Enforcement Report - Week of October 9, 2024

Class I Drugs Event

Event ID:
94949

Product Type:
Drugs

Status:
Ongoing

Date Terminated:
N/A

Recall Initiation Date:
07/12/2024

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
10/02/2024

Initial Firm Notification of Consignee or Public:
Press Release

Recalling Firm:
Supercore Products Group Inc.
230 Peachtree St Nw Ste 2200
Atlanta, GA 30303-1534
United States

Distribution Pattern:
Nationwide US (2014), Israel (2), Canada (12), Republic of Kosovo (1), Pakistan (1), Australia (3), Morocco (1), United Kingdom (1)

Associated Products

Product Description:
Hard Steel Capsules packaged in 1 count blister packs in boxes of 10, 20 and 30, Manufactured in U.S.A.

Product Quantity:
729

Reason for Recall:
Marketed without an approved NDA/ANDA: FDA analysis found products to be tainted with undeclared acetaminophen and sildenafil.

Recall Number:
D-0003-2025

Code Information:
All lots

Product Description:
Gold Hard Steel Plus Liquid, 2 FL OZ bottles, UPC 787188873199

Product Quantity:
615

Reason for Recall:
Marketed without an approved NDA/ANDA: FDA analysis found products to be tainted with undeclared acetaminophen and sildenafil.

Recall Number:
D-0004-2025

Code Information:
All lots

Class I Drugs Event

Event ID:
95399

Product Type:
Drugs

Status:
Ongoing

Date Terminated:
N/A

Recall Initiation Date:

Voluntary / Mandated:

09/19/2024

Center Classification Date:
10/03/2024

Recalling Firm:
Gilead Sciences, Inc.
333 Lakeside Dr
Foster City, CA 94404-1147
United States

Distribution Pattern:
Nationwide in the U.S.A.

Voluntary / Mandated:
Voluntary: Firm initiated

Initial Firm Notification of Consignee or Public:
Letter

Associated Products

Product Description:
Veklury (remdesivir) for injection, 100 mg/vial, Single-Dose Vial, Rx only, Manufactured for: Gilead Sciences, Inc., Foster City, CA 94404, NDC 61958-2901-2

Product Quantity:
105,000 vials

Reason for Recall:
Presence of Particulate Matter: Presence of glass particle.

Recall Number:
D-0005-2025

Code Information:
Lot: 47035CFA, Exp. 11/2025

Class II Drugs Event

Event ID:
95389

Status:
Ongoing

Recall Initiation Date:
09/24/2024

Center Classification Date:
10/03/2024

Recalling Firm:
Glenmark Pharmaceuticals Inc., USA
750 Corporate Dr
Mahwah, NJ 07430-2009
United States

Distribution Pattern:
Nationwide in the USA

Product Type:
Drugs

Date Terminated:
N/A

Voluntary / Mandated:
Voluntary: Firm initiated

Initial Firm Notification of Consignee or Public:
Letter

Associated Products

Product Description:
Ryaltris (olopatadine hydrochloride and mometasone fluorate) Nasal Spray, 665 mcg/25 mcg per spray, 240 Metered Sprays/bottle, 29 g net fill weight, Distr. by Hikma Specialty USA Inc., Columbus, OH 43328, hikma, Glenmark Specialty SA. NDC 59467-700-27.

Product Quantity:
45,504 bottles

Reason for Recall:
Defective Delivery System: The dip tube is clogged causing the spray not to work.

Recall Number:

D-0006-2025

Code Information:
Lots 14230425, Exp Date, Nov-25; 14240024, Exp Date Dec-25; 14240029, Exp Date Dec-25; 14240076, Exp Date Jan-26; 14240082 Exp Date, Jan-26, 14240090, Exp Date Jan-26; and 14240100, Exp Date Jan-26

Class II Drugs Event

Event ID:
95418

Product Type:
Drugs

Status:
Ongoing

Date Terminated:
N/A

Recall Initiation Date:
09/24/2024

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
10/02/2024

Initial Firm Notification of Consignee or Public:
E-Mail

Recalling Firm:
Nivagen Pharmaceuticals Inc
3100 Fite Cir
Sacramento, CA 95827-1805
United States

Distribution Pattern:
Nationwide within the U.S

Associated Products

Product Description:
Atorvastatin Calcium Tablets, USP, 40mg, Rx only, 1000 Tablets per bottle, Manufactured for: Nivagen Pharmaceuticals, Inc. Sacramento, CA 95827, USA, Manufactured by: Umedica Laboratories Pvt Ltd., Vapi Gujarat 396195, India, NDC: 75834-257-01.

Product Quantity:
2328 bottles

Reason for Recall:
Presence of Foreign Tablets/Capsules: A Carbamazepine Extended-Release 400 mg tablet was found in a 1000-count bottle of Atorvastatin Calcium Tablets, USP 40 mg.

Recall Number:
D-0001-2025

Code Information:
Lot #: U24T0408A, Exp: 03/31/2026

Class II Drugs Event

Event ID:
95420

Product Type:
Drugs

Status:
Ongoing

Date Terminated:
N/A

Recall Initiation Date:
09/23/2024

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
10/03/2024

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Advanced Accelerator Applications USA, Inc.
57 E Willow St
Millburn, NJ 07041-1416
United States

Distribution Pattern:
FL, MA, NJ, NY, PA, and VA

Associated Products

Product Description:
Pluvicto, 1000 MBq/mL (27 mCi/mL), lutetium, LU 177, vipivotide tetraxetan injection, Single-dose vial, Sterile, Manufacturer Advanced Accelerator Applications, 57 E. Willow Street, NJ 07041, Millburn USA. NDC 69488-0010-61

Product Quantity:
99 doses

Reason for Recall:
CGMP deviations

Recall Number:
D-0007-2025

Code Information:
Lot#: LPS240919B-16, 24-Sep-2024 Lot#: LPS240920B-16, 25-Sep-2024 Lot#: LPS240920C-16, 25-Sep-2024

Class III Drugs Event

Event ID:
95444

Product Type:
Drugs

Status:
Ongoing

Date Terminated:
N/A

Recall Initiation Date:
09/30/2024

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
10/02/2024

Initial Firm Notification of Consignee or Public:
N/A

Recalling Firm:
Glenmark Pharmaceuticals Inc., USA
750 Corporate Dr
Mahwah, NJ 07430-2009
United States

Distribution Pattern:
Nationwide in the US.

Associated Products

Product Description:
Ciclopirox Gel 0.77%, For Dermatologic Use Only, Not for Use in Eyes, Rx Only, a) 30 gm Tube, NDC 68462-0455-35; b) 45 gm Tube, NDC 68462-0455-47; c) 100 gm Tube, NDC 68462-0455-94, Manufactured by: Glenmark Pharmaceuticals, Ltd., Colvale-Bardez, Goa 403513, India, Manufactured for: Glenmark Pharmaceuticals Inc., USA, Mahwah, NJ 07430.

Product Quantity:
11,568 tubes

Reason for Recall:
Defective Container: Firm received complaints of broken tube at the seal.

Recall Number:
D-0002-2025

Code Information:
Lot #s: a) 19242028, Exp. 04/30/2026; b) 19242028, Exp. 04/30/2026; c) 19242028, Exp. 04/30/2026