COMPANY ANNOUNCEMENT

Vi-Jon, LLC Expands Voluntary Nationwide Recall of All Flavors and Lots Within Expiry of Magnesium Citrate Saline Laxative Oral Solution Due to Microbial Contamination

When a company announces a recall, market withdrawal, or safety alert, the FDA posts the company's announcement as a public service. FDA does not endorse either the product or the company.

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Summary

Company Announcement Date:

July 25, 2022

FDA Publish Date:

July 26, 2022

Product Type:

Drugs

Reason for Announcement:

Potential Gluconacetobacter liquefaciens contamination

Company Name:

Vi-Jon, LLC

Brand Name:

Multiple Brands

Product Description:

Magnesium Citrate Saline Laxative Oral Solution

Company Announcement

FOR IMMEDIATE RELEASE – **July 25, 2022** – 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 $\frac{1}{2}$ to 6 hours. The product is packaged in a 10 oz clear round plastic bottle.

In addition to the lemon flavor, the recall now includes the Cherry flavor and Grape flavor noted below in the table in bold print.

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

Affected Brand	NDC #	UPC #
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 100Z CHERRY CITRATE	11822-4303-2	011822433037
SIGNATURE CARE 100Z LEMON MAG CIT	21130-709-38	321130779155
SIGNATURE CARE 100Z CHERRY CIT	21130-165-38	321130789710
SOUND BODY 100Z LEMON MAG CIT	50594-166-38	072785114791
SUNMARK 100Z LEMON MAG CIT	70677-0051-1	010939908445
SUNMARK 100Z CHERRY CIT	70677-0053-1	010939910448
SWAN 100Z LEMON MAG CITRATE	0869-0166-38	072785134058

Affected Brand	NDC #	UPC #
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

The product was distributed Nationwide to wholesale and retail outlets. Vi-Jon, LLC is continuing their investigation into the cause of the problem.

Vi-Jon, LLC is notifying its customers by phone and email and is arranging for return or destruction of all recalled product. Consumers that have this recalled product should stop using and return any remaining product to the place of purchase.

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.www.vijon.comExternal Link Disclaimer

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.

- Complete and submit the report Online
- Regular Mail or Fax: <u>Download form</u> 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

This recall is being conducted with the knowledge of the U.S. Food and Drug Administration.