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***American Regent Initiates Nationwide Voluntary Recall of
Caffeine & Sodium Benzoate Injection, USP
250 mg/mL, 2 mL Single Dose Vial
Due to Visible Particulates***

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FOR IMMEDIATE RELEASE

May 5, 2011 - Shirley, NY - American Regent is conducting a nationwide voluntary recall to the consumer and user level of the following product:

**Caffeine & Sodium Benzoate Injection, USP, 250 mg/mL, 2 mL Single Dose Vial,
NDC # 0517-2502-10, Lot # 0084, Exp Date February, 2012**

PLEASE NOTE: This recall, initiated on May 5, 2011 to the User or Consumer Level, is for Lot # 0084 Only. No other lots of Caffeine & Sodium Benzoate Injection, USP are subject to this voluntary recall.

This voluntary recall was initiated because some of the vials of this lot 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 lung, localized inflammation (swelling and redness), 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 voluntary recall in consideration of the potential for safety issues, if this lot of Caffeine & Sodium Benzoate Injection, USP is administered to patients.

Caffeine and Sodium Benzoate Injection has been used in conjunction with supportive measure to treat respiratory depression associated with overdose with CNS depressant drugs (e.g., narcotic analgesics, alcohol). However, because of questionable benefit and transient action, most authorities believe caffeine and other analeptics should not be used in these conditions and recommend other supportive therapy.

The product was distributed to wholesalers and distributors nationwide.

Hospitals, Emergency Rooms, Clinics and other healthcare facilities should not use American Regent Inc., Caffeine & Sodium Benzoate Injection, USP, 250 mg/mL, 2 mL Single Dose Vials with Lot # 0084 for patient care and should immediately quarantine any product for return.

American Regent is notifying its distributors and consumers by email, 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 product with this lot #. 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 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) 650-0170 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

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 Caffeine & Sodium Benzoate 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."*

Caffeine & Sodium Benzoate 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.