

Enforcement Report - Week of October 21, 2020

Class III Drugs Event

Event ID:

86525

Product Type:

Drugs

Status:

Ongoing

Date Terminated:
Recall Initiation Date:

09/24/2020

Voluntary / Mandated:

Voluntary: Firm initiated

Center Classification Date:

10/15/2020

Initial Firm Notification of Consignee or Public:

Letter

Recalling Firm:

Leadiant Biosciences, Inc.
9841 Washingtonian Blvd Ste 500
Gaithersburg MD United States

Distribution Pattern:

PA and Italy

Associated Products

Product Description:

Cystaran (cysteamine ophthalmic solution) 0.44%, For Ophthalmic Use Only, 15 mL bottle, Sterile, Rx Only, Manufactured by Hi-Tech Pharmacal Co Inc., Amityville, NY 11701 for Leadiant Biosciences, Inc., Gaithersburg, MD 20878, NDC 54482-020-01

Product Quantity:

1380 bottles

Reason for Recall:

Subpotent Drug: Product testing identified a decreased level of the active ingredient, Cysteamine HCl.

Recall Number:

D-0034-2021

Code Information:

Lot #: 370655, Exp. 10/31/2020

Not Yet Classified Drugs Event

Event ID:

86546

Product Type:

Drugs

Status:

Ongoing

Date Terminated:
Recall Initiation Date:

10/01/2020

Voluntary / Mandated:

Voluntary: Firm initiated

Center Classification Date:
Initial Firm Notification of Consignee or Public:

Press Release

Recalling Firm:

ASHTEL STUDIOS, INC.
1610 E Philadelphia St
Ontario CA United States

Distribution Pattern:

Pouches of .84 oz. hand sanitizer were distributed to the following states: CA, IL, and Ontario Canada

Associated Products

Product Description:

Smart Care HAND SANITIZER, Ethyl Alcohol 62%, packaged in 0.84 FL.OZ (25 mL), labeled as a) Paw Patrol (Item #: 92321-144, UPC 8 50016 92321 9, NDC 70108-042-01); b) JoJo Siwa Dreamer (Item #: 92320-144, UPC 8 50016 92320 2, NDC 70108-044-01); c) Hot Wheels (Item #: 92317-144, UPC 8 50016 92317 2, NDC 70108-045-01); d) Barbie (Item #: 92318-144, UPC 8 50016 92318 9, NDC 70108-046-01); e) Trolls (Item #: 92322-144, UPC 8 50016 92322 6, NDC 70108-047-01); and f) Minions (Item #: 92319-144, UPC 8 50016 92319 6, NDC 70108-043-01);
Distributed by Ashtel Studios Inc., Ontario, CA 91761

Product Quantity:**Reason for Recall:**

Labeling: Not Elsewhere Classified. Container packaging is made, formed or filled to be misleading, resembling food and drink pouches

Recall Number:**Code Information:**

All lots codes within expiry