets, packaged in a 30-count bottle, DISTRIBUIDOR POR: Naturistas Especializados, Alce Blanco 180-A Fracc. Industrial, Edo. de Mexico C.P. 53370

Product Quantity:
20 bottles

Reason for Recall:
Marketed Without An Approved NDA/ANDA: FDA laboratory analysis found the product to contain undeclared diclofenac and methocarbamol,

Recall Number:
D-0558-2024

Code Information:
Lot Number: H29585, No Expiration date

Class II Drugs Event

Event ID:
94723

Product Type:
Drugs

Status:
Ongoing

Date Terminated:
N/A

Recall Initiation Date:
05/30/2024

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
06/18/2024

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Lupin Pharmaceuticals Inc.
Harborplace Tower 111 S Calvert St Fl 21st
Baltimore, MD 21202-6174
United States

Distribution Pattern:
Nationwide in the US

Associated Products

Product Description:
Cefixime for Oral Suspension USP 200 mg/5 mL (50 mL Pack size), Powder for oral suspension, Rx only, Manufactured for: Lupin Pharmaceuticals, Inc., Baltimore Maryland, Manufactured by: Lupin Limited, Mandideep, India NDC 68180-407-03

Product Quantity:
3,552 bottles

Reason for Recall:
Failed Content Uniformity Specifications

Recall Number:
D-0559-2024

Code Information:
Lot F201519, Expiry: November 2024

Class II Drugs Event

Event ID:
94750

Product Type:
Drugs

Status:
Ongoing

Date Terminated:
N/A

Recall Initiation Date:
06/04/2024

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
06/18/2024

Initial Firm Notification of Consignee or Public:
N/A

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

Distribution Pattern:
Nationwide within the United States

Associated Products

Product Description:
Amoxicillin and Clavulanate Potassium Tablets USP, Chewable 400mg/57mg, 20-count bottles, Rx only, Manufactured in Canada By: Teva Canada Limited, Toronto, Canada M1B 2K9; Manufactured For: Teva Pharmaceuticals USA, Inc., North Wales, PA 19454 NDC 0093-2272-34

Product Quantity:
34,448 bottles

Reason for Recall:
Subpotent Drug

Recall Number:
D-0561-2024

Code Information:
Lot #: 100047634 Exp. Date 4/2025; 35449379A, Exp. Date 7/2024

Class III Drugs Event

Event ID:
94680

Product Type:
Drugs

Status:
Ongoing

Date Terminated:
N/A

Recall Initiation Date:
05/22/2024

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
06/14/2024

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Eugia US LLC
279 Princeton Hightstown Rd
East Windsor, NJ 08520-1401
United States

Distribution Pattern:
USA nationwide.

Associated Products

Product Description:
Eptifibatide injection 20mg/10mL (2mg/mL), 10mL Single-Dose Vial, Rx only, Mfd. In India for: AuroMedics Pharma, LLC, E. Windsor, NJ 08520, NDC 55150-219-10

Product Quantity:
15,500 single dose vials

Reason for Recall:
Failed Impurities/Degradation Specifications: failed related substance identified as Eptifibatide dimer.

Recall Number:
D-0556-2024

Code Information:
Lot #: 3EF22003, Exp 6/30/2025