Enforcement Report - Week of March 5, 2025

Class II Drugs Event

Event ID:
96210

Product Type:
Drugs

Status:
Ongoing

Date Terminated:
N/A

Recall Initiation Date:
02/12/2025

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
02/21/2025

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Wuxi Medical Instrument Factory Co., Ltd.
D, Zhangjing No. 43 Xixin Road; Xibeizhen Xishan
Wuxi
China

Distribution Pattern:
FL

Associated Products

Product Description:
ViaMed Alcohol Prep Pads, For External Use Only, 70% Isopropyl Alcohol, Sterile, 100 pieces per Box, 100 boxes per Carton, Sterile, Manufactured by Wuxi Medical Instrument Factory Co., Ltd., Made in China, Manufactured for: Rece International Corp., Miami Lakes, FL, 33014, USA, NDC: 70006-500-01.

Product Quantity:
37,500 Boxes

Reason for Recall:
Lack of assurance of sterility and cGMP deviations observed at the manufacturing site.

Recall Number:
D-0247-2025

Code Information:
Lot #s: 200830, Exp 08/29/2025; 210925, Exp 09/24/2026; 221225, Exp 12/24/2027.

Class II Drugs Event

Event ID:
96245

Product Type:
Drugs

Status:
Ongoing

Date Terminated:
N/A

Recall Initiation Date:
02/06/2025

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
02/21/2025

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Padagis US LLC
3940 Quebec Ave N
Minneapolis, MN 55427-1244
United States

Distribution Pattern:
Nationwide in the USA

Associated Products

Product Description:
Estradiol Gel, 0.1%, 0.25 mg/g, 30 packets per carton, Rx Only, For Topical Use Only, Manufactured by Padagis, Yeruham, Israel, NDC: 45802-0134-30

Product Quantity:
4944 cartons

Reason for Recall:
Defective Container: Some packets may not be fully sealed, potentially allowing for loss of Ethanol from the product.

Recall Number:
D-0246-2025

Code Information:
Lot # 193109; Exp. 07/31/2026

Class II Drugs Event

Event ID:
96306

Product Type:
Drugs

Status:
Ongoing

Date Terminated:
N/A

Recall Initiation Date:
02/18/2025

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
02/21/2025

Initial Firm Notification of Consignee or Public:
E-Mail

Recalling Firm:
Turbare Manufacturing
925 Jeanette Dr
Conway, AR 72032-6651
United States

Distribution Pattern:
Nationwide in the USA

Associated Products

Product Description:
Avastin 1.25 mg/0.05 mL in 0.25 mL Syringe, For Intravitreal Injection Only, Office Use Only - Not for Resale - Single Use, This drug product was repackaged by Turbare Manufacturing, 925 Jeanette Drive, Conway, AR 72032, NDC: 83556-0101-01.

Product Quantity:
1,147 syringes

Reason for Recall:
Lack of Assurance of Sterility: due to a quality control process deviation. During an internal quality assurance review, an Acceptable Quality Limit (AQL) inspection was not conducted on a statistically sound number of samples. This may result in the inability to assure that the impacted products meet the identity, strength, quality, and purity characteristics that they are purported or represented to possess and may lead to products of unacceptable quality.

Recall Number:
D-0248-2025

Code Information:
Lot #s: 12122024@2 (BUD: 3/12/2025); 12192024@2 (BUD: 4/18/2025).