Enforcement Report - Week of August 27, 2025

Class II Drugs Event

Event ID:
97344

Product Type:
Drugs

Status:
Ongoing

Date Terminated:
N/A

Recall Initiation Date:
07/22/2025

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
08/18/2025

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Taizhou Kangping Medical Science And Technology Co., Ltd.
Hailing Industrial Park 27 Tai'An Road
Taizhou
China

Distribution Pattern:
NY

Associated Products

Product Description:
BZK Antiseptic Towelette, Sterile, For External Use Only, benzalkonium chloride 0.13%, Antiseptic, 100 towelettes per carton , For Professional use, Mfg by: Taizhou Kangping Medical, Taizhou, JiangSu, China, NDC: 71310-111-01

Product Quantity:
3.85 million Cartons

Reason for Recall:
Lack of Assurance of Sterility.

Recall Number:
D-0589-2025

Code Information:
Lot Numbers: 220583459, 230553459, 232743459, 110523, 031524, 052224, 247793459

Class II Drugs Event

Event ID:
97364

Product Type:
Drugs

Status:
Ongoing

Date Terminated:
N/A

Recall Initiation Date:
08/04/2025

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
08/18/2025

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
PFIZER INC
68 Hudson Blvd E
New York, NY 10001-2188
United States

Distribution Pattern:
U.S. Nationwide

Associated Products

Product Description:
Vial Label: Epinephrine Injection, USP, 1mg/10mL (0.1 mg/mL), Rx only, Distributed by Hospira, Inc., Lake Forest, IL 60045, USA. NDC 0409-4933-05. Case: NDC 0409-4933-10.

Product Quantity:
49,620 vials

Reason for Recall:
Lack of Assurance of Sterility.

Recall Number:
D-0590-2025

Code Information:
Lot #: LY3681, LY4360, LY4416, Exp. 02/28/2026

Product Description:
Vial Label: 8.4% Sodium Bicarbonate Injection, USP, 50mEq/50 mL (1 mEq/mL), Rx only, Hospira, Inc., Lake Forest, IL 60045, USA, NDC 0409-6637-24. Case NDC: 00409-6637-14.

Product Quantity:
15,750 vials

Reason for Recall:
Lack of Assurance of Sterility.

Recall Number:
D-0591-2025

Code Information:
Lot #: LH2671, Exp. 11/30/2026

Class II Drugs Event

Event ID:
97424

Product Type:
Drugs

Status:
Ongoing

Date Terminated:
N/A

Recall Initiation Date:
08/12/2025

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
08/21/2025

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
VIONA PHARMACEUTICALS INC
20 Commerce Dr Ste 340
Cranford, NJ 07016-3617
United States

Distribution Pattern:
Nationwide in the USA

Associated Products

Product Description:
Tavaborole Topical Solution 5%, 10 mL per glass bottle, Rx Only, For Topical Use Only, Manufactured by: Zydus Lifesciences Ltd., Changodar Ahmedabad, India. Distributed by: Viona Pharmaceuticals Inc., Cranford, NJ 07016. NDC: 72578-102-04

Product Quantity:
3960 bottles

Reason for Recall:
Discoloration

Recall Number:
D-0595-2025

Code Information:
Lot #: T401968

Class II Drugs Event

Event ID:
97449

Product Type:
Drugs

Status:
Ongoing

Date Terminated:
N/A

Recall Initiation Date:
08/20/2025

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
08/21/2025

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:
Product was distributed nationwide within the United States.

Associated Products

Product Description:
Carvedilol Tablets USP, 12.5 mg, 100- Tablets, (10x10) cartons, Rx Only, Packaged and distributed by Major Pharmaceuticals, Indianapolis, IN, 46268, USA, NDC 0904-7307-61

Product Quantity:
26,628 cartons

Reason for Recall:
CGMP Deviations: Results for N-Nitroso Carvedilol Impurity-1 (NNCI) impurity observed to be above the FDA-recommended limit of NMT 4.0 ppm

Recall Number:
D-0594-2025

Code Information:
Lot #: T05693, Exp. Date 03/2026

Class III Drugs Event

Event ID:
97304

Product Type:
Drugs

Status:
Ongoing

Date Terminated:
N/A

Recall Initiation Date:
07/24/2025

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
08/20/2025

Initial Firm Notification of Consignee or Public:
Letter

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

Distribution Pattern:
U.S. Nationwide.

Associated Products

Product Description:
Albuterol Sulfate, Inhalation Aerosol, 90 mcg, 200 metered Inhalations, NET CONTENT 6.7 g, Manufactured by: Cipla Ltd, Indore, SEZ, Pithampur, India; Manufactured for: Cipla USA, Inc. 10 Independence Boulevard, Suite 300, Warren, NJ 07059, NDC 69097-142-60.

Product Quantity:
20352 packs (1x 200 MD)

Reason for Recall:
Failed Stability Specifications: Out of specification results was observed in Induction Port during the analysis of Particle size distribution at the 12-month time point.

Recall Number:
D-0593-2025

Code Information:
Lot#: 4IB0519, Exp. 04/30/2026

Class III Drugs Event

Event ID:
97382

Product Type:
Drugs

Status:
Ongoing

Date Terminated:
N/A

Recall Initiation Date:
08/05/2025

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
08/19/2025

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Haleon US Holdings LLC
3169 Route 145
East Durham, NY 12423-1416
United States

Distribution Pattern:
Nationwide in the USA.

Associated Products

Product Description:
Sensodyne PRONAMEL (Potassium nitrate 5%, Sodium fluoride 0.25%) Active SHIELD Toothpaste for Sensitive Teeth, Fresh Mint, Net WT 3.4OZ (96.4g) Tube, 6 tubes x 2 inners, per case, Distributed by GSK Consumer Healthcare, Warren, NJ 07059. UPC 3 10158 35691 2

Product Quantity:
46,692 tubes

Reason for Recall:
Labeling: Label Mix-up: The outer carton is labelled Fresh Mint. The tube is labelled Cool Mint/Whitening. The toothpaste inside the tube is Fresh Mint as indicated on the outer carton

Recall Number:
D-0592-2025

Code Information:
Lot # for Case: 5058RB, Exp. date: 08/31/2027 Lot # for Carton and Tube: NJ2A, Exp 08/31/2027