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Class 1 Device Recall Fresenius GranuFlo (powder) Acid Concentrate

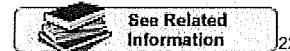


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Class 1 Device Recall Fresenius GranuFlo (powder) Acid Concentrate



Date Posted	June 25, 2012
Recall Status ¹	Open
Recall Number	Z-1827-2012
Recall Event ID	62108 ²³
510(K)Number	<u>K030497</u> ²⁴
Product Classification	<u>Dialysate concentrate for hemodialysis (liquid or powder)</u> ²⁵ - Product Code KPO ²⁶
Product	<p>Fresenius GranuFlo (powder) Acid Concentrate Product Codes: OFD1201-3B, OFD1251-3B, OFD2123-3B, OFD2201-3B, OFD2220-3B, OFD2223-3B, OFD2225-3B, OFD2231-3B, OFD2251-3B, OFD2301-3B, OFD2323-3B, OFD2325-3B, OFD3201-3B, OFD3231-3B, OFD3251-3B, OFD3301-3B.</p> <p>For the treatment of acute and chronic renal failure during hemodialysis procedure.</p>
Code Information	All lots
Recalling Firm/Manufacturer	Fresenius Medical Care Holdings, Inc. 920 Winter St Waltham MA 02451-1521
For Additional Information Contact	800-662-1237
Manufacturer Reason for Recall	Risk of Alkalosis with acetate containing dialysis acid concentrates
FDA Determined Cause ²	Labeling False and Misleading
Action	Fresenius Medical Care sent an "IMPORTANT PRESCRIBING INFORMATION" letter dated March 29, 2012 to all affected customers. The letter identifies the product, problem, and actions to be taken by the customers. A Reply Form was enclosed for customers to complete and return via fax to 781-699-9635. Contact Customer Service at 1-800-323-5188 or Medical Information at 1-855-616-2309 for questions regarding this recall.
Distribution	Nationwide Distribution and the country of Guam.
Total Product Life Cycle	<u>TPLC Device Report</u> ²⁷

¹ For details about termination of a recall see [Code of Federal Regulations \(CFR\) Title 21 §7.55](#)²⁸

² Per FDA policy, recall cause determinations are subject to modification up to the point of termination of the recall.

510(K) Database

[510\(K\)s with Product Code = KPO and Original Applicant = FRESENIUS MEDICAL CARE](#)²⁹

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