Enforcement Report - Week of May 17, 2017

Class II Drugs Event

Event ID:
77109

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
04/24/2017

Voluntary / Mandated:
Voluntary: Firm Initiated

Center Classification Date:
05/11/2017

Initial Firm Notification of Consignee or Public:
Letter

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

Distribution Pattern:
Nationwide

Associated Products

Product Description:
Clozapine Tablets USP, 25 mg, 100-count bottle (NDC 0093-4359-01), 500- count bottle (NDC 0093-4359-05), 100 Unit Dose Blisters per carton (NDC 0093-4359-93), Individual Blister Pack (NDC 0093-4359-19), Rx Only, Manufactured By: Teva Pharmaceutical Industries Ltd., Jerusalem, 9777600, Israel

Product Quantity:

Reason for Recall:
Microbial Contamination of Non-Sterile Products

Recall Number:
D-0705-2017

Code Information:
100 (NDC 0093-4359-01) and 500 count bottles (NDC 0093-4359-05)- Lot # 07C160; Exp. 03/18 100 Unit Dose Blisters/Carton (NDC 0093-4359-93) and Individual Blister Pack (NDC 0093-4359-19) - Lot # 07C160A; Exp. 03/18

Class II Drugs Event

Event ID:
77169

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
04/28/2017

Voluntary / Mandated:
Voluntary: Firm Initiated

Center Classification Date:
05/09/2017

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
PAR Sterile Products LLC
870 Parkdale Rd
Rochester MI United States

Distribution Pattern:
Nationwide in the USA

Associated Products

Product Description:
Buprenorphine HCl Injection, 0.3 mg/mL, 1 mL Single Dose Vial (NDC 42023-179-01), packaged in 1 mL x 5 Single Dose Vials per carton (NDC 42023-179-05), Rx Only, Distributed by: Par Pharmaceuticals Companies, Inc., Spring Valley, NY 10977.

Product Quantity:
122,469 cartons

Reason for Recall:
Crystallization: due to the presence of white, crystalline particulates, adhered to the side and bottom of the glass vials, which are comprised of principally dextrose and the buprenorphine active component.

Recall Number:
D-0698-2017

Code Information:
Lot #: 821102, 821103, Exp 01/18; 821104, 821106, 821107, Exp 02/18; 821108, Exp 03/18; 821884, 821885, Exp 07/18; 821886, 821887, Exp 08/18; 822767, Exp 09/18; 824183, Exp 10/18.

Class III Drugs Event

Event ID:
76819

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
03/22/2017

Voluntary / Mandated:
Voluntary: Firm Initiated

Center Classification Date:
05/10/2017

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 and Puerto Rico

Associated Products

Product Description:
Olanzapine Tablets, 2.5 mg, 1000-count bottles, Rx Only, Distributed by: Sun Pharmaceutical Industries, Inc., Cranbury, NJ 08512, Manufactured by: Sun Pharmaceutical Ind. Ltd., Halol-Baroda Highway, Halol-389 350, Gujarat, India, NDC 62756-551-18.

Product Quantity:
60 bottles

Reason for Recall:
Failed Impurities/Degradation Specifications: out of specification results for the related substances test parameter (impurities).

Recall Number:
D-0699-2017

Code Information:
Lot #: JKP2751A, Exp 05/17; JKR5048A, Exp 04/18

Product Description:
Olanzapine Tablets, 7.5 mg, packaged in a) 30-count bottles (NDC 62756-553-83), b) 100-count bottles (NDC 62756-553-88), and c) 1000-count bottles (NDC 62756-553-18), Rx Only, Distributed by: Sun Pharmaceutical Industries, Inc., Cranbury, NJ 08512, Manufactured by: Sun Pharmaceutical Ind. Ltd., Halol-Baroda Highway, Halol-389, 350 Gujarat, India.

Product Quantity:
6,138 bottles

Reason for Recall:
Failed Impurities/Degradation Specifications: out of specification results for the related substances test parameter (impurities).

Recall Number:
D-0700-2017

Code Information:
Lot #: a) JKP3150B, Exp 06/17, JKR5749A, Exp 06/18; b) JKP2757A, Exp 05/17, JKP3149A, JKP3150A, Exp 06/17, JKR5049A, Exp 04/18; c) JKP2758B, Exp 05/17

Product Description:
Olanzapine Tablets, 10 mg, packaged in a) 30-count bottles (NDC 62756-554-83), b) 100-count bottles (NDC 62756-554-88), and c) 1000-count bottles (NDC 62756-554-18), Rx Only, Distributed by: Sun Pharmaceutical Industries, Inc., Cranbury, NJ 08512, Manufactured by: Sun Pharmaceutical Ind. Ltd., Halol-Baroda Highway, Halol-389, 350 Gujarat, India, NDC 62756-551-18.

Product Quantity:
38,316 bottles

Reason for Recall:
Failed Impurities/Degradation Specifications: out of specification results for the related substances test parameter (impurities).

Recall Number:
D-0701-2017

Code Information:
Lot #: a) JKP1354A, Exp 03/17, JKP2746A, Exp 06/17, JKR5751A, Exp 04/18; b) JKP1355A, Exp 03/17, JKP2738A, JKP3145A, Exp 06/17, JKR5476A, Exp 04/18; c) JKP1353A, Exp 03/17, JKP3146A, JKP2746B, Exp 06/17

Product Description:
Olanzapine Tablets, 20 mg, packaged in a) 30-count bottles (NDC 62756-556-83), b) 100-count bottles (NDC 62756-556-88), and c) 1000-count bottles (NDC 62756-556-18), Rx Only, Distributed by: Sun Pharmaceutical Industries, Inc., Cranbury, NJ 08512, Manufactured by: Sun Pharmaceutical Ind. Ltd., Halol-Baroda Highway, Halol-389, 350 Gujarat, India.

Product Quantity:
14,784 bottles

Reason for Recall:
Failed Impurities/Degradation Specifications: out of specification results for the related substances test parameter (impurities).

Recall Number:
D-0702-2017

Code Information:
Lot #: a) JKR5759A, Exp 04/18; b) JKP0943A, Exp 04/17, JKR5520A, Exp 04/18; c) JKP0988A, Exp 04/17

Class III Drugs Event

Event ID:
76871

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
03/28/2017

Voluntary / Mandated:
Voluntary: Firm Initiated

Center Classification Date:
05/11/2017

Initial Firm Notification of Consignee or Public:
Letter

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

Distribution Pattern:
Nationwide

Associated Products

Product Description:
PrednisoLONE Oral Solution USP, 15 mg/5mL, alcohol content: 5%(v/v) 240 mL bottle, Rx Only, Manufactured in Canada By: CONTRACT PHARMACEUTICALS LIMITED CANADA, Ontario, Canada, L5N 6L6, Manufactured For: TEVA PHARMACEUTICALS USA, Sellersville, PA 18960, NDC 0093-6118-87

Product Quantity:
49,089 bottles

Reason for Recall:
Failed Stability Specifications

Recall Number:
D-0703-2017