Enforcement Report - Week of December 26, 2018

Class II Drugs Event

Event ID:
81354

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
11/26/2018

Voluntary / Mandated:
Voluntary: Firm Initiated

Center Classification Date:
12/17/2018

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Tris Pharma Inc.
2033 US Highway 130
Monmouth Junction NJ United States

Distribution Pattern:
One distributor in PA who further distributed Nationwide in the USA.

Associated Products

Product Description:
infants* IBUPROFEN, Concentrated Ibuprofen Oral Suspension, USP (NSAID), 50 mg per 1.25 mL, Dye-Free Berry Flavor, 0.5 FL OZ (15 mL) bottle, Distributed by Wal-Mart Stores, Inc., Bentonville, AR 72716, NDC 49035-125-23, UPC 0 78742 02016 7.

Product Quantity:
164,304 bottles

Reason for Recall:
Superpotent Drug: recalled lots may have higher concentration of ibuprofen.

Recall Number:
D-0335-2019

Code Information:
Lot #: 00717009A, Exp 02/19; 00717015A, Exp 04/19; 00717024A, Exp 08/19

Product Description:
Infants' Ibuprofen, Concentrated Ibuprofen Oral Suspension, USP, (NSAID), 50 mg per 1.25 mL, Dye-Free Non-Staining Berry Flavor, 0.5 FL OZ (15 mL) bottle, Distributed by Family Dollar Services, Inc., 10301 Monroe Road, Matthews, NC 28105, NDC 55319-250-23, UPC 0 32251 03374 2.

Product Quantity:
19,488 bottles

Reason for Recall:
Superpotent Drug: recalled lots may have higher concentration of ibuprofen.

Recall Number:
D-0336-2019

Code Information:
Lot #: 00717024A, Exp 08/19

Product Description:
Infants' Ibuprofen, Concentrated Ibuprofen Oral Suspension, USP, (NSAID), 50 mg per 1.25 mL, Dye Free, Non-staining Berry Flavor, 0.5 FL OZ (15 mL) bottle, Distributed by: CVS Pharmacy, Inc., One CVS Drive, Woonsocket, RI 02895, UPC 0 50428 39338 3.

Product Quantity:
20,736 bottles

Reason for Recall:
Superpotent Drug: recalled lots may have higher concentration of ibuprofen.

Recall Number:
D-0337-2019

Code Information:
Lot #: 00717024A, Exp 08/19

Class II Drugs Event

Event ID:
81629

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
11/19/2018

Voluntary / Mandated:
Voluntary: Firm Initiated

Center Classification Date:
12/20/2018

Initial Firm Notification of Consignee or Public:
Telephone

Recalling Firm:
Pharm D Solutions, LLC
1304 S Loop W
Houston TX United States

Distribution Pattern:
WA

Associated Products

Product Description:
Human Chorionic Gonadotropin 3000 IU, Rx only, Pharm D. Solutions 1304 South Loop West, Houston, TX 77054 1-844-263-6843 --- NDC: 69699-1738-10

Product Quantity:
85 vials

Reason for Recall:
Lack of Assurance of Sterility: Inadequate processes and equipment to assure the sterility of products intended to be sterile.

Recall Number:
D-0343-2019

Code Information:
Lot: 10292018:21 Exp. 3/31/2019

Class II Drugs Event

Event ID:
81691

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
10/29/2018

Voluntary / Mandated:
Voluntary: Firm Initiated

Center Classification Date:
12/14/2018

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
GE Healthcare Inc. Life Sciences
100 Results Way
Marlborough MA United States

Distribution Pattern:
TN

Associated Products

Product Description:
Omnipaque (iohexol) Injection, 180mgI/mL, 20 mL Single-Dose Vial, packaged in 10 x 20 mL Vials per carton, Rx only, Distributed by GE Healthcare Inc., Marlborough, MA 01752 U.S.A.; Manufactured by GE Healthcare AS, Oslo, Norway; NDC 0407-1411-20.

Product Quantity:
1092 cartons

Reason for Recall:
Defective Container: vial defect was identified that could potentially impact the container closure and result in a lack of sterility assurance and/or the potential for glass particles.

Recall Number:
D-0319-2019

Code Information:
Lot #: 14301544, Exp 21Sep21

Class II Drugs Event

Event ID:
81719

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
12/10/2018

Voluntary / Mandated:
Voluntary: Firm Initiated

Center Classification Date:
12/17/2018

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Gordon Laboratories
6801 Ludlow St
Upper Darby PA United States

Distribution Pattern:
Nationwide in the USA.

Associated Products

Product Description:
Monsel's (Ferric Subsulfate) Solution, 8 mL amber glass bottle, packaged as one dozen bottles with applicators per box, Rx only, Gordon Laboratories, Upper Darby, PA 19082, NDC 10481-0112-8.

Product Quantity:
1,155 boxes

Reason for Recall:
Superpotent Drug: contains higher levels of Iron than labeled.

Recall Number:
D-0338-2019

Code Information:
Batch #: 579602, 579604, 579606, Exp 12/18; 579609, Exp 04/19.

Class II Drugs Event

Event ID:
81729

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
12/04/2018

Voluntary / Mandated:
Voluntary: Firm Initiated

Center Classification Date:
12/14/2018

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Epic Pharma, LLC
22715 N Conduit Ave
Laurelton NY United States

Distribution Pattern:
U.S.A. Nationwide

Associated Products

Product Description:
Estradiol Tablets, USP, 2 mg, 100-count bottle, Rx Only, Distributed by: Epic Pharma, LLC Laurelton, NY 11413, NDC 42806-089-01

Product Quantity:
2976 bottles

Reason for Recall:
Presence of foreign tablet/capsule: A single foreign tablet was found in pharmacy dispensed bottle of 30 Estradiol 2 mg tablets.

Recall Number:
D-0297-2019

Code Information:
Lot #: 18103A, Exp 6/20

Class II Drugs Event

Event ID:
81730

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
12/05/2018

Voluntary / Mandated:
Voluntary: Firm Initiated

Center Classification Date:
12/15/2018

Initial Firm Notification of Consignee or Public:
Telephone

Recalling Firm:
Pharmedium Services, LLC
150 N Field Dr Ste 350
Lake Forest IL United States

Distribution Pattern:
Nationwide in the USA.

Associated Products

Product Description:
Fentanyl Citrate 2 mcg per mL (100 mcg per 50 mL) and Ropivacaine HCl 0.1% in Sodium Chloride 0.9%, Injection, 50 mL total volume in a 60 mL BD Syringe, Rx Only, PharMEDium Services, LLC. 913 N. Davis Ave. Cleveland, MS 38732 NDC 61553-644-75.

Product Quantity:
295 50 ml in 60 ml syringes

Reason for Recall:
Sub-potent

Recall Number:
D-0333-2019

Code Information:
Lot: 183220013C Exp. 12/19/2018

Product Description:
Fentanyl Citrate 2 mcg per mL (200 mcg per 100 mL) and Ropivacaine HCl 0.2% in Sodium Chloride 0.9%, Injection, 100 mL total volume in a 150 mL Intravia Bag, Rx Only,PharMEDium Services, LLC. 913 N. Davis Ave. Cleveland, MS 38732. NDC 61553-148-48

Product Quantity:
295 100 mL in 150 mL Intravia bags

Reason for Recall:
Sub-potent

Recall Number:
D-0334-2019

Code Information:
Lot: 183230004C Exp. 02/17/2019

Class II Drugs Event

Event ID:
81731

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
12/06/2018

Voluntary / Mandated:
Voluntary: Firm Initiated

Center Classification Date:
12/18/2018

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Pfizer Inc.
235 E 42nd St
New York NY United States

Distribution Pattern:
Nationwide within the United States

Associated Products

Product Description:
Levoxyl (levothyroxine sodium tablets, USP) tablets 112 mcg, 100-count bottle, Rx Only,Distributed by Pfizer Inc. New York, NY 10017, NDC 60793-855-01

Product Quantity:
1996 bottles

Reason for Recall:
Superpotent Drug.

Recall Number:
D-0339-2019

Code Information:
Lot #:18A18, Exp. 01/2020

Class II Drugs Event

Event ID:
81804

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
12/11/2018

Voluntary / Mandated:
Voluntary: Firm Initiated

Center Classification Date:
12/19/2018

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
KVK-Tech, Inc.
110 Terry Dr
Newtown PA United States

Distribution Pattern:
Product was distributed by 10 major distributors throughout the United States.

Associated Products

Product Description:
Oxybutynin Chloride Tablets, USP, 5 mg, 500-count bottle, Rx only, Mfd. By: KVK-Tech, Inc., Newtown, PA 18940, NDC 10702-201-50

Product Quantity:
156 bottles

Reason for Recall:
Labeling: Wrong bar code

Recall Number:
D-0340-2019

Code Information:
Lot #: 15079A, Exp 10/20

Class III Drugs Event

Event ID:
81775

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
12/10/2018

Voluntary / Mandated:
Voluntary: Firm Initiated

Center Classification Date:
12/20/2018

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
CBI Laboratories, Inc.
4201 Diplomacy Rd
Fort Worth TX United States

Distribution Pattern:
United States, Maldives, Canada, United Arab Emirates, and New Zealand

Associated Products

Product Description:
Advanced Protection Sunscreen spf 30 (Octinoxate 7.5%, Octisalate 5%, Oxybenzone 6%), 4.5 Oz/127.5 g tube.

Product Quantity:
5363 tubes

Reason for Recall:
Subpotent Drug:Out of specification for percentage of active pharmaceutical ingredients.

Recall Number:
D-0341-2019

Code Information:
Lot #: 131965, Exp 12/2018; 127426 Exp. 01/2019; 129045, 130424 Exp. 06/2019; 130432 Exp. 10/2019; 131870 Exp. 06/2019; 132648, Exp. 03/2020; 133732 Exp. 04/2020; 134400 Exp. 02/2020; 135345 Exp. 08/2020

Product Description:
Options Rx Anti-Oxidant Oil-Free Sunscreeen (Octinoxate 7.5%, Octisalate 5%, Oxybenzone 6%), 4.5 oz./128 g tube, Mfg. For Credentials Skincare

Fort Worth, TX 76155

Product Quantity:
2055 tubes

Reason for Recall:
Subpotent Drug:Out of specification for percentage of active pharmaceutical ingredients.

Recall Number:
D-0342-2019

Code Information:
Lot #: 129114 Exp. 06/2019; 131927,133239 Exp. 03/2020; 126292, Exp.01/2019.

Not Yet Classified Drugs Event

Event ID:
81639

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
11/27/2018

Voluntary / Mandated:
Voluntary: Firm Initiated

Center Classification Date:

Initial Firm Notification of Consignee or Public:
Letter

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

Distribution Pattern:
Nationwide

Associated Products

Product Description:
Aprepitant Capsules, USP 40 mg, 1 capsule Unit Blister Pack, Rx Only, Manufactured in India for: Glenmark Pharmaceuticals Inc., USA Mahwah, NJ 07430. UPC 368462583401. NDC 68462-583-40

Product Quantity:
5,016 blister packs

Reason for Recall:
Shortfill: Aprepitant capsules 40 mg is being recalled due to customer reports of missing capsule in the blister pack.

Recall Number:

Code Information:
Lot: 17180918, EXP June 2020

Not Yet Classified Drugs Event

Event ID:
81684

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
11/30/2018

Voluntary / Mandated:
Voluntary: Firm Initiated

Center Classification Date:

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
VistaPharm, Inc.
7265 Ulmerton Rd
Largo FL United States

Distribution Pattern:
Nationwide in the USA and Puerto Rico

Associated Products

Product Description:
NYSTATIN Oral Suspension, USP 500,000 Units/5mL, unit dose 5ml cups, packaged in a) 50 unit dose cups (10x5ml unit dose cups per tray, 5 trays per case) NDC 66689-037-50; b) 100 unit dose cups (10x5ml unit dose cups per tray, 10 trays per case) NDC 66689-037-99. Rx Only, Manufactured by VistaPharm, Inc. Largo, FL 33771

Product Quantity:
4,065,550 5 ml cups

Reason for Recall:
Failed Impurities/Degradation Specifications:Out of specification for impurities.

Recall Number:

Code Information:
Lots: a) 505300 Exp. Dec 2018; 522200 Exp. Apr 2019; 534400 Exp. Jul 2019; 539000 Exp. Aug 2019; 543400 Exp. Sep 2019; b) 523600, 522200X Exp. Apr 2019; 535500 Exp. Jul 2019; 540700 Exp. Aug 2019; 543300 Exp. Sep 2019; 550100 Exp. Oct 2019.

Not Yet Classified Drugs Event

Event ID:
81741

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
12/11/2018

Voluntary / Mandated:
Voluntary: Firm Initiated

Center Classification Date:

Initial Firm Notification of Consignee or Public:
Press Release

Recalling Firm:
Asclemed USA Inc. dba Enovachem
379 Van Ness Ave Ste 1403
Torrance CA United States

Distribution Pattern:
Enovachem is notifying its distributors and customers by letter and is arranging for return of the recalled product. Enovachem estimates a recovery of 26% of the Dyural-40 and 24% of the Dyrual-80.

Associated Products

Product Description:
Dyural-40 Injection Kit, containing recalled component: 0.9% Sodium Chloride Injection, USP, 10 mL fill in a 10 mL vial, Rx only, Distributed by Enovachem Pharmaceuticals, Torrance, CA 90501, NDC 76420-0750-01

Product Quantity:

Reason for Recall:
Labeling: Not eslewhere classified - The product insert states that stoppers for both the 10mL and the 20mL vials of 09.% NaCl USP Injection do not contain natural rubber latex; the tray label for the two vial sizes and the vial label for the 20mL vial also state that the stoppers do not contain latex. The product is being recalled because the stoppers contain natural rubber latex.

Recall Number:

Code Information:
Sodium Chloride lot number: 6016261. Dyural-40 kit lot numbers: 050518X5, 062818X1, 082318X4, 091818X3, 092818X4, 051618X1, 072518X3, 083118X1, 091818X4, 101018X5, 052318X4, 072718X1, 090518X4, 091818X5, 101018X3, 052318X5, 080318X2, 091818X2, 092418X1, 102418X5.

Product Description:
Dyural-80 Injection Kit, containing recalled component: 0.9% Sodium Chloride Injection, USP, 10 mL fill in a 10 mL vial, Rx only, Distributed by Enocachem Pharmaceuticals, Torrance, CA 90501, NDC 76420-0755-01

Product Quantity:

Reason for Recall:
Labeling: Not eslewhere classified - The product insert states that stoppers for both the 10mL and the 20mL vials of 09.% NaCl USP Injection do not contain natural rubber latex; the tray label for the two vial sizes and the vial label for the 20mL vial also state that the stoppers do not contain latex. The product is being recalled because the stoppers contain natural rubber latex.

Recall Number:

Code Information:
Sodium Chloride Lot No. 6016261 Dyural-80 Lot Nos.: 050918X1, 061418X2, 071018X5, 080218X3, 090718X5, 101618X7, 051518X4, 061518X1, 071118X5, 080718X7, 091118X7, 101618X8, 051618X10, 061518X2, 071118X4, 080918X3, 091318X5, 101818X3, 051818X4, 061918X2, 071718X2, 083018X2, 091918X1, 101918X1, 051818X5, 062518X2, 072018X6, 083118X2, 092718X1, 102318X1, 052118X4, 062718X1, 072418X3, 083118X5, 092718X2, 103118X1, 052118X5, 062718X2, 072418X4, 090518X5, 092818X3, 103118X2, 052918X7, 062818X3, 072518X2, 090518X6, 100518X6, 103118X3, 061118X8, 062818X4, 073018X4, 090718X2, 101118X3, 110618X1, 061118X9, 070918X1, 073018X8, 090718X3, 101518X2, 110818X1, 061118X10.

Not Yet Classified Drugs Event

Event ID:
81742

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
12/14/2018

Voluntary / Mandated:
Voluntary: Firm Initiated

Center Classification Date:

Initial Firm Notification of Consignee or Public:
Telephone

Recalling Firm:
Results RNA, LLC
1272 S 1380 W
Orem UT United States

Distribution Pattern:
Nationwide within the United States

Associated Products

Product Description:
Lubrisine eye drops (polyethylene glycol 400 0.4% and Propylene glycol 0.3%), 30 ML bottle, Manufactured and Distributed by: Results RNA, LLC, 1272 S 1380 W., Orem, UT 84058, UPC 7 9238230723 4

Product Quantity:
10, 297 bottles

Reason for Recall:
Lack of Sterility Assurance and Incorrect/Undeclared excipient: Product was found to contain undeclared colloidal silver

Recall Number:

Code Information:
All Lots

Not Yet Classified Drugs Event

Event ID:
81765

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
12/07/2018

Voluntary / Mandated:
Voluntary: Firm Initiated

Center Classification Date:

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Sun Pharmaceutical Industries, Inc.
270 Prospect Plains Rd
Cranbury NJ United States

Distribution Pattern:
Nationwide in the USA

Associated Products

Product Description:
Absorica (Isotretinoin) Capsules 30 mg USP, 30 capsules (3x10 Prescription Packs) Rx only, Manufactured by: Galephar Pharmaceutical Research Inc. Humacao, PR 00792, Distributed by: Sun Pharmaceutical Industries Inc. Cranbury, NJ 08512, UPC 310631117313, NDC 10631-117-31 (carton) NDC10631-117-69 (prescription pack)

Product Quantity:
47,520 prescription packs

Reason for Recall:
Subpotent Drug: Isotretinoin content results were lower than the specification limit obtained during routing product monitoring.

Recall Number:

Code Information:
Lot: 17F28AA, Exp 1/2020

Not Yet Classified Drugs Event

Event ID:
81795

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
12/14/2018

Voluntary / Mandated:
Voluntary: Firm Initiated

Center Classification Date:

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Cipla Limited
L129 - 146 S - 103 - 105 S - 107 - 112 L147 - L147/1/2/3 L147/A
Vasco Da Gama India

Distribution Pattern:
Nationwide within the United States

Associated Products

Product Description:
Nevirapine Extended Release Tablets, 400 mg, 30-count bottle, Rx Only, Manufactured by: Cipla Ltd. Verna Goa, India, Manufactured for: Cipla USA Inc. 9100 S Dadeland Blvd., Suite 1500 Miami, FL 33156, NDC 69097-403-02

Product Quantity:
4800 bottles

Reason for Recall:
Failed Dissolution Specifications.

Recall Number:

Code Information:
Lot #: GG80257, Exp. 12/2019