



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

**VIA E-MAIL, OVERNIGHT COURIER,  
 AND/OR FACSIMILE**

August 2, 2011

**URGENT: VOLUNTARY RECALL**  
 American Regent, Inc.

PRODUCT	Product: Vasopressin Injection, USP			
	Strength: 20 units/mL			
	Manufactured by: Luitpold Pharmaceuticals, Inc.			
	NDC #: 0517-0410-10			
	Vial Size: 10 mL multiple dose			
	Package Size: 10			
	Lot #	Exp Date	Exp Period	First Distribution Date
	9677	October 2011	24 months	11/24/2009
	0052	January 2012	24 months	02/17/2010
	0294	October 2011	18 months	05/28/2010
	0442	December 2011	18 months	08/11/2010
	0663	April 2012	18 months	11/09/2010
	NDC #: 0517-1020-25			
	Vial Size: 1 mL multiple dose			
	Package Size: 25			
Lot #	Exp Date	Exp Period	First Distribution Date	
9532	August 2011	24 months	09/02/2009	
9618	September 2011	24 months	10/14/2009	
9707	October 2011	24 months	11/17/2009	
0104	February 2012	24 months	04/05/2010	
0124	February 2012	24 months	04/23/2010	
0273	October 2011	18 months	05/14/2010	
0346	November 2011	18 months	07/12/2010	
0400	December 2011	18 months	08/19/2010	
0437	December 2011	18 months	10/05/2010	
0618	March 2012	18 months	11/15/2010	
0758	May 2012	18 months	12/21/2010	
NDC #: 0517-0510-25				
Vial Size: 0.5 mL multiple dose				
Package Size: 25				
Lot #	Exp Date	Exp Period	First Distribution Date	
0103	February 2012	24 months	03/11/10	

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<b>REASON</b>	<p>This is to notify you that lots of the above product, distributed by American Regent, Inc., is the subject of a voluntary Recall by Luitpold Pharmaceuticals, Inc., as the manufacturer. Recall of this product to the <b><u>RETAIL/HOSPITAL LEVEL</u></b> was initiated because some vials may not maintain potency throughout its shelf-life.</p> <p>Safety Information: Potential adverse events after administration of solutions that are below potency limits may include lack of desired effect.</p>
<b>ACTION(s)</b>	<ol style="list-style-type: none"><li>1. Further use or distribution of these lots of product should cease immediately.</li><li>2. You are hereby instructed to isolate your inventory of the above lot numbers.</li><li>3. You are required to acknowledge receipt of this recall notification. In addition, notify us of quantities on hand, if any, by completing the attached form.</li><li>4. As a direct account, please return product in inventory to American Regent Inc. as instructed below. If you have no product on hand, indicate "0 vials" per lot # on the form. <u>Return the form</u> electronically to <a href="mailto:recall@americanregent.com">recall@americanregent.com</a> or via facsimile at 1-866-597-1991.</li><li>5. Contact the end user that purchased these lots and alert them that American Regent Inc. has initiated a voluntary recall and to immediately cease use of these lots of product.</li><li>6. Instruct all end user accounts to contact American Regent, Inc. to arrange for product return by calling our Customer Service Department at 1-877-788-3232.</li><li>7. Instruct all end user customers to contact American Regent to arrange for product return by using our recall website at <a href="http://www.americanregent.com/recall/vaso">www.americanregent.com/recall/vaso</a> or by calling our Customer Service Department at 1-877-788-3232.</li></ol>
<b>OTHER INFORMATION</b>	<p>Be advised American Regent will coordinate all customer returns. American Regent, Inc. will be responsible for all shipping costs incurred by you or your customers.</p> <p>American Regent's Customer Service Department will reply electronically or verbally with a Return Authorization number (RA #) for your shipment of returned product.</p> <p>We will arrange for the product to be returned to our Shirley, New York facility. Please prepare the shipment as follows:</p> <p style="text-align: center;"><b>American Regent, Inc.</b> <b>26 Precision Drive</b> <b>Shirley, NY 11967</b> <b>Attention: Shipping Department</b> <b>RA # (to be issued)</b></p>

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	<p>A credit will be issued to your account. If you have any questions or problems regarding this matter, please contact Customer Service at 1-877-788-3232.</p>
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	<p>This activity previously described is being performed with the knowledge of the U.S. Food and Drug Administration.</p>
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Sincerely,

AMERICAN REGENT, INC.



Lindon M. Fellows

*Vice President, Quality and Regulatory Affairs*