Enforcement Report - Week of October 4, 2017

Class II Drugs Event

Event ID:
78060

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
09/05/2017

Voluntary / Mandated:
Voluntary: Firm Initiated

Center Classification Date:
09/28/2017

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Teva Pharmaceuticals USA
1090 Horsham Rd
North Wales PA United States

Distribution Pattern:
Nationwide in the USA

Associated Products

Product Description:
Acarbose Tablets, 25 mg, 100-count bottle, Rx only, Manufactured by: Arrow Pharm (Malta) Ltd., Birzebbugia BBG3000, Malta; Distributed by: Actavis Pharma, Inc., Parsippany, NJ 07054; NDC 16252-523-01.

Product Quantity:
3,275 bottles

Reason for Recall:
Labeling: Incorrect or Missing Lot and/or Exp Date: An incorrect expiration date of July 2018 is printed on the product labeling rather than the correct expiration date of July 2017.

Recall Number:
D-1178-2017

Code Information:
Lot #: 1082710A, Exp 07/18

Class II Drugs Event

Event ID:
78146

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
08/22/2017

Voluntary / Mandated:
Voluntary: Firm Initiated

Center Classification Date:
09/22/2017

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
RemedyRepack Inc.
625 Kolter Dr Ste 4
Indiana PA United States

Distribution Pattern:
Product was distributed to one consignee in Louisiana.

Associated Products

Product Description:
Ketorolac Trom 30 mg/mL Injection, packaged in a) 1 mL vials, NDC 61786-0741-01 (Orig: 00548-9021-00), Ref: 33631 and b) 10 x 1 mL vials per tray, NDC 61786-0741-08 (Orig: 00548-9021-00), Ref: 33632, Rx only, Packaged by: RemedyRepack Inc, Indiana, PA 15704; Mfg by: Amphastar, Rancho Cucamonga, CA 91730.

Product Quantity:
40 vials

Reason for Recall:
Crystallization: Product is being recalled due to the manufacturer's recall due to the presence of visible particulate in vials that has been identified as crystalline ketorolac calcium salt.

Recall Number:
D-1176-2017

Code Information:
Lot #: a) B0158730-060816 (Mfg: XI002A6), Exp: 12/2017 ; and b) B0160669-061516 (Mfg: XI003A6), Exp 12/2017

Class III Drugs Event

Event ID:
78169

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
09/25/2017

Voluntary / Mandated:
Voluntary: Firm Initiated

Center Classification Date:
09/28/2017

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Sandoz Inc
100 College Rd W
Princeton NJ United States

Distribution Pattern:
Nationwide in the USA and Puerto Rico

Associated Products

Product Description:
Ampicillin for Injection, USP, 500 mg per vial, single vial (NDC 0781-3407-78) packaged in 10-count shrink wrap packs (NDC 0781-3407-95), Rx only, Manufactured in Austria by Sandoz GmbH or Sandoz Inc., Princeton, NJ 08540.

Product Quantity:
13,435 shrink wrap packs

Reason for Recall:
Labeling: Missing Label: customer complaint that some vials of ampicillin within the shrink wrap pack are missing labels.

Recall Number:
D-1179-2017

Code Information:
Lot: GH8254, Exp 06/19