Enforcement Report - Week of June 11, 2025

Class II Drugs Event

Event ID:
96898

Product Type:
Drugs

Status:
Ongoing

Date Terminated:
N/A

Recall Initiation Date:
05/15/2025

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
06/02/2025

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Amerisource Health Services LLC
2550 John Glenn Ave Ste A
Columbus, OH 43217-1188
United States

Distribution Pattern:
Nationwide in the USA

Associated Products

Product Description:
Indomethacin Extended-Release Capsules, USP, 75 mg, 30 capsules (3 x 10 blister cards) per carton, Rx Only, Distributed by: American Health Packaging, Columbus, Ohio 43217, NDC 68084-411-21 (carton), NDC 68084-411-11 (blister card).

Product Quantity:
21 cartons

Reason for Recall:
cGMP deviations

Recall Number:
D-0454-2025

Code Information:
Lot #: 1021950, Exp. 11/30/2026

Class II Drugs Event

Event ID:
96953

Product Type:
Drugs

Status:
Ongoing

Date Terminated:
N/A

Recall Initiation Date:
05/28/2025

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
06/03/2025

Initial Firm Notification of Consignee or Public:
Two or more of the following: Email, Fax, Letter, Press Release, Telephone, Visit

Recalling Firm:
Apotex Corp.
2400 N Commerce Pkwy Ste 400
Weston, FL 33326-3253
United States

Distribution Pattern:
US Nationwide.

Associated Products

Product Description:
Lacosamide Oral Solution, USP, 10 mg/mL, 200 mL, Rx Only, Manufactured by: Apotex Inc., Toronto, Ontario, Canada M9L 1T9, Manufactured for: Apotex Corp., Weston FL 33326, NDC 60505-0405-4

Product Quantity:
20,648 bottles

Reason for Recall:
Defective Container: This recall is being initiated due to a leaking unit stored horizontally.

Recall Number:
D-0457-2025

Code Information:
Batch # TZ5589, Exp Date: 01/31/2026

Class II Drugs Event

Event ID:
96960

Product Type:
Drugs

Status:
Ongoing

Date Terminated:
N/A

Recall Initiation Date:
05/23/2025

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
06/05/2025

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Consumer Product Partners, LLC
1 Swan Dr
Smyrna, TN 37167-2099
United States

Distribution Pattern:
Nationwide in the USA.

Associated Products

Product Description:
Spectrum Advanced Gel Hand Sanitizer, Ethyl alcohol 70%, 8 FL OZ (236 mL) per bottle, Manufactured for Medline Industries, Inc., Three Lakes Drive, Northfield, IL 60693 USA. NDC: 53329-202-08, UPC 8 88277 34945 5

Product Quantity:
125,040 bottles

Reason for Recall:
Subpotent product: Product has cloudy appearance and tested below assay label claim for 70% Ethyl Alcohol

Recall Number:
D-0458-2025

Code Information:
Lot, expiry: Lot 0644682, exp 2026/11/14; Lot 0644683, exp 2026/11/16

Class II Drugs Event

Event ID:
96983

Product Type:
Drugs

Status:
Ongoing

Date Terminated:
N/A

Recall Initiation Date:
05/27/2025

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
06/02/2025

Initial Firm Notification of Consignee or Public:
E-Mail

Recalling Firm:
Torrent Pharma Inc.
106 Allen Rd Ste 305
Basking Ridge, NJ 07920-3851
United States

Distribution Pattern:
U.S. Nationwide.

Associated Products

Product Description:
Fluoxetine Tablets, USP, 20 mg, 30-count bottle, Rx only, Manufactured by: TORRENT PHARMACEUTIALS LTD., Indrad-382 721 INDIA; Manufactured for: TORRENT PHARMA INC., Basking Ridge, NJ 07920. NDC: 13668-473-30

Product Quantity:
3672 Bottles

Reason for Recall:
CGMP Deviations: Presence of N-Nitroso Fluoxetine exceeding interim acceptable intake limit.

Recall Number:
D-0455-2025

Code Information:
Lot# BDX6K001; Exp. Date 06/30/2025

Product Description:
Fluoxetine Tablets, USP, 20 mg, 28-count Carton (4x7 Unit-dose), Manufactured by: TORRENT PHARMACEUTIALS LTD., Indrad-382 721 INDIA; Manufactured for: TORRENT PHARMA INC., Basking Ridge, NJ 07920. NDC: 13668-473-91 (Carton); 13668-473-70 (Blister)

Product Quantity:
972 Cartons

Reason for Recall:
CGMP Deviations: Presence of N-Nitroso Fluoxetine exceeding interim acceptable intake limit.

Recall Number:
D-0456-2025

Code Information:
Lot# BDX6K001; Exp. Date: 06/30/2025