Enforcement Report - Week of May 21, 2025

Class II Drugs Event

Event ID:
96390

Product Type:
Drugs

Status:
Ongoing

Date Terminated:
N/A

Recall Initiation Date:
03/05/2025

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
05/09/2025

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
L'Oreal USA
222 Terminal Ave
Clark, NJ 07066-1317
United States

Distribution Pattern:
Nationwide in the USA

Associated Products

Product Description:
La Roche-Posay Laboratoire Dermatologique Effaclar Duo Dual Action Acne Treatment, 5.5% Benzoyl Peroxide Acne Medication, 40 mL (135 FL. OZ.) Tube per carton, La Roche-Posay LLC, 10 Hudson Yards, New York, NY 10001, La Roche-Posay, Laboratoire Dermatologique, CAI 86270, La Roche-Posay, France, UPC 883140500759.

Product Quantity:
2,226,801 bottles

Reason for Recall:
Chemical Contamination: This recall has been initiated due to detected trace levels of benzene.

Recall Number:
D-0417-2025

Code Information:
Lot #: MYX46W, Exp 04/30/2025

Product Description:
La Roche-Posay Laboratoire Dermatologique Effaclar Dermatological Acne System, 3 Step Acne Routine Kit, Medicated Gel Cleanser 3.4 fl. oz. (100 mL) Tube, Clarifying Solution 3.4 fl. oz. (100 mL) Tube, Dual Action Acne Treatment 0.7 fl. oz. (20 mL: UPC 883140035275) Tube, (benzoyl peroxide 0.5% and benzoyl peroxide 5.5% and salicylic acid 2%), La Roche-Posay LLC, 10 Hudson Yards, New York, NY 10001, La Roche-Posay, France, UPC 883140035282 (kit).

Product Quantity:
14,460 bottles

Reason for Recall:
cGMP Deviations: The recall was initiated due to detected trace levels of benzene in a specific lot of this product lot (MYX46W), however out of an abundance of caution, the firm voluntarily recalled all La Roche-Posay Effaclar Duo Dual Action Acne Treatment lots.

Recall Number:
D-0418-2025

Code Information:
Lot #s, Expiration Dates: MYX30W, Exp 03/31/2025 MYX32W, Exp 03/31/2025 MYX33W, Exp 03/31/2025 MYX41W, Exp 04/30/2025 MYX42W, Exp 04/30/2025 MYX43W, Exp 04/30/2025 MYX44W, Exp 04/30/2025 MYX45W, Exp 04/30/2025 MYX50W, Exp 05/31/2025 MYX51W, Exp 04/30/2025 MYX52W, Exp 04/30/2025 MYX53W, Exp 05/31/2025 MYX70W, Exp 07/31/2025 MYX80W, Exp 07/31/2025 MYX81W, Exp 07/31/2025 MYX90W, Exp 08/31/2025 MYX91W, Exp 08/31/2025 MYX92W, Exp 08/31/2025 MYX93W, Exp 08/31/2025 MYXD0W, Exp 09/30/2025 MYXO1W, Exp 09/30/2025 MYXO2W, Exp 09/30/2025 MYXO3W, Exp 09/30/2025 MYXO4W, Exp 09/30/2025 MYXO5W, Exp 09/30/2025 MYY21W, Exp 02/28/2026 MYY23W, Exp 02/28/2026 MYY26W, Exp 02/28/2026 MYY27W, Exp 02/28/2026 MYY31W, Exp 03/31/2026 MYY32W, Exp 11/30/2025

MYY33W, Exp 11/30/2025 MYY34W, Exp 03/31/2026 MYY50W, Exp 05/31/2026 MYY51W, Exp 05/31/2026 MYY60W, Exp 05/31/2026 MYY61W, Exp 03/31/2026 MYY62W, Exp 06/30/2026 MYY63W, Exp 06/30/2026 MYY64W, Exp 06/30/2026 MYY72W, Exp 06/30/2026 MYY73W, Exp 06/30/2026 MYY74W, Exp 06/30/2026 MYY75W, Exp 06/30/2026 MYY76W, Exp 06/30/2026.

Product Description:
La Roche-Posay Laboratoire Dermatologique Effaclar Duo Dual Action Acne Treatment, 5.5% Benzoyl Peroxide Acne Medication, a) UPC 3606000508804, 20 mL (0.7 fl. oz.) Tube per Carton, b) 883140500759, 40 mL (1.35 fl. oz.) Tube per Carton, La Roche-Posay LLC, 10 Hudson Yards, New York, NY 10001, La Roche-Posay, France.

Product Quantity:
N/A

Reason for Recall:
cGMP Deviations: The recall was initiated due to detected trace levels of benzene in a specific lot of this product lot (MYX46W), however out of an abundance of caution, the firm voluntarily recalled all La Roche-Posay Effaclar Duo Dual Action Acne Treatment lots.

Recall Number:
D-0419-2025

Code Information:
a) Lot #s, Expiration dates: MYX30W 03/2025 MYX43W 04/2025 MYX41W 04/2025 MYX42W 04/2025 MYX40W 04/2025 MYX51W 05/2025 MYX50W 05/2025 MYX60W 05/2025 MYX71W 06/2025 MYX90W 08/2025 MYX91W 09/2025 MYX92W 08/2025 MYXO0W 09/2025 MYX93W 09/2025 MYXD1W 11/2025 MYXD2W 11/2025 MYXDOW 09/2025 MYXD4W 11/2025 MYXD3W 11/2025 MYY22W 02/2026 MYY21W 02/2026 MYY20W 02/2026 MYY41W 04/2026 MYY40W 04/2026 MYY42W 04/2026 MYY43W 04/2026 MYY52W 05/2026 MYY51W 05/2026 MYY50W 05/2026 MYY60W 06/2026 b) Lot #s, Expiration dates MYX31W 3/2025 MYX32W 3/2025 MYX33W 3/2025 MYX34W 3/2025 MYX35W 3/2025 MYX40W 3/2025 MYX41W 4/2025 MYX42W 4/2025 MYX44W 4/2025 MYX45W 4/2025 MYX47W 4/2025 MYX48W 4/2025 MYX49W 4/2025 MYX50W 5/2025 MYX51W 5/2025 MYX52W 5/2025 MYX70W 6/2025 MYX71W 6/2025 MYX72W 7/2025 MYX73W 7/2025 MYX74W 7/2025 MYX75W 7/2025 MYX77W 7/2025 MYX78W 7/2025 MYX80W 8/2025 MYX81W 7/2025 MYX82W 8/2025 MYX83W 8/2025 MYX84W 7/2025 MYXO0W 9/2025 MYXO1W 8/2025 MYXO3W 8/2025 MYXO4W 9/2025 MYXO5W 9/2025 MYXO7W 9/2025 MYXO8W 8/2025 MYXO9W 9/2025 MYXD0W 11/2025 MYXD1W 12/2025 MYXD2W 11/2025 MYXD3W 11/2025 MYXD4W 11/2025 MYXD5W 11/2025 MYXD6W 12/2025 MYY22W 02/2026 MYY23W 02/2026 MYY30W 02/2026 MYY31W 03/2026 MYY32W 03/2026 MYY40W 03/2026 MYY41W 04/2026 MYY42W 04/2026 MYY43W 04/2026 MYY51W 04/2026 MYY60W 06/2026 MYY61W 06/2026 MYY62W 06/2026 MYY63W 06/2026 MYY64W 06/2026 MYY65W 06/2026 MYY66W 06/2026

Class II Drugs Event

Event ID:
96808

Product Type:
Drugs

Status:
Ongoing

Date Terminated:
N/A

Recall Initiation Date:
05/02/2025

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
05/09/2025

Initial Firm Notification of Consignee or Public:
E-Mail

Recalling Firm:
Empower Clinic Services, LLC dba Empower Pharmacy
7601 N Sam Houston Pkwy W Ste 100
Houston, TX 77064-3595
United States

Distribution Pattern:
USA Nationwide

Associated Products

Product Description:
Testosterone Cypionate Injection, 200 mg/mL, CIII, Rx Only, 5 mL Sterile Multiple-Dose Vial, Compounded by: Empower Pharmacy, 7601 N Sam Houston Pkwy W Ste 100, Houston, TX, 77064, Phone: (877) 562-8577, Compounding Date: 08/20/2024, Beyond Use by Date: 05/28/2025, Lot 202364.

Product Quantity:
8,230 vials

Reason for Recall:
Lack of Assurance of Sterility

Recall Number:
D-0420-2025

Code Information:
Lot #: 202364, Exp 5/28/2025