Enforcement Report - Week of November 30, 2022

Class II Drugs Event

Event ID:
91146

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
07/25/2022

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
11/22/2022

Initial Firm Notification of Consignee or Public:

Recalling Firm:
SUN PHARMACEUTICAL INDUSTRIES INC
2 Independence Way
Princeton NJ United States

Distribution Pattern:
Nationwide in the USA.

Associated Products

Product Description:
Pantoprazole Sodium for Delayed-Release Oral Suspension*40 mg* suspension in apple juice or applesauce only Each packet contains 40 mg pantoprazole equivalent to 45.1 mg of pantoprazole sodium USP (sesquihydrate), Rx Only, distributed by: Sun Pharmaceutical Industries, Inc. Cranbury, NJ 08512, manufactured by: Sun Pharmaceutical Industries Limited Mohali, INDIA, NDC 62756-071-60

Product Quantity:
14, 064 (30 sachets in a carton)

Reason for Recall:
Discoloration

Recall Number:
D-0068-2023

Code Information:
Lot #: MHC1317A, Exp 07/2023

Class III Drugs Event

Event ID:
91149

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
11/14/2022

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
11/23/2022

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Acella Pharmaceuticals, LLC
1880 Mcfarland Pkwy Ste 110
Alpharetta GA United States

Distribution Pattern:
Nationwide in the USA.

Associated Products

Product Description:
Phenytoin Sodium Injection, USP 100 mg/2 mL, NDC 42192-614-02, packaged in 10 x 2 mL vials per carton, NDC 42192-614-10, Rx only, Manufactured for: Acella Pharmaceuticals, LLC Alpharetta, GA 30005

Product Quantity:
574 cartons

Reason for Recall:
Labeling: Not elsewhere classified; the product is being recalled because of customer complaints that the primary vial label was missing a barcode.

Recall Number:
D-0069-2023

Code Information:
Lot: E025A001 Exp. 07/2023

Product Description:
Phenytoin Sodium Injection, USP, 250 mg/5 mL, NDC 42192-614-05, packaged in 10 x 5 mL vials per carton, NDC 42192-614-30, Rx only, Manufactured for: Acella Pharmaceuticals, LLC Alpharetta, GA 30005

Product Quantity:
637 cartons

Reason for Recall:
Labeling: Not elsewhere classified; the product is being recalled because of customer complaints that the primary vial label was missing a barcode.

Recall Number:
D-0070-2023

Code Information:
Lot: E026A001 Exp. 06/2023