Enforcement Report - Week of June 17, 2020

Class I Drugs Event

Event ID:
85504

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
04/20/2020

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
06/08/2020

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

Recalling Firm:
Fresenius Kabi USA, LLC
3 Corporate Dr
Lake Zurich IL United States

Distribution Pattern:
USA Nationwide and Puerto Rico

Associated Products

Product Description:
Ketorolac Tromethamine Injection, USP, 30 mg per mL, packaged in 1 mL Single Dose Vials (NDC 63323-162-00); 25 x 1 mL Single Dose Vials per tray (NDC 63323-162-01); For IM or IV use, Rx only, Fresenius Kabi, Lake Zurich, IL 60047.

Product Quantity:
5,314,400 vials

Reason for Recall:
Presence of Particulate Matter - found in reserve sample vials at the firm.

Recall Number:
D-1296-2020

Code Information:
Lot #: 6118737, 6118902, Exp 04/2020; 6119052, Exp 05/2020; 6119752, Exp 08/2020; 6122349, Exp 07/2021; 6122538, Exp 09/2021

Class II Drugs Event

Product Description:
Ketorolac Tromethamine Injection, USP, 60 mg per 2 mL (30 mg per mL), packaged in 2 mL Single Dose Vials (NDC 63323-162-03), 25 x 2 mL Single Dose Vials per tray (NDC 63323-162-02); For IM use only, Not for IV use, Rx only, Fresenius Kabi, Lake Zurich, IL 60047.

Product Quantity:
3,497,575 vials

Reason for Recall:
Presence of Particulate Matter - found in reserve sample vials at the firm.

Recall Number:
D-1297-2020

Code Information:
Lot #: 6119229, 6119273, Exp 06/2020; 6119843, Exp 09/2020; 6121115, Exp 02/2021; 6121451, 6121452, 6121496, Exp 03/2021

Class II Drugs Event

Event ID:
85745

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
05/19/2020

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
06/08/2020

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
American Health Packaging
2550 John Glenn Ave Ste A
Columbus OH United States

Distribution Pattern:
USA Nationwide

Associated Products

Product Description:
Doxycycline Hyclate Tablets, USP, 100 mg, 30 Tablets per carton (3 x 10), Rx only, Distributed by: American Health Packaging, Columbus, Ohio 43217, NDC Carton 62584-693-21; NDC Unit Dose 62584-693-11

Product Quantity:
15,755 cartons

Reason for Recall:
Failed dissolution specification - dissolution results of 59% (spec. NLT 85%) at the 24 month time point (end of shelf life).

Recall Number:
D-1293-2020

Code Information:
Lots 179605, Exp 06/30/2020; 181105, Exp 08/31/2020; 183019, Exp 01/31/2021

Class II Drugs Event

Event ID:
85754

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
05/29/2020

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
06/12/2020

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Pfizer Inc.
235 E 42nd St
New York NY United States

Distribution Pattern:
Distributed Nationwide in the US

Associated Products

Product Description:
Unasyn (ampicillin sodium/sulbacatam) for injection, 1.5 g* per vial, Rx Only, 10 vials/carton, Made in Italy Distributed by Roerig Division of Pfizer Inc. New York, NY 10017 vial NDC 0049-0013-81, carton NDC 0049-0013-83

Product Quantity:
94320 units

Reason for Recall:
Presence of Particulate Matter: particulate matter identified after reconstitution.

Recall Number:
D-1306-2020

Code Information:
Lot # 3301612, EXP 02/2022

Class II Drugs Event

Event ID:
85770

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
05/28/2020

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
06/08/2020

Initial Firm Notification of Consignee or Public:
Letter

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

Distribution Pattern:
Nationwide within the US.

Associated Products

Product Description:
Lisinopril Tablets, USP, 5 mg, Rx Only, 1000-count bottle, Manufactured for: Lupin Pharmaceuticals Inc., Baltimore, MD 21202, Manufactured by: Lupin Limited, Nagpur - 441 108, India, NDC 68180-513-03.

Product Quantity:
4,224 bottles

Reason for Recall:
Product Mix Up: Lisinopril 10 mg tablets were found in Lisinopril 5 mg 1000-count bottle.

Recall Number:
D-1290-2020

Code Information:
Lot # Q900683, Exp. 10/31/2022

Class II Drugs Event

Event ID:
85773

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
05/28/2020

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
06/11/2020

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
QuVa Pharma, Inc.
1075 W Park One Dr Ste 100
Sugar Land TX United States

Distribution Pattern:
USA Nationwide

Associated Products

Product Description:
oxyTOCIN 30 Units/500 mL (0.06 Units/mL) added to 0.9% Sodium Chloride Injection for IV Use, Rx only, QuVa Pharma 1075 West Park One Drive, Suite 100 Sugar Land, TX 77478 888-339-0874, NDC 70092-1068-07

Product Quantity:
648 bags

Reason for Recall:
Subpotent drug - Product did not contain drug.

Recall Number:
D-1302-2020

Code Information:
Lot#: 30010515

Class III Drugs Event

Event ID:
85764

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
05/26/2020

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
06/08/2020

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
UNICHEM PHARMACEUTICALS USA INC
1 Tower Center Blvd Ste 2200
East Brunswick NJ United States

Distribution Pattern:
Nationwide within the United States

Associated Products

Product Description:
Clonodine Hydrochloride Tablets, USP 0.1 mg 100-count bottles, Rx only, Manufactured by: Unichem Laboratories LTD. Pilerne Ind. Estate, Pilerne, Bardez, Goa 403 511, India Manufactured for : Unichem Pharmaceuticals (USA), Inc. East Brunswick, NJ 08816, NDC 29300-135-01

Product Quantity:
190,992 bottles

Reason for Recall:
Failed Impurities/Degradation Specifications: potential migration of benzophenone at very low level into the product from container.

Recall Number:
D-1291-2020

Code Information:
Lot #: GCLL19034, GCLL19035, GCLL19036, Exp. 4/30/2021; GCLL19044, Exp. 6/30/2021

Not Yet Classified Drugs Event

Event ID:
85801

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
06/05/2020

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:

Initial Firm Notification of Consignee or Public:
Letter

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

Distribution Pattern:
Distributed Nationwide in the USA

Associated Products

Product Description:
Prednisolone Sodium Phosphate Oral Solution, 5 mg/5 mL, 120 mL Bottle, Rx only, HI-TECH PHARMACAL CO., INC., Amityville, NY 11701. NDC: 50383-040-04

Product Quantity:
17,424 bottles

Reason for Recall:
Discoloration: Out of Specification (OOS) result for APHA Color Test.

Recall Number:

Code Information:
Lot# 365566, 365568