

Enforcement Report - Week of November 22, 2023

Class II Drugs Event

Event ID:

93159

Product Type:

Drugs

Status:

Ongoing

Date Terminated:
Recall Initiation Date:

10/20/2023

Voluntary / Mandated:

Voluntary: Firm initiated

Center Classification Date:

11/14/2023

Initial Firm Notification of Consignee or Public:

E-Mail

Recalling Firm:

Omega & Delta Co., Inc.

Carr. 887 Km 0 Hm 8 Julio N. Matos Ind. Park Bldg#10

Carolina PR United States

Distribution Pattern:

Distributed in Puerto Rico only.

Associated Products

Product Description:

DOP Instant Hand Sanitizer (Ethyl Alcohol 65%) with Moisturizers, Original, 4FL OZ (118 ml) bottle, Hecho en Puerto Rico por: Omega & Delta Co., Inc. UPC 7 42699 00027 4

Product Quantity:

48,145 4 oz bottles

Reason for Recall:

Sub Potent and Super Potent Product: During an impact assessment of the DOP Hand Sanitizer product, it was identified that several lots distributed did not comply with the finished good acceptance criteria established.

Recall Number:

D-0103-2024

Code Information:

Lot #s 1327034, 1328034, 1277029, 1278029, 1202015, 1203015, 0246097, 0247097, 0247099, 0248099, 0252099

Product Description:

DOP Instant Hand Sanitizer (Ethyl Alcohol 65%) with Moisturizers, 8FL OZ (237mL) bottle, Hecho en Puerto Rico por: Omega & Delta Co., Inc. UPC 7 42699 00030 4

Product Quantity:

23,136 8 OZ bottles

Reason for Recall:

Sub Potent and Super Potent Product: During an impact assessment of the DOP Hand Sanitizer product, it was identified that several lots distributed did not comply with the finished good acceptance criteria established.

Recall Number:

D-0104-2024

Code Information:

Lot #s 1113005, 1116005, 0237088, 0232084, 012764, 012864, 0244096, 0245096.

Product Description:

Equate Hand Sanitizer (Ethyl Alcohol 62%), 7.5 FL.OZ. (221 mL) UPC 6 81131 05961 9

Product Quantity:

4,848 7.5 oz bottles

Reason for Recall:

Sub Potent and Super Potent Product: During an impact assessment of the DOP Hand Sanitizer product, it was identified that several lots

distributed did not comply with the finished good acceptance criteria established.

Recall Number:

D-0105-2024

Code Information:

Lot #s 006511

Class II Drugs Event

Event ID:

93418

Product Type:

Drugs

Status:

Ongoing

Date Terminated:**Recall Initiation Date:**

11/09/2023

Voluntary / Mandated:**Center Classification Date:**

11/16/2023

Initial Firm Notification of Consignee or Public:

Letter

Recalling Firm:

Family Medical Supply Inc
2011 W Cumberland St
Dunn NC United States

Distribution Pattern:

Nationwide

Associated Products

Product Description:

Oxygen, Compressed USP, UN 1072, packaged in cylinders labeled as Size: a) C; b) D; c) E; d) H; e) M; f) M6, Rx only, Family Medical Supply, 2011 W Cumberland St. Dunn, NC 28334.

Product Quantity:

26,657 Cylinders

Reason for Recall:

cGMP Deviations

Recall Number:

D-0106-2024

Code Information:

All lots manufactured and distributed May 10, 2023, through October 31, 2023.