Enforcement Report - Week of September 20, 2023

Class II Drugs Event

Event ID:
92916

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
08/30/2023

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
09/11/2023

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
VistaPharm LLC
7265 Ulmerton Rd
Largo FL United States

Distribution Pattern:
Distributed nationwide to 68 consignees in the U.S.

Associated Products

Product Description:
Sucralfate Oral Suspension 1g per 10mL, FOR ORAL ADMINISTRATION ONLY (414 mL bottle), Rx Only, Manufactured and Distributed by: VistaPharm, Inc. Largo, FL 33771, NDC 66689-305-16

Product Quantity:
14,400 bottles

Reason for Recall:
Superpotent/Subpotent single ingredient Drug: Out of Specification Assay results

Recall Number:
D-1149-2023

Code Information:
Lot #: 921100; Exp. 02/2025

Class II Drugs Event

Event ID:
92968

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
09/05/2023

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
09/11/2023

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
BE PHARMACEUTICALS AG
Bundesstrasse 3
Zug Switzerland

Distribution Pattern:
Nationwide in the USA

Associated Products

Product Description:
Pantoprazole Sodium for Injection 40mg per vial, Single dose vials NDC 71839-122-01 Packaged as (a) 10 Single-dose vials, NDC 71839-122-10; (b) 25 Single-dose vials, NDC 71839-122-25; Rx Only, Mfd. in India for and Distributed by: BE Pharmaceuticals Inc. 203 New Edition Court Cary, NC 27511.

Product Quantity:
41,148 vials

Reason for Recall:
Lack of Assurance of Sterility: Powder discoloration due to small crack in some vials.

Recall Number:
D-1148-2023

Code Information:
Lots: (a) GSC04002A, GSC04003A, GSC04004A, GSC04006A, Exp Mar-2024; GSC05001A, GSC05006A, GSC05007A, Exp April-2024; GSC10003A, GSC10005A Exp Sep-2024;GSC06004A, GSC06005A, Exp May-2024; GSC07001A, GSC07007A, GSC07008A, GSC07009A, Exp Jun-2024; GSC08001A, Exp Jul-2024; GSC05009A, Exp Apr-2024; (b) GSC04005A, Exp Mar-2024; GSC06003A, Exp May-2024; GSC10001A, Exp Sep-2024; GSC07006A,Exp Jun-2024; GSC08002A, Exp Jul-2024; GSD02012A, Exp Jan-2025; GSD03005A, GSD03008A, Exp Feb-2025;

Not Yet Classified Drugs Event

Event ID:
92979

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
08/25/2023

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:

Initial Firm Notification of Consignee or Public:
Press Release

Recalling Firm:
Hua Da Trading, Inc. dba Wefun Inc.
6306 20th Ave
Brooklyn NY United States

Distribution Pattern:
Distributed Nationwide in the USA via internet at www.eshoponlineusa.com.

Associated Products

Product Description:
WEFUN 825 mg Capsules, 1x10 blister pack per carton, Manufactured by WEFUN Brooklyn NY 11204 www.eshoponlineusa.com Bar Code X00358V0O5

Product Quantity:
300 cartons

Reason for Recall:
Marketed Without an Approved NDA/ANDA: FDA analysis found the product to be tainted with sildenafil.

Recall Number:

Code Information:
Lot # #18520168, Exp. date 09/30/2026 .