Enforcement Report - Week of May 9, 2018

Class II Drugs Event

Event ID:
79772

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
03/27/2018

Voluntary / Mandated:
Voluntary: Firm Initiated

Center Classification Date:
05/03/2018

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
AuroMedics Pharma LLC
279 Princeton Hightstown Rd
East Windsor NJ United States

Distribution Pattern:
US Nationwide

Associated Products

Product Description:
Linezolid Injection 600 mg per 300 mL (2 mg/mL) For Intravenous Administration, Rx only, Manufactured By: Aurobindo Pharma Limited IDA Pashamylaram - 502307, India, Manufactured for AuroMedics Pharma, LLC, NDC 55150-242-51

Product Quantity:
395150 bags

Reason for Recall:
Lack of Assurance of Sterility; confirmed customer report of a leaking bags and mold found between the outer bag and the overwrap

Recall Number:
D-0703-2018

Code Information:
Lot/Batch #'s: CLZ160002, CLZ160003, CLZ160004 exp July 2018; CLZ160005, CLZ160006, CLZ160008, CLZ160009, CLZ160012, exp August 2018; CLZ160013, CLZ160014, CLZ160015, CLZ160016, exp October 2018; CLZ160017, CLZ160018, CLZ160019, CLZ160021, CLZ160022, CLZ160023, exp November 2018; CLZ170001, CLZ170002, CLZ170003, CLZ170004, CLZ170005, CLZ170006, exp March 2019; CLZ170007, CLZ170008, CLZ170009, CLZ170010, exp May 2019; CLZ170011, CLZ170012, exp June 2019; CLZ170013, CLZ170014, CLZ170015, CLZ170016, exp, September 2019; CLZ170017, exp October 2019

Product Description:
Levofloxacin in 5% Dextrose Injection, 250 mg Levofloxacin (5 mg/mL) in 50 mL of 5% Dextrose, For Intravenous Infusion, Rx only, Manufactured By: Aurobindo Pharma Limited IDA Pashamylaram - 502307, India, Manufactured for: AuroMedics Pharma, LLC, NDC 55150-243-46.

Product Quantity:
46824 bags

Reason for Recall:
Lack of Assurance of Sterility; confirmed customer report of a leaking bags and mold found between the outer bag and the overwrap

Recall Number:
D-0704-2018

Code Information:
Lot/Batch #'s: CLF160002, CLF160004, CLF160005 exp May 2018; CLF160006, CLF160007 exp June 2018; CLF170027 exp July 2019; CLF170029 exp August 2019

Product Description:
Levetiracetam in 0.82% Sodium Chloride Injection, 500 mg per 100 mL (5 mg/mL), For Intravenous Infusion Only, Distributed By: AuroMedics Pharma LLC, E. Windsor, NJ 08520, NDC 55150-246-47.

Product Quantity:
261250 bags

Reason for Recall:
Lack of Assurance of Sterility; confirmed customer report of a leaking bags and mold found between the outer bag and the overwrap

Recall Number:
D-0705-2018

Code Information:
Lot/Batch #'s: CLV160016, CLV160017, and CLV160018, exp Sept 2018, CLV160019, exp Oct 2018, CLV160020, CLV160021, and CLV160031, exp Nov 2018; CLV160032 and CLV170001, exp 12/18; CLV170008 and CLV170009, exp April 2019, CLV170020, CLV170021 and CLV170022, exp Oct 2019

Product Description:
Levetiracetam in 0.75% Sodium Chloride Injection, 1000 mg per 100 mL (10 mg/mL), For Intravenous Infusion Only, Distributed By: AuroMedics Pharma LLC, E. Windsor, NJ 08520, NDC 55150-247-47.

Product Quantity:
188941 bags

Reason for Recall:
Lack of Assurance of Sterility; confirmed customer report of a leaking bags and mold found between the outer bag and the overwrap

Recall Number:
D-0706-2018

Code Information:
Lot/Batch #'s: CLV160013, CLV160014 and CLV160015, exp Sept 2018; CLV160022, CLV160023, CLV160024, CLV160025, CLV160026, CLV160027, CLV160028, CLV160029, CLV160030 exp Oct 2018; CLV170002, Dec 2018; CLV170010, exp April 2019; CLV170027, CLV170028, CLV170029 and CLV170030 exp Oct 2019

Product Description:
Levetiracetam in 0.54% Sodium Chloride Injection, 1,500 mg per 100 mL (15 mg/mL), For Intravenous Infusion Only, Distributed By: AuroMedics Pharma LLC, E. Windsor, NJ 08520, NDC 55150-248-47.

Product Quantity:
67300 bags

Reason for Recall:
Lack of Assurance of Sterility; confirmed customer report of a leaking bags and mold found between the outer bag and the overwrap

Recall Number:
D-0707-2018

Code Information:
Lot/Batch #'s: CLV160004, CLV160005, and CLV160006 exp September 2018; CLV170011, CLV170015, CLV170016 exp June 2019

Product Description:
Levofloxacin in 5% Dextrose Injection, 500 mg Levofloxacin (5 mg/mL) in 100 mL of 5% Dextrose, For Intravenous Infusion, Rx only, Manufactured By: Aurobindo Pharma Limited IDA Pashamylaram - 502307, India, Manufactured for AuroMedics Pharma, LLC, NDC 55150-244-47

Product Quantity:
308472 bags

Reason for Recall:
Lack of Assurance of Sterility; confirmed customer report of a leaking bags and mold found between the outer bag and the overwrap

Recall Number:
D-0708-2018

Code Information:
Lot/Batch #'s: CLF160008, CLF160009, CLF160010, CLF160011, exp June 2018; CLF160015, CLF160016 , CLF160017, exp August 2018; CLF170001 exp December 2018; CLF170023, CLF170024, exp May 2019; CLF170039, CLF170040, CLF170041, CLF170042, CLF170043, CLF170044, CLF170045, CLF170046, CLF170047 exp August 2019

Product Description:
Levofloxacin in 5% Dextrose Injection, 750 mg Levofloxacin (5 mg/mL) in 150 mL of 5% Dextrose, For Intravenous Infusion, Rx only, Manufactured By: Aurobindo Pharma Limited IDA Pashamylaram - 502307, India, Manufactured for AuroMedics Pharma, LLC, NDC 55150-245-52

Product Quantity:
308112 bags

Reason for Recall:
Lack of Assurance of Sterility; confirmed customer report of a leaking bags and mold found between the outer bag and the overwrap

Recall Number:
D-0709-2018

Code Information:
Lot/Batch #'s: CLF160012, CLF160014 exp July 2018; CLF170007, CLF170008, CLF170009, CLF170010, CLF170011, CLF170012, CLF170013 exp February 2019; CLF170014, CLF170015, CLF170016 exp March 2019; CLF170017, CLF170018, CLF170019, exp April 2019; CLF170020, CLF170021, CLF170022 exp May 2019; CLF170035, CLF170036, CLF170037, CLF170038 exp August 2019; CLF170048, CLF170049, CLF170050, CLF170051, CLF170052 exp September 2019

Class III Drugs Event

Event ID:
79820

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
04/17/2018

Voluntary / Mandated:
Voluntary: Firm Initiated

Center Classification Date:
05/03/2018

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Rhodes Pharmaceuticals, L.P.
498 Washington St
Coventry RI United States

Distribution Pattern:
Nationwide within the USA

Associated Products

Product Description:
Aptensio XR (methylphenidate HCl extended-release) capsules 15 mg Rx Only 90-count bottle. Marketed by: Rhodes Pharmaceuticals L.P., Coventry, RI 02816. Manufactured by: Patheon Manufacturing Services LLC, Greenville, NC 27834. NDC 42858-402-45

Product Quantity:
2454 bottles

Reason for Recall:
Failed Dissolution Specification: Low dissolution outside of specifications

Recall Number:
D-0710-2018

Code Information:
Lot# AG8679B Exp. 01/2020