



One Luitpold Drive, P.O. Box 9001, Shirley, New York 11967
(631) 924-4000 • (800) 645-1706 • Fax (631) 924-1731

March 15, 2011

VIA EMAIL, OVERNIGHT COURIER,
AND/OR FACSIMILE

URGENT: VOLUNTARY DRUG RECALL
RE: CONCENTRATED SODIUM CHLORIDE INJECTION, USP, 23.4%
NDC # 0517-2930-25 and NDC # 0517-2900-25

Attention: Wholesaler/Distributor

Dear Sir or Madam:

This is to notify you that the following lots for the Concentrated Sodium Chloride Injection, USP, 23.4%, 30 mL vials, NDC # 0517-2930-25, and 100 mL Pharmacy Bulk Packs, NDC # 0517-2900-25, distributed by American Regent, Inc., are the subject of a voluntary recall by Luitpold Pharmaceuticals, Inc., as the manufacturer. This voluntary recall was initiated because some of the vials of these lots may contain visible particulates. Potential adverse events after intravenous administration of solutions containing particulates may include disruption of blood flow within small blood vessels in the lungs, localized inflammation (swelling and accumulation of inflammatory cells), and granuloma formation. American Regent is undertaking this voluntary recall in consideration of the potential for safety issues if these lots of product are administered to patients.

The product was distributed to wholesalers and distributors nationwide.

Concentrated Sodium Chloride Injection, USP, is indicated as an additive in parenteral fluid therapy for use in patients who have special problems of sodium electrolyte intake or excretion. It is intended to meet the specific requirement of the patient with unusual fluid and electrolyte needs.

The following lots are under voluntary recall to all accounts to the USER or CONSUMER LEVEL. Further use or distribution of these lots of product should cease immediately.

Concentrated Sodium Chloride Injection, USP, 23.4%
30 mL Vial
NDC # 0517-2930-25

Lot No.	Exp. Date	First Distribution Date
9198	03/2011	4/21/2009
9252	04/2011	5/12/2009
9299	04/2011	6/1/2009
9305	05/2011	6/23/2009
9402	06/2011	7/13/2009
9423	06/2011	7/30/2009
9432	06/2011	8/20/2009
9553	08/2011	9/11/2009

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Lot No.	Exp. Date	First Distribution Date
9595	08/2011	10/5/2009
9646	09/2011	10/28/2009
9681	10/2011	11/23/2009
9737	10/2011	12/21/2009
9797	11/2011	1/11/2010
9831	12/2011	2/8/2010
0051	01/2012	3/2/2010
0095	02/2012	3/17/2010

Concentrated Sodium Chloride Injection, USP, 23.4%
100 mL Vial
NDC # 0517-2900-25

Lot No.	Exp. Date	First Distribution Date
9225	04/2011	5/6/2009
9492	07/2011	8/7/2009
9711	10/2011	11/3/2009
0007	01/2012	1/26/2010
0058	01/2012	3/2/2010

You are hereby instructed to isolate your inventory of the above mentioned lots of Concentrated Sodium Chloride Injection, USP.

You are required to acknowledge receipt of this voluntary recall notification. Please notify us of quantities on hand, if any, by completing the attached form. As a direct account, please return product in inventory. If you have no product on hand, check the box, "We DO NOT Have Any Inventory of the Affected Lot to Return". Please return the form electronically to recall@americanregent.com or via facsimile at 1-866-597-1991.

The voluntary recall of these lots requires the return of product to American Regent, Inc. by all accounts to the **USER or CONSUMER LEVEL**. We request the following:

1. Contact the end user that purchased the lots listed of Concentrated Sodium Chloride Injection, USP NDC# 0517-2930-25 beginning distribution on April 21, 2009 or NDC# 0517-2900-25 beginning distribution on May 6, 2009, and alert them that American Regent has initiated a voluntary recall and to immediately cease use of these lots of the product.

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2. Instruct all end user customers to contact American Regent to arrange for product return by using our recall website at www.americanregent.com/recall/sc or by calling our Customer Service Department at 1-877-788-3232.
3. Provide American Regent with a list of end users including Customer Name, Address, City, State, Zip Code, DEA/HIN, distribution center. Please send this information to Dianne Ragoonath at dragoonath@americanregent.com.

Be advised American Regent, Inc. will coordinate all customer returns. American Regent, Inc. will be responsible for all shipping costs incurred by you or your customers.

American Regent's Customer Service Department will reply via email or verbally with a Return Authorization number for your shipment of returned product.

We will arrange for the product to be returned to our Shirley, New York facility. Please prepare the shipment as follows:

American Regent, Inc.
26 Precision Drive
Shirley, NY 11967


Attention: Shipping Department
RA # (to be issued)

A credit will be issued to your account. If you have any questions or problems regarding this matter, please contact our Customer Service Department at 1-877-788-3232.

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

Your cooperation is appreciated.

Sincerely,



Jean Poulos, M.S., M.B.A.
Vice President, Quality & Regulatory Operations