Enforcement Report - Week of December 6, 2023

Class I Drugs Event

Event ID:
93391

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
11/06/2023

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
12/07/2023

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Bayer Healthcare Pharmaceuticals Inc.
100 Bayer Blvd
Whippany NJ United States

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

Associated Products

Product Description:
VITRAKVI (larotractenib) oral solution, 20mg/mL, 100 mL bottle, Rx only, Manufactured for Bayer HealthCare Pharmaceuticals Inc., Whippany, NJ 07981. NDC 50419-392-01

Product Quantity:
192 bottles

Reason for Recall:
Microbial Contamination of Non-Sterile Products: microbial contamination identified as Penicillium brevicompactum observed during routine ongoing stability testing

Recall Number:
D-0145-2024

Code Information:
Lot# 2114228, EXP. 02/29/2024

Class II Drugs Event

Event ID:
93353

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
11/01/2023

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
11/27/2023

Initial Firm Notification of Consignee or Public:
E-Mail

Recalling Firm:
Apotex Corp.
2400 N Commerce Pkwy Ste 400
Weston FL United States

Distribution Pattern:
Nationwide

Associated Products

Product Description:
Paroxetine Hydrochloride Tablets USP, RX only, 10 mg a) 30-count bottle, NDC#: 60505-0097-1; b) 100-count bottle, NDC#: 60505-0097-2; c) 1000-count bottle, NDC#: 60505-0097-4, Manufactured by: Apotex Inc., Toronto, Ontario, Canada M9L 1T9, Manufactured for: Apotex Corp., Weston, Florida 33326.

Product Quantity:
34,392

Reason for Recall:
Failed Impurities/Degradation Specifications-Out of specification (OOS) results for the excipient Amadori Glucose adduct of Paroxetine

Recall Number:
D-0119-2024

Code Information:
Lot numbers: a)100 count bottle: RV2376, RV2377; b) 1000 count bottle: RV2379, RV2380; c) 30 count bottle: RV2375; Exp. 08/2024

Product Description:
Paroxetine Hydrochloride Tablets USP, RX only, 20 mg, a) 100-count bottle, NDC#:60505-0083-2; b) 1000-count bottle, NDC#: 60505-0083-4 Manufactured by: Apotex Inc., Toronto, Ontario, Canada M9L 1T9, Manufactured for: Apotex Corp., Weston, Florida 33326.

Product Quantity:
48,623

Reason for Recall:
Failed Impurities/Degradation Specifications-Out of specification (OOS) results for the excipient Amadori Glucose adduct of Paroxetine

Recall Number:
D-0120-2024

Code Information:
Lot numbers: a)100 count bottle: RV2384, RV2385; b) 1000 count bottle: RV2396, RV2397; Exp. 08/2024

Product Description:
Paroxetine Hydrochloride Tablets USP, RX only, 30 mg, a)30-count bottle, NDC#: 60505-0084-1, b)100-count bottle, NDC#:60505-0084-2, c)1000-count bottle, NDC#: 60505-0084-4, Manufactured by: Apotex Inc., Toronto, Ontario, Canada M9L 1T9, Manufactured for: Apotex Corp., Weston, Florida 33326.

Product Quantity:
25,776

Reason for Recall:
Failed Impurities/Degradation Specifications-Out of specification (OOS) results for the excipient Amadori Glucose adduct of Paroxetine

Recall Number:
D-0121-2024

Code Information:
Lot numbers: a)100 count bottle: RV8686; b) 1000 count bottle: RX0119; c) 30 count bottle: RV2254; Exp. 08/2024

Product Description:
Paroxetine Hydrochloride Tablets USP, RX only, 40 mg, 1000-count bottle, NDC#:60505-0101-4 Manufactured by: Apotex Inc., Toronto, Ontario, Canada M9L 1T9, Manufactured for: Apotex Corp., Weston, Florida 33326.

Product Quantity:
4,074

Reason for Recall:
Failed Impurities/Degradation Specifications-Out of specification (OOS) results for the excipient Amadori Glucose adduct of Paroxetine

Recall Number:
D-0122-2024

Code Information:
Lot numbers: RV0131, RV2387, RV2389, RW3296, RV2388; Exp. 08/2024

Class II Drugs Event

Event ID: **Product Type:**

93368

Status:
Ongoing

Recall Initiation Date:
11/07/2023

Center Classification Date:
11/27/2023

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

Distribution Pattern:
Nationwide

Product Type:
Drugs

Date Terminated:

Voluntary / Mandated:
Voluntary: Firm initiated

Initial Firm Notification of Consignee or Public:
Letter

Associated Products

Product Description:
Indomethacin 25mg Capsules, USP, 100-count bottle, Rx Only, Manufactured by: Glenmark Pharmaceuticals Ltd. Colvale-Bardez, Goa 403513, India, Manufactured for: Glenmark Pharmaceuticals Inc., USA Mahwah, NJ 07430, NDC 68462-406-01

Product Quantity:
37,200 bottles

Reason for Recall:
Labeling: Label Mix-Up-Indomethacin bottles may be labeled as Naproxen

Recall Number:
D-0123-2024

Code Information:
Lot# 19231903; Exp 4/2025 Lot# 19231858; Exp 4/2025 Lot# 19231881; Exp 4/2025 Lot# 19233484; Exp 8/2025 Lot# 19233490; Exp 8/2025

Product Description:
Naproxen Tablets, USP 250mg, 100-count bottle, Rx Only, Manufactured by: Glenmark Pharmaceuticals Ltd. Colvale-Bardez, Goa 403513, India, Manufactured for: Glenmark Pharmaceuticals Inc., USA Mahwah, NJ 07430, NDC 68462-188-01.

Product Quantity:

Reason for Recall:
Labeling: Label Mix-Up-Indomethacin bottles may be labeled as Naproxen

Recall Number:
D-0124-2024

Code Information:
Lot# 19231903; Exp 4/2025 Lot# 19231858; Exp 4/2025 Lot# 19231881; Exp 4/2025 Lot# 19233484: Exp 8/2025 Lot# 19233490; Exp 8/2025

Class II Drugs Event

Event ID:
93431

Status:
Ongoing

Recall Initiation Date:
11/10/2023

Center Classification Date:
11/30/2023

Recalling Firm:
Golden State Medical Supply Inc.

Product Type:
Drugs

Date Terminated:

Voluntary / Mandated:
Voluntary: Firm initiated

Initial Firm Notification of Consignee or Public:
Letter

5187 Camino Ruiz
Camarillo CA United States

Distribution Pattern:
Nationwide in the USA

Associated Products

Product Description:
PAROXETINE tablets, USP, 10 mg, Packaged as a) 30-count bottle, NDC 60429-734-30; b) 90-count bottle NDC 60429-734-90; c)1000-count bottle, NDC 60429-734-10; Rx Only, Manufactured by Apotex, Inc., Toronto, Ontario, Canada, M9L 1T9, Packaged by GSMS, Incorporated, Camarillo, CA 93012.

Product Quantity:
1941 bottles

Reason for Recall:
Failed Impurities/Degradation Specifications-Manufacturer Apotex Inc. recalling lots due to Out of specification results for the excipient Amadori Glucose adduct of Paroxetine

Recall Number:
D-0128-2024

Code Information:
Lot # a) Lot GS041383, GS042141, Exp. 08/31/2024; b) Lot GS040841, Lot GS041384, Lot GS042039, Exp. 08/31/2024; c) Lot GS040910, Lot GS041621, Lot GS042237, Exp. 08/31/2024;

Product Description:
PAROXETINE tablets, USP, 20 mg, Packaged as a) 90-count bottle NDC 60429-735-90; b)1000-count bottle, NDC 60429-735-10; Rx Only, Manufactured by Apotex, Inc., Toronto, Ontario, Canada, M9L 1T9, Packaged by GSMS, Incorporated, Camarillo, CA 93012.

Product Quantity:
2502 bottles

Reason for Recall:
Failed Impurities/Degradation Specifications-Manufacturer Apotex Inc. recalling lots due to Out of specification results for the excipient Amadori Glucose adduct of Paroxetine

Recall Number:
D-0129-2024

Code Information:
Lot # a) GS036696, GS037068, GS037934, GS038564, Exp. 08/31/2024 b) GS036381, GS036712, GS037116, GS037692, GS038388, Exp. 08/31/2024;

Product Description:
PAROXETINE tablets, USP, 40 mg, Packaged as a) 30-count bottle, NDC 60429-737-30; b) 90-count bottle NDC 60429-737-90; c)1000-count bottle, NDC 60429-737-10; Rx Only, Manufactured by Apotex, Inc., Toronto, Ontario, Canada, M9L 1T9, Packaged by GSMS, Incorporated, Camarillo, CA 93012.

Product Quantity:
5626 bottles

Reason for Recall:
Failed Impurities/Degradation Specifications-Manufacturer Apotex Inc. recalling lots due to Out of specification results for the excipient Amadori Glucose adduct of Paroxetine

Recall Number:
D-0130-2024

Code Information:
Lot # a) GS036488, GS037091, GS037701, Exp. 08/31/2024; b) GS037090, GS037702, Exp. 08/31/2024; c) GS036677, GS037117, GS037699, Exp. 08/31/2024

Class III Drugs Event

Event ID:
93261

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
10/17/2023

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
11/28/2023

Initial Firm Notification of Consignee or Public:

Recalling Firm:
VistaPharm LLC
7265 Ulmerton Rd
Largo FL United States

Distribution Pattern:
Nationwide USA

Associated Products

Product Description:
Aminocaproic Acid Oral Solution, 0.25 grams/mL, Rx only, packaged in 8 Fl. Oz. (236.5 mL) HDPE bottles, Manufactured for: VistaPharm, Inc., Largo, FL 33771, UAS, NDC 66689-330-08

Product Quantity:
Prod Lot number 22ZKY1, EXP 11/27/23, 600 bottles dist; 22ZMC1 EXP12/21/23 600 bottles; 22ZTP1 EXP 03/29/24 588 bottles; 23ZAD1 EXP 07/07/24 564 bottl

Reason for Recall:
Failed Excipient Specifications: high content of ethylene glycol (EG)

Recall Number:
D-0126-2024

Code Information:
Lot #: 22ZKY1, Exp. 11/27/23; 22ZMC1, Exp. 12/21/23; 22ZTP1, Exp. 03/29/24; 23ZAD1, Exp. 07/07/24.

Class III Drugs Event

Event ID:
93409

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
11/10/2023

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
11/29/2023

Initial Firm Notification of Consignee or Public:

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

Distribution Pattern:
USA nationwide

Associated Products

Product Description:
Testosterone Gel, 1.62% CIII (Alcohol 80% v/v), packaged in 30 unit-dose packets per carton, Rx only, Teva Pharmaceuticals USA, Inc., North Wales, PA 19454, NDC 0591-2926-30

Product Quantity:

Reason for Recall:
OOS for viscosity

Recall Number:
D-0127-2024

Code Information:
Lot #: 100029472, Exp. 2/29/2024

Class III Drugs Event

Event ID:
93453

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
11/10/2023

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
11/28/2023

Initial Firm Notification of Consignee or Public:
Telephone

Recalling Firm:
Fagron Compounding Services
8710 E 34th St N
Wichita KS United States

Distribution Pattern:
Nationwide in the USA

Associated Products

Product Description:
Tropicamide 1% (10mg/mL), Cyclopentolate 1% (10mg/mL), Phenylephrine 2.5% (25mg/mL), Ketorolac 0.5% (5mg/mL), 5 mL bottles, For Topical Ophthalmic Use Only, Not for IV Use, This is a Compounded Drug, Hospital & Office Use Only, Fagron Sterile Services, 8710 E 34th St N Wichita, KS 67226. NDC 71266-8240-01

Product Quantity:
756 bottles

Reason for Recall:
Labeling: Label Mix-Up: The label of a dropper bottle mistakenly states the container is a 0.5mL single-use syringe instead of a 5 mL dropper

Recall Number:
D-0125-2024

Code Information:
Lot #: C274-000033372, Exp. Date 01-17-2024; C274-000033764, Exp. Date 02-06-2024

Not Yet Classified Drugs Event

Event ID:
93257

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
10/20/2023

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:

Initial Firm Notification of Consignee or Public:
Telephone

Recalling Firm:
Botanical Be
360 Jardin Bello
El Paso TX United States

Distribution Pattern:
USA Nationwide

Associated Products

Product Description:
Artri King tablets, packaged in 100-count bottles, Manufactured by: Plantas medicinales de Mexico, Melchol Ocampo # 65 Local D, Delegacion Xochimilco CP 16800, Mexico DF, UPC 7 501031 111138

Product Quantity:

Reason for Recall:
Marketed Without an Approved NDA/ANDA: products found to contain undeclared diclofenac.

Recall Number:

Code Information:
All lots

Product Description:
Reumo Flex caplets, packaged in 30-count boxes, Manufactured by: Grupo Yepenza de Mexico, SA de CV, Comerciantes 5824 Col Arcos de Guadalupe, Zapopan Jal Mexico, UPC 7 502214 014598

Product Quantity:

Reason for Recall:
Marketed Without an Approved NDA/ANDA: products found to contain undeclared diclofenac.

Recall Number:

Code Information:
All lots

Product Description:
Kuka Flex Forte caplets, packaged in 100-count bottles, Manufactured by: Kukamonga, Gonzalez Ortega No 170 Col Centro, 44100 Guadalajara Jal, UPC 0736640810265

Product Quantity:

Reason for Recall:
Marketed Without an Approved NDA/ANDA: products found to contain undeclared diclofenac.

Recall Number:

Code Information:
All lots