

Enforcement Report - Week of November 20, 2024

Class II Drugs Event

Event ID:

95587

Product Type:

Drugs

Status:

Ongoing

Date Terminated:

N/A

Recall Initiation Date:

11/06/2024

Voluntary / Mandated:

Voluntary: Firm initiated

Center Classification Date:

11/12/2024

Initial Firm Notification of Consignee or Public:

Letter

Recalling Firm:

Trinity Gold Nutrition
201 Tom Hall St STE 2107
Fort Mill, SC 29715-2313
United States

Distribution Pattern:

Nationwide within the United States; additionally Canada, England, and Australia.

Associated Products

Product Description:

Trinity Gold Nutrition, 60 Capsule, 30 day Supply, Distributed by Trinity Gold Nutrition 201 Tom Hall St. Ste. 2107, Fortmill, SC 29716, USA, Ph: 704-629-8203, www.trinitygold.com, Made in India, UPC 802992001009

Product Quantity:

150

Reason for Recall:

Marketed without an Approved NDA/ANDA: FDA analysis found product to be tainted with undeclared acetaminophen, diclofenac and phenylbutazone.

Recall Number:

D-0042-2025

Code Information:

Lot #: IN-030, Exp. Date: NOV 2027

Class II Drugs Event

Event ID:

95611

Product Type:

Drugs

Status:

Ongoing

Date Terminated:

N/A

Recall Initiation Date:

10/23/2024

Voluntary / Mandated:

Voluntary: Firm initiated

Center Classification Date:

11/12/2024

Initial Firm Notification of Consignee or Public:

Letter

Recalling Firm:

Cipla USA, Inc.
10 Independence Blvd
Warren, NJ 07059-2730
United States

Distribution Pattern:

USA nationwide.

Associated Products

Product Description: Lanthanum Carbonate Chewable Tablets, 1000mg, 10-count bottle, Rx only, Manufactured for Cipla USA, NDC 69097-0936-98
Product Quantity: 1,875 boxes (cipla and exlan)
Reason for Recall: Failed Tablet/Capsule Specifications: Complaints received of crushed and broken tablets.
Recall Number: D-0043-2025
Code Information: Lot # NB240316, Exp 12/31/25

Product Description: Lanthanum Carbonate Chewable Tablets, 1000mg, 10-count bottle, Rx only, Manufactured for Exelan Pharmaceuticals, NDC 76282-0478-90
Product Quantity: N/A
Reason for Recall: Failed Tablet/Capsule Specifications: Complaints received of crushed and broken tablets.
Recall Number: D-0044-2025
Code Information: Lot# NB240873, Exp 03/31/2026

Class II Drugs Event

Event ID: 95647	Product Type: Drugs
Status: Ongoing	Date Terminated: N/A
Recall Initiation Date: 10/17/2024	Voluntary / Mandated: Voluntary: Firm initiated
Center Classification Date: 11/14/2024	Initial Firm Notification of Consignee or Public: Letter
Recalling Firm: Keystone Industries 480 S Democrat Rd Gibbstown, NJ 08027-1239 United States	
Distribution Pattern: Nationwide within the United States	

Associated Products

Product Description: Perio Maintenance Rinse 0.63% Stannous Fluoride Concentrated Solution, Rx Only, Net Wt. 10 oz. (283.5 g) pumps, Mint flavor, Manufactured by: Keystone Industries, 480 S. Democrat Rd., Gibbstown, NJ 08027, NDC 68400-202-10
Product Quantity: 787 pumps
Reason for Recall: Subpotent Drug
Recall Number:

D-0046-2025

Code Information:

Lot #: PVC-003015, Exp. Date Sep-21-2025; PVC-003061, Exp. Date Apr-30-2026

Class III Drugs Event

Event ID:

95700

Product Type:

Drugs

Status:

Ongoing

Date Terminated:

N/A

Recall Initiation Date:

11/05/2024

Voluntary / Mandated:

Voluntary: Firm initiated

Center Classification Date:

11/14/2024

Initial Firm Notification of Consignee or Public:

Letter

Recalling Firm:

The Harvard Drug Group LLC dba Major Pharmaceuticals and Rugby Laboratories
341 Mason Rd
La Vergne, TN 37086-3606
United States

Distribution Pattern:

Nationwide in the US.

Associated Products

Product Description:

Hydralazine HCl Tablets, USP, 25mg, Rx only, 100 tablets per carton, Distributed by: Avet Pharmaceuticals Inc., East Brunswick, NJ 08816,
Distributed by: MAJOR Pharmaceuticals, Livonia, MI, 48152, USA, NDC 0904-6441-61.

Product Quantity:

25814 tablets

Reason for Recall:

Failed impurities/degradation specifications during routine stability testing for impurities.

Recall Number:

D-0045-2025

Code Information:

Lot#: T04888, Exp 11/2024; T04946, Exp 12/2024; T04970, Exp 07/2025