

Enforcement Report - Week of September 18, 2024

Class II Drugs Event

Event ID:

95250

Product Type:

Drugs

Status:

Ongoing

Date Terminated:

N/A

Recall Initiation Date:

08/28/2024

Voluntary / Mandated:

Voluntary: Firm initiated

Center Classification Date:

09/09/2024

Initial Firm Notification of Consignee or Public:

E-Mail

Recalling Firm:

PREQUEL SKIN

8560 W Sunset Blvd Ste 800

W Hollywood, CA 90069-2340

United States

Distribution Pattern:

Distributed nationwide in USA and on line

Associated Products

Product Description:

BARRIER THERAPY SKIN PROTECTANT CREAM (1% colloidal oatmeal), 10 FL OZ/296 ML- tube, Distributed By: Prequel, LOS ANGELES, CA 90069. UPC 8 10129 11007 4

Product Quantity:

30,946 tubes

Reason for Recall:

Microbial contamination of non-sterile Products -

Recall Number:

D-0657-2024

Code Information:

Lot: X4054A, Exp: 2/2026; X4136A, X4137A, X4138A, Exp: 5/2026

Class III Drugs Event

Event ID:

95219

Product Type:

Drugs

Status:

Ongoing

Date Terminated:

N/A

Recall Initiation Date:

08/20/2024

Voluntary / Mandated:

Voluntary: Firm initiated

Center Classification Date:

09/12/2024

Initial Firm Notification of Consignee or Public:

Letter

Recalling Firm:

Elevate Oral Care

342 Pike Rd Ste 23

West Palm Beach, FL 33411-3820

United States

Distribution Pattern:

120 direct customers, Nationwide US. No foreign, DOD/VA.

Associated Products

Product Description:

Just Right 5000, 1.1% Sodium Fluoride, Candy Apple Flavor, Net Wt. 3.4oz (97g), Rx Only, Manufactured for Elevate Oral Care, LLC in the U.S.A with imported pump, 346 Pike Rd, Suite 5, West Palm Beach, FL 33411, NDC 57511-002-1

Product Quantity:

N/A

Reason for Recall:

LABELING: LABEL MIX-UP.

Recall Number:

D-0658-2024

Code Information:

Lot #G073DC, Exp 3/31/2026