

Enforcement Report - Week of August 12, 2020

Class I Drugs Event

Event ID:

85574

Status:

Ongoing

Recall Initiation Date:

04/15/2020

Center Classification Date:

08/06/2020

Recalling Firm:

Summitt Labs
6375 Harney Rd Suite 106
Tampa FL United States

Distribution Pattern:

Nationwide in the USA

Product Type:

Drugs

Date Terminated:**Voluntary / Mandated:**

Voluntary: Firm initiated

Initial Firm Notification of Consignee or Public:

Telephone

Associated Products

Product Description:

KORE ORGANIC CBD Oil Watermelon 15mg*, 30 mL dropper bottles, Handcrafted By Summitt Labs, UPC 8 5765000812 8, www.KOREORGANIC.com 833.810.KORE.

Product Quantity:

236 bottles

Reason for Recall:

Chemical Contamination; product contains elevated levels of lead

Recall Number:

D-1489-2020

Code Information:

Lot# 730, Batch# K018, Exp. 8/20

Class I Drugs Event

Event ID:

85854

Status:

Ongoing

Recall Initiation Date:

06/18/2020

Center Classification Date:

08/04/2020

Recalling Firm:

MICHIGAN HERBAL REMEDIES
904 Chicago Dr
Jenison MI United States

Distribution Pattern:

Nationwide via internet sales,retailers and distributors in the USA

Product Type:

Drugs

Date Terminated:**Voluntary / Mandated:**

Voluntary: Firm initiated

Initial Firm Notification of Consignee or Public:

E-Mail

Associated Products

Product Description:

Tasty Drops Hemp Oil Extract, Natural, 1 FL. OZ (30ML) bottles, 500mg CBD, Dist by: Tasty Hemp Oil, Jenison, MI, UPC 6 96305 29084 2

Product Quantity:

220 bottles

Reason for Recall:

Chemical Contamination: product contains elevated levels of undeclared lead.

Recall Number:

D-1447-2020

Code Information:

FG003138 and FG003248

Product Description:

Tasty Drops Hemp Oil Extract, Berry, 1 FL. OZ (30ML) bottles, 300MG CBD, Dist by: Tasty Hemp Oil, Jenison, MI, UPC 8 02991 76469 1

Product Quantity:

213 bottles

Reason for Recall:

Chemical contamination: product contains elevated levels of undeclared lead.

Recall Number:

D-1448-2020

Code Information:

FG003175

Product Description:

Tasty Drops Hemp Oil Extract, Spearmint, 1 FL. OZ (30ML) bottles, 300MG CBD, Dist by: Tasty Hemp Oil, Jenison, MI, UPC 8 02991 76472 1

Product Quantity:

213 bottles

Reason for Recall:

Chemical contamination: product contains elevated levels of undeclared lead.

Recall Number:

D-1449-2020

Code Information:

FG003167

Product Description:

Tasty Drops Hemp Oil Extract, Vanilla, 1 FL. OZ (30ML) bottles, 300MG CBD, Dist by: Tasty Hemp Oil, Jenison, MI, UPC 8 02991 76471 4

Product Quantity:

104 bottles

Reason for Recall:

Chemical contamination: product contains elevated levels of undeclared lead.

Recall Number:

D-1450-2020

Code Information:

FG003126

Product Description:

Made by Hemp 1000MG Hemp Extract, French Vanilla, 1 OZ (30 ML) bottles, Dist by: MHR Brands, Jenison, MI, UPC 8 02991 76553 7

Product Quantity:

495 bottles

Reason for Recall:

Chemical contamination: product contains elevated levels of undeclared lead.

Recall Number:

D-1451-2020

Code Information:

FG003107

Product Description:

Made by Hemp 1000MG Hemp Extract, Mojito Lime, 1 OZ (30 ML) bottles, Dist by: MHR Brandsl, Jenison, M,I UPC 8 02991 76552 0

Product Quantity:

486 bottles

Reason for Recall:

Chemical contamination: product contains elevated levels of undeclared lead.

Recall Number:

D-1452-2020

Code Information:

FG003110

Product Description:

Made by Hemp 1000MG Hemp Extract, Strawberry Creme, 1 OZ (30 ML) bottles, Dist by: MHR Brands, Jenison, MI, UPC 8 02991 76554 4

Product Quantity:

496 bottles

Reason for Recall:

Chemical contamination: product contains elevated levels of undeclared lead.

Recall Number:

D-1453-2020

Code Information:

FG003109

Product Description:

A Clean Choice CBD, Hemp Oil Extract Tincture, French Vanilla, 1000 mg, 1 fl oz (30 ml) bottles, Made in Michigan for A Clean Choice, A Division of A Clean Cigarette, Inc., 3055 Bay Road Suite 1, Saginaw, MI 48603

Product Quantity:

350 bottles

Reason for Recall:

Chemical contamination: product contains elevated levels of undeclared lead.

Recall Number:

D-1454-2020

Code Information:

FG003106

Product Description:

A Clean Choice CBD, Hemp Oil Extract Tincture, Strawberry Creme, 1000mg, 1 fl oz (30 ml) bottles, Made in Michigan for A Clean Choice, A Division of A Clean Cigarette, Inc., 3055 Bay Rd Suite 1, Saginaw, MI 48603

Product Quantity:

350 bottles

Reason for Recall:

Chemical contamination: product contains elevated levels of undeclared lead.

Recall Number:

D-1455-2020

Code Information:

FG003108

Product Description:

A Clean Choice CBD, Hemp Oil Extract Tincture, Sweet Mint, 500mg, 1 fl oz (30 ml) bottles, Made in Michigan for A Clean Choice, A Division of A Clean Cigarette, Inc., 3055 Bay Rd Suite 1, Saginaw, MI 48603

Product Quantity:

200 bottles

Reason for Recall:

Chemical contamination: product contains elevated levels of undeclared lead.

Recall Number:

D-1456-2020

Code Information:

FG003113

Product Description:

BC Hemp Co., Full Spectrum Hemp Extract, CBD Oil, Berry Blast, 500mg CBD, 1 FL. OZ (30 ML) bottles, Distributed by: B.C. Hemp Co., LLC, P.O. Box 146, Eau Claire, MI 49111

Product Quantity:

25 bottles

Reason for Recall:

Chemical contamination: product contains elevated levels of undeclared lead.

Recall Number:

D-1457-2020

Code Information:

FG003312

Product Description:

BC Hemp Co., Full Spectrum Hemp Extract, CBD Oil, Natural 500MG CBD, 1 FL. OZ (30 ML) bottles, Distributed by: B.C. Hemp Co., LLC, P.O. Box 156, Eau Claire, MI 49111

Product Quantity:

72 bottles

Reason for Recall:

Chemical contamination: product contains elevated levels of undeclared lead.

Recall Number:

D-1458-2020

Code Information:

FG003171, FG003183, FG003316

Product Description:

BC Hemp Co., Full Spectrum Hemp Extract, CBD Oil, Spearmint, 500mg CBD, 1 FL. OZ (30 ML) bottles, Distributed by: B.C. Hemp Co., LLC, P.O. Box 156, Eau Claire, MI 49111

Product Quantity:

25 bottles

Reason for Recall:

Chemical contamination: product contains elevated levels of undeclared lead.

Recall Number:

D-1459-2020

Code Information:

FG003315

Product Description:

Goodness Gurus, Healthy Hemp Drops, 500MG/Berry, 1 FL. OZ bottles, Distributed by: Goodness Gurus, Inc., Carlisle, PA, UPC 6 53341 99271 0

Product Quantity:

50 bottles

Reason for Recall:

Chemical contamination: product contains elevated levels of undeclared lead.

Recall Number:

D-1460-2020

Code Information:

FG003236

Product Description:

Goodness Gurus, Healthy Hemp Drops, 500MG/Spearmint, 1 FL. OZ bottles, Distributed by: Goodness Gurus, Inc., Carlisle, PA, UPC 6 53341 99261 1

Product Quantity:

150 bottles

Reason for Recall:

Chemical contamination: product contains elevated levels of undeclared lead.

Recall Number:

D-1461-2020

Code Information:

FG003234

Product Description:

Herbzeedy, Hemp Oil Full Spectrum, Natural, 500 MG CBD, 1 FL OZ (30 ML) bottles, Distributed by: Herbzeedy, Statesboro, GA

Product Quantity:

134 bottles

Reason for Recall:

Chemical contamination: product contains elevated levels of undeclared lead.

Recall Number:

D-1462-2020

Code Information:

FG003122, FG003123

Product Description:

Javan Anti Aging and Wellness Institute, CBD Oil, Full Spectrum Hemp Oil, Spearmint, 300MG CBD, 1 FL. OZ (30 ML) bottles, Dist by: Javan Wellness LLC, 1445 Church St NW Unit 24, Washington, DC 20005

Product Quantity:

100 bottles

Reason for Recall:

Chemical contamination: product contains elevated levels of undeclared lead.

Recall Number:

D-1463-2020

Code Information:

FG003283

Product Description:

Pathway To Wellness, CBD Oil, Premium Hemp Oil Drops, Natural, 1000MG CBD, 1 FL OZ (30 ML) bottles, Distributed by: Pathway to Wellness

Product Quantity:

100 bottles

Reason for Recall:

Chemical contamination: product contains elevated levels of undeclared lead.

Recall Number:

D-1464-2020

Code Information:

FG003151

Product Description:

SP, hemp oil, Berry, 300MG CBD, 1 FL. OZ (30 ML) bottles, Distributed by: The Spiffy Piff

Product Quantity:

25 bottles

Reason for Recall:

Chemical contamination: product contains elevated levels of undeclared lead.

Recall Number:

D-1465-2020

Code Information:

FG003277

Product Description:

SP, hemp oil, Spearmint, 300MG CBD, 1 FL. OZ (30 ML) bottles, Distributed by: The Spiffy Piff

Product Quantity:

25 bottles

Reason for Recall:

Chemical contamination: product contains elevated levels of undeclared lead.

Recall Number:

D-1466-2020

Code Information:

FG003276

Product Description:

Recovery Releaf, Pure CBD Oil, Vanilla, 1000MG, 25MG per serving, 1 fl. oz (30 ml) bottles, Distributed by: Recovery Releaf, West Palm Beach, FL

Product Quantity:

100 bottles

Reason for Recall:

Chemical contamination: product contains elevated levels of undeclared lead.

Recall Number:

D-1467-2020

Code Information:

FG003133

Product Description:

Acadia Farms, Equilibrium, vermont maple, 300 MG Hemp Oil, 1 FI OZ (30 ML) bottles, Distributed by: Acadia Farms, Rehobeth, Massachusetts

Product Quantity:

100 bottles

Reason for Recall:

Chemical contamination: product contains elevated levels of undeclared lead.

Recall Number:

D-1468-2020

Code Information:

FG003181

Product Description:

Acadia Farms, Serenity, soothing mint, 300 MG Hemp Oil, 1 FI OZ (30 ML) bottles, Distributed by: Acadia Farms, Rehobeth, Massachusetts

Product Quantity:

100 bottles

Reason for Recall:

Chemical contamination: product contains elevated levels of undeclared lead.

Recall Number:

D-1469-2020

Code Information:

FG003177

Product Description:

Tasty Drops, Hemp Oil Extract, Berry, 500MG CBD, 1 FL. OZ (30ML) bottles, Dist by: Tasty Hemp Oil, Jenison, MI, UPC 6 96305 29083 5

Product Quantity:

201 bottles

Reason for Recall:

Chemical contamination: product contains elevated levels of undeclared lead.

Recall Number:

D-1470-2020

Code Information:

FG003137, FG003174, FG003197, FG0057

<p>Product Description: Tasty Drops, Hemp Oil Extract, Berry, 1500MG CBD, 1 FL. OZ (30ML) bottles, Dist by: Tasty Hemp Oil, Jenison, MI, UPC 6 96305 29087 3</p> <p>Product Quantity: 150 bottles</p> <p>Reason for Recall: Chemical contamination: product contains elevated levels of undeclared lead.</p> <p>Recall Number: D-1471-2020</p> <p>Code Information: FG003141, FG003202, FG003296</p>

<p>Product Description: Tasty Drops, Hemp Oil Extract, Natural, 1500MG CBD, 1 FL. OZ (30ML) bottles, Dist by: Tasty Hemp Oil, Jenison, MI, UPC 6 96305 29088 0</p> <p>Product Quantity: 100 bottles</p> <p>Reason for Recall: Chemical contamination: product contains elevated levels of undeclared lead.</p> <p>Recall Number: D-1472-2020</p> <p>Code Information: FG003142, FG003247</p>

<p>Product Description: Tasty Drops, Hemp Oil Extract, Spearmint, 500MG CBD, 1 FL. OZ (30ML) bottles, Dist by: Tasty Hemp Oil, Jenison, MI, UPC 6 96305 29081 1</p> <p>Product Quantity: 366 bottles</p> <p>Reason for Recall: Chemical contamination: product contains elevated levels of undeclared lead.</p> <p>Recall Number: D-1473-2020</p> <p>Code Information: FG003139, FG003166, FG003191, FG003225, FG003253, FG003263</p>
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<p>Product Description: Tasty Drops, Hemp Oil Extract, Spearmint, 1000MG CBD, 1 FL. OZ (30ML) bottles, Dist by: Tasty Hemp Oil, Jenison, MI, UPC 8 02991 76539 1</p> <p>Product Quantity: 391 bottles</p> <p>Reason for Recall: Chemical contamination: product contains elevated levels of undeclared lead.</p> <p>Recall Number: D-1474-2020</p> <p>Code Information: FG003095</p>

<p>Product Description: Tasty Drops, Hemp Oil Extract, Spearmint, 1500MG CBD, 1 FL. OZ (30ML) bottles, Dist by: Tasty Hemp Oil, Jenison, MI, UPC 6 96305 29085 9</p> <p>Product Quantity: 250 bottles</p> <p>Reason for Recall: Chemical contamination: product contains elevated levels of undeclared lead.</p> <p>Recall Number: D-1475-2020</p>
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Code Information:

FG003143, FG003180, FG003201, FG003224, FG003262

Product Description:

Tasty Drops, Hemp Oil Extract, Vanilla, 500MG CBD, 1 FL. OZ (30ML) bottles, Dist by: Tasty Hemp Oil, Jenison, MI, UPC 6 96305 29082 8

Product Quantity:

152 bottles

Reason for Recall:

Chemical contamination: product contains elevated levels of undeclared lead.

Recall Number:

D-1476-2020

Code Information:

FG003140, FG003182, FG003246

Product Description:

Tasty Drops, Hemp Oil Extract, Vanilla, 1500MG CBD, 1 FL. OZ (30ML) bottles, Dist by: Tasty Hemp Oil, Jenison, MI, UPC 6 96305 29086 6

Product Quantity:

100 bottles

Reason for Recall:

Chemical contamination: product contains elevated levels of undeclared lead.

Recall Number:

D-1477-2020

Code Information:

FG003144, FG003249

Product Description:

BC Hemp Co., Full Spectrum Hemp Extract, CBD Oil , Berry Blast, 1000MG CBD, 1 FL. OZ (30ML) bottles, Distributed by: B.C. Hemp Co., LLC, P.O. Box 156, Eau Claire, MI 49111

Product Quantity:

50 bottles

Reason for Recall:

Chemical contamination: product contains elevated levels of undeclared lead.

Recall Number:

D-1478-2020

Code Information:

FG003164

Product Description:

BC Hemp Co., Full Spectrum Hemp Extract, CBD Oil, Natural, 1000MG CBD, 1 FL. OZ (30 ML) bottles, Distributed by: B.C. Hemp Co., LLC, P.O. Box 156, Eau Claire, MI 49111

Product Quantity:

25 bottles

Reason for Recall:

Chemical contamination: product contains elevated levels of undeclared lead.

Recall Number:

D-1479-2020

Code Information:

FG003318

Product Description:

Goodness Gurus, Healthy Hemp Drops Full Strength, 1000 MG/Spearmint, 1 FL. OZ bottles, Distributed by: Goodness Gurus, Inc., Carlisle, PA, UPC 53341 99311 3

Product Quantity:

50 bottles

Reason for Recall:

Chemical contamination: product contains elevated levels of undeclared lead.

Recall Number:

D-1480-2020

Code Information:

FG003238

Product Description:

Goodness Gurus, Healthy Hemp Drops, 1500 MG/Spearmint, 1 FL. OZ bottles, Distributed by: Goodness Gurus, Inc., Carlisle, PA, UPC 6 53341 99411 0

Product Quantity:

50 bottles

Reason for Recall:

Chemical contamination: product contains elevated levels of undeclared lead.

Recall Number:

D-1481-2020

Code Information:

FG003237

Product Description:

Herbzeedy, Hemp Oil Full Spectrum, Natural, 1500 MG CBD, 1 FL OZ (30 ML) bottles, Distributed by: Herbzeedy, Statesboro, GA

Product Quantity:

33 bottles

Reason for Recall:

Chemical contamination: product contains elevated levels of undeclared lead.

Recall Number:

D-1482-2020

Code Information:

FG003121

Class I Drugs Event

Event ID:

85956

Status:

Ongoing

Recall Initiation Date:

07/07/2020

Center Classification Date:

08/04/2020

Recalling Firm:Mylan Institutional LLC
4901 Hiawatha Dr
Rockford IL United States**Distribution Pattern:**

USA Nationwide

Product Type:

Drugs

Date Terminated:**Voluntary / Mandated:**

Voluntary: Firm initiated

Initial Firm Notification of Consignee or Public:

Two or more of the following: Email, Fax, Letter, Press Release, Telephone, Visit

Associated Products

Product Description:

Daptomycin for Injection, 500 mg/vial, Single-Dose Vial, Rx only, Sterile, Manufactured for: Mylan Institutional, LLC, Rockford, IL 61103 USA, NDC 67457-813-50

Product Quantity:

18,480 vials

Reason for Recall:

Presence of Particulate Matter

Recall Number:

D-1484-2020

Code Information:

Lot #: 7605112, Exp 10/2021

Class II Drugs Event

Event ID:

86007

Status:

Ongoing

Recall Initiation Date:

06/13/2020

Center Classification Date:

08/06/2020

Recalling Firm:

Yusef Manufacturing Laboratories, LLC

Freeport West, F-4, #3

Clearfield UT United States

Distribution Pattern:

USA Nationwide

Product Type:

Drugs

Date Terminated:**Voluntary / Mandated:**

Voluntary: Firm initiated

Initial Firm Notification of Consignee or Public:

Letter

Associated Products

Product Description:

Tropical Lip Moisturizer, SPF 30, UVA/UVB Lip Protection, Active Ingredients: Oxybenzone 5%, Octisalate 5%, Octinoxate 7.5%, Meradimate 5%, Made in USA

Product Quantity:**Reason for Recall:**

Superpotent Drug: The beginning portion of the batch appears to be approximately 25% superpotent for active ingredient Meradimate.

Recall Number:

D-1486-2020

Code Information:

Lot #: 12750, Exp 5/2021

Class II Drugs Event

Event ID:

86069

Status:

Ongoing

Recall Initiation Date:

07/24/2020

Center Classification Date:

08/06/2020

Recalling Firm:

Vilvet Pharmaceuticals Inc.

1208 Kimberton Rd Ste 101

Chester Springs PA United States

Product Type:

Drugs

Date Terminated:**Voluntary / Mandated:**

Voluntary: Firm initiated

Initial Firm Notification of Consignee or Public:

Letter

Distribution Pattern:

Nationwide within the US

Associated Products**Product Description:**

VILAMIT MB (118 mg methenamine, 36 mg phenyl salicylate, 40.8 mg sodium phosphate monobasic, 10.0 mg methylene blue and 0.12 mg hyoscyamine sulfate), Rx Only, 100 Capsules per Bottle, Manufactured for: Vilvet Pharmaceuticals Inc., Chester Springs, PA 18425, NDC 71186-002-35.

Product Quantity:

11,640 bottles

Reason for Recall:

cGMP deviations

Recall Number:

D-1487-2020

Code Information:

LOT M824H18-1 EXP 08/20 LOT M824J18-1 EXP 09/20 LOT M824L18-1 EXP 11/20 LOT M824A19-1 EXP 01/21 LOT M824C19-1 EXP 03/21 LOT M824G19-1 EXP 07/21

Product Description:

VILEVEV MB Urinary Antispetic (81.0 mg methenamine, 40.8 mg sodium phosphate monobasic and 10.8 mg methylene blue, 0.12 mg hyoscyamine sulfate and 32.4 mg phenyl salicylate), Rx Only, 90 Tablets per Bottle, Manufactured for: Vilvet Pharmaceuticals, Inc., Chester Springs, PA 19425, NDC 71186-000-24.

Product Quantity:

1,716 bottles

Reason for Recall:

cGMP deviations

Recall Number:

D-1488-2020

Code Information:

LOT M823J18-1, M823J18-2, M823J18-3 EXP 09/20; LOT M823D19-1 EXP 04/21

Class II Drugs Event**Event ID:**

86074

Product Type:

Drugs

Status:

Ongoing

Date Terminated:**Recall Initiation Date:**

07/20/2020

Voluntary / Mandated:

Voluntary: Firm initiated

Center Classification Date:

08/04/2020

Initial Firm Notification of Consignee or Public:

Letter

Recalling Firm:

Pfizer Inc.
235 E 42nd St
New York NY United States

Distribution Pattern:

United States including Puerto Rico

Associated Products**Product Description:**

Fentanyl Citrate Inj., USP 100 mcg Fentanyl/2 mL (50 mcg/mL) 2 mL Single-dose Fliptop Vials, Rx only, Distributed by Hospira, Inc. Lake Forest, IL 60045 USA NDC 0409-9094-12

Product Quantity:

19,144 vials

Reason for Recall:

Lack of Assurance of Sterility; potential loose metal overseal crimp defects.

Recall Number:

D-1446-2020

Code Information:

Lots: Tray lot: 13405DK Vial lot: 13-405 DK Exp. 1JUL2021, Tray lot: 17096DK Vial lot: 17-096-DK Exp. 1NOV2021

Not Yet Classified Drugs Event

Event ID:

85978

Product Type:

Drugs

Status:

Ongoing

Date Terminated:**Recall Initiation Date:**

07/01/2020

Voluntary / Mandated:

Voluntary: Firm initiated

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

E-Mail

Recalling Firm:

Spartan Chemical Co Inc
1110 Spartan Dr
Maumee OH United States

Distribution Pattern:

Nationwide USA, Panama, St. Maarten

Associated Products

Product Description:

Lemon Blossom Hand Sanitizer (benzalkonium chloride 0.1% - antimicrobial), For Institutional and Industrial Use Only, a) foamyIQ 42.27 oz/1250 mL cartridge, UPC code: 753727264544; b) Lite 'n Foamy 1 gallon/3.79 L container UPC code: 753727261130, Spartan Chemical Company, Inc., 1110 Spartan Drive, Maumee, OH 43537 USA.

Product Quantity:

1 Gallon: 105 cases; 42.27 oz: 15,199 cases

Reason for Recall:

Microbial contamination of non-sterile products: positive microbial contamination in product.

Recall Number:**Code Information:**

a) 42.27 oz cartridge: 518491, 518492, 518498, 518499, 518500, 520057, 520058, 520060, 520061; b) 1 gallon container: 520032, Exp. 06/30/2022.