Enforcement Report - Week of February 5, 2025

Class I Drugs Event

Event ID:
96008

Product Type:
Drugs

Status:
Ongoing

Date Terminated:
N/A

Recall Initiation Date:
12/23/2024

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
01/29/2025

Initial Firm Notification of Consignee or Public:
Press Release

Recalling Firm:
Astellas Pharma US Inc.
2375 Waterview Dr
Northbrook, IL 60062-6145
United States

Distribution Pattern:
Nationwide in the USA

Associated Products

Product Description:
Astagraf XL (tacrolimus extended-release capsules) 0.5 mg, 30-count bottles, RX Only, Product of Japan, Distributed by: Astellas Pharma US Inc., Northbrook, IL 60062, NDC 0469-0647-73.

Product Quantity:
3,500 30-count bottles

Reason for Recall:
Failed Tablet/Capsule Specifications: Bottles shipped to the USA may contain empty capsules

Recall Number:
D-0210-2025

Code Information:
Lot# 0R3092A, EXP 03/31/2026

Product Description:
Prograf (tacrolimus) capsules, USP, 0.5 mg, 100-count bottle, Rx Only, Product of Japan, Distributed by: Astellas Pharma US, Inc., Northbrook, IL 60062, NDC 0469-0607-73.

Product Quantity:
14,340 100-count bottles

Reason for Recall:
Failed Tablet/Capsule Specifications: Bottles shipped to the USA may contain empty capsules

Recall Number:
D-0211-2025

Code Information:
Lot# 0E3353D, Exp 03/31/2026

Class II Drugs Event

Event ID:
96105

Product Type:
Drugs

Status:
Ongoing

Date Terminated:
N/A

Recall Initiation Date:
01/13/2025

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
01/29/2025

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:
Nationwide within the United States

Associated Products

Product Description:
Duloxetine Delayed-Release Capsules USP, 20 mg, packaged in a) 30 Unit Doses (3x10 blister packs) NDC 0904-7043-04 and b) 100 Unit Doses (10x10 blister packs) NDC 0904-7043-61, Rx only, Packaged and Distributed by: Major Pharmaceuticals, Indianapolis, IN 46268 USA.

Product Quantity:
a) 6408 boxes and b)1488 boxes

Reason for Recall:
Failed Impurities/Degradation Specifications: Due to presence of Nitrosamine Drug Substances Related Impurity (NDSRI), N-Nitroso-Duloxetine above the interim acceptable intake limit of 5 ppm.

Recall Number:
D-0212-2025

Code Information:
Lot #: a) N01530, Exp. Date 01/2025; b) N01540, Exp. Date. 01/2025

Class II Drugs Event

Event ID:
96167

Product Type:
Drugs

Status:
Ongoing

Date Terminated:
N/A

Recall Initiation Date:
01/17/2025

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
01/30/2025

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
McKesson
6555 State Highway 161
Irving, TX 75039-2402
United States

Distribution Pattern:
Nationwide USA

Associated Products

Product Description:
Inflectra (infliximab-dyyb), For injection, 100mg per vial, packaged in 10 mL single-dose vial, Rx only, Mfd by: CELLTRION, INC, Dist. by: Pfizer Labs, Division of Pfizer Inc., New York, NY 10001, NDC 0069-0809-01

Product Quantity:
192 vials

Reason for Recall:
cGMP Deviations: Product intended for quarantine was inadvertently distributed.

Recall Number:
D-0213-2025

Code Information:
Lot# 04647349, Exp Date 5/31/2029

Class III Drugs Event

Event ID:
96122

Product Type:
Drugs

Status:
Ongoing

Date Terminated:
N/A

Recall Initiation Date:
01/17/2025

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
01/29/2025

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
The W.S. Badger Company, Inc.
768 Route 10
Gilsum, NH 03448-7503
United States

Distribution Pattern:
Distributed Nationwide in the USA

Associated Products

Product Description:
BADGER 50, ADVENTURE SPORT MINERAL SUNSCREEN WITH CLEAR ZINC, (uncoated 25% zinc oxide), 2.4 oz., Tin, W.S. Badger Company, Inc, 768 Route 10, Gilsum NH, 03448 UPC 6 34084 47150 2

Product Quantity:
4,834 tins

Reason for Recall:
Labeling: Missing Label: The finished product potentially missing the labeling with the drug facts panel, bar code and directions for use.

Recall Number:
D-0209-2025

Code Information:
LOT# 091923A, Exp. Date 09/19/26