

Enforcement Report - Week of May 13, 2020

Class II Drugs Event

Event ID:

85146

Status:

Ongoing

Recall Initiation Date:

03/05/2020

Center Classification Date:

05/05/2020

Recalling Firm:

Teva Pharmaceuticals USA
400 Interpace Pkwy
Parsippany NJ United States

Distribution Pattern:

Product was distributed to 1 wholesaler who still had all units within their possession and had not shipped or further distributed any of the product.

Product Type:

Drugs

Date Terminated:**Voluntary / Mandated:**

Voluntary: Firm initiated

Initial Firm Notification of Consignee or Public:

Letter

Associated Products

Product Description:

Epinephrine Injection USP, 0.3 mg (Auto-Injector), 0.3 mg/ 0.3 mL pre-filled syringe, Rx Only, Manufactured for Teva Pharmaceuticals USA, Inc. North Wales, PA 19454. NDC 0093-5986-27

Product Quantity:

600 cartons/2 auto-injector per carton

Reason for Recall:

CGMP Deviations: Precautions taken due to Out-of-specification for trigger force for a non-marketed lot number that shares the same component.

Recall Number:

D-1260-2020

Code Information:

Lot # 007F19AA, exp. date 04/2021

Class II Drugs Event

Event ID:

85538

Status:

Ongoing

Recall Initiation Date:

04/21/2020

Center Classification Date:

05/01/2020

Recalling Firm:

Sandoz, Inc
506 Carnegie Ctr Ste 400
Princeton NJ United States

Distribution Pattern:

Nationwide within the United States

Product Type:

Drugs

Date Terminated:**Voluntary / Mandated:**

Voluntary: Firm initiated

Initial Firm Notification of Consignee or Public:

Letter

Associated Products

Product Description:

Infuvite PEDiatric Pharmacy, kit in 1 carton (40 mL fill in a 50 mL) vial 1 and (10 mL) in vial 2, Rx Only, Distributed by: Baxter Healthcare Corporation
Clintec Nutrition Division Deerfield, IL 60015 USA, NDC 54643-5647-0

Product Quantity:

17,500 units

Reason for Recall:

Defective Container: Sub-optimal crimping in vial of Pediatric Infuvite Multiple Vitamins

Recall Number:

D-1259-2020

Code Information:

Lot #: JX907, Exp. Date 02/2021