Enforcement Report - Week of January 16, 2019

Class I Drugs Event

Event ID:
81796

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
12/20/2018

Voluntary / Mandated:
Voluntary: Firm Initiated

Center Classification Date:
01/14/2019

Initial Firm Notification of Consignee or Public:
Letter

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

Distribution Pattern:
Nationwide in the USA and Puerto Rico.

Associated Products

Product Description:
Ceftriaxone for Injection USP, 250 mg, packaged in a) one Single Use Vial (NDC 68180-611-01) and b) 10 Single Use 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:
a) 12,000 vials; b) 11,763 boxes

Reason for Recall:
Presence of Particulate Matter: Product complaints received of grey flecks, identified as shredded rubber particulate matter from the stopper observed in reconstituted vials.

Recall Number:
D-0355-2019

Code Information:
Lot #: a) C600142, Exp 08/19; b) C600136, Exp 08/19; C600182, Exp 09/19, C700147, Exp 05/20; C700207, Exp 09/20 Additional lots added 12/19/2018 - C600142, C700147 and C700207

Product Description:
Ceftriaxone for Injection USP, 500 mg, packaged in a) one Single Use Vial (NDC 68180-622-01) and b) 10 Single Use 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:
a) 8,000 vials; b) 32,045 boxes

Reason for Recall:
Presence of Particulate Matter: Product complaints received of grey flecks, identified as shredded rubber particulate matter from the stopper observed in reconstituted vials.

Recall Number:
D-0356-2019

Code Information:
Lot #: a) C600173, Exp 08/19; C600218, Exp 09/19; b) C600126, C600127, C600137, C600143, Exp 08/19; C600219, Exp 09/19; C700146, Exp 05/20; C700208, C700209, Exp 09/20.

Product Description:
Ceftriaxone for Injection USP, 1 g, packaged in a) one Single Use Vial (NDC 68180-633-01) and b) 10 Single Use Vials per box (NDC 68180-633-10); Rx only, Manufactured for: Lupin Pharmaceuticals, Inc., 111 South Calvert Street, Baltimore, Maryland 21202; Manufactured by: Lupin Limited, Mandideep 462 046 INDIA.

Product Quantity:
a) 35,000 vials; b) 112,641 boxes

Reason for Recall:
Presence of Particulate Matter: Product complaints received of grey flecks, identified as shredded rubber particulate matter from the stopper observed in reconstituted vials.

Recall Number:
D-0357-2019

Code Information:
Lot #: a) C600110, Exp 05/19; C600130, Exp 08/19; C700113, Exp 03/20; C700143, Exp 05/20; b) C600106, C600108, Exp 05/19; C600128, C600138, Exp 08/19; C600174, C600179, C600180, C600181, Exp 09/19; C700108, C700109, C700110, C700111, C700112, Exp 03/20; C700129, C700130, C700131, C700132, C700138, C700142, C700145, Exp 05/20

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

Product Quantity:
3,792 boxes

Reason for Recall:
Presence of Particulate Matter: Product complaints received of grey flecks, identified as shredded rubber particulate matter from the stopper observed in reconstituted vials.

Recall Number:
D-0358-2019

Code Information:
Lot #: C600109, Exp 05/19; C600129, C600135, Exp 08/19

Class I Drugs Event

Event ID:
81891

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
01/03/2019

Voluntary / Mandated:
Voluntary: Firm Initiated

Center Classification Date:
01/14/2019

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:
Vecuronium Bromide for Injection 10 mg*, *1mg/mL when reconstituted to 10 mL Lyophilized, 10 x 10 mg vials, Rx only, Manufactured by: Sun Pharmaceutical Industries Ltd. Halol-Baroda Highway Halol-389 350, Gujarat, India. Distributed by: Sun Pharmaceutical Industries, Inc. Cranbury, NJ 08512 NDC 47335-931-40 [vial] NDC 47335-931-44 [carton]

Product Quantity:
12,534 cartons, 125,340 vials

Reason for Recall:
Presence of Particulate Matter: Foreign matter identified as glass detected in Vecuronium Bromide for Injection.

Recall Number:
D-0372-2019

Code Information:
Lot #: JKS0443A, JKS0444A, JKS0477A, EXP 03/2019

Product Description:
Vecuronium Bromide for Injection 20 mg* *1mg/mL when reconstituted to 20 mL Lyophilized, 10 x 20 mg vials, Rx Only, Manufactured by: Sun Pharmaceutical Industries Ltd. Halol-Baroda Highway Halol-389 350, Gujarat, India. Distributed by: Sun Pharmaceutical Industries, Inc. Cranbury, NJ 08512 NDC: 47335-932-40 [vial] 47335-932-44 [carton]

Product Quantity:
1,384 cartons, 13,840 vials

Reason for Recall:
Presence of Particulate Matter: Foreign matter identified as glass detected in Vecuronium Bromide for Injection.

Recall Number:
D-0373-2019

Code Information:
Lot #: JKS0400A, EXP 03/2019

Class II Drugs Event

Event ID:
81855

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
12/20/2018

Voluntary / Mandated:
Voluntary: Firm Initiated

Center Classification Date:

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Allergan, PLC.
5 Giralda Farms
Madison NJ United States

Distribution Pattern:
Product was distributed to various accounts throughout the United States including VA and Government Accounts

Associated Products

Product Description:
OZURDEX (dexamethasone intravitreal implant) 0.7 mg), 1 single-use plastic applicator contained within carton, Rx only, Allergan Inc Irvine, CA 92612, NDC 0023-3348-07

Product Quantity:
133,716 Cartons

Reason for Recall:
GMP Deviations: A silicone particulate was noted in Ozurdex.

Recall Number:

Code Information:
E78689, exp. date 06/21/2019 E78726, exp. date 06/29/2019 E78729, exp. date 07/01/2019 E78894, exp. date 08/09/2019 E79157, exp. date 09/05/2019 E79233, exp. date 09/15/2019 E79366, exp. date 10/06/2019 E79891, exp. date 12/07/2019 E80122, exp. date 01/18/2020 E80216, exp. date 02/06/2020 E81080, exp. date 05/09/2020 E81083, exp. date 05/22/2020 E81273, exp. date 05/31/2020 E81344, exp. date 06/21/2020 E82526, exp. date 12/11/2020 E82638, exp. date 12/20/2020 E82738, exp. date 01/18/2021 E82741, exp. date 01/23/2021 E82847, exp. date 01/29/2021 E82852, exp. date 02/01/2021 E83029, exp. date 02/26/2021 E83364, exp. date 04/18/2021

Class II Drugs Event

Event ID:
81876

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
12/26/2018

Voluntary / Mandated:
Voluntary: Firm Initiated

Center Classification Date:
01/08/2019

Initial Firm Notification of Consignee or Public:
Letter

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

Distribution Pattern:
Product was distributed to 5 retailers and 4 distributors throughout the United States who may have further distributed the recalled product.

Associated Products

Product Description:
Estradiol Vaginal Inserts, USP, 10 mcg, Rx only, packaged in a) 8 count (NDC 68462-711-71) and b) 18 count (NDC 68462-711-88) cartons, Manufactured by: Glenmark Pharmaceuticals, Ltd., Colvale, Goa India, Manufactured for: Glenmark Pharmaceuticals, Inc., USA Mahwah, NJ

Product Quantity:
96,240 applicators

Reason for Recall:
Defective Delivery System: Customer complaints of malfunctioning plunger of the applicator

Recall Number:
D-0350-2019

Code Information:
Batch numbers: a) 20180393, exp. date 01/31/2020, 20180424, exp. date 02/29/2020, 20180425, exp. date 02/29/2020, 20180427, exp. date 02/29/2020; b) 20180338, exp. date 12/31/2019, 20180386, exp. date 01/31/2020

Class II Drugs Event

Event ID:
81881

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
01/02/2019

Voluntary / Mandated:
Voluntary: Firm Initiated

Center Classification Date:
01/08/2019

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Baxter Healthcare Corporation
1 Baxter Pkwy
Deerfield IL United States

Distribution Pattern:
Nationwide in the USA to Wholesaler/Distributors, Healthcare Facilities and Home Patients.

Associated Products

Product Description:
Dianeal Low Calcium (2.5 mEq/L) Peritoneal Dialysis Solution with 1.5% Dextrose, 2000 mL UltraBag container bag, Rx only; Baxter Healthcare Corporation, Deerfield, IL 60015; Product Code 5B9766, NDC 0941-0424-52.

Product Quantity:
29,370 bags

Reason for Recall:
Lack of Assurance of Sterility: Confirmed customer complaints for leaks on the tubing.

Recall Number:
D-0351-2019

Code Information:
Lot #: Y281477, Expiry: 02/2020

Class II Drugs Event

Event ID:
81888

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
01/02/2019

Voluntary / Mandated:
Voluntary: Firm Initiated

Center Classification Date:
01/15/2019

Initial Firm Notification of Consignee or Public:
Letter

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

Distribution Pattern:
Nationwide within the United States

Associated Products

Product Description:
Cefdinir for Oral Suspension USP, 125mg/5mL, packaged in a) 60mL (NDC 68180-722-20), b)100mL (NDC 68180-722-10), Rx Only, Manufactured for: Lupin Pharmaceuticals Inc. Baltimore, MD 21202; Manufactured by: Lupin Limited Mandideep 462 046 INDIA

Product Quantity:
287,784 bottles

Reason for Recall:
CGMP Deviations: Product complaints received indicating reconstituted suspension was observed to be thick.

Recall Number:
D-0375-2019

Code Information:
a) Lot #: F700329, F700330, F700328, Exp. January 2019; F700544, F700545, F700668, F700669, F700670, Exp. March 2019; F700958, Exp. April 2019 b) Lot #: F700327, F700392, F700393, Exp. January 2019; F700546, F700547, F700664, Exp. March 2019; F700967, Exp. April 2019, F701106, F701107, F701108, F701109, Exp. May 2019.

Product Description:
Cefdinir for Oral Suspension USP, 250mg/5mL, packaged in a) 60mL (NDC 68180-723-20), b)100mL (NDC 68180-723-10), Rx Only, Manufactured for: Lupin Pharmaceuticals Inc. Baltimore, MD 21202; Manufactured by: Lupin Limited Mandideep 462 046 INDIA

Product Quantity:
287,784 bottles

Reason for Recall:
CGMP Deviations: Product complaints received indicating reconstituted suspension was observed to be thick.

Recall Number:
D-0376-2019

Code Information:
a) Lot #: F700343, F700344, F700345, F700346, F700347,F700376, F700377, F700415, F700146,F700417, F700418, Exp. Jan 2019; F700419, F700420, F700492, F700493,F700508,F700665, Exp. February 2019; F700784, Exp. April 2019; b) Lot #: F700324, F700325, F700326, Exp. January 2019; F700618, F700619, F700620, Exp. February 2019.

Class II Drugs Event

Event ID:
81895

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
01/02/2019

Voluntary / Mandated:
Voluntary: Firm Initiated

Center Classification Date:
01/14/2019

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
PharMEDium Services, LLC.
913 N Davis Ave
Cleveland MS United States

Distribution Pattern:
Product was distributed throughout the United States.

Associated Products

Product Description:
0.9% Buffered Lidocaine HCl (buffered in 8.4% Sodium Bicarbonate) a.) 1 mL in 3 mL BD Syringe, 10 per carton, b.) 0.9% Buffered Lidocaine HCl (buffered in 8.4% Sodium Bicarbonate) 5 mL in 5 mL BD Syringe, 10 per carton Rx Only, Compounded by PharMEDium Services, LLC, Sugar Land, TX 77478.

Product Quantity:
7,711 syringes

Reason for Recall:
Subpotent

Recall Number:
D-0374-2019

Code Information:
Service Code 2K2466 and 2K2470 183320004S, 183330008S, 183340002S, 183340003S, 183300004S, 183310007S, 183370041S, 183310043S, 183370042S, 183320003S, 183380007S, 183250013S, 183250014S, 183320005S, 183330009S, 183370007S, 183390044S, 183400006S, 183410003S.

Class II Drugs Event

Event ID:
81896

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
01/02/2019

Voluntary / Mandated:
Voluntary: Firm Initiated

Center Classification Date:
01/08/2019

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Heritage Pharmaceuticals, Inc.
1 Tower Center Blvd Ste 1700
East Brunswick NJ United States

Distribution Pattern:
Nationwide

Associated Products

Product Description:
Cidofovir Injection 375mg/5mL (75mg/mL) vial injection. 5 mL vials, Rx only, Mfd by: Emcure Pharmaceuticals Ltd., Hinjawadi, Pune, India Mfg. for :

Heritage Pharmaceuticals Inc. NDC 23155-0216-31

Product Quantity:
5,060 units

Reason for Recall:
Lack of Assurance of Sterility: complaints received about dried powder on the outside of bottle

Recall Number:
D-0352-2019

Code Information:
Lot #: VCIA082, Exp. MAY 2020; VCIA083, VCIA084, Exp. JUNE 2020