1/29/25, 11:00 AM Print View

Enforcement Report - Week of January 29, 2025

Class I Drugs Event

Event ID:

95994

Status:

Ongoing

Recall Initiation Date:

12/16/2024

Center Classification Date:

01/22/2025

Recalling Firm:

SHOPPERS- PLAZA Fouad Panchibyaya 12816 Hawthorne, CA 90250

United States

Distribution Pattern:

Nationwide via internet sales

Product Type:

Drugs

Date Terminated:

N/A

Voluntary / Mandated:

Voluntary: Firm initiated

Initial Firm Notification of Consignee or Public:

Press Release

Associated Products

Product Description:

FOUZEE SugarLin HERBAL FORMULA capsules, 180 capsules per bottle, Sold and Distributed by Shoppers-Plaza, Hawthorne, CA 90250. Product of India. UPC 8 26656 69047 7

Product Quantity:

172 180-count bottles

Reason for Recall:

Marketed without an Approved NDA/ANDA; FDA laboratory analysis confirmed product tainted with undeclared metformin and glyburide

Recall Number:

D-0207-2025

Code Information:

Batch # 001, exp. date 09/10/2026

Class II Drugs Event

Event ID:

95655

Status:

Ongoing

Recall Initiation Date:

11/13/2024

Center Classification Date:

01/17/2025

Recalling Firm:

Brands International Corporation

594 Newpark Blvd

Newmarket

Canada

Distribution Pattern:

Nationwide USA

Product Type:

Drugs

Date Terminated:

N/A

Voluntary / Mandated:

Voluntary: Firm initiated

Initial Firm Notification of Consignee or Public:

Letter

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Associated Products

Product Description:

Kissable Diabetics Foot Cream, NET WT 4 oz (113 g) per tube, Manufactured By: Brands International Corp., Newmarket, ON, L3X 2S2. UPC 6

Product Quantity:

unknown

Reason for Recall:

CGMP Deviations: lack of adequate release testing.

Recall Number:

D-0205-2025

Code Information:

Lots: 23319025, 23318024, 23313023, 23311022, 23310021, 23222021, 23220020, 23215019, 23215018, 23214017, 23213016, 23208015, 2313014, 2312213, 2312212, 2312111, 2312110, 2311709, 2311708, 2311607, 2311506, 2311405, 2307904, 23073003, 23072002, 2306901 and 24135003. All expiration dates within expiry.

Class II Drugs Event

Event ID:

96052

Status: Ongoing

Recall Initiation Date:

12/23/2024

Center Classification Date:

01/21/2025

Recalling Firm:

First Aid Beauty Ltd 70 Bridge St Suite 203

Newton, MA 02458-1140

United States

Distribution Pattern:

Nationwide

Product Type:

Drugs

Date Terminated:

N/A

Voluntary / Mandated:

Voluntary: Firm initiated

Initial Firm Notification of Consignee or Public:

E-Mail

Associated Products

Product Description:

First Aid Beauty Ultra Repair Cream, colloidal oatmeal 0.5%, Coconut Vanilla, Net Wt. 396.8 g (14 OZ), DISTR. BY: First Aid Beauty LTD, Newton, MA, 02458, UPC 8 15517 02955 6

Product Quantity:

2756 jars

Reason for Recall:

CGMP Deviations; product intended for quarantine was inadvertently distributed

Recall Number:

D-0206-2025

Code Information:

Lots 24D44, Exp 4/10/2026 & 24D45, 4/11/2026