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Enforcement Report - Week of September 15, 2021

Class II Drugs Event

Event ID: Product Type:

88275 Drugs

Status **Date Terminated:** Ongoing

Recall Initiation Date: Voluntary / Mandated: 07/12/2021 Voluntary: Firm initiated

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

09/09/2021

Recalling Firm:

NATIVE PROMOTIONS, INC 1927 S Boston Ave Ste 205 Tulsa OK United States

Distribution Pattern:

Tribal nations in the following states: NC, MS, NY, FL, AL, SC, ME, CT, MA, VA, TX, LA, RI

Associated Products

Product Description:

QiYu Hand Sanitizer (ethyl alcohol 75% (v/v)), 16.9 FL OZ (500 ML) bottles, Manufactured by: Guangzhou Minghui Cosmetics Co., Ltd, Baiyun District, Guanzhou, China Distributed by Native Promotional Products, Tulsa, OK NDC 74447-010

Product Quantity:

4,320 bottles

Reason for Recall:

Subpotent

Recall Number:

D-0793-2021

Code Information:

Production Batch No.: Q20200510

Class II Drugs Event

Event ID: Product Type: 88552 Drugs

Status: **Date Terminated:**

Completed

Recall Initiation Date: Voluntary / Mandated: 09/02/2020 Voluntary: Firm initiated

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

Letter

09/08/2021

Recalling Firm:

Charles Paint Research Inc 2401 E 85th St

Kansas City MO United States

Distribution Pattern:

Distributed in Michigan

Associated Products

Product Description:

HAND SANITIZER (alcohol 80%), Alchol Antiseptic 80% topical solution, Hand Sanitizer non-sterile solution, Net weight (6 lbs 14.2 oz) 1 gallon; Net Quantity (3785 mL), Manufactured by Soapdaddy LLC, 2401 E. 85th Street, Kansas City, MO 64131

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Product Quantity:

3,900 gallons

Reason for Recall:

CGMP Deviations: Product manufactured in same facility where product was found to contain acetaldehyde and acetal above the allowable

Recall Number:

D-0791-2021

Code Information:

Lot# 20-151 to 20-159 and 20-161 to20-163, Exp 06/11/2022

Product Description:

HAND SANITIZER (alcohol 80%), Alchol Antiseptic 80% topical solution, Hand Sanitizer non-sterile solution, Net weight (6 lbs 14.2 oz) 1 gallon; Net Quantity (3785 mL), Manufactured by Soapdaddy LLC, 2401 E. 85th Street, Kansas City, MO 64131

Product Quantity:

600 gallons

Reason for Recall:

CGMP Deviations: Product contains acetaldehyde and acetal above the allowable limits.

Recall Number:

D-0792-2021

Code Information:

Lot# 20-160, Exp 06/11/2022