Enforcement Report - Week of June 25, 2025

Class I Drugs Event

Event ID:
96914

Product Type:
Drugs

Status:
Ongoing

Date Terminated:
N/A

Recall Initiation Date:
05/21/2025

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
06/24/2025

Initial Firm Notification of Consignee or Public:
Press Release

Recalling Firm:
Umary-USA.com
243 W Crawford St STE 40026
Nogales, AZ 85621-3208
United States

Distribution Pattern:
U.S. Nationwide via internet.

Associated Products

Product Description:
UNAVY ACIDO HIALURONICO, Conenido: 30 capletas de 850mg, distribuido por: EREN NATURAL S.A. DE C.V, Zappan, Jal. C.P, UPC 7 503046 054295

Product Quantity:
1,342 30-count bottles

Reason for Recall:
Marketed without approved NDA/ANDA- Laboratory analysis found product to be tainted with undeclared ingredients: Dexamethasone, Diclofenac and Omeprazole.

Recall Number:
D-0492-2025

Code Information:
All Lots; All Expiration Dates.

Product Description:
UMOVY ACIDO HIALURONICO, Conenido: 30 capletas de 850mg, distribuido por: EREN NATURAL S.A. DE C.V, Zappan, Jal. C.P, UPC 7503046054134

Product Quantity:
1,704 30-count bottles

Reason for Recall:
Marketed without approved NDA/ANDA- Laboratory analysis found product to be tainted with undeclared ingredients: Dexamethasone and Diclofenac.

Recall Number:
D-0493-2025

Code Information:
All Lots; All Expiration Dates.

Class II Drugs Event

Event ID:
96907

Product Type:
Drugs

Status:
Ongoing

Date Terminated:
N/A

Recall Initiation Date:
05/22/2025

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
06/17/2025

Initial Firm Notification of Consignee or Public:
E-Mail

Recalling Firm:
Aurobindo Pharma USA Inc
279 Princeton Hightstown Rd
East Windsor, NJ 08520-1401
United States

Distribution Pattern:
USA Nationwide.

Associated Products

Product Description:
Acetaminophen Tablets, 325 mg, 100-count bottles, Distributed by: Amazon.com Services LLC, 410 Terry Avenue N., Seattle, WA 98109, NDC 72288-405-10

Product Quantity:
4,608 bottles

Reason for Recall:
cGMP deviations: Due to confirmed consumer complaints received with the observation of tablet discoloration (brown surface on tablets).

Recall Number:
D-0471-2025

Code Information:
Lot#: AEF124004A, Exp date 08/31/2026

Class II Drugs Event

Event ID:
96976

Product Type:
Drugs

Status:
Ongoing

Date Terminated:
N/A

Recall Initiation Date:
05/29/2025

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
06/18/2025

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Eugia US LLC
279 Princeton Hightstown Rd
East Windsor, NJ 08520-1401
United States

Distribution Pattern:
Nationwide in the USA

Associated Products

Product Description:
Gentamicin Injection, USP, (PEDIATRIC), 20 mg per 2 mL (10 mg per mL*), 2 mL Single-Dose Vial, Rx Only, Mfd. in India for: Eugia US LLC, E. Windsor, NJ, 08520 Vial- NDC 55150-401-01, Carton NDC 55150-401-25

Product Quantity:
48,000 vials

Reason for Recall:
Failed Stability Specifications: Out of specification results for the Color Absorbance test during 12 Month sample analysis.

Recall Number:
D-0472-2025

Code Information:
Batch 3GT23006, 3GT23007, 3GT23008, Exp Date: November, 30, 2025