Enforcement Report - Week of March 6, 2024

Class II Drugs Event

Event ID:
93885

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
01/30/2024

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
02/28/2024

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Brassica Pharma Pvt Ltd
Plot No. T-68, T 68 (Pt), T-63, Midc Tarapur, Boisar
Thane India

Distribution Pattern:
Nationwide within the United States

Associated Products

Product Description:
Equate Lubricant Eye Ointment (Mineral Oil 42.5%, White Petrolatum 57.3%), Packaged in 3.5 gram tubes, Distributed by Walmart Inc., Bentonville, AR 72716, NDC 79903-026-35, UPC 681131395298

Product Quantity:
315,842 units

Reason for Recall:
Lack of Assurance of Sterility

Recall Number:
D-0351-2024

Code Information:
Lot #: A2E01, Exp. Date Apr-24; A2L05, Exp. Date Nov-24, A3B01, Exp. Date Jan-25; A3C01, Exp. Date Feb-25

Product Description:
Equate Stye Lubricant Eye Ointment (Mineral Oil 31.9%, White Petrolatum 57.7%), Packaged in 3.5 g tubes, Distributed by Walmart Inc., Bentonville, AR 72716, NDC 79903-028-35, UPC 681131395304

Product Quantity:
355,633 units

Reason for Recall:
Lack of Assurance of Sterility

Recall Number:
D-0352-2024

Code Information:
Lot #: A2D08, Exp. Date Mar-24; A2F02, Exp. Date May-24; A2I03, Exp. Date Aug-24; A2L03, A2L04, Exp. Date Nov-24; A3C03, A3C05, Exp. Date Feb-25 A3H01, A3H03, Exp. Date Jul-25

Product Description:
CVS Health Lubricant Eye Ointment (Mineral oil 31.9% Emollient, White petrolatum 57.7% Emollient), Packaged in in 3.5 gram tubes, Distributed by: CVS Pharmacy, Inc. One CVS Drive Woonsocket, RI 02895, NDC 76168-707-35, UPC 050428634141

Product Quantity:
159,334 units

Reason for Recall:

Lack of Assurance of Sterility

Recall Number:
D-0353-2024

Code Information:
Lot #: A2F03, Exp. Date May-24; A2I02, Exp. Date Aug-24; A2L02, Exp. Date Nov-24; A3C04, Exp. Date Feb-25; A3H04, Exp. Date Jul-25

Product Description:
Lubricant PM Ointment (Mineral Oil 42.5% and White Petrolatum 57.3%), Packaged in 3.5 gram tubes, Distributed by: AACE Pharmaceuticals, Inc., Fairfield, NJ 07004, NDC 71406-124-35, UPC 371406124356

Product Quantity:
355,120 units

Reason for Recall:
Lack of Assurance of Sterility

Recall Number:
D-0354-2024

Code Information:
Lot #: A2G01, A2G02, Exp. Date Jun-24; A3F08, A3F09, Exp. Date May-25; A3J17, A3J18, Exp. Date Sep-25

Class II Drugs Event

Event ID:
93909

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
02/05/2024

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
02/23/2024

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 U.S.

Associated Products

Product Description:
Mesalamine Extended-Release Capsules, USP 500mg, Rx Only, 120 Capsules per bottle, Manufactured by: Sun Pharmaceutical Industries Limited, Mohali, INDIA, Distributed by: Sun Pharmaceutical Industries, Inc., Cranbury, NJ 08512, NDC 63304-089-13.

Product Quantity:
54,960 bottles

Reason for Recall:
Failed Dissolution Specifications: Out of specification for dissolution.

Recall Number:
D-0350-2024

Code Information:
Lot #s: MHD0606A, MHD0612A, Exp. 04/30/2024; MHD0613A, MHD0652A, MHD0657A, MHD0672A, MHD0673A, Exp. 05/31/2024; MHD0767A, MHD0768A, MHD0769A, MHD0785A, MHD0799A, MHD0800A, MHD0801A, Exp. 06/30/2024; MHD0827A, MHD0828A, MHD0875A, MHD0876A, MHD0898A, MHD0901A, Exp. 07/31/2024; MHD1081A, MHD1082A, MHD1087A Exp. 09/30/2024.

Class II Drugs Event

Event ID:
93911

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
02/02/2024

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
02/28/2024

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Bausch Health Companies, Inc.
400 Somerset Corporate Blvd
Bridgewater NJ United States

Distribution Pattern:
Nationwide

Associated Products

Product Description:
Omeprazole and Sodium Bicarbonate For Oral Suspension 40mg/1,680mg, This packet contains 40mg of omeprazole and 1,680mg of sodium bicarbonate, Directions for Use: Empty packet contents into a small cup containing 1 to 2 tablespoons of WATER. DO NOT USE OTHER LIQUIDS OR FOODS. Stir well and drink immediately. Rx Only, Distributed by: Oceanside Pharmaceuticals, a division of Bausch Health US, LLC, Bridgewater, NJ 08807, NDC 68682-991-30.

Product Quantity:
3,600 cartons

Reason for Recall:
Subpotent Drug: Out of specification for assay

Recall Number:
D-0355-2024

Code Information:
Lot #0013R; Exp. 01/2026

Class II Drugs Event

Event ID:
93986

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
02/19/2024

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
02/29/2024

Initial Firm Notification of Consignee or Public:
E-Mail

Recalling Firm:
Seatex LLC
445 Highway 36 N
Rosenberg TX United States

Distribution Pattern:
Nationwide in the US and Puerto Rico

Associated Products

Product Description:
PROBLEND Antibacterial Foaming Silk All-In-One Foaming Hand Sanitizer & Cleanser, Benzalkonium Chloride 0.13% Antibacterial, a) 1250 mL cases, b) 1 G cases, mountain spring scent, Seatex LLC, 445 TX Hwy 36 Rosenberg, TX 77471.

Product Quantity:
1,450 cases

Reason for Recall:
CGMP Deviations: deficiencies were identified during an FDA inspection of Seatex's manufacturing facility.

Recall Number:
D-0356-2024

Code Information:
Lot #s: a) 263647, Exp. 06/09/2024; 271382, Exp. 01/18/2025; b) 261675, Exp. 04/09/2024; 263647, Exp. 06/09/2024; 272766, Exp.02/15/2025.

Product Description:
PROBLEND E3 Foaming Hand Sanitizer, All-In-One Foaming Hand Sanitizer & Cleanser, Seatex LLC, 445 TX Hwy 36 Rosenberg, TX 77471

Product Quantity:
274 cases

Reason for Recall:
CGMP Deviations: deficiencies were identified during an FDA inspection of Seatex's manufacturing facility.

Recall Number:
D-0357-2024

Code Information:
Lot #: 265029, Exp. 03/27/2024; 273759, Exp. 11/29/2024.

Product Description:
7 Eleven FOR GAS ISLAND USE ONLY, Hand Sanitizer, Ethanol 70% v/v Antiseptic, Mountain Spring Scent, 330 Gal. cases, Distributed by: Magnus, 16005 Gateway Drive, Suite 300, Frisco, TX 75033

Product Quantity:
3 cases

Reason for Recall:
CGMP Deviations: deficiencies were identified during an FDA inspection of Seatex's manufacturing facility.

Recall Number:
D-0358-2024

Code Information:
Lot #: 251176, Exp. 06/23/2024.

Product Description:
7 Eleven Hand Sanitizer Gel, Ethanol 70% v/v Antiseptic, Mountain Spring Scent, 1250 mL cases, Magnus 16005 Gateway Drive, Ste 300, Frisco, TX 75033

Product Quantity:
1,282 cases

Reason for Recall:
CGMP Deviations: deficiencies were identified during an FDA inspection of Seatex's manufacturing facility.

Recall Number:
D-0359-2024

Code Information:
Lot #s: 266029, Exp. 03/27/2024; 255917, Exp. 06/23/2024; 261521, Exp. 06/27/2024.

Product Description:
PROBLEND Hand Sanitizer, Refreshing Gel Hand Sanitizer, Ethanol 70% v/v Antiseptic, mountain spring scent, 1250 mL cases, Seatex LLC, 445 TX Hwy 36 Rosenberg, YX 77471

Product Quantity:
480 cases

Reason for Recall:
CGMP Deviations: deficiencies were identified during an FDA inspection of Seatex's manufacturing facility.

Recall Number:
D-0360-2024

Code Information:
Lot #: 266029, Exp. 03/27/2024.

Class II Drugs Event

Event ID:
94071

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
02/20/2024

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
02/29/2024

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Denver Solutions, LLC DBA Leiters Health
13796 Compark Blvd
Englewood CO United States

Distribution Pattern:
Nationwide in the USA

Associated Products

Product Description:
Moxifloxacin PF, 1mg/ml, in Sterile Balanced Salt Solution (BSS) Sterile injection, Intracameral Use Only, Single- Dose Vial, Leiters 13796 Compark Blvd, Englewood, CO 80112, NDC 71449-096-42

Product Quantity:
40,090 vials

Reason for Recall:
Presence of Particulate Matter: glass vials from the manufacturer showed signs of glass delamination.

Recall Number:
D-0361-2024

Code Information:
Lot #:2331147, Exp:6-Mar-24; 2331180, Exp: 21-Mar-24; 2331256, Exp: 2-Apr-24; 2331279, Exp: 3-Apr-24; 2331283, Exp: 7-Apr-24; 2331345, Exp: 20-Apr-24; 2331422, Exp: 27-Apr-24; 2331563, Exp: 29-May-24.

Product Description:
Moxifloxacin 5mg/ml, 1 ml in a Single- Dose Vial, Rx Only, Leiters 13796 Compark Blvd, Englewood, CO 80112, NDC 71449-097-42

Product Quantity:
10,020 vials

Reason for Recall:
Presence of Particulate Matter: glass vials from the manufacturer showed signs of glass delamination.

Recall Number:
D-0362-2024

Code Information:
Lot #:2331123, Exp:28-Feb-24; 2331298, Exp: 24-Mar-24.

Product Description:
Lidocaine HCL 1% (10mg/mL), PHENYLephrine HCL 1.5% (15mg/mL), 1 ml in a Single- Dose Vial, RX Only, Leiters 13796 Compark Blvd, Englewood, CO 80112, NDC 71449-090-42

Product Quantity:
40,890 vials

Reason for Recall:
Presence of Particulate Matter: glass vials from the manufacturer showed signs of glass delamination.

Recall Number:
D-0363-2024

Code Information:
Lot #:2331104, Exp:9-Mar-24; 2331137, Exp: 3-Mar-24; 2331196, Exp: 11-Mar-24; 2331264, Exp: 6-Apr-24; 2331282, Exp: 18-Apr-24; 2331464, Exp: 8-May-24; 2331481, Exp: 16-May-24; 2331500, Exp: 20-May-24.