FRESENIUS MEDICAL CARE

*** URGENT MEDICAL DEVICE Recall ***
FMCNA NaturaLyte® Liquid Bicarbonate Concentrate

DATE: **April 10, 2014**

REASON: **Bacterial Contamination**

PART NUMBER: **08-4000-LB**

Dear Unit Administrator/Director of Nursing/Clinical Manager/Chief Technician/Home Program Coordinator:

The purpose of this letter is to inform you that Fresenius Medical Care North America (FMCNA) is initiating a voluntary recall involving 49 lots of **NaturaLyte® Bicarbonate Concentrate 6.4 Liter Bottle** (Product Code 08-4000-LB). FMCNA has determined the product may contain higher levels of bacterial contamination than allowed by our internal specification. FMCNA is currently conducting testing to identify the organism/s. When testing is complete, the identity of the organism/s will be provided.

Product Information (Affected Lot/Expiration Date)

Lot #	Exp. Date	Lot #	Exp. Date	Lot #	Exp. Date
13KMLB001	7/31/2014	13LMLB001	8/31/2014	14AMLB001	12/31/2014
13KMLB002	7/31/2014	13LMLB002	8/31/2014	14AMLB002	12/31/2014
13KMLB003	7/31/2014	13LMLB003	8/31/2014	14AMLB003	12/31/2014
13KMLB004	7/31/2014	13LMLB004	8/31/2014	14AMLB004	12/31/2014
13KMLB005	7/31/2014	13LMLB005	8/31/2014	14AMLB005	12/31/2014
13KMLB006	7/31/2014	13LMLB006	8/31/2014	14AMLB006	12/31/2014
13KMLB007	7/31/2014	13LMLB007	8/31/2014	14AMLB007	12/31/2014
13KMLB008	7/31/2014	13LMLB008	8/31/2014	14AMLB008	12/31/2014
13KMLB009	7/31/2014	13LMLB009	8/31/2014	14AMLB009	12/31/2014
13KMLB010	7/31/2014	13LMLB010	8/31/2014	14AMLB010	12/31/2014
13KMLB011	7/31/2014	13LMLB011	8/31/2014	14AMLB012	12/31/2014
13KMLB012	7/31/2014	13LMLB012	8/31/2014		
13KMLB013	7/31/2014	13LMLB013	8/31/2014	13JMLB005	6/30/2014
13KMLB014	7/31/2014	13LMLB014	8/31/2014	13JMLB008	6/30/2014
13KMLB015	7/31/2014	13LMLB015	8/31/2014	13JMLB006	6/30/2014
13KMLB016	7/31/2014	13LMLB016	8/31/2014	13JMLB007	6/30/2014
13KMLB017	7/31/2014			13JMLB004	6/30/2014

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Please note this is a voluntary recall. No pyrogenic reactions, bacterial infections or related adverse events have been reported.

Pyrogenic reactions may occur when a patient is exposed to a significant amount of endotoxins, present in the bacterial cell wall of gram negative bacteria, resulting in fever, hypotension, flushing, chills, and/or breathing difficulties. The effects of endotoxins are only temporary. Patients may develop long range health consequences secondary to the severity of the reaction (i.e., hypotension, breathing difficulties). In addition, a high bioburden in the dialysis concentrate may lead to transient bacteremia.

Our records indicate that you received one or more bottles of the above referenced product, which were distributed between the dates of 08/15/2013 and 04/7/2014.

We ask that you please do the following:

- **Immediately examine your stock to determine whether you have any NaturaLyte® Liquid Bicarbonate Concentrate from the lots listed above.**
- **If any of these lots are found, discontinue use *immediately.***
- **Place all units in a secure, segregated area.**
- **If affected product was on the machine prior to patient treatment, perform a [Heat Disinfect] program.**
- **Contact your FMCNA Customer Service Team at 1-800-323-5188 for instructions on how to return the recalled product.**
- **Promptly fill out and return the attached fax-back reply form.**

Please note that only the NaturaLyte® Liquid Bicarbonate Concentrate matching the Lot Numbers listed in the Product Information table above are affected by this recall.

Please route this letter to others in your organization that may have any of the affected product that is subject to this recall.

This recall notice has been sent by Certified Mail, Return Receipt Requested.

Please complete and return the attached FAX BACK FORM to confirm that you have received this notice and to indicate whether or not you have the affected product in your possession.

Adverse reactions or quality problems experienced with the use of this product may be reported to the FDA's MedWatch Adverse Event Reporting by:

- Linking to the MedWatch website at www.fda.gov/medwatch
- Calling 1-800-FDA-1088
- Faxing at 1-800-FDA-0178, or by
- Mailing to: MedWatch, HF-2, FDA, 5600 Fishers Lane, Rockville, MD 20852-9787

The FDA has been advised of this product recall.

If you have any additional questions, please contact your FMCNA Customer Service Team at 1-800-323-5188.

We apologize for any inconvenience this product recall may cause. We thank you for your cooperation and timely response.

Sincerely,

Denise Oppermann
Senior Director
Regulatory Affairs-Devices