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

## FOR IMMEDIATE RELEASE

**March 16, 2011**

**Contact Information:**
Walter Tozzi, R.Ph., M.S., M.B.A.
Sr. Director of Professional Services
631-924-4000

# *American Regent Initiates Voluntary Nationwide Recall of Dexamethasone Sodium Phosphate Injection, USP, 4 mg/mL, 1 mL Single Dose Vials; 5 mL and 30 mL Multiple Dose Vials*

**Shirley, NY (March 16, 2011) -** American Regent is conducting a nationwide voluntary recall of the following:

**Dexamethasone Sodium Phosphate Injection, 4 mg/mL, 1 mL Single Dose Vials**
**NDC # 0517-4901-25;**
**and**
**Dexamethasone Sodium Phosphate Injection, 4 mg/mL, 5 mL Multiple Dose Vials**
**NDC # 0517-4905-25;**
**and**
**Dexamethasone Sodium Phosphate Injection, 4 mg/mL, 30 mL Multiple Dose Vials**
**NDC # 0517-4930-25**

***PLEASE NOTE*: This voluntary recall, initiated on March 16, 2011 to the User Level, is for ALL unexpired lots of all 3 sizes of Dexamethasone Sodium Phosphate Injection, USP. See attached Appendix for Lot #s, Expiration Dates and Dates of First Distribution.**

This voluntary recall was initiated because some vials of these lots either contain particulates or have the potential to form particulates prior to their respective expiration dates. Potential adverse events after intravenous administration of solutions containing particulates, may include disruption of blood flow within small blood vessels in the lung, localized inflammation (swelling and redness due to accumulation of inflammatory cells), and granuloma formation. Intramuscular administration could result in foreign body inflammatory response, with local pain, swelling and possible long term granuloma formation. American Regent is undertaking this recall in consideration of the potential for safety issues, if these lots of product are administered to patients.

Dexamethasone Sodium Phosphate Injection, USP, is a synthetic adrenocortical steroid used to treat a variety of inflammatory and allergic conditions. See the Full Prescribing Information at www.americanregent.com for a complete listing of indications and uses.

The product was distributed to wholesalers and distributors nationwide.

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

Hospitals, emergency rooms, infusion centers, clinics, physician offices and other healthcare providers and facilities should not use American Regent Inc., Dexamethasone Sodium Phosphate Injection, USP 4mg/mL, 1mL Single Dose Vials, 5mL and 30 mL Multiple Dose Vials with the lot #s listed in the attached Appendix for patient care and should immediately quarantine any product for return.

While American Regent continues to investigate this issue, the company is taking precautionary action and initiated this voluntary nationwide recall. American Regent has informed the FDA of its actions and is maintaining ongoing discussions with the agency.

As is standard practice, and as stated in the Dexamethasone Sodium Phosphate Injection, USP Product Package Insert, "*Parenteral drug products should be inspected visually for particulate matter and discoloration prior to administration, whenever solution and container permit.*"

**American Regent will credit accounts for all returned product with these lot #'s. Those with product to return may do so by accessing our recall website at www.americanregent.com/recall/adx. If you have questions about the return or recall process, please contact our Customer Service Department at 1-877-788-3232: Monday thru Friday from 8:30AM to 7:00PM ET or by email at recall@americanregent.com.**

**Hospitals, emergency rooms, infusion centers, clinics, physician offices and other healthcare providers, or patients with product quality complaints, medical or other questions concerning the use of the product or reasons for this recall should contact the Professional Services Department at 1-877-788-3232.**

**Any adverse reactions experienced with the use of this product should be reported to American Regent, Inc. via email at pv@luitpold.com, by fax to (610) 650-7781 or (610) 650-0170 or by phone at 1-800-734-9236. TO EXPEDITE HANDLING PLEASE DO NOT REPORT ANYTHING OTHER THAN SPECIFIC ADVERSE EVENTS TO THIS EMAIL ADDRESS OR FAX OR PHONE.**

Adverse reactions or quality problems experienced with the use of this product may be reported to the FDA's MedWatch Adverse Event Reporting program online, or regular mail or by fax.

- **Online**:www.fda.gov/medwatch/report.htm
- **Regular Mail**: use postage-paid, pre-addressed Form FDA 3500 available at: www.fda.gov/MedWatch/getforms.htm. Mail to address on the pre-addressed form.
- **Fax**: 1-800-FDA-0178

Dexamethasone Sodium Phosphate Injection, USP is manufactured by Luitpold Pharmaceuticals, Inc. and is distributed by American Regent, Inc. (Shirley, NY).

Source: Luitpold Pharmaceuticals, Inc.

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

# APPENDIX

## American Regent Recall Lots of Dexamethasone Sodium Phosphate Injection, USP

**Dexamethasone Sodium Phosphate Injection, USP**
**4 mg/mL, 1 mL Single Dose Vial**

**NDC # 0517-4901-25**

| Lot Number | Expiration Date | First Distribution Date |
|---|---|---|
| 9153 | 03/2011 | 04/07/2009 |
| 9170 | 03/2011 | 04/15/2009 |
| 9182 | 03/2011 | 04/28/2009 |
| 9218 | 03/2011 | 05/06/2009 |
| 9254 | 04/2011 | 05/18/2009 |
| 9295 | 04/2011 | 05/27/2009 |
| 9329 | 05/2011 | 06/08/2009 |
| 9352 | 05/2011 | 06/18/2009 |
| 9368 | 05/2011 | 06/30/2009 |
| 9385 | 06/2011 | 07/14/2009 |
| 9422 | 06/2011 | 07/24/2009 |
| 9425 | 06/2011 | 08/04/2009 |
| 9441 | 06/2011 | 08/14/2009 |
| 9512 | 07/2011 | 08/25/2009 |
| 9549 | 08/2011 | 09/08/2009 |
| 9565 | 08/2011 | 09/21/2009 |
| 9605 | 09/2011 | 09/30/2009 |
| 9615 | 09/2011 | 10/14/2009 |
| 9615A | 09/2011 | 10/20/2009 |
| 9656 | 09/2011 | 10/26/2009 |
| 9668 | 09/2011 | 11/06/2009 |
| 9690 | 10/2011 | 11/18/2009 |
| 9710 | 10/2011 | 12/01/2009 |
| 9722 | 10/2011 | 12/14/2009 |
| 9743 | 10/2011 | 12/23/2009 |
| 0135 | 03/2011 | 04/01/2010 |
| 0138 | 03/2011 | 04/12/2010 |
| 0164 | 03/2011 | 04/13/2010 |

| Lot Number | Expiration Date | First Distribution Date |
|---|---|---|
| 0215 | 03/2011 | 04/22/2010 |
| 0229 | 04/2011 | 04/26/2010 |
| 0245 | 04/2011 | 05/05/2010 |
| 0271 | 04/2011 | 05/19/2010 |
| 0277 | 04/2011 | 06/01/2010 |
| 0282 | 04/2011 | 06/16/2010 |
| 0296 | 04/2011 | 06/30/2010 |
| 0302 | 05/2011 | 07/15/2010 |
| 0305 | 05/2011 | 07/28/2010 |
| 0324 | 05/2011 | 08/12/2010 |
| 0331 | 05/2011 | 08/24/2010 |
| 0342 | 05/2011 | 09/07/2010 |
| 0409 | 06/2011 | 09/21/2010 |
| 0444 | 06/2011 | 10/04/2010 |
| 0593 | 09/2011 | 10/13/2010 |
| 0599 | 09/2011 | 10/26/2010 |
| 0639 | 09/2011 | 11/08/2010 |
| 0678 | 10/2011 | 11/15/2010 |
| 0710 | 10/2011 | 11/23/2010 |
| 0736 | 10/2011 | 12/08/2010 |
| 0773 | 11/2011 | 12/21/2010 |
| 0792 | 11/2011 | 12/21/2010 |
| 0803 | 11/2011 | 12/28/2010 |
| 0819 | 11/2011 | 01/03/2011 |
| 0836 | 12/2011 | 01/25/2011 |
| 0846 | 12/2011 | 02/10/2011 |
| 0853 | 12/2011 | 02/23/2011 |
| 0879 | 12/2011 | 03/11/2011 |

AMERICAN REGENT®

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

# APPENDIX

## American Regent Recall Lots of Dexamethasone Sodium Phosphate Injection, USP

**Dexamethasone Sodium Phosphate Injection, USP**
**4 mg/mL, 5 mL Multiple Dose Vial**

**NDC # 0517-4905-25**

| Lot Number | Expiration Date | First Distribution Date |
|---|---|---|
| 9210 | 03/2011 | 04/16/2009 |
| 9250 | 04/2011 | 05/18/2009 |
| 9335 | 05/2011 | 06/11/2009 |
| 9393 | 05/2011 | 07/06/2009 |
| 9417 | 06/2011 | 08/03/2009 |
| 9516 | 08/2011 | 09/02/2009 |
| 9571 | 08/2011 | 09/29/2009 |
| 9620 | 09/2011 | 10/21/2009 |
| 9667 | 09/2011 | 11/18/2009 |
| 0157 | 03/2011 | 04/01/2010 |
| 0217 | 03/2011 | 04/27/2010 |
| 0269 | 04/2011 | 05/20/2010 |
| 0317 | 05/2011 | 06/16/2010 |
| 0392 | 06/2011 | 07/14/2010 |
| 0404 | 06/2011 | 08/10/2010 |
| 0407 | 06/2011 | 09/01/2010 |
| 0556 | 08/2011 | 09/30/2010 |
| 0624 | 09/2011 | 10/26/2010 |
| 0704 | 10/2011 | 11/22/2010 |
| 0765 | 11/2011 | 12/20/2010 |
| 0805 | 11/2011 | 12/23/2010 |
| 0878 | 12/2011 | 01/18/2011 |
| 1055 | 01/2012 | 02/22/2011 |

**Dexamethasone Sodium Phosphate Injection, USP**
**4 mg/mL, 30 mL Multiple Dose Vial**

**NDC # 0517-4930-25**

| Lot Number | Expiration Date | First Distribution Date |
|---|---|---|
| 0213 | 03/2011 | 05/04/2010 |
| 0306 | 05/2011 | 06/23/2010 |
| 0387 | 06/2011 | 08/02/2010 |
| 0565 | 08/2011 | 09/22/2010 |
| 0679 | 10/2011 | 11/03/2010 |
| 0771 | 11/2011 | 12/22/2010 |
| 0840 | 12/2011 | 01/14/2011 |