

Enforcement Report - Week of May 3, 2017

Class II Drugs Event

Event ID:
76680

Status:
Ongoing

Recall Initiation Date:
03/28/2017

Center Classification Date:
04/21/2017

Recalling Firm:
Gary Wood
1810 Oak Tree St
Saint Peters MO 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:

hCG Body Shaper, Highly Purified Human Chorionic Gonadotrophin 5000 IU, Colloidal Silver B12, Stabilizers/Excipients, Not For Medical Use, Must Be Refrigerated, Distributed by HCG Body Shaper, St. Peters, MO

Product Quantity:
1305-1400 bottles

Reason for Recall:

Marketed without an Approved NDA/ANDA; FDA analysis has found the product to be tainted with human chorionic gonadotropin, rendering it an unapproved drug

Recall Number:
D-0677-2017

Code Information:
No code information printed on bottle

Class II Drugs Event

Event ID:
76951

Status:
Ongoing

Recall Initiation Date:
04/06/2017

Center Classification Date:
04/26/2017

Recalling Firm:
Isomeric Pharmacy Solution, LLC
2401 S Foothill Dr Ste D
Salt Lake City UT United States

Distribution Pattern:
Nationwide in the USA and Puerto Rico

Product Type:
Drugs

Date Terminated:

Voluntary / Mandated:
Voluntary: Firm Initiated

Initial Firm Notification of Consignee or Public:
Two or more of the following: Email, Fax, Letter, Press Release, Telephone, Visit

Associated Products

Product Description:

Methylprednisolone Acetate 40 mg/mL, Lidocaine HCl 10 mg/mL, 10 mL Multi-Dose Vial For Injection, Rx Only, Isomeric Pharmacy Solutions, 2401 Foothill Drive, SLC, UT 84109, Part # 1010, barcode 3 70285 10101 4.

Product Quantity:
4,001 vials

Reason for Recall:

Lack of Assurance of Sterility: due to concerns with production processes which cannot assure sterility of products intended to be sterile.

Recall Number:
D-0681-2017

Code Information:
Lot #: 09007, Exp 04/04/17; 09016, Exp 04/16/17; 09020, Exp 04/18/17; 09025, Exp 04/23/17; 10026, 10030, Exp 05/28/17; 11007, Exp 05/30/17; 11008, Exp 05/31/17; 11020, Exp 06/07/17; 11028, Exp 06/12/17; 11043, Exp 06/26/17.

Product Description:

Methylprednisolone Acetate 80 mg/mL, Lidocaine HCl 10 mg/mL, 10 mL Multi-Dose Vial For Injection, Rx Only, Isomeric Pharmacy Solutions, 2401 Foothill Dr, SLC, UT 84109, Part # 1011, barcode 3 70285 10111 3.

Product Quantity:
2,352 vials

Reason for Recall:

Lack of Assurance of Sterility: due to concerns with production processes which cannot assure sterility of products intended to be sterile.

Recall Number:
D-0682-2017

Code Information:
Lot #: 09022, Exp 04/22/17; 10001, Exp 05/02/17; 11001, Exp 05/31/17; 11010, Exp 06/03/17; 11037, Exp 06/19/17; 11041, Exp 06/25/17.

Product Description:

Triamcinolone Acetonide 40 mg/mL, Lidocaine HCl 10 mg/mL, 10 mL Multi-Dose Vial For Injection, Rx Only, Isomeric Pharmacy Solutions, 2401 Foothill Dr, SLC, UT 84109, Part # 1020, barcode 3 70285 10201 1.

Product Quantity:
2,335 vials

Reason for Recall:

Lack of Assurance of Sterility: due to concerns with production processes which cannot assure sterility of products intended to be sterile.

Recall Number:

D-0683-2017

Code Information:

Lot #: 09032, Exp 04/06/17; 10017, Exp 04/19/17; 10022, Exp 04/26/17; 10031, Exp 05/04/17; 11021, Exp 05/17/17; 12007, Exp 06/16/17.

Product Description:

Triamcinolone Diacetate 40 mg/mL, 10 mL Multi-Dose Vial For Injection, Rx Only, Isomeric Pharmacy Solutions, 2401 Foothill Drive, SLC, UT 84109, Part # 1021, barcode 3 70285 10211 0.

Product Quantity:

1,951 vials

Reason for Recall:

Lack of Assurance of Sterility: due to concerns with production processes which cannot assure sterility of products intended to be sterile.

Recall Number:

D-0684-2017

Code Information:

Lot #: 10013, Exp 05/10/17; 10020, Exp 05/20/17; 10029, Exp 05/27/17; 11002, Exp 05/30/17; 11013, Exp 06/04/17.

Product Description:

Cyanocobalamin 1 mg/mL/ Methionine 25 mg/mL/ Inositol 50 mg/mL/ Choline 50 mg/mL, 30 mL Multi-Dose Vial For Injection, Rx Only, Isomeric Pharmacy Solutions, 2401 Foothill Drive, SLC, UT 84109, Part # 1101, barcode 3 70285 11013 9.

Product Quantity:

851 vials

Reason for Recall:

Lack of Assurance of Sterility: due to concerns with production processes which cannot assure sterility of products intended to be sterile.

Recall Number:

D-0685-2017

Code Information:

Lot #: 09003, Exp 04/17/17; 11003, Exp 06/21/17; 11035, Exp 07/03/17; 11039, Exp 07/05/17; 12002, Exp 07/23/17; 12012, Exp 07/30/17.

Product Description:

Testosterone Cypionate 200 mg/mL, Testosterone Propionate 20 mg/mL, 30 mL Multi-Dose Vial For Injection, Rx Only, Isomeric Pharmacy Solutions, 2401 Foothill Dr, SLC, UT 84109, Part # 1200, barcode 3 70285 12003 9.

Product Quantity:

2,156 vials

Reason for Recall:

Lack of Assurance of Sterility: due to concerns with production processes which cannot assure sterility of products intended to be sterile.

Recall Number:

D-0686-2017

Code Information:

Lot #: 09018, Exp 04/17/17; 09023, Exp 04/22/17; 09024, Exp 04/23/17; 09027, Exp 04/25/17; 09031, Exp 04/30/17; 10005, Exp 05/06/17; 10010, Exp 05/09/17; 11022, Exp 06/10/17; 11038, Exp 06/18/17; 11044, Exp 07/04/17; 12003, Exp 07/08/17; 12010, Exp 07/12/17; 12021, Exp 07/30/17.

Product Description:

Phenylephrine 2.5%, Tropicamide 1%, 15 mL Multi-Dose Ophthalmic (spelled Ophthalmic) Drops in a bottle, Rx Only, Isomeric Pharmacy Solutions, 2401 Foothill Dr, SLC, UT 84109, Part # 1300, barcode 3 70285 13001 4.

Product Quantity:

5,165 bottles

Reason for Recall:

Lack of Assurance of Sterility: due to concerns with production processes which cannot assure sterility of products intended to be sterile.

Recall Number:

D-0687-2017

Code Information:

Lot Numbers: 10003, Exp 04/05/17; 10018, Exp 04/17/17; 10023, Exp 04/23/17; 10025, Exp 04/24/17; 10027, Exp 04/29/17; 11011, 11012, Exp 05/07/17; 11024, 11026, Exp 05/14/17; 11029, Exp 05/16/17; 11030, Exp 05/17/17; 11032, Exp 05/21/17; 11045, Exp 06/04/17; 12008, Exp 06/13/17; 12014, 12015, Exp 06/20/17; 12022, 12024, Exp 06/28/17; 13001, 13002, Exp 07/03/17; 13011, 13012, Exp 07/09/17.

Class III Drugs Event**Event ID:**

76756

Status:

Ongoing

Recall Initiation Date:

03/22/2017

Center Classification Date:

04/21/2017

Recalling Firm:Novartis Pharmaceuticals Corp.
1 Health Plz
East Hanover 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:**

Isopto Carpine (pilocarpine hydrochloride ophthalmic solution) 4%, packaged in 15 mL bottle, Rx only, Manufactured by: Alcon Laboratories, Inc. Fort Worth Texas 76134 USA NDC 0998-0206-15

Product Quantity:**Reason for Recall:**

Failed Impurities/Degradation Specifications.

Recall Number:

D-0678-2017