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***American Regent Initiates Nationwide Voluntary Recall of  
Methyldopate HCL Injection, USP  
5 mL Single Dose Vial  
Due to Glass Particulates***

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**FOR IMMEDIATE RELEASE**

**June 6, 2011 - Shirley, NY** - American Regent is conducting a nationwide voluntary recall to the consumer and user level of the following product:

**Methyldopate HCL Injection, USP, 250 mg/5 mL (50mg/mL), 5 mL Single Dose Vial  
NDC # 0517-8905-10, Lot # 0152, Exp Date March, 2012.**

PLEASE NOTE: This recall, initiated on June 6, 2011 to the User or Consumer Level, is for Lot # 0152 only. No other lots of Methyldopate HCL Injection, USP are subject to this voluntary recall.

This voluntary recall was initiated because some of the vials of this lot contained translucent visible particles consistent with glass delamination. The glass particles (flakes) ranged in size from <50 microns to 200 microns.

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), and granuloma formation. American Regent is undertaking this voluntary recall in consideration of the potential for safety issues if this lot of Methyldopate HCL Injection, USP is administered to patients. American Regent has not received any reports of adverse events related to this recall.

Methyldopate HCL Injection, USP is used to treat hypertension, when parenteral medication is indicated.

The product was distributed to wholesalers and distributors nationwide.

Hospitals, Emergency Rooms, Clinics, and other healthcare facilities and providers should not use American Regent Inc., Methyldopate HCL Injection, USP, 250mg/5mL, Single Dose Vials, with Lot # 0152, for patient care and should immediately quarantine any product for return.

American Regent is notifying its distributors and consumers by e-mail, facsimile and/or overnight courier and is arranging for return of all recalled product. Consumers/distributors/retailers that have product which is being recalled should stop use.

American Regent will credit accounts for all returned Methyldopate HCL Injection, USP, 250mg/5mL, Single Dose Vials, with Lot # 0152. Those with questions about the return or recall process, please call our Customer Service Department at 1-877-788-3232: Monday thru Friday from 8:30AM to 7:00PM EDT.

Hospitals, emergency rooms, clinics, and other healthcare facilities and 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 e-mail at [pv@luitpold.com](mailto:pv@luitpold.com) by fax to (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 E-MAIL ADDRESS OR FAX OR PHONE.**

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

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

While American Regent continues to investigate this issue, the company is taking precautionary action and initiated this voluntary 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 Methyldopate HCL 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.*"

Methyldopate HCL Injection, USP is manufactured by Luitpold Pharmaceuticals, Inc. and is distributed by American Regent, Inc. (Shirley, NY).

Source: Luitpold Pharmaceuticals, Inc.

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

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