

Enforcement Report - Week of March 31, 2021

Class I Drugs Event

Event ID:
87324

Status:
Ongoing

Recall Initiation Date:
02/15/2021

Center Classification Date:
03/19/2021

Recalling Firm:
Adams.Secret.co
29-31 Industrial Ave
Fairview NJ United States

Distribution Pattern:
in the USA

Product Type:
Drugs

Date Terminated:

Voluntary / Mandated:
Voluntary: Firm initiated

Initial Firm Notification of Consignee or Public:
Press Release

Associated Products

Product Description:

Adam's Secret Extra Strength 1500, 800 mg, 10 count blister packs, Distributed by KP Inc., Made in USA, UPC 6 09728 43462 5

Product Quantity:

218 boxes

Reason for Recall:

Marketed without Approved NDA/ANDA: FDA analysis results obtained the presence of tadalafil and sildenafil.

Recall Number:

D-0310-2021

Code Information:

All lots within expiry.

Product Description:

Adam's Secret Extra Strength 3000, 840 mg, 10 count blister packs, Distributed by AS Inc., Made in USA, UPC 6 09728 43452 6.

Product Quantity:

Reason for Recall:

Marketed without Approved NDA/ANDA: FDA analysis results obtained the presence of tadalafil and sildenafil.

Recall Number:

D-0311-2021

Code Information:

All lots within expiry.

Class II Drugs Event

Event ID:
87484

Status:
Ongoing

Recall Initiation Date:
03/09/2021

Center Classification Date:
03/25/2021

Recalling Firm:
ICU Medical Inc

Product Type:
Drugs

Date Terminated:

Voluntary / Mandated:
Voluntary: Firm initiated

Initial Firm Notification of Consignee or Public:
Letter

600 N Field Dr
Lake Forest IL United States

Distribution Pattern:

Distributed Nationwide in the USA to include Puerto Rico

Associated Products**Product Description:**

0.9% SODIUM CHLORIDE Irrigation, USP 1000 mL Semi-Rigid Bottle, Rx only, Manufactured for ICU Medical, Inc., Lake Forest, Illinois, 60045 USA. NDC 0990-7138-09

Product Quantity:

425,628 bottles

Reason for Recall:

Presence of particulate matter.one confirmed customer report of particulate matter within two semi-rigid bottles identified prior to use

Recall Number:

D-0313-2021

Code Information:

Lots: 16-808-4B, 16-803-4B, 16-809-4B, Exp. April 01, 2023

Class II Drugs Event**Event ID:**

87566

Product Type:

Drugs

Status:

Ongoing

Date Terminated:**Recall Initiation Date:**

03/19/2021

Voluntary / Mandated:

Voluntary: Firm initiated

Center Classification Date:

03/24/2021

Initial Firm Notification of Consignee or Public:

Letter

Recalling Firm:

Golden State Medical Supply Inc.
5187 Camino Ruiz
Camarillo CA United States

Distribution Pattern:

Sold to two wholesalers/distributors under government contract located in PA and TX

Associated Products**Product Description:**

Omeprazole Delayed Release Capsules, USP, 20 mg, 1000-count bottles, Rx only, Packaged by GSMS Incorporated, Camarillo, CA 93012-8601 USA, NDC 51407-129-10

Product Quantity:**Reason for Recall:**

Failed Impurities/Degradation Specifications: Out of Specification results obtained for unknown impurities during stability testing by manufacturer

Recall Number:

D-0312-2021

Code Information:

Lot #: GS029673, Exp. Date 5/2021