Enforcement Report - Week of April 13, 2016

Biologics | Cosmetics | Devices | Drugs | Food | Tobacco | Veterinary

Class II Drugs Event

Event ID:
73474
Product Type:
Drugs

Status:
Ongoing
Recalling Firm:
Actavis Elizabeth LLC
200 Elmora Ave
Elizabeth NJ United States
Recall Initiation Date:
02/16/2016
Center Classification Date:
04/07/2016
Date Terminated:

Voluntary / Mandated:
Voluntary: Firm Initiated
Initial Firm Notification of Consignee or Public:
Letter
Distribution Pattern:
US: Nationwide

Associated Products

Product Description:
Dextroamphetamine Saccharate, Amphetamine Aspartate, Dextroamphetamine Sulfate, and Amphetamine Sulfate Tablets, 5 mg, 100 ct. bottle, Rx Only. Manufactured by: Actavis Elizabeth LLC, Elmora Avenue, Elizabeth, NJ 07207. Distributed by: Actavis, Inc., 80 Columbia Road, Bldg B, Morristown, NJ 07960. NDC: 45963-743-11.
Product Quantity:
38,507 Bottles
Code Information:
Lot #: 5245M141, Expiry: 6/16; Lot #:

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

Recall Number:
D-0816-2016

0953C151, Expiry date: 8/16Lot #: 1728D151, Expiry: 9/16; Lot #: 3205G152, Expiry: 3/17.

Product Description:
Dextroamphetamine Saccharate, Amphetamine Aspartate, Dextroamphetamine Sulfate, and Amphetamine Sulfate Tablets, 10 mg, 100 ct. bottle, Rx Only. Manufactured by: Actavis Elizabeth LLC, Elmora Avenue, Elizabeth, NJ 07207. Distributed by: Actavis, Inc., 80 Columbia Road, Bldg B, Morristown, NJ 07960. NDC: 45963-745-11.

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

Product Quantity:
114,388 Bottles

Recall Number:
D-0813-2016

Code Information:
Lot #: 2172#141, Expiry: 3/16; Lot #: 4217K141, Expiry: 3/16; Lot #: 0420A151, Expiry: 7/16; Lot #: 0421A151, Expiry: 7/16; Lot #: 0854B151, Expiry: 10/16; Lot #: 1329C151, Expiry: 10/16; Lot #: 2692F151, Expiry; 2/17; Lot #: 3202G151, Expiry: 3/17; Lot #: 3796J151, Expiry: 3/17; Lot #: 3797J151, Expiry: 4/17.

Product Description:
Dextroamphetamine Saccharate, Amphetamine Aspartate, Dextroamphetamine Sulfate, and Amphetamine Sulfate Tablets, 20 mg, 100 ct. bottle, Rx Only. Manufactured by: Actavis Elizabeth LLC, Elmora Avenue, Elizabeth, NJ 07207. Distributed by: Actavis, Inc., 80 Columbia Road, Bldg B, Morristown, NJ 07960. NDC: 45963-748-11.

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

Product Quantity:
257,746 Bottles

Recall Number:
D-0814-2016

Code Information:
Lot #: 3992J141, Expiry: 5/16; Lot #:

3993J142, Expiry: 5/16; Lot #:
0695B151, Expiry: 7/16; Lot #:
0696B151, Expiry: 7/16; Lot #:
0378A151, Expiry: 7/16; Lot #:
0379A151, Expiry: 7/16; Lot #:
0697B151, Expiry: 8/16; Lot #:
2427F151, Expiry: 11/16; Lot #:
1947E151, Expiry: 11/16; Lot #:
1330C151, Expiry: 11/16; Lot #:
1331C151, Expiry: 11/16; Lot #:
1946E151, Expiry: 11/16; Lot #:
3652H151, Expiry: 2/17; Lot #:
3653H151, Expiry: 3/17, Lot #:
3654H151, Expiry: 3/17; Lot #:
4251K151, Expiry: 3/17; Lot #:
4250K151, Expiry: 4/17; Lot #:
4252K151, Expiry: 4/17; Lot #:
4249K151, Expiry: 4/17; Lot #:
5101M151, Expiry: 5/17.

Product Description:
Dextroamphetamine Saccharate, Amphetamine Aspartate, Dextroamphetamine Sulfate, and Amphetamine Sulfate Tablets, 30 mg, 100 ct. bottle, Rx Only. Manufactured by: Actavis Elizabeth LLC, Elmora Avenue, Elizabeth, NJ 07207. Distributed by: Actavis, Inc., 80 Columbia Road, Bldg B, Morristown, NJ 07960. NDC: 45963-749-11.

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

Product Quantity:
182,378 Bottles

Recall Number:
D-0815-2016

Code Information:
Lot #: 1879E141, Expiry 02/16; Lot #:
1880E141, Expiry: 02/16; Lot #:
5034M142; Expiry: 5/16; Lot #:
0422A151, Expiry: 7/16; Lot #:
0423A151, Expiry: 7/16; Lot #:
1053C151, Expiry: 8/16; Lot #:
1054C151, Expiry: 8/16; Lot #:
2197E152, Expiry: 11/16; Lot #:
2198E151, Expiry: 12/16; Lot #:
2662F151, Expiry: 12/16; Lot #:

2672F152, Expiry: 3/17; Lot #:
3121G152, Expiry: 3/17; Lot #:
3798J151, Expiry: 4/17; Lot #:
5104M151, Expiry: 5/17.

Class II Drugs Event

Event ID:
73537
Product Type:
Drugs

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
Distribution Pattern:
Nationwide

Status:
Ongoing
Recalling Firm:
Meditech Laboratories, Inc
3200 Polaris Ave Ste 27
Las Vegas NV United States
Recall Initiation Date:
03/14/2016
Center Classification Date:
04/01/2016
Date Terminated:

Associated Products

Product Description:
Formula 2 (Papaverine 9 mg, Phentolamine 1 mg, Atropine 0.1 mg, PGE 10 mcg/mL) Injection, 5 mL vials, Rx only, Meditech Laboratories, Inc., 3200 Polaris Ave., Suite 27, Las Vegas, NV 89102.
Product Quantity:
1320 vials - all formulas
Code Information:
Lot #: 110115-2, Exp 01/01/16

Reason for Recall:
Superpotent Drug: one ingredient was found to be above assay specification.

Recall Number:
D-0802-2016

Product Description:
Formula 4 (Papaverine 18 mg,

Reason for Recall:
Lack of Assurance of Sterility:

Phentolamine 2 mg, Atropine 0.2 mg/mL) Injection, 5 mL vials, Rx only, Meditech Laboratories, Inc., 3200 Polaris Ave., Suite 27, Las Vegas, NV 89102. .

Product Quantity:
1320 vials - all formulas

Code Information:
Lot#: 022316-4, Exp 04/08/16

incomplete or missing data regarding production.

Recall Number:
D-0803-2016

Product Description:
Formula 9 (Papaverine 0.9 mg, Phentolamine 0.1 mg, Atropine 0.01 mg, PGE 20 mcg/mL) Injection, 5 mL vial, Rx only, Meditech Laboratories, Inc., 3200 Polaris Ave., Suite 27, Las Vegas, NV 89102.

Product Quantity:
1320 vials - all formulas

Code Information:
Lot#: 022416-9, Exp 04/09/16.

Reason for Recall:
Lack of Assurance of Sterility: incomplete or missing data regarding production.

Recall Number:
D-0804-2016

Product Description:
Formula 1 (Papaverine 1.8 mg, Phentolamine 0.2 mg, Atropine 0.02 mg, PGE 18 mcg/mL) Injection, 5 mL vial, Rx only, Meditech Laboratories, Inc., 3200 Polaris Ave., Suite 27, Las Vegas, NV 89102.

Product Quantity:
1320 vials - all formulas

Code Information:
Lot#: 011916-1, Exp 04/19/16; 020316-1, Exp 05/03/16

Reason for Recall:
Stability Does Not Support Expiry: manufactured with an active ingredient that expired before the labeled Beyond Use Date.

Recall Number:
D-0805-2016

Product Description:
Formula 3 (Papaverine 20 mg, Phentolamine 3 mg, Atropine 0.2 mg, PGE 20 mcg/mL) Injection, 5 mL vials, Rx only, Meditech Laboratories, Inc., 3200 Polaris Ave., Suite 27, Las Vegas, NV 89102.

Product Quantity:

Reason for Recall:
Stability Does Not Support Expiry: manufactured with an active ingredient that expired before the labeled Beyond Use Date.

Recall Number:

1320 vials - all formulas
Code Information:
Lot#: 011716-3, Exp 04/17/16;
012416-3, Exp 04/24/16.

D-0806-2016

Product Description:
Formula 0 (PGE 20 mcg/mL) Injection, 5 mL vials, Rx only, Meditech Laboratories, Inc., 3200 Polaris Ave., Suite 27, Las Vegas, NV 89102.
Product Quantity:
1320 vials - all formulas
Code Information:
Lot#: 020716-0, Exp 05/07/16

Reason for Recall:
Lack of Assurance of Sterility: incomplete or missing data regarding production.

Recall Number:
D-0807-2016

Product Description:
Formula 2 (Papaverine 9 mg, Phentolamine 1 mg, Atropine 0.1 mg, PGE 10 mcg/mL), 5 mL vials, Meditech Laboratories, Inc., 3200 Polaris Ave., Suite 27, Las Vegas, NV 89102.
Product Quantity:
1320 vials - all formulas
Code Information:
Lot #: 12216-2, Exp 04/22/16

Reason for Recall:
Stability Does Not Support Expiry: manufactured with an active ingredient that expired before the labeled Beyond Use Date.

Recall Number:
D-0808-2016

Class III Drugs Event

Event ID:
72819
Product Type:
Drugs

Status:
Ongoing
Recalling Firm:
Bio-pharm, Inc.
2091 Hartel Ave
Levittown PA United States
Recall Initiation Date:
12/17/2015
Center Classification Date:

Voluntary / Mandated:
Voluntary: Firm Initiated
Initial Firm Notification of Consignee or Public:
Letter
Distribution Pattern:
Nationwide and Puerto Rico

04/01/2016
Date Terminated:

Associated Products

Product Description:
Ranitidine Syrup (Ranitidine Oral Solution, USP), 15 mg/mL (75 mg/5 mL), 16 fl oz Bottle, Rx only, Mfd For: Heritage Pharmaceuticals Inc., Eatontown, NJ 07724, NDC 23155-291-51
Product Quantity:
103,664 Bottles
Code Information:
Lot #s: 14G008, 14G013, 14G010, 14G015, 14G016, 14G021, 14G026, 14G028, Exp. 01/2016; 14K027, 14K023, Exp. 04/2016; 15B040, 15B041, Exp. 08/2016; 15E042, Exp. 11/2016; 15F019, 15F021, Exp. 12/2016; 15G038, Exp. 01/2017; 15H004, 15H008, Exp. 02/2017

Reason for Recall:
Failed Impurities/Degradation Specifications: Product recalled due to elevated impurity result detected during routine stability testing.

Recall Number:
D-0809-2016

Class III Drugs Event

Event ID:
73295
Product Type:
Drugs

Status:
Ongoing
Recalling Firm:
Virtus Pharmaceuticals, Llc
2649 Causeway Center Dr
Tampa FL United States
Recall Initiation Date:
12/17/2015
Center Classification Date:
04/01/2016
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
Distribution Pattern:
Nationwide

Associated Products

Product Description:
VP-CH-PNV PRENATAL/POSTNATAL Prescription Folic Acid-Containing Dietary Supplement, 30-count Softgel bottles, Rx, Manufactured for Vitrus Pharmaceuticals, LLC, Tampa, FL 33619, NDC 69543-224-30, UPC 369543224305

Reason for Recall:
Defective Delivery System: Product may contain leaking capsules.

Product Quantity:
688 bottles (20,640 softgel capsules)

Recall Number:
D-0801-2016

Code Information:
Lot #21506132; Exp. 05/17

Class III Drugs Event

Event ID:
73326

Voluntary / Mandated:
Voluntary: Firm Initiated

Product Type:
Drugs

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

Status:
Ongoing

Distribution Pattern:
All product was shipped to KY and further distributed Nationwide

Recalling Firm:
Apace KY LLC
12954 Fountain Run Rd
Fountain Run KY United States

Recall Initiation Date:
02/12/2016

Center Classification Date:
04/05/2016

Date Terminated:

Associated Products

Product Description:
Minocycline Hydrochloride Capsules USP, 100 mg*, 30 Capsules (3 x 10)

Reason for Recall:
Labeling: Incorrect or Missing Lot and/or Exp Date: the individual blisters

Unit Dose blisters (NDC 50268-569-11, barcode 5026856911) per carton (NDC 50268-569-13, barcode 5026856913), Rx only, Manufactured for: AvKARE, Inc., Pulaski, TN 38478.

Product Quantity:
291 cartons

Code Information:
Outer Cases and Cartons Lot #: 13650, EXP 06/2017; Blisters Lot #: 13560, EXP 06/2017

are mislabeled with an incorrect lot number of 13560 rather than the correct lot number of 13650.

Recall Number:
D-0811-2016

Class III Drugs Event

Event ID:
73586

Product Type:
Drugs

Status:
Ongoing

Recalling Firm:
Jubilant Draximage Inc
16751 Rte Trans-Canada
Kirkland Canada

Recall Initiation Date:
03/11/2016

Center Classification Date:
04/06/2016

Date Terminated:

Voluntary / Mandated:
Voluntary: Firm Initiated

Initial Firm Notification of Consignee or Public:
E-Mail

Distribution Pattern:
Nationwide

Associated Products

Product Description:
SODIUM IODIDE I 131 CAPSULE, USP DIAGNOSTIC ORAL , Rx only, Manufactured by Jubilant DraxImage, Inc., Kirkland, QC, Canada, NDC 65174-461-05

Product Quantity:
90 vials (450 capsules)

Code Information:
Lot Number 1670123; Exp 04/16

Reason for Recall:
Labeling: Label Error on Declared Strength

Recall Number:
D-0812-2016

Class III Drugs Event

Event ID:
73709
Product Type:
Drugs

Status:
Ongoing

Recalling Firm:
Purdue Pharma L.P.
201 Tresser Blvd
Stamford CT United States
Recall Initiation Date:
03/31/2016
Center Classification Date:
04/04/2016
Date Terminated:

Voluntary / Mandated:
Voluntary: Firm Initiated
Initial Firm Notification of Consignee or Public:
Letter
Distribution Pattern:
U.S. Including: FL, LA, MI, MS, NC, NJ, OH and SC.

Associated Products

Product Description:
Intermezzo (zolpidem tartrate) sublingual tablet 1.75 mg, CIV, 30 Ct Cartons, Rx Only. Dist by Purdue Pharma L.P., Stamford, CT 06901-3431. NDC: 59011-256-30.
Product Quantity:
2172 Cartons
Code Information:
Lot #: 3126431B, Expiry: 09/30/17

Reason for Recall:
Failed Dissolution Specifications

Recall Number:
D-0810-2016