

Enforcement Report - Week of June 8, 2016

Biologics

Cosmetics

Devices

Drugs

Food

Tobacco

Veterinary

Class II Drugs Event

Event ID:

73698

Product Type:

Drugs

Status:

Ongoing

Recalling Firm:

Invisiblu International LLC
620 SE 13th St
Fort Lauderdale FL United States

Recall Initiation Date:

03/31/2016

Center Classification Date:

05/27/2016

Date Terminated:**Voluntary / Mandated:**

Voluntary: Firm Initiated

Initial Firm Notification of Consignee or Public:

Press Release

Distribution Pattern:

Nationwide and Brazil.

Associated Products**Product Description:**

LGD-Xtreme (ligandrol LGD-4033), capsules, 3 mg, 90-count bottle,
Manufactured for Continuum Labs,
Fort Lauderdale, FL

Product Quantity:

3,319 bottles

Code Information:

Lot # 21511166, Exp 11/18

Reason for Recall:

Marketed Without An Approved
NDA/ANDA: Contains an unapproved
drug, ligandrol LGD-4033

Recall Number:

D-0910-2016

Class II Drugs Event

Event ID:**Voluntary / Mandated:**

73899

Voluntary: Firm Initiated

Product Type:

Drugs

Initial Firm Notification of Consignee or Public:

Telephone

Status:

Ongoing

Distribution Pattern:

Arkansas

Recalling Firm:Baptist Health Medical Towers Pharmacy
and Infusion Services

9601 Baptist Health Dr Ste 109

Little Rock AR United States

Recall Initiation Date:

04/18/2016

Center Classification Date:

05/29/2016

Date Terminated:**Associated Products****Product Description:**0.9% Sodium Chloride a) 500 mL b)
2000 mL and c) 3000 mL bags, FOR
IV USE ONLY, Baptist Health Medical
Towers Pharmacy & Infusion, Little
Rock, AR**Reason for Recall:**

Lack of Sterility Assurance

Product Quantity:

a) 6 bags b) 1 bag c) 2 bags

Recall Number:

D-0911-2016

Code Information:

All product remaining within expiry

Product Description:1/2 Normal Saline 2000 mL + Sodium
Acetate 80 mEq., FOR IV USE ONLY,
Baptist Health Medical Towers
Pharmacy & Infusion, Little Rock, AR**Reason for Recall:**

Lack of Sterility Assurance.

Product Quantity:

7 bags

Recall Number:

D-0912-2016

Code Information:

All product remaining within expiry.

Product Description:

70% Ethanol-lock Solution, 2 mL

Reason for Recall:

Lack of Sterility Assurance

Syringe, FOR IV USE ONLY, Baptist Health Medical Towers Pharmacy & Infusion, Little Rock, AR

Product Quantity:

18 syringes

Code Information:

All product remaining within expiry

Recall Number:

D-0913-2016

Product Description:

Ascorbic Acid 500 mg (1 mL) Syringe, FOR IV USE ONLY, Baptist Health Medical Towers Pharmacy & Infusion, Little Rock, AR

Product Quantity:

21 syringes

Code Information:

All product remaining within expiry

Reason for Recall:

Lack of Sterility Assurance

Recall Number:

D-0914-2016

Product Description:

Cefazolin 6 grams in 292 mL 0.9% NS bags, FOR IV USE ONLY, Baptist Health Medical Towers Pharmacy & Infusion, Little Rock, Arkansas

Product Quantity:

11 bags

Code Information:

All product remaining within expiry

Reason for Recall:

Lack of Sterility Assurance

Recall Number:

D-0915-2016

Product Description:

Ceftriaxone 1 gram Add-Vantage in a) 50 mL and b) 100 mL 0.45% NS bags, FOR IV USE ONLY, Baptist Health Medical Towers Pharmacy & Infusion, Little Rock, AR

Product Quantity:

a) 39 bags and b) 8 bags

Code Information:

All product remaining within expiry

Reason for Recall:

Lack of Sterility Assurance

Recall Number:

D-0916-2016

Product Description:

Ceftriaxone 2 gram Add-Vantage in 100 mL 0.45% NS bag, FOR IV USE

Reason for Recall:

Lack of Sterility Assurance

ONLY, Baptist Health Medical Towers
Pharmacy & Infusion, Little Rock, AR

Product Quantity:

16 bags

Code Information:

All product remaining within expiry

Recall Number:

D-0917-2016

Product Description:

Ceftriaxone 2 gram in 100 mL 0.9%
NS bags, FOR IV USE ONLY, Baptist
Health Medical Towers Pharmacy &
Infusion, Little Rock, AR

Product Quantity:

32 bags

Code Information:

All product remaining within expiry

Reason for Recall:

Lack of Sterility Assurance

Recall Number:

D-0918-2016

Product Description:

Clindamycin 900 mg in 100 mL 0.9%
NS bag, FOR IV USE ONLY, Baptist
Health Medical Towers Pharmacy &
Infusion, Little Rock, AR

Product Quantity:

16 bags

Code Information:

All product remaining within expiry

Reason for Recall:

Lack of Sterility Assurance

Recall Number:

D-0919-2016

Product Description:

D5 1/2 NS 1000 mL with Electrolytes
bag, FOR IV USE ONLY, Baptist
Health Medical Towers Pharmacy &
Infusion, Little Rock, AR

Product Quantity:

6 bags

Code Information:

All product remaining within expiry

Reason for Recall:

Lack of Sterility Assurance

Recall Number:

D-0920-2016

Product Description:

Daptomycin 650 mg in 50 mL 0.9% NS
bag, FOR IV USE ONLY, Baptist
Health Medical Towers Pharmacy &
Infusion, Little Rock, AR

Reason for Recall:

Lack of Sterility Assurance

Product Quantity:

14 bags

Recall Number:

D-0921-2016

Code Information:

All product remaining within expiry

Product Description:

Deferoxamine 2 grams/51 mL NS
cassette, FOR SUBCUTANEOUS USE
ONLY, Baptist Health Medical Towers
Pharmacy & Infusion, Little Rock, AR

Reason for Recall:

Lack of Sterility Assurance.

Product Quantity:

5 cassettes

Recall Number:

D-0922-2016

Code Information:

All product remaining within expiry.

Product Description:

Deferoxamine 4 grams/NS 101 mL
Cassette, FOR SUBCUTANEOUS
USE ONLY, Baptist Health Medical
Towers Pharmacy & Infusion, Little
Rock, AR

Reason for Recall:

Lack of Sterility Assurance

Product Quantity:

3 cassettes

Recall Number:

D-0923-2016

Code Information:

All product remaining within expiry

Product Description:

Deferoxamine 3300 mg/20 mL Sterile
Water for Injection syringe, FOR
SUBCUTANEOUS USE ONLY, Baptist
Health Medical Towers Pharmacy &
Infusion, Little Rock, AR

Reason for Recall:

Lack of Sterility Assurance

Product Quantity:

5 bags

Recall Number:

D-0924-2016

Code Information:

All product remaining within expiry

Product Description:

Dobutamine 2000 mcg/mL in a) D5W-
500 mL, b) D5W-750 mL, c) D5W-
1000 mL, d) D5W-1750 mL Bags, FOR
IV USE ONLY, Baptist Health Medical

Reason for Recall:

Lack of Sterility Assurance.

Towers Pharmacy & Infusion, Little Rock, AR

Product Quantity:

a) 10 bags, b) 23 bags, c) 9 bags, d) 6 bags

Code Information:

All product remaining within expiry.

Recall Number:

D-0925-2016

Product Description:

Ertapenem 1 gram Add-Vantage in a) 50 mL and b) 100 mL 0.45% NS bag, FOR IV USE ONLY, Baptist Health Medical Towers Pharmacy & Infusion, Little Rock, AR

Product Quantity:

a) 16 bags and b) 18 bags

Code Information:

All product remaining within expiry

Reason for Recall:

Lack of Sterility Assurance.

Recall Number:

D-0926-2016

Product Description:

Hydromorphone 2 mg/mL (500 mg in 250 mL NS) bag, FOR IV USE ONLY, Baptist Health Medical Towers Pharmacy & Infusion, Little Rock, AR

Product Quantity:

3 bags

Code Information:

All product remaining within expiry

Reason for Recall:

Lack of Sterility Assurance

Recall Number:

D-0927-2016

Product Description:

Invanz 1 gram Add-Vantage in 100 mL 0.45% NS bag, FOR IV USE ONLY, Baptist Health Medical Towers Pharmacy & Infusion, Little Rock, AR

Product Quantity:

24 bags

Code Information:

All product remaining within expiry.

Reason for Recall:

Lack of Sterility Assurance.

Recall Number:

D-0928-2016

Product Description:

Meropenem 2 grams in 100 mL 0.9% NS bag, FOR IV USE ONLY, Baptist

Reason for Recall:

Lack of Sterility Assurance

Health Medical Towers Pharmacy &
Infusion, Little Rock, AR

Product Quantity:

22 bags

Code Information:

All product remaining within expiry

Recall Number:

D-0929-2016

Product Description:

Milrinone 200 mcg/mL in a) D5W-300 mL, b) D5W-400 mL, c) D5W-500 mL and d) D5W-600 mL Bags, FOR IV USE ONLY, Baptist Health Medical Towers Pharmacy & Infusion, Little Rock, AR

Product Quantity:

a) 15 bags, b) 15 bags, c) 15 bags, d) 4 bags

Code Information:

All product remaining within expiry

Reason for Recall:

Lack of Sterility Assurance

Recall Number:

D-0930-2016

Product Description:

Nafcillin 3 grams in 277 mL 0.9% NS bag, FOR IV USE ONLY, Baptist Health Medical Towers Pharmacy & Infusion, Little Rock, AR

Product Quantity:

7 bags

Code Information:

All product remaining within expiry

Reason for Recall:

Lack of Sterility Assurance

Recall Number:

D-0931-2016

Product Description:

Nafcillin 12 grams in 322 mL 0.9% NS bag, FOR IV USE ONLY, Baptist Health Medical Towers Pharmacy & Infusion, Little Rock, AR

Product Quantity:

11 bags

Code Information:

All product remaining within expiry

Reason for Recall:

Lack of Sterility Assurance

Recall Number:

D-0932-2016

Product Description:

Piperacillin-Tazobactam 9 grams/NS

Reason for Recall:

Lack of Sterility Assurance

302 mL bags, FOR IV USE ONLY,
Baptist Health Medical Towers
Pharmacy & Infusion, Little Rock, AR

Product Quantity:

4 bags

Code Information:

All product remaining within expiry

Recall Number:

D-0933-2016

Product Description:

Piperacillin-Tazobactam 10.125
grams/NS 307 mL BAG, FOR IV USE
ONLY, Baptist Health Medical Towers
Pharmacy & Infusion, Little Rock, AR

Product Quantity:

14 bags

Code Information:

All product remaining within expiry

Reason for Recall:

Lack of Sterility Assurance

Recall Number:

D-0934-2016

Product Description:

Piperacillin-Tazobactam 13.5
grams/NS 322 mL bag, FOR IV USE
ONLY, Baptist Health Medical Towers
Pharmacy & Infusion, Little Rock, AR

Product Quantity:

53 bags

Code Information:

All product remaining within expiry

Reason for Recall:

Lack of Sterility Assurance

Recall Number:

D-0935-2016

Product Description:

Remicade 600 mg in 250 mL 0.9% NS
bag, FOR IV USE ONLY, Baptist
Health Medical Towers Pharmacy &
Infusion, Little Rock, AR

Product Quantity:

1 bag

Code Information:

All product remaining within expiry.

Reason for Recall:

Lack of Sterility Assurance

Recall Number:

D-0936-2016

Product Description:

Sodium Chloride 0.9% 1000 mL with
Electrolytes bag, FOR IV USE ONLY,
Baptist Health Medical Towers

Reason for Recall:

Lack of Sterility Assurance

Pharmacy & Infusion, Little Rock, AR

Product Quantity:

7 bags

Code Information:

All product remaining within expiry

Recall Number:

D-0937-2016

Product Description:

TPN 1, (amino acid 20%) 2000 ml bag
(140), FOR IV USE ONLY, Baptist
Health Medical Towers Pharmacy &
Infusion, Little Rock Arkansas

Product Quantity:

7 bags

Code Information:

All product remaining within expiry.

Reason for Recall:

Lack of Sterility Assurance.

Recall Number:

D-0938-2016

Product Description:

TPN 2, (amino acid 20%) 2000 ml bag
(140), FOR IV USE ONLY, Baptist
Health Medical Towers Pharmacy &
Infusion, Little Rock Arkansas

Product Quantity:

86 bags

Code Information:

All product remaining within expiry

Reason for Recall:

Lack of Sterility Assurance

Recall Number:

D-0939-2016

Product Description:

Water for Injection 1000 mL Bags,
FOR IV USE ONLY, Baptist Health
Medical Towers Pharmacy & Infusion,
Little Rock Arkansas

Product Quantity:

7 bags

Code Information:

All product remaining within expiry

Reason for Recall:

Lack of Sterility Assurance

Recall Number:

D-0940-2016

Product Description:

Vancomycin 500 mg in 250 mL 0.9%
NS bag, FOR IV USE ONLY, Baptist
Health Medical Towers Pharmacy &
Infusion, Little Rock, AR

Product Quantity:**Reason for Recall:**

Lack of Sterility Assurance

Recall Number:

1 bag

D-0941-2016

Code Information:

All product remaining within expiry

Product Description:

Vancomycin 750 mg in 250 mL 0.9%
NS bag, FOR IV USE ONLY, Baptist
Health Medical Towers Pharmacy &
Infusion, Little Rock, AR

Product Quantity:

47 bags

Code Information:

All product remaining within expiry.

Reason for Recall:

Lack of Sterility Assurance.

Recall Number:

D-0942-2016

Product Description:

Vancomycin 1000 mg in 250 mL 0.9%
NS bag, FOR IV USE ONLY, Baptist
Health Medical Towers Pharmacy &
Infusion, Little Rock, AR

Product Quantity:

59 bags

Code Information:

All product remaining within expiry

Reason for Recall:

Lack of Sterility Assurance

Recall Number:

D-0943-2016

Product Description:

Vancomycin 1250 mg in 250 mL 0.9%
NS bags, FOR IV USE ONLY, Baptist
Health Medical Towers Pharmacy &
Infusion, Little Rock, AR

Product Quantity:

84 bags

Code Information:

All product remaining within expiry.

Reason for Recall:

Lack of Sterility Assurance.

Recall Number:

D-0944-2016

Product Description:

Vancomycin 1500 mg in 270 mL 0.9%
NS bag, FOR IV USE ONLY, Baptist
Health Medical Towers Pharmacy &
Infusion, Little Rock, AR

Product Quantity:

88 bags

Reason for Recall:

Lack of Sterility Assurance.

Recall Number:

D-0945-2016

Code Information:

All product remaining within expiry

Product Description:

Vancomycin 1750 mg in 270 mL 0.9%
NS bag, FOR IV USE ONLY, Baptist
Health Medical Towers Pharmacy &
Infusion, Little Rock, AR

Product Quantity:

54 bags

Code Information:

All product remaining within expiry

Reason for Recall:

Lack of Sterility Assurance

Recall Number:

D-0946-2016

Product Description:

Vancomycin 1 grams in 250 mL 0.9%
NS bags, FOR IV USE ONLY, Baptist
Health Medical Towers Pharmacy &
Infusion, Little Rock, AR

Product Quantity:

2 bags

Code Information:

All product remaining within expiry

Reason for Recall:

Lack of Sterility Assurance

Recall Number:

D-0947-2016

Product Description:

Vancomycin 2 grams in 540 mL 0.9%
NS bags, FOR IV USE ONLY, Baptist
Health Medical Towers Pharmacy &
Infusion, Little Rock, AR

Product Quantity:

11 bags

Code Information:

All product remaining within expiry.

Reason for Recall:

Lack of Sterility Assurance.

Recall Number:

D-0948-2016

Class II Drugs Event**Event ID:**

74099

Product Type:

Drugs

Status:**Voluntary / Mandated:**

Voluntary: Firm Initiated

**Initial Firm Notification of Consignee
or Public:**

Letter

Distribution Pattern:

Ongoing

Nationwide and Puerto Rico.

Recalling Firm:

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

Recall Initiation Date:

05/17/2016

Center Classification Date:

05/29/2016

Date Terminated:**Associated Products****Product Description:**

Sulfacetamide Sodium Ophthalmic
Solution, USP, 10%, Sterile, Rx Only,
15 mL bottles, Mfd. by: Akorn, Inc.,
Lake Forest, IL 60045 --- NDC 17478-
221-12

Product Quantity:

57,920 bottles

Code Information:

Lot# 5A17A, Expiry 06/16 Lot# 5K21A,
Expiry 03/17 Lot# 6A08A, Expiry 06/17

Reason for Recall:

Lack of Assurance of Sterility; some
lots failed Antimicrobial Effectiveness
Testing on stability

Recall Number:

D-0949-2016

Class III Drugs Event**Event ID:**

73829

Product Type:

Drugs

Status:

Ongoing

Recalling Firm:

Taro Pharmaceuticals U.S.A., Inc.
3 Skyline Dr
Hawthorne NY United States

Recall Initiation Date:

03/31/2016

Voluntary / Mandated:

Voluntary: Firm Initiated

**Initial Firm Notification of Consignee
or Public:**

Letter

Distribution Pattern:

U.S. Including: CA, CT, MA, MD, NY, NJ,
OK, TX, and WA

Center Classification Date:

05/31/2016

Date Terminated:**Associated Products****Product Description:**

¿ Topicort (desoximetasone) Cream
USP, 0.05%, Packaged in 5 g Tubes,
Professional Sample Only, Rx Only.
Mfd. by: Taro Pharmaceuticals Inc.,
Brampton, Ontario, Canada L6T 1C1,
Dist. by: TaroPharma a division of Taro
Pharmaceuticals U.S.A., Inc.,
Hawthorne, NY 10532. NDC: 51672-
5205-5.

Product Quantity:

62,800 Tubes

Code Information:

Lot # A5192-18338, Expiry: 12/2016

Reason for Recall:

Subpotent Drug

Recall Number:

D-0950-2016

Class III Drugs Event**Event ID:**

73830

Product Type:

Drugs

Status:

Ongoing

Recalling Firm:

Lupin Pharmaceuticals Inc.
111 S Calvert St Fl 21ST
Baltimore MD United States

Recall Initiation Date:

03/11/2016

Center Classification Date:

06/02/2016

Date Terminated:**Voluntary / Mandated:**

Voluntary: Firm Initiated

**Initial Firm Notification of Consignee
or Public:**

E-Mail

Distribution Pattern:

Nationwide and Puerto Rico

Associated Products

Product Description:

Ceftriaxone for Injection USP, 250 mg, Single Use Vial, packaged in a) 1-count Vials per box (NDC 68180-611-01), and b) 10-count Vials per box (NDC 68180-611-10), Rx only, Manufactured for: Lupin Pharmaceuticals, Inc., 111 South Calvert Street, Baltimore, Maryland 21202; Manufactured by: Lupin Limited, Mandideep 462 046 INDIA.

Product Quantity:

15408 vials

Code Information:

Lot #: a) C500031, Exp 12/17; b) C500026, Exp 12/17; C500036, C500043, Exp 01/18

Reason for Recall:

CGMP Deviations: finished products manufactured using active pharmaceutical ingredients whose intermediates failed specifications.

Recall Number:

D-0951-2016

Product Description:

Ceftriaxone for Injection USP, 500 mg, Single Use Vial, packaged in a) 1-count Vials per box (NDC 68180-622-01), and b) 10-count Vials per box (NDC 68180-622-10), Rx only, Manufactured for: Lupin Pharmaceuticals, Inc., 111 South Calvert Street, Baltimore, Maryland 21202; Manufactured by: Lupin Limited, Mandideep 462 046 INDIA.

Product Quantity:

7908 vials

Code Information:

Lot #: a) C500006, Exp 11/17; b) C500001, Exp 11/17

Reason for Recall:

CGMP Deviations: finished products manufactured using active pharmaceutical ingredients whose intermediates failed specifications.

Recall Number:

D-0952-2016

Product Description:

Ceftriaxone for Injection USP, 1 g, Single Use Vial (NDC 68180-633-01) packaged in 10-count Vials per box (NDC 68180-633-10), Rx only, Manufactured for: Lupin Pharmaceuticals, Inc., 111 South Calvert Street, Baltimore, Maryland 21202; Manufactured by: Lupin

Reason for Recall:

CGMP Deviations: finished products manufactured using active pharmaceutical ingredients whose intermediates failed specifications.

Limited, Mandideep 462 046 INDIA,
NDC 68180-633-01.

Product Quantity:

30586 vials

Code Information:

Lot #: C400180, Exp 07/17; C500003,
C500028, C500029, Exp 122/17;
C500038, Exp 01/18; C500044, Exp
02/18

Recall Number:

D-0953-2016

Product Description:

Ceftriaxone for Injection USP, 2 g,
Single Use Vial (NDC 68180-644-01)
packaged in 10-count Vials per box
(NDC 68180-644-10), Rx only,
Manufactured for: Lupin
Pharmaceuticals, Inc., 111 South
Calvert Street, Baltimore, Maryland
21202; Manufactured by: Lupin
Limited, Mandideep 462 046 INDIA,
NDC 68180-633-01.

Product Quantity:

570 vials

Code Information:

Lot #: C500037, Exp 01/18

Reason for Recall:

CGMP Deviations: finished products
manufactured using active
pharmaceutical ingredients whose
intermediates failed specifications.

Recall Number:

D-0954-2016

Product Description:

Ceftriaxone Sodium (Sterile) USP
active pharmaceutical ingredient, DMF
No. 15931; Manufactured by: Lupin
Limited, Unit-1, 198-202, New
Industrial Area No. 2, Dist. Raisen,
Mandideep-462 046, (Madhya
Pradesh) India; Regd. Office: 159,
CST Road Kalina, Santacruz (E),
Mumbai- 400 098, (Maharashtra)
India.

Product Quantity:

741.171 kg

Code Information:

Lot #: B4000935, Exp 01/17;
B4005178, Exp 06/17; B4008730,
B4008729, B4008727, B4008724, Exp
10/17; B5001647, B5001648,

Reason for Recall:

CGMP Deviations: active
pharmaceutical ingredient
intermediates failed specifications.

Recall Number:

D-0955-2016

B5001649, Exp 02/18