Enforcement Report - Week of October 7, 2020

Class II Drugs Event

Event ID:
86283

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
08/24/2020

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
10/01/2020

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Strides Inc.
201 S Main St Ste 3
Lambertville NJ United States

Distribution Pattern:
nationwide

Associated Products

Product Description:
Strides Pharma Inc.Potassium Chloride Extended-Release Tablets, USP 8mEq (600 mg) 100 Tablets Rx Only Manufactured by: Strides Pharma Science Limited Bengaluru -562106 India Distributed by: Strides Pharma Inc., East Brunswick NJ 08816 NDC 64380-860-06

Product Quantity:
11,280 bottles

Reason for Recall:
Failed Dissolution Specifications

Recall Number:
D-0001-2021

Code Information:
7240675A; Exp. 12/31/2021

Class II Drugs Event

Event ID:
86361

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
09/03/2020

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
09/30/2020

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Akorn, Inc.
1925 W Field Ct Ste 300
Lake Forest IL United States

Distribution Pattern:
Nationwide in CA, IN, VA, NJ, NY, RI, FL, TX, MO, PA, MI, AL, TN, SC

Associated Products

Product Description:
Eye Itch Relief, Ketotifen Fumarate Ophthalmic Solution 0.035%, Sterile, 5 mL, Distributed by CVS Pharmacy, Inc. Woonsocket, RI 02895, NDC 59779-920-01

Product Quantity:
25,843 bottles

Reason for Recall:
CGMP Deviations

Recall Number:
D-1628-2020

Code Information:
Lot 8A11A exp 12/20

Class II Drugs Event

Event ID:
86379

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
09/04/2020

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
10/01/2020

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Teva Pharmaceuticals USA
400 Interpace Pkwy
Parsippany NJ United States

Distribution Pattern:
Nationwide in the U.S. and PR

Associated Products

Product Description:
Buprenorphine Transdermal System 5 mcg/hour, 4 transdermal systems/4 disposal units per carton, Rx Only, Manufactured by: 3M Drug Delivery Systems, 19901 Nordhoff street, Northridge, CA 91324 USA, Manufactured for: Teva Pharmaceuticals USA Inc., North Wales, PA 19454, carton NDC: 0093-3656-40, patch NDC: 0093-3656-21.

Product Quantity:
32,543 cartons

Reason for Recall:
Failed Stability Specifications: Below specification result for buprenorphine release rate.

Recall Number:
D-0003-2021

Code Information:
Lot # 190017, exp. 02/2021; 190161, exp. 08/2021

Class II Drugs Event

Event ID:
86405

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
09/02/2020

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
09/30/2020

Initial Firm Notification of Consignee or Public:
E-Mail

Recalling Firm:
pH-D Feminine Health
305 Williams Ave
Madison TN United States

Distribution Pattern:
Nationwide in the U.S.

Associated Products

Product Description:
pH-D Feminine Health Boric Acid Vaginal Suppositories, 24 vaginal suppositories per box, 600 mg each, pH-D Feminine Health, LLC Madison, TN 37115, UPC Code: 3 49597 00044 5.

Product Quantity:
a. 37,000 boxes; b. 45,000 boxes; c. 6,100 boxes

Reason for Recall:
Marketed without an Approved NDA/ANDA.

Recall Number:
D-1627-2020

Code Information:
Lot #: a) 2PA20021, 2PA20061; b) D-160, D-155, D-162; c) 7PA20071.

Class II Drugs Event

Event ID:
86464

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
09/23/2020

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
10/01/2020

Initial Firm Notification of Consignee or Public:
Press Release

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

Distribution Pattern:
Nationwide

Associated Products

Product Description:
RIOMET ER (metformin hydrochloride for extended-release oral suspension), 500 mg per 5 mL 16 oz. For Oral Use Only Rx Only Manufactured by: Sun Pharmaceuticals Industries Limited Mohali, India Distributed by: Sun Pharmaceuticals Industries, Inc. Cranbury, NJ 08512 NDC 10631-019-17

Product Quantity:
747 bottles

Reason for Recall:
CGMP Deviations: Detection of N-nitrosodimethylamine (NDMA) impurity in finished drug product.

Recall Number:
D-0002-2021

Code Information:
Lot #: AB06381; Exp 10/2021

Class II Drugs Event

Event ID:
86487

Product Type:
Drugs

Status:
Completed

Date Terminated:

Recall Initiation Date:
03/12/2019

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Direct Rx
94 Worldwide Dr
Dawsonville GA United States

Distribution Pattern:
FL

Associated Products

Product Description:
Losartan Pot/HCTZ 50/12.5 mg 90 Tabs Packaged and Distributed By: Direct Rx Dawsonville, GA 30534 Mfg For: Torrent Pharma, Inc. Basking Ridge, NJ 07920 NDC 61919-040-90

Product Quantity:
33 bottles

Reason for Recall:
CGMP deviation: Trace amounts of impurity detected to be N-Methylnitrosobutyric acid (NMBA) in the API.

Recall Number:

Code Information:
Lot: 12DE1806 Exp. 01/31/2021

Class III Drugs Event

Event ID:
86392

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
09/16/2020

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
09/28/2020

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Arbor Pharmaceuticals Inc.
6 Concourse Pkwy Ste 1800
Atlanta GA United States

Distribution Pattern:
Nationwide within the United States

Associated Products

Product Description:
Nymalize (nimodipine) oral solution, 60 mg/20 mL, 12 Unit-Dose Cups and 12 Oral Syringes, 2 inner cartons per outer shipping carton, Rx Only, Distributed by arbor Atlanta, GA, NDC 24338-200-12

Product Quantity:
1846 cartons

Reason for Recall:
Subpotent Drug

Recall Number:
D-1625-2020

Code Information:
Lot #: 356884 Exp. 11/30/2021

Class III Drugs Event

Event ID:
86403

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
09/09/2020

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
10/01/2020

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
P & L Developments, LLC
200 Hicks St
Westbury NY United States

Distribution Pattern:
Recalled product was distributed to one retailer type in NY and MD who may have further distributed the product throughout the United States.

Associated Products

Product Description:
Nicotine Gum, Nicotine Polacrilex Gum USP, 2 mg (nicotine), 110-count pieces per carton, Distributed By: Rite Aid, 30 Hunter Lane, Camp Hill, PA 17011, NDC 11822-3328-3.

Product Quantity:
4,752 cartons

Reason for Recall:
Labeling: Incorrect or Missing Package Insert: The package insert included in the finished product is for the Canadian market and is not part of the current approved drug labeling.

Recall Number:
D-0004-2021

Code Information:
Lot # WJ04186, exp. date 01/23

Class III Drugs Event

Event ID:
86471

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
09/24/2020

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
09/30/2020

Initial Firm Notification of Consignee or Public:
E-Mail

Recalling Firm:
Legacy Pharmaceutical Packaging LLC
13333 Lakefront Dr
Earth City MO United States

Distribution Pattern:
Walmart distribution centers in GA and AR

Associated Products

Product Description:
Metformin Hydrochloride Tablets USP, 1000 mg, 60-count bottles, Rx Only, Manufactured for: Heritage Pharmaceuticals Inc., East Brunswick, NJ 08816, Packaged by: Legacy Pharmaceutical Packaging LLC, Earth City, MO 63045, Distributed by: Wal-Mart, Bentonville, AR 72716. NDC 68645-545-59

Product Quantity:
111,948 bottles

Reason for Recall:
Presence of Foreign Tablets/Capsules: Metformin 1000mg with different imprint was found in bottles.

Recall Number:
D-1626-2020

Code Information:
Lot #: 201626, Exp. Date 08/2022

Not Yet Classified Drugs Event

Event ID:
86022

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
07/11/2020

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:

Initial Firm Notification of Consignee or Public:
Press Release

Recalling Firm:
4e Brands North America, Llc
17806 Ih-10 Ste 300
San Antonio TX United States

Distribution Pattern:
Distributed Nationwide in the USA

Associated Products

Product Description:
blumen ADVANCED INSTANT HAND SANITIZER Clear ETHYL ALCOHOL 70% Natural Boost with Tea Tree Oil, (70% ethyl alcohol), Packaged as a) 18 fl oz / 532 ml bottle, UPC 8 14266 02408 9 b) 33.8 fl oz / 1L bottle, UPC 8 14266 02374 7, Distributed in USA and Canada BY: 4e Brands Northamerica LLC. 17806 IH-10W, Suite 300, San Antonio, Texas, 78257. Made in Mexico.

Product Quantity:
17,359,247 total bottles and pumps

Reason for Recall:
Chemical Contamination and CGMP Deviations: Products tested to contained methanol and below the label claim for ethanol content. Other products were recalled because they were manufactured in the same facility as the product found to contain methanol.

Recall Number:

Code Information:
All lots within expiry

Product Description:
blumen ADVANCED HAND SANITIZER, 70% ALCOHOL CONTENT, (70% ethyl alcohol), packaged as a) 3.4 fl oz / 100 ml bottle, UPC 8 14266 02359 4 b) 7.5 fl. oz./221 ml bottle, UPC 8 14266 02362 4 b) 33.8 fl. oz./1L bottle, UPC 8 14266 02369 3, Distributed in USA and Canada By: 4e Brands Northamerica LLC, 17806 IH-10W, Suite 300, San Antonio, Texas, 78257, Made in Mexico.

Product Quantity:
17,359,247 total bottles and pumps

Reason for Recall:
Chemical Contamination and CGMP Deviations: Products tested to contained methanol and below the label claim for ethanol content. Other products were recalled because they were manufactured in the same facility as the product found to contain methanol.

Recall Number:

Code Information:
All lots within expiry

Product Description:
blumen Clear ADVANCED HAND SANITIZER with 70% ALCOHOL, (ethyl alcohol 70% v/v), Packaged as a) 2 fl oz / 60 ml bottle, UPC 8 14266 02371 6 b) 7.5 fl oz / 221 ml bottle, UPC 8 14266 02362 4 c) 15.2 fl oz (450 ml) bottle, UPC 8 14266 02392 1, d) 17 fl oz / 503 ml bottle with blue cap or pump bottle, UPC 8 14266 02409 6, e) 18 fl oz / 532 ml bottle, UPC 8 14266 02391 4, f) 33.8 fl oz / 1 L straight or curved bottle, UPC 8 14266 02369 3 g) 70 fl oz / 2.07L bottle, UPC 8 14266 02367 9 h) 1.05 GAL / 4L bottle, UPC 8 14266 02368 6; Distributed in USA and Canada By: 4e Brands Northamerica LLC, 17806 IH-10W, Suite 300, San Antonio, Texas, 78257, Made in Mexico.

Product Quantity:
17,359,247 total bottles and pumps

Reason for Recall:
Chemical Contamination and CGMP Deviations: Products tested to contained methanol and below the label claim for ethanol content. Other products were recalled because they were manufactured in the same facility as the product found to contain methanol.

Recall Number:

Code Information:
All lots within expiry.

Product Description:
blumen Aloe ADVANCED HAND SANITIZER 70% ALCOHOL CONTENT (70% ethyl alcohol v/v), 3.4 fl. oz./100 mL bottle, Distributed in USA and Canada By: 4e Brands Northamerica LLC, 17806 IH-10W, Suite 300, San Antonio, Texas, 78257, Made in Mexico. UPC 8 14266 02358 7

Product Quantity:
17,359,247 total bottles and pumps

Reason for Recall:
Chemical Contamination and CGMP Deviations: Products tested to contained methanol and below the label claim for ethanol content. Other products were recalled because they were manufactured in the same facility as the product found to contain methanol.

Recall Number:

Code Information:
All lots within expiry.

Product Description:
ASSURED Instant Hand Sanitizer Vitamin E and Aloe, (70% ethyl alcohol), Packaged as a) 8 fL oz / 236 ml bottle, UPC 6 39277 49069 8 b) 10 fL oz / 296 ml bottle, UPC 6 39277 49069 8, Distributed by Geenbrier International, Inc., 500 Volvo Parkway, Chesapeake, VA 23320, Made in Mexico

Product Quantity:
17,359,247 total bottles and pumps

Reason for Recall:
Chemical Contamination and CGMP Deviations: Products tested to contained methanol and below the label claim for ethanol content. Other products were recalled because they were manufactured in the same facility as the product found to contain methanol.

Recall Number:

Code Information:
All lots within expiry

Product Description:
ASSURED Instant Hand Sanitizer Aloe & Moisturizers, (70% ethyl alcohol), Packaged as a) 8 fL oz / 236 ml bottle, UPC 6 39277 49070 4 b) 10 fL oz / 295 ml bottle, UPC 6 39277 49070 4, Distributed by Greenbrier International, Inc., 500 Volvo Parkway, Chesapeake, VA 23320, Made in Mexico

Product Quantity:
17,359,247 total bottles and pumps

Reason for Recall:
Chemical Contamination and CGMP Deviations: Products tested to contained methanol and below the label claim for ethanol content. Other products were recalled because they were manufactured in the same facility as the product found to contain methanol.

Recall Number:

Code Information:
All lots within expiry

Product Description:
Modesa instant HAND SANITIZER with moisturizers & vitamin E, (70% ethyl alcohol), 33.8 FL OZ (1 L) bottle, Distributed by Greenbrier International, Inc., 500 Volvo Parkway, Chesapeake, VA 23320, Made in Mexico. UPC 0 32251 49935 7

Product Quantity:
17,359,247 total bottles and pumps

Reason for Recall:
Chemical Contamination and CGMP Deviations: Products tested to contained methanol and below the label claim for ethanol content. Other products were recalled because they were manufactured in the same facility as the product found to contain methanol.

Recall Number:

Code Information:
All lots within expiry

Product Description:
blumen Clear ADVANCED HAND SANITIZER with 70% ALCOHOL, (ethyl alcohol 70% v/v), Packaged as a) 2 fl oz / 60 ml bottle, UPC 8 14266 02371 6 b) 17 fl oz / 503 ml bottle with blue cap or pump bottle, UPC 8 14266 02409 6 c) 33.8 fl oz / 1 L straight or curved bottle, UPC 8 14266 02369 3. Distributed in USA and Canada By: 4e Brands Northamerica LLC, 17806 IH-10W, Suite 300, San Antonio, Texas, 78257, Made in Mexico.

Product Quantity:
17,359,247 total bottles and pumps

Reason for Recall:
Chemical Contamination and CGMP Deviations: Products tested to contained methanol and below the label claim for ethanol content. Other products were recalled because they were manufactured in the same facility as the product found to contain methanol.

Recall Number:

Code Information:
Lot #: a) 2141, Exp 04/04/23; 3005, Exp 05/08/23; b) 3005, Exp 05/08/23; 2879, 2892, 2911, Exp 4/23/23; 2515, Exp 4/20/23; 3270, Exp 5/09/23; c) 3095, Exp 05/07/23; 2839, Exp 04/20/23; 2879, Exp 04/23/23; 2894, Exp 04/27/23;

Product Description:
blumen ADVANCED INSTANT HAND SANITIZER Clear with Tea Tree Oil, (70% ethyl alcohol), 33.8 fl oz / 1 L bottle, Distributed in USA and Canada by: 4e Brands 4e Brands Northamerica LLC. 17806 IH-10W, Suite 300, San Antonio, Texas, 78257. Made in Mexico. UPC 8 14266 02374 7

Product Quantity:

Reason for Recall:
Chemical Contamination and CGMP Deviations: Products tested to contained methanol and below the label claim for ethanol content. Other products were recalled because they were manufactured in the same facility as the product found to contain methanol.

Recall Number:

Code Information:
Lot #: 2221, Exp 04/09/23; 2252, Exp 04/12/23;

Product Description:
blumen ADVANCED HAND SANITIZER 70% ALCOHOL CONTENT, (ethyl alcohol 70% v/v) Packaged as a) 3.4 fl oz / 100 ml bottle, UPC 8 14266 02359 4, b) 7.5 fl oz / 221 ml bottle, UPC 8 14266 02362 4, Distributed in USA and Canada By: 4e Brands Northamerica LLC, 17806 IH-10W, Suite 300, San Antonio, Texas, 78257, Made in Mexico.

Product Quantity:
17,359,247 total bottles and pumps

Reason for Recall:
Chemical Contamination and CGMP Deviations: Products tested to contained methanol and below the label claim for ethanol content. Other products were recalled because they were manufactured in the same facility as the product found to contain methanol.

Recall Number:

Code Information:
Lot #: a) 2141, Exp 04/40/23; 2879, Exp 04/23/23; 3005, Exp 05/08/23; b) 2911, Exp 04/23/23;

Not Yet Classified Drugs Event

Event ID:
86428

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
08/14/2020

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:

Initial Firm Notification of Consignee or Public:
Telephone

Recalling Firm:
Volu-Sol, Inc.
5095 W 2100 S
Salt Lake City UT United States

Distribution Pattern:
Sold to one distributor located in CA and one hospital system located in UT.

Associated Products

Product Description:
Volu-Sol Handrub Sanitizing Solution (Ethyl Alcohol, 69% v/v and Isopropyl Alcohol, 7.2% v/v) Topical Solution, 473 mL/ 16 fl oz., Vou-Sol 5095 W 2100 S, Salt Lake City, UT 84120, NDC 74401-800-16

Product Quantity:

Reason for Recall:
Marketed Without an Approved NDA/ANDA: OTC hand sanitizer formulation contains methanol and methanol listed as an inactive ingredient on the label

Recall Number:

Code Information:
Lot #: WHO100, WHO101, Exp. Date 4/2022; WHO104, WHO105, WHO108, WHO109, Exp. Date 05/2022