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

American Regent Initiates Nationwide Voluntary Recall of Cyanocobalamin Injection, USP, 1000 mcg/mL, 1mL Vial Lot #s 1662, 1679, 1683 Due to Cracks in the Vials

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FOR IMMEDIATE RELEASE

April 2, 2012 - Shirley, NY - American Regent is conducting a nationwide voluntary recall to the Retail/Hospital level of the following product:

Cyanocobalamin Injection, USP, 1000 mcg/mL, 1 mL Vial
NDC # 0517-0031-25

Lot # 1662, Exp Date: November, 2013
Lot # 1679, Exp Date: November, 2013
Lot # 1683, Exp Date: November, 2013

PLEASE NOTE: This recall, initiated on April 2, 2012 to the Retail/Hospital Level, is for these lot numbers only. **No other lots or sizes of Cyanocobalamin Injection, USP are subject to this voluntary recall.**

American Regent is undertaking this voluntary recall of Cyanocobalamin Injection, USP, lots: 1662, 1679, and 1683 because cracks can form in the heel (bottom) and sides of some vials of these lots. These cracks may lead to a lack of assurance of sterility and the potential for development of glass particulates.

Although cracks were only observed in lot 1683, American Regent, as a precautionary measure, is also recalling lots 1662 and 1679 because these lots were manufactured with the same lot of glass vials as lot 1683. **American Regent has not received any reports of adverse events related to these lots.**

The intramuscular or subcutaneous injection of a solution whose sterility may have been compromised may result in a systemic infection, abscess formation, or infection at the injection site.

Muscle and adipose tissue damage may occur by the intramuscular or subcutaneous injection of solutions containing particulates.

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Cyanocobalamin Injection, USP is indicated for vitamin B12 deficiencies due to malabsorption which may be associated with the following conditions:

Addisonian (pernicious) anemia

Gastrointestinal pathology, dysfunction, or surgery, including gluten enteropathy or sprue, small bowel bacteria overgrowth, total or partial gastrectomy

Fish tapeworm infestation

Malignancy of pancreas or bowel

Folic acid deficiency

Please see Full Prescribing Information for more details for other indications and uses.

The product was distributed to wholesalers and distributors nationwide.

Hospitals, Retail Pharmacies, Clinics and Physician Offices, and other healthcare facilities and providers should not use American Regent Cyanocobalamin Injection, USP, 1000 mcg/mL, 1 mL vials, with lot #s 1662, 1679, or 1683 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 its use.

American Regent will credit accounts for all returned Cyanocobalamin Injection, USP, 1000 mcg/mL, 1 mL vials with lot #s 1662, 1679, or 1683. Those with questions about the return or recall process, please call our Customer Service Department at 1-800-645-1706: Monday thru Friday from 8:30 AM to 7:00 PM ET.

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: Monday thru Friday from 9:00 AM to 5:00 PM ET.

Any adverse reactions experienced with the use of this product should be reported to American Regent via e-mail at pv@luitpold.com, or by fax to 610-650-0170, or by phone at 1-800-734-9236: Monday thru Friday from 9:00 AM to 5:00 PM ET. TO EXPEDITE HANDLING PLEASE DO NOT REPORT ANYTHING OTHER THAN SPECIFIC ADVERSE EVENTS TO THIS E-MAIL ADDRESS OR FAX OR PHONE.

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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, by 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, "*Parenteral drug products should be inspected visually for particulate matter and discoloration prior to administration, whenever solution and container permit.*"

Cyanocobalamin 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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