Enforcement Report - Week of November 12, 2025

Class II Drugs Event

Event ID:
97795

Product Type:
Drugs

Status:
Ongoing

Date Terminated:
N/A

Recall Initiation Date:
10/13/2025

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
11/03/2025

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Teva Pharmaceuticals USA, Inc
400 Interpace Pkwy Bldg A
Parsippany, NJ 07054-1120
United States

Distribution Pattern:
Distributed in three (3) States: MS, OH, CA.

Associated Products

Product Description:
Amoxicillin and Clavulanate Potassium for Oral Suspension USP, 200 mg/28.5 mg per 5mL, 100 mL (when reconstituted), Rx only, manufactured in Canada by: Teva Canada Limited, Toronto, Canada M1B 2K9; Manufactured For: Teva Pharmaceuticals USA, Inc., Parsippany, NJ 07054 NDC 0093-2277-7.

Product Quantity:
4680 cartons

Reason for Recall:
Subpotent drug; Clavulanate Potassium component

Recall Number:
D-0151-2026

Code Information:
Lot # 100062316, Exp Date: 01/2026

Class II Drugs Event

Event ID:
97809

Product Type:
Drugs

Status:
Ongoing

Date Terminated:
N/A

Recall Initiation Date:
10/17/2025

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
11/05/2025

Initial Firm Notification of Consignee or Public:
E-Mail

Recalling Firm:
Aero Healthcare
616 Corporate Way Ste 6
Valley Cottage, NY 10989-2047
United States

Distribution Pattern:
US Nationwide.

Associated Products

Product Description:
Acetaminophen 500mg Caffeine 65mg caplets, packaged as 2 caplets per packet further packaged in a 50-count box, AERO TAB, Manufactured for AERO HEALTHCARE US, Valley-Cottage, NY, 10989, NDC 55305-135-01

Product Quantity:
N/A

Reason for Recall:
Labeling: Label Mix-up. This issue affects the outer box labeling only. The box incorrectly states the ingredients Acetaminophen 500mg and Caffeine 65mg. The inner pouch correctly states the ingredients are Aspirin (NSAID)*500mg and Caffeine 32.5mg.

Recall Number:
D-0155-2026

Code Information:
Lot # 9282, Exp Date: 2026-09-01; Lot # 9310, Exp Date: 2026-11-01

Class II Drugs Event

Event ID:
97856

Product Type:
Drugs

Status:
Ongoing

Date Terminated:
N/A

Recall Initiation Date:
10/22/2025

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
11/04/2025

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

Recalling Firm:
Zydus Pharmaceuticals (USA) Inc
73 Route 31 N
Pennington, NJ 08534-3601
United States

Distribution Pattern:
Nationwide in the US

Associated Products

Product Description:
clomiPRAMINE Hydrochloride, Capsules, USP, 25 mg, packaged in a) 30-count bottles (NDC 16714-849-01), b) 90-count bottles (NDC 16714-849-02), c) 100-count bottles (NDC 16714-849-03), Rx only, Manufactured for: Northstar Rx LLC, Memphis, TN 38141, Manufactured by: Zydus Lifesciences Ltd., Ahmedabad, India

Product Quantity:
N/A

Reason for Recall:
cGMP deviations: an observed Out of Specification of Nitrosamine Drug Substance-Related Impurities (NDSRIs), N-Nitroso Desmethyl-Clomipramine, above the FDA acceptable intake limit.

Recall Number:
D-0152-2026

Code Information:
a) Lot # E408871, Exp Date: 10/2026; Lot # E405282, Exp Date: 06/2026; Lot # E400386, Exp Date: 12/2025 b) Lot # E408872, Exp Date: 10/2026; Lot # E405280, Exp Date: 06/2026 c) Lot # E408873, Exp Date: 10/2026; Lot # E405281, Exp Date: 06/2026; Lot # E400387, Exp Date: 12/2025

Product Description:
clomiPRAMINE Hydrochloride, Capsules, USP, 50 mg, packaged in a) 30-count bottles (NDC 16714-850-01), b) 90-count bottles (NDC 16714-850-

02), c) 100-count bottles (NDC 16714-850-03), Rx only, Manufactured for: Northstar Rx LLC, Memphis, TN 38141, Manufactured by: Zydus Lifesciences Ltd., Ahmedabad, India

Product Quantity:
N/A

Reason for Recall:
cGMP deviations: an observed Out of Specification of Nitrosamine Drug Substance-Related Impurities (NDSRIs), N-Nitroso Desmethyl-Clomipramine, above the FDA acceptable intake limit.

Recall Number:
D-0153-2026

Code Information:
a) Lot # E410157, Exp Date: 12/2026; Lot # E407176, Exp Date: 08/2026; Lot # E405845, Exp Date: 06/2026; Lot # E400943, Exp Date: 01/2026 b)Lot # E410156, Exp Date: 12/2026; Lot # E400942, Exp Date: 01/2026 c) Lot # E410158, Exp Date: 12/2026; Lot # E407128, Exp Date: 08/2026; Lot # E405846, Exp Date: 06/2026; Lot # E400944, Exp Date: 01/2026

Product Description:
clomiPRAMINE Hydrochloride, Capsules, USP, 75 mg, packaged in a) 30-count bottles (NDC 16714-851-01), b) 90-count bottles (NDC 16714-851-02), c) 100 capsules, NDC 16714-851-03 Rx only, Manufactured for: Northstar Rx LLC, Memphis, TN 38141, Manufactured by: Zydus Lifesciences Ltd., Ahmedabad, India.

Product Quantity:
N/A

Reason for Recall:
cGMP deviations: an observed Out of Specification of Nitrosamine Drug Substance-Related Impurities (NDSRIs), N-Nitroso Desmethyl-Clomipramine, above the FDA acceptable intake limit.

Recall Number:
D-0154-2026

Code Information:
a) Lot # E403069, Exp Date: 04/2026; Lot # E406504, Exp Date: 07/2026; Lot # E309177, Exp Date: 11/2025; Lot # E400262, Exp Date: 12/2025; Lot # E404200, Exp Date: 05/2026 b) Lot # E403070, Exp Date: 04/2026; Lot # E406505, Exp Date: 07/2026; Lot # E407631, Exp Date: 08/2026; Lot # E400263, Exp Date: 12/2025; Lot # E404202, Exp Date: 05/2026 c) Lot # E403071, Exp Date: 04/2026; Lot # E407632, Exp Date: 08/2026; Lot # E405848, E405284, Exp Date: 07/2026; Lot # E400264, Exp Date: 12/2025; Lot # E404201, Exp Date: 05/2026