Enforcement Report - Week of September 6, 2017

Class II Drugs Event

Event ID:
77798

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
06/15/2017

Voluntary / Mandated:
Voluntary: Firm Initiated

Center Classification Date:
08/29/2017

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Tris Pharma Inc.
2033 US Highway 130
Monmouth Junction NJ United States

Distribution Pattern:
U.S.A. Nationwide

Associated Products

Product Description:
Morphine Sulfate Oral Solution, 100 mg/ 5 mL (20 mg/mL), packaged in a 1 oz. bottle containing 30 mL with an oral syringe, Rx Only, Manufactured by: Tris Pharma, Inc. Monmouth Junction, NJ 08852, NDC 27808-082-01

Product Quantity:
34,824 bottles

Reason for Recall:
Defective container: Oral solution leaking from container.

Recall Number:
D-1126-2017

Code Information:
Lot #: 08215001A, Exp 6/30/2017; 08215002A, 08215004A, Exp 7/31/2017

Class II Drugs Event

Event ID:
77933

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
08/10/2017

Voluntary / Mandated:
Voluntary: Firm Initiated

Center Classification Date:
08/29/2017

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Morton Grove Pharmaceuticals, Inc.
6451 Main St
Morton Grove IL United States

Distribution Pattern:
Nationwide in the USA and Puerto Rico.

Associated Products

Product Description:
Amoxicillin and Clavulanate Potassium for Oral Suspension, USP, 250/62.5 mg per 5 mL, 100 mL (when reconstituted) bottle, Rx Only, Manufactured By: Cipla Ltd. at Medispray Laboratories Pvt. Ltd., Kundaim Goa, India; Manufactured For: Wockhardt USA, LLC, Parsippany, NJ 07054, NDC 60432-065-00.

Product Quantity:
7332 bottles

Reason for Recall:
Presence of Foreign Substance: customer complaint of blue foreign material identified as a portion of a nitrile glove was discovered in product.

Recall Number:
D-1125-2017

Code Information:
Batch #: KH60276, Exp 10/18

Class II Drugs Event

Event ID:
77988

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
08/15/2017

Voluntary / Mandated:
Voluntary: Firm Initiated

Center Classification Date:
08/29/2017

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Amphastar Pharmaceuticals, Inc.
11570 6th St
Rancho Cucamonga CA United States

Distribution Pattern:
Distributed throughout the United States

Associated Products

Product Description:
Ketorolac Tromethamine Injection, USP 30 mg/mL, packaged in 1 mL single-dose vials, Rx only, Amphastar Pharmaceuticals, Inc., Rancho Cucamonga, CA 91730, NDC 0548-9021-00

Product Quantity:
637,810 vials

Reason for Recall:
Crystallization: Particulate matter (Ketorolac Calcium Salt) was observed from several lots of retained samples.

Recall Number:
D-1124-2017

Code Information:
Lot # XI002A6, XI003A6, Exp 12/17; XI004G6, XI005G6, Exp 6/18; XI007H6, Exp 7/18; XI00816, XI00916, XI01016, XI01116, Exp 8/18; XI012J6, XI013J6, Exp 9/18; XI015K6, Exp 10/18; XI016L6, Exp 11/18; XL018A7, XI019A7, Exp 12/18; XI020B7, XI021B7, Exp 1/19; XI022C7, XI023C7, Exp 2/19; XI025D7, Exp 3/19.