Enforcement Report - Week of November 29, 2023

Class I Drugs Event

Event ID:
93265

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
10/18/2023

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
11/22/2023

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Exela Pharma Sciences LLC
1245 Blowing Rock Blvd
Lenoir NC United States

Distribution Pattern:
Nationwide

Associated Products

Product Description:
8.4% Sodium Bicarbonate Injection, USP, 50 mEq/50 mL (1mEq/mL), a) 20x50 mL Single Dose Vials (Vial NDC 51754-5001-1; Carton NDC 51754-5001-5) and b) 25x50 mL Single Dose Vials (Vial NDC 51754-5001-1; Carton NDC 51754-5001-4), For Intravenous Use Only, RX Only, Manufactured and Distributed by: Exela Pharma Sciences, LLC, Lenoir, NC 28645; ALSO LABELED 8.4% Sodium Bicarbonate Injection, USP, 50 mEq/50 mL (1mEq/mL), c) 20x50 mL Single Dose Vials, (Vial NDC 72572-740-01; Carton NDC 72572-740-20), Rx Only, Mfd for: Civica, Inc., Lehi, Utah, 84043, Mfd by: Exela Pharma Sciences, LLC, Lenoir, NC 28645.

Product Quantity:
355,220 vials

Reason for Recall:
Presence of Particulate Matter: Silicone

Recall Number:
D-0116-2024

Code Information:
a) P0001429, EXP 11/30/2023 b) P0001900, P0001902, EXP 08/31/2024; P0001903, P0001909, P0001945, EXP 09/30/2024; P0002002, EXP 11/30/2024; P0002052, EXP 12/31/2024 c) P0001912, EXP 08/31/2024

Product Description:
Midazolam in 0.8% Sodium Chloride Injection 100 mg/100 mL (1mg/mL), 100 mL Single-Dose Vial, 25 count carton, Ready to Use For Intravenous Infusion Only Preservative Free, Rx Only, Manufactured and Distributed by Exela Pharma Sciences, LLC, Lenoir, NC 28645, (Vial NDC 51754-2131-1; Carton NDC 51754-2131-4).

Product Quantity:
23,425 vials

Reason for Recall:
Presence of Particulate Matter: Silicone

Recall Number:
D-0117-2024

Code Information:
Lot # 10001088 exp 07/31/2024

Product Description:
ELCYS (cysteine hydrochloride injection), USP, 500 mg/10mL (50 mg/mL), 10x10 mL Single Dose Sterile Vials, For Intravenous Infusion Only, Rx Only, Manufactured and Distributed by Exela Pharma Sciences, LLC, Lenoir, NC 28645, (Vial: NDC 51754-1007-1; Carton: 51754-1007-3).

Product Quantity:
38,200 vials

Reason for Recall:
Presence of Particulate Matter: Silicone

Recall Number:
D-0118-2024

Code Information:
Lot # 10000798, Expiration Date 03/31/2025

Class I Drugs Event

Event ID:
93339

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
10/31/2023

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
11/17/2023

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
The Harvard Drug Group LLC dba Major Pharmaceuticals and Rugby Laboratories
341 Mason Rd
La Vergne TN United States

Distribution Pattern:
Nationwide within the United States

Associated Products

Product Description:
Polyvinyl Alcohol 1.4% Lubricating Eye Drops, packaged in 0.5 FL OZ (15mL) bottles, Dist. by: RUGBY LABORATORIES, Livonia, MI 48152, NDC 0536-1325-94.

Product Quantity:
1,271,810 bottles

Reason for Recall:
Non-Sterility: FDA found insanitary conditions and positive bacterial test results from environmental sampling at the manufacturing facility.

Recall Number:
D-0107-2024

Code Information:
All lots

Product Description:
Lubricating Tears Eye Drops (Dextran/Hypromellose), 0.1%/0.3%, packaged in 0.5 FL OZ (15mL) bottles, Distributed by: RUGBY LABORATORIES, Livonia, MI 48152, NDC 0536-1282-94

Product Quantity:
65,880 bottles

Reason for Recall:
Non-Sterility: FDA found insanitary conditions and positive bacterial test results from environmental sampling at the manufacturing facility.

Recall Number:
D-0108-2024

Code Information:
All lots

Class I Drugs Event

Event ID:
93346

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
10/31/2023

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
12/01/2023

Initial Firm Notification of Consignee or Public:
Press Release

Recalling Firm:
Cardinal Health Inc.
7000 Cardinal Pl
Dublin OH United States

Distribution Pattern:
Nationwide in the USA

Associated Products

Product Description:
LEADER brand Eye Irritation Relief (Polyvinyl alcohol 0.5%, Povidone 0.6%, Tetrahydrozoline Hydrochloride 0.05%), 0.5 FL OZ (15 mL) dropper bottles, Sterile, Distributed By Cardinal Health, Dublin, Ohio 43017, Made in India NDC: 70000-0087-1

Product Quantity:
11629 units

Reason for Recall:
Non-Sterility: FDA found insanitary conditions and positive bacterial test results from environmental sampling at the manufacturing facility.

Recall Number:
D-0131-2024

Code Information:
ALL LOTS

Product Description:
LEADER brand Dry Eye Relief (Carboxymethylcellulose Sodium, 1%); 0.5 FL OZ (15 mL) dropper bottle, Sterile, Distributed By Cardinal Health, Dublin, Ohio. 43017, Made in India NDC: 70000-0089-1

Product Quantity:
21,802 bottles

Reason for Recall:
Non-Sterility: FDA found insanitary conditions and positive bacterial test results from environmental sampling at the manufacturing facility.

Recall Number:
D-0132-2024

Code Information:
ALL LOTS

Product Description:
LEADER brand Lubricant Eye Drops (Carboxymethylcellulose Sodium, 0.5%); 0.5 FL OZ (15 mL) dropper bottles, Sterile, Distributed By Cardinal Health, Dublin, Ohio 43017. Made in India NDC: 70000-0090-1

Product Quantity:
119,871 bottles

Reason for Recall:
Non-Sterility: FDA found insanitary conditions and positive bacterial test results from environmental sampling at the manufacturing facility.

Recall Number:
D-0133-2024

Code Information:
ALL LOTS

Product Description:
LEADER brand Lubricant Eye Drops (Carboxymethylcellulose Sodium, 0.5%); 2 bottles, 0.5 FL OZ (15 mL) dropper bottles, Sterile, Distributed By Cardinal Health, Dublin, Ohio 43017, Made in India NDC:70000-0090-2 (Carton); 70000-0090-1 (Bottle)

Product Quantity:
28477 cartons

Reason for Recall:
Non-Sterility: FDA found insanitary conditions and positive bacterial test results from environmental sampling at the manufacturing facility.

Recall Number:
D-0134-2024

Code Information:
ALL LOTS

Product Description:
LEADER brand Dry Eye Relief (Polyethylene Glycol 400, 0.4% Propylene Glycol, 0.3%); 0.33 FL OZ (10 mL) dropper bottle, Sterile, Distributed By Cardinal Health, Dublin, Ohio 43017, Made in India NDC: 70000-0088-1

Product Quantity:
11,782 bottles

Reason for Recall:
Non-Sterility: FDA found insanitary conditions and positive bacterial test results from environmental sampling at the manufacturing facility.

Recall Number:
D-0135-2024

Code Information:
ALL LOTS

Product Description:
LEADER brand Lubricant Eye Drops (Propylene Glycol, 0.6%); 0.33 FL OZ (10 mL) dropper bottles, Sterile, Distributed By Cardinal Health, Dublin, Ohio 43017. Made in India NDC: 70000-0587-1

Product Quantity:
8,784 bottles

Reason for Recall:
Non-Sterility: FDA found insanitary conditions and positive bacterial test results from environmental sampling at the manufacturing facility.

Recall Number:
D-0136-2024

Code Information:
ALL LOTS

Class II Drugs Event

Event ID:
93199

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
10/18/2023

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
11/20/2023

Initial Firm Notification of Consignee or Public:
E-Mail

Recalling Firm:
Integrity Bio-Chemicals LLC
1100 N Cresson Hwy
Cresson TX United States

Distribution Pattern:
Distributed to one distributor in OK with possibility of further distribution

Associated Products

Product Description:
Integrity Biochem HSC 70-LM, Alcohol Antiseptic 70%, Hand Sanitizer, Lemon Scented Topical Gel, 208.19 L (55 gallons) drum, Integrity Biochem, 1100 North Cresson Hwy, Cresson, TX 76035. Made in the USA NDC: 77512-044-03

Product Quantity:
1 55-gallon drum

Reason for Recall:
CGMP Deviation: Third party test results showing a presence of acetal and acetaldehyde at levels above USP specified amounts.

Recall Number:
D-0109-2024

Code Information:
Lot #: 2133607, Manufacturing Date 11/23/2021 No Exp date on label.

Product Description:
Integrity Biochem HSC70-LV, Alcohol Antiseptic 70%, Hand Sanitizer, Lavender Scented Topical Gel 208.19L (55 gallons) drum, Integrity Biochem, 1100 North Cresson Hwy, Cresson, TX 76035. Made in the USA, NDC: 77512-047-03

Product Quantity:
1 55-gallon drum

Reason for Recall:
CGMP Deviation: Third party test results showing a presence of acetal and acetaldehyde at levels above USP specified amounts.

Recall Number:
D-0110-2024

Code Information:
Lot #: 2133608, No exp Date. Manufacturing Date: 11/23/21

Product Description:
Integrity Biochem HSC 70-VA, Alcohol Antiseptic 70%, Hand Sanitizer, Vanilla Scented Topical Gel 208.19L (55 gallons)- drum. Integrity Biochem, 1100 North Cresson Hwy, Cresson, TX 76035. Made in the USA, NDC: 77512-052-03

Product Quantity:
1-55 gallon drum

Reason for Recall:
CGMP Deviation: Third party test results showing a presence of acetal and acetaldehyde at levels above USP specified amounts.

Recall Number:
D-0111-2024

Code Information:
Lot #: 2134106, No Exp date, Manufacturing Date: 11/23/21

Class II Drugs Event

Event ID:
93278

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
10/20/2023

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
11/21/2023

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
ITF PHARMA INC

850 Cassatt Rd
Berwyn PA United States

Distribution Pattern:
Distributed to one distributor in TN who may have further distributed.

Associated Products

Product Description:
Tiglutik (riluzole) Oral Suspension 50 mg/10 mL (5 mg/mL), 600 mL (two bottles/300 mL each), RX only, Manufactured for ITF Pharma, Inc., Berwyn, PA 19312 USA NDC:70726-0303-1 (carton) and 70726-0303-2 (bottle)

Product Quantity:
1,792 bottles

Reason for Recall:
Failed Viscosity Specifications: Out-of-specification test results for viscosity

Recall Number:
D-0115-2024

Code Information:
LOT# 2231901, Exp. 11/30/2025; 2307901, Exp. 03/31/2026

Class III Drugs Event

Event ID:
93262

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
10/23/2023

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
11/20/2023

Initial Firm Notification of Consignee or Public:
Letter

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

Distribution Pattern:
Nationwide in the USA

Associated Products

Product Description:
Esomeprazole Magnesium Delayed-Release Capsules, USP 20mg, Packaged as (a) 30-count bottle, NDC 68462-390-30; (b) 1000-count Bottle, NDC 68462-390-10: RX Only, Manufactured for: Glenmark, Pharmaceuticals Inc., USA, Mahwah, NJ 07430, Product of India,

Product Quantity:
8,448 30-count bottles, 168 1000-count bottles

Reason for Recall:
Failed Impurities/Degradation Specifications:Out of Specification result reported for the test of organic impurities for the drug product,at the 18 month time point in long term stability study (25¿C/60% RH).

Recall Number:
D-0112-2024

Code Information:
Lot # 17220002, Exp Date 11/30/2023

Class III Drugs Event

Event ID:
93336

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
10/27/2023

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
11/21/2023

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
NCS Healthcare of Kentucky Inc
120 Carroll Knicely Dr
Glasgow KY United States

Distribution Pattern:
Nationwide USA

Associated Products

Product Description:
Buspirone Hydrochloride Tabs USP 10 mg, packaged in a) 15-count blister card (NDC 0615-7718-05) b) 30-count blister card (NDC 0615-7718-39), Rx only, Mfd By Pliva HRVATSKA for Teva USA, PKG by Vangard Glasgow, KY 42141.

Product Quantity:
1,344 cards

Reason for Recall:
Presence of Foreign Tablets: Potential of stray tablet(s) of Amlodipine Besylate 10 mg Tablet within the recalled lots

Recall Number:
D-0113-2024

Code Information:
Lot#: a) 7718-3008, Exp 08/31/2024; b) 7718-3008, Exp 08/31/2024

Product Description:
Lisinopril Tablets USP 20 mg, packaged in a) 15-count blister card (NDC 0615-7718-05), b) 30-count blister card (NDC 0615-8255-39), Rx only, Mfd By Lupin, PKG by Vangard Glasgow, KY 42141.

Product Quantity:
12 cards

Reason for Recall:
Presence of Foreign Tablets: Potential of stray tablet(s) of Amlodipine Besylate 10 mg Tablet within the recalled lots

Recall Number:
D-0114-2024

Code Information:
Lot#: a) 8255-3012, Exp 08/31/2024; b) 8255-3012, Exp 08/31/2024