Enforcement Report - Week of December 20, 2017

Class II Drugs Event

Event ID:
78217

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
04/18/2017

Voluntary / Mandated:
Voluntary: Firm Initiated

Center Classification Date:
12/13/2017

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

Associated Products

Product Description:
Riomet (metformin hydrochloride) Oral Solution Cherry Flavored 500 mg /5 mL, 4 fl. oz. (NDC 10631-206-01) and 16 fl. oz. (NDC 10631-206-02) HDPE bottles, Rx only, Manufactured for: Ranbaxy Laboratories Inc. Jacksonville, FL 32257 USA, Distributed by: Sun Pharmaceutical Industries, Cranbury, NJ 08512

Product Quantity:

Reason for Recall:
Microbial Contamination of Non-Sterile Products

Recall Number:
D-0109-2018

Code Information:
A lot # 160031A, A160031B; Exp. 11/17

Class III Drugs Event

Event ID:
78641

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
11/28/2017

Voluntary / Mandated:
Voluntary: Firm Initiated

Center Classification Date:
12/13/2017

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 and Puerto Rico.

Associated Products

Product Description:
Penicillin V Potassium for Oral Solution, USP, 125 mg (200,000 U) per 5 mL, 100 mL (when mixed) bottle, Rx only, Manufactured In Canada By: Teva Canada Limited, Toronto, Canada M1B 2K9; Manufactured For: Teva Pharmaceuticals USA, Inc., North Wales, PA 19454; NDC 0093-4125-73.

Product Quantity:
42,384 bottles

Reason for Recall:
Failed Impurities/Degradation Specifications: high out of specification test results obtained for individual and total impurities.

Recall Number:
D-0108-2018

Code Information:
Lot # 35433115A, Exp 01/18