



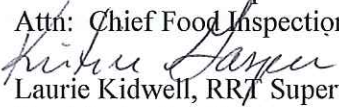
**Indiana State
Department of Health**
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Michael R. Pence
Governor

William C. VanNess II, MD
State Health Commissioner

DATE: May 22, 2014

TO: All Local Health Departments
Attn: Chief Food Inspection Officer

FROM: 
Laurie Kidwell, RRT Supervisor
Food Protection Program

SUBJECT: Fresenius Medical Care North America (FMCNA) – RECALL [Drug]

**AFFECTED
PRODUCT:** NaturaLyte® Liquid Bicarbonate Concentrate

SUMMARY: Class 1 Recall; The product is being recalled because it may develop higher bacteria levels than is allowed by the company's internal specification during its shelf life.

The recalled product is 56 lots of NaturaLyte® Liquid Bicarbonate Concentrate, 6.4 liters (intended for use in hemodialysis machines).

The product was distributed nationwide.

**SUGGESTED
ACTION:** For consumer inquiry only. Customers can contact Fresenius Medical Care's customer service teams at 1-800-323-5188 or if they have additional questions.

Recall -- Firm Press Release

FDA posts press releases and other notices of recalls and market withdrawals from the firms involved as a service to consumers, the media, and other interested parties. FDA does not endorse either the product or the company.

Voluntary Nationwide and Canada Recall of NaturaLyte® Liquid Bicarbonate Concentrate Due to Potential Health Risk

Contact
Consumer:
1-800-323-5188



2 North Meridian Street • Indianapolis, IN 46204
317.233.1325 tdd 317.233.5577
www.statehealth.in.gov

To promote and provide
essential public health services.

Media:

Jon Stone, Fresenius Medical Care

Jonathan.d.stone@fmc-na.com

781-699-9704 (o), 781-392-4680 (cell)

FOR IMMEDIATE RELEASE - May 21, 2014 - Fresenius Medical Care North America (FMCNA) announced today that its voluntary recall of 56 lots of NaturaLyte® Liquid Bicarbonate Concentrate, 6.4 liters (intended for use in hemodialysis machines) from distribution has been classified as a Class 1 Recall.

The affected lots were produced in its Montreal, Canada facility and are being recalled because they may develop higher bacteria levels than is allowed by the company's internal specification during their shelf life.

Laboratory testing has identified the bacteria as Halomonas (species 1, 2, 3), a Gram Negative bacteria, typically found in water with high salinity (salt concentration). According to a few case reports in the medical literature, bacterial contamination of the dialysate may lead to bacteremia or systemic infection. The dialysis filter (dialyzer) and the use of the Diasafe™ filter or equivalent create an effective bacteria and endotoxin barrier that makes this event unlikely.

Customer notifications were published on April 10th and May 1st, 2014. The customer notifications (available at www.fmcna.com) include a list of the product lot numbers which should be permanently removed from use and returned.

As part of its voluntary recall, the company informed the U.S. Food and Drug Administration (FDA) and Health Canada, as well as its customers - on April 10th and May 1st, 2014 - about these findings and promptly took steps to remove all of the affected lots from distribution, and discontinue their use.

Customers are encouraged to contact the FDA through the following means if they experience adverse reactions or quality problems from using this product:

- Complete and submit the report **Online:** www.fda.gov/medwatch/report.htm
- **Regular Mail or Fax:** Download form www.fda.gov/MedWatch/getforms.htm 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

Customers can contact Fresenius Medical Care's customer service teams at 1-800-323-5188 to report these issues, or if they have additional questions.

About Fresenius Medical Care North America

Through its leading network of more than 2,150 dialysis facilities in North America and vascular access centers, laboratory, pharmacy and affiliated hospitals and nephrology practices, Fresenius Medical Care provides renal services to hundreds of thousands of people throughout the United States, Mexico and Canada. It is also the continent's top producer of dialysis equipment, dialyzers and related disposable products and a major supplier of renal pharmaceuticals. For more information about the company, visit www.fmcna.com; for information about patient services, visit www.ultracare-dialysis.com.

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