Class 2 Recall Fresenius NaturaLyte

See Related Information[23]

Date Posted	June 22, 2015
Recall Status[1]	Open
Recall Number	Z-1827-2015
Recall Event ID	71160[24]
Product	NaturaLyte Liquid Bicarbonate Concentrate (Dialysate Concentrate for Hemodialysis (liquid), 6.4 Liter Bottle Catalog Number: 08-4000-LB This concentrate is formulated to be used with a three steam hemodialysis machine which is calibrated for acid and bicarbonate concentrates.
Code Information	Affected lots begin with: 14DMLB, 14EMLB, 14HMLB, 14JMLB, 14KMLB, 14LMBL, 14NMLB, 14PMLB, and 14SMLB.
Recalling Firm/ Manufacturer	Fresenius Medical Care Holdings, Inc. 920 Winter St Waltham, Massachusetts 02451-1521
Manufacturer Reason for Recall	Bacterial contamination.
Action	Fresenius Medical Care sent an Urgent Medical Device Recall letter dated May 15, 2015, to all affected customers. Users were requested to Immediately examine stock to determine whether they have any Naturalyte® Liquid Bicarbonate Concentrate of the lots. " If any product of these lots is 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. " Your dialysis schedule should not be interrupted. If interruption of your dialysis schedule is expected, please discuss your options with your health care provider. " Contact 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 reply form Additional medical concerns or questions, please contact Medical Information and Communication: 855-616-2309 or Website: www.fresenius-medinfo.com. For questions regarding this recall call 800-662-1237.
Quantity in Commerce	1,856,619 Bottles
Distribution	Nationwide Distribution

[1] For details about termination of a recall see Code of Federal Regulations (CFR) Title 21 §7.55[25]

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