Enforcement Report - Week of August 23, 2023

Class II Drugs Event

Event ID:
92835

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
08/10/2023

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
08/14/2023

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Colgate Palmolive Company
909 River Rd
Piscataway NJ United States

Distribution Pattern:
Nationwide in the USSA

Associated Products

Product Description:
hello wild strawberry fluoride toothpaste, sodium fluoride 0.24% (0.15% w/v fluoride ion), NET WT 4.2 OZ (119 g), Distributed by Hello Products LLC, Montclair, NJ 07042, UPC 8 19156 02026 4 (carton), 12-count case GTIN: 20819156020268; strawberry tubes also sold in Strawberry 3-pack overwrap UPC 8 19156 02349 4, UPC 10819156023491 case; in the variety 3-pack of Strawberry + Unicorn + Grape UPC 8 19156 02332 6, UPC 10819156023323 case; and in a 24-count Toothpaste Floorstand, UPC 819156020684 (case).

Product Quantity:
182,046 tubes

Reason for Recall:
Labeling: Label Mix-Up: Some hello wild strawberry fluoride toothpaste, packaged in cartons labeled as hello wild strawberry fluoride toothpaste were incorrectly filled in tubes labeled as hello fresh watermelon fluoride free toothpaste.

Recall Number:
D-1084-2023

Code Information:
Lot #: 004287, 2267USA94A, 2271USA94A, EXP 08/2024; 3053USA94A, Exp 01/2025; 3156USA94A, 3157USA94A, EXP 05/2025

Class III Drugs Event

Event ID:
92811

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
07/27/2023

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
08/17/2023

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
ALEMBIC PHARMACEUTICALS, INC.
550 Hills Dr Ste 104b
Bedminster NJ United States

Distribution Pattern:
Nationwide in the USA

Associated Products

Product Description:
Tobramycin Opthalmic Solution USP, 0.3%, 5mL bottle, Rx only, Manufactured for: Alembic Pharmaceuticals, Bedminster, NJ 07921, USA, NDC 62332-518-05

Product Quantity:
82,400 bottles

Reason for Recall:
Failed Impurities/Degradation Specifications

Recall Number:
D-1086-2023

Code Information:
Lot #: AMR103, Exp: 10/2023; Lot#: AMR201, Exp: 06/2024

Class III Drugs Event

Event ID:
92845

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
08/07/2023

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
08/15/2023

Initial Firm Notification of Consignee or Public:

Recalling Firm:
Advanced Accelerator Applications USA, Inc.
57 E Willow St
Millburn NJ United States

Distribution Pattern:
Distributed Nationwide in the USA

Associated Products

Product Description:
PLUVICTO 1,000MBq/mL (27 mCi/mL), lutetium Lu 177 vipivotide tetraxetan injection, 9.2 mL Single-dose vial, Manufacturer: Advanced Accelerator Appllications USA, Inc., 57 E. Willow Street NJ 07041, Milburn, USA, NDC 69488-010-61

Product Quantity:
10

Reason for Recall:
Labeling: Incorrect or Missing Lot and/or Exp Date: vials were labeled with the incorrect lot number and expiration date

Recall Number:
D-1085-2023

Code Information:
Lot # LPS230729B-16, Exp 8/3/2023 at 10:00am, LPS230804B-16, Exp 8/9/2023 at 10:00am.