

DEFENSE LOGISTICS AGENCY TROOP SUPPORT 700 ROBBINS AVENUE PHILADELPHIA, PENNSYLVANIA 19111-5092

DSCP-FTW ALFOODACT 2022-024 July 26, 2022

MEMORANDUM FOR RECORD

SUBJECT: UPDATE to Vi-Jon, LLC Expands Voluntary Nationwide Recall of Magnesium Citrate Saline Laxative Oral Solution Lemon Flavor Due to Microbial Contamination

- 1. **REFERENCE.** DHA-MSR 6025.01/AR 40-660/ DLAR 6025.01/NAVSUPINST 10110.8D/AFI 48-161_IP/MCO 10110.38D, DOD Hazardous Food & Nonprescription Drug Recall System, 6 September 2018.
- 2. **COMPANY ANNOUNCEMENT.** Smyrna, TN, Vi-Jon, LLC is expanding its voluntary recall to include all lots of all flavors of Magnesium Citrate Saline Laxative Oral Solution within expiry to the consumer level. This expansion includes all lots of Cherry Flavor and Grape Flavor of Magnesium Citrate Saline Laxative Oral Solution, 10 FL OZ (296 mL) within expiry. On July 14, 2022, Vi-Jon, LLC recalled all lots of Magnesium Citrate Saline Laxative Oral Solution Lemon Flavor, 10 FL OZ (296 mL) within expiry. The recall was initiated after Vi-Jon, LLCs third party microbial testing identified the presence of *Gluconacetobacter liquefaciens*.

Risk Statement: Immunocompromised patients, who consume this product, may be at increased risk for invasive infections caused by *Gluconacetobacter liquefaciens* that could lead to serious, life-threatening adverse health consequences. To date, Vi-Jon, LLC is aware of **3 (three)** reports of serious adverse reactions potentially related to this recall. Vi-Jon, LLC is in the process of investigating these reports.

The product is used for relief of occasional constipation (irregularity) and generally produces bowel movement in ½ to 6 hours. The product is packaged in a 10 oz clear round plastic bottle.

The product was distributed Nationwide to wholesale and retail outlets. Vi-Jon, LLC is continuing their investigation into the cause of the problem. This recall is being conducted with the knowledge of the U.S. Food and Drug Administration.

3. **PRODUCTS AFFECTED:** In addition to the lemon flavor, the recall now includes the Cherry and Grape flavored products within expiry noted below in the table in red.

Affected Brand	NDC#	UPC#
BEST CHOICE 100Z LEMON MAG CIT	63941-533-38	070038200499
BEST CHOICE 100Z CHERRY CITRATE	63941-516-38	070038587903

DECT CHOICE 4007 CDADE CITDATE	62044 462 20	070020662204
BEST CHOICE 100Z GRAPE CITRATE	63941-162-38	070038662204
CARE ONE 100Z LEMON MAG CIT	72476-001-38	341520313226
CARE ONE 100Z CHERRY CIT	72476-002-38	341520000553
CARIBA 100Z LEMON MAG CITRATE	67860-166-38	646702057012
CRUZ BLANC 100Z LEMON MAG CIT	N/A	308697403082
CVS 100Z LEMON MAG CIT	63868-929-38	050428335178
CVS 100Z LEMON MAG CIT	69842-983-38	050428305942
CVS 100Z CHERRY CITRATE	69842-647-38	050428297339
CVS 100Z CHERRY CITRATE	69842-647-38	00050428285152
CVS 100Z CLR GRAPE CITRATE	69842-763-38	050428307458
CVS 100Z CLR GRAPE CITRATE	69842-763-38	00050428325032
DISCOUNT DRUG MART 100Z LEMON MAG CITRATE	53943-166-38	093351028205
EQUALINE 100Z LEMON MAG CIT	41163-709-38	041163500679
EQUALINE 100Z CHERRY CITRATE	41163-769-38	041163500686
EQUATE 100Z LEMON MAG CIT SRP	49035-506-38	681131287142
EQUATE 100Z CHERRY CIT SRP	49035-593-38	681131287166
EQUATE 100Z GRAPE MAG CIT SRP	49035-592-38	681131287159
EXCHANGE SELECT 100Z LEMON MAG CIT	55301-166-38	614299404205
FAMILY WELLNESS 100Z LEMON CITRATE	55319-666-38	032251580826
FAM WELLNS 100Z CHERRY CITRATE	55319-164-38	032251577888
GOOD SENSE 100Z LEMON MAG CIT	50804-166-38	846036007374
GOOD SENSE 100Z CHERRY CITRATE	50804-164-38	846036007398
HARRIS TEETER 100Z LEMON MAG CITRATE	72036-002-38	072036726124
HEB 100Z LEMON MAG CITRATE	37808-769-38	041220510863
HEB 100Z CHERRY CITRATE	37808-673-38	00041220510870
HEB 100Z GRAPE MAG CITRATE	37808-695-38	00041220510887
HEALTH MART 100Z LEMON MAG CIT	62011-0380-1	052569142158
HEALTH MART 100Z CHERRY CIT	62011-0381-1	052569142165
KROGER 100Z LEMON MAG CITRATE	30142-899-38	041260001826
KROGER 100Z GRAPE CITRATE	30142-806-38	041260008719
LEADER 100Z LEMON MAG CIT	70000-0424-1	096295135541
LEADER 100Z CHERRY CIT	70000-0575-1	096295141061
LEADER 100Z GRAPE MAG CIT	70000-0576-1	096295141054
MAJOR 100Z LEMON MAG CITRATE	0904-6787-44	309046787440
MEIJER 100Z LEMON MAG CIT	41250-708-38	713733459457
MEIJER 100Z CHERRY CITRATE	41250-769-38	713733459440
PREMIER VALUE 100Z LOW SOD LEM CIT	68016-696-38	840986035302
PREMIER VALUE 100Z CHERRY CIT	68016-701-38	840986035296
PUBLIX 100Z LEMON MAG CIT	56062-266-38	041415506732
PUBLIX 100Z CHERRY CITRATE	56062-264-38	041415505735
QUALITY CHOICE 100Z LEMON MAG CIT	63868-929-38	635515901254
QUALITY CHOICE 100Z CHERRY CITRATE	63868-018-38	635515901117
REXALL 100Z LEMON MAG CITRATE	55910-183-38	072785134188
REXALL 100Z CHERRY CIT	55910-961-38	072785134164
REXALL 100Z GRAPE MAG CIT	55910-615-38	072785134171
RITE AID 100Z LEMON CITRATE	11822-4330-2	011822433006
RITE AID 1002 CHERRY CITRATE	11822-4303-2	011822433037
SIGNATURE CARE 100Z LEMON MAG CIT	21130-709-38	321130779155
SIGNATURE CARE 1002 CHERRY CIT	21130-709-38	321130779133
SOUND BODY 100Z LEMON MAG CIT	50594-166-38	072785114791
SUNMARK 100Z LEMON MAG CIT		010939908445
JUNIVIARY TOOL FEINION INING CLI	70677-0051-1	010333308443

SUNMARK 100Z CHERRY CIT	70677-0053-1	010939910448
SWAN 100Z LEMON MAG CITRATE	0869-0166-38	072785134058
SWAN 100Z CHRY CITRATE	0869-0164-38	308690693381
TOPCARE 100Z LEMON MAG CITRATE	36800-709-38	036800455290
TOPCARE 100Z CHERRY CIT	36800-164-38	036800455306
UP&UP 100Z LEMON MAG CIT	11673-708-38	072785128835
UP&UP 100Z LEMON MAG CIT	11673-666-38	072785128835
WALGREENS 100Z LEMON MAG CIT	0363-8166-38	311917201603
WALGREENS 100Z CHERRY CIT	0363-8164-38	311917201580
WALGREENS 100Z GRAPE MAG CIT	0363-7162-38	311917201597

^{*}Immediately discontinue use/sale of products and place on medical hold. Contact your supplier for disposition instructions.

4. PRODUCT LABELS/PICTURES:



5. **CONTACT INFORMATION.** Consumers with questions regarding this recall can contact Vi-Jon, LLC by e-mail (Recalls@Vijon.com) Monday-Friday, from 7:30 am to 4:30 pm, Central Time. Consumers should contact their physician or healthcare provider if they have experienced any problems that may be related to taking or using this drug product. Adverse reactions or

quality problems experienced with the use of this product may be reported to the FDA's MedWatch Adverse Event Reporting program either online, by regular mail or by fax. For reporting online or by mail, see the FDA recall notice at this site for links to the forms: https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/vi-jon-llc-expands-voluntary-nationwide-recall-all-flavors-and-lots-within-expiry-magnesium-citrate, or call 1- 800-332-1088 to request a reporting form, then complete and return to the address on the pre-addressed form, or submit by fax to 1-800-FDA-0178

6. POSITIVE AND NEGATIVE FINDINGS.

a. Army Veterinary Services and Air Force Public Health Personnel: Report negative and positive findings in the Veterinary Service Information Management System (VSIMS) Subsistence Recalls application. If you are not in one of these two groups, please use the instructions below (paragraphs b-d).

b. Navy:

- 1) SHIPS AT SEA: Must report positive and negative findings to supporting Veterinary Service unit. Are authorized to destroy or dispose of recalled products utilizing the procedures and reporting requirements outlined in NAVSUP P-486 Paragraph 5302 and 6000(4), to include completion of a DD Form 200 and Standard Form 364. Procedures for completing the DD Form 200 are found in NAVSUP P-486 Paragraph 6001. Procedures for completing Standard Form 364 are found in NAVSUP P-486 Paragraph 5300(2)(c).
- 2) SHIPS IN PORT/HOMEPORTED/ASHORE GALLEYS: Supporting Veterinary Service unit will conduct inspection and report positive and negative findings in VSIMS Subsistence Recalls application. Contact the appropriate DLA Account Manager via Regional NAVSUP Fleet Logistics Center (NAVSUP FLC) to arrange pickup of recall items. Contact your supporting (NAVSUP FLC) for any issues regarding PV Pickup. Proceed with the same guidance in the paragraph above.
- c. **Defense Logistics Agency (DLA) Contractors**: Report positive and negative findings to your Contracting Officer, Contracting Specialist, TVLS, and <u>dscpconssafofc@dla.mil</u> within 72-hours.

Positive Response Information required: (Vendor must provide all the following information):

- 1) ALFOODACT 2021-XXX
- 2) DLA Contract Number:
- 3) Unit of Measure:
- 4) Quantity Currently in Stock:
- 5) List of customers that received product AND (a-h) for each customer:
 - a) Customer name and location:
 - b) DLA Purchase Order Number:
 - c) Vendor Invoice Number:
 - d) Item Stock number (LSN, NSN):
 - e) Quantity Shipped:
 - f) Date Shipped:

- g) Value of Affected Product:
- h) Amount of credit due:
- d. AAFES, MWR, NEX, MCCS, DeCA, DLA, dining facilities, and all other agencies, report your findings in accordance with the procedures outlined by your agency.
- 7. If you know of others who need to receive Subsistence Recall messages, click <u>Subscribe</u>. If you no longer need to receive Subsistence Recall messages, click <u>Unsubscribe</u>.
- 8. Previous recalls are available on the DLA-TS Food Safety Office website: https://www.dla.mil/TroopSupport/Subsistence/FoodSafety/fso/ALFOODACT/.
- 9. Point of contact for ALFOODACT messages is the undersigned at commercial telephone 215-737-7788/DSN: 312-444-7788, or dscpconssafofc@dla.mil.

ADELAIDE F. GREEN Major, U.S. Army Food Safety Officer