Indiana State Department of Health
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Mitchell E. Daniels, Jr.
Governor

Gregory N. Larkin, M.D., F.A.A.F.P.
State Health Commissioner

DATE: July 20, 2011

TO: All Local Health Departments
Attn: Chief Food Inspection Officer

FROM: A. Scott Gilliam, MBA, CP-FS
Director, Food Protection Program

ASG

SUBJECT: American Regent Recall

SUGGESTED ACTION: **Unclassified Recall; Vials of this lot may contain silicone particles; Recommend notification of affected stores via phone, fax or e-mail.**

From the information provided by FDA, the product being recalled may have been distributed in the State of Indiana. The product was distributed to wholesalers and distributors nationwide. Hospitals, infusion centers, clinics and other healthcare facilities should not use American Regent Inc., Calcium Gluconate Injection, USP, 10%, Lot # 1006 for patient care, and should immediately quarantine any product for return to American Regent, Inc. Detail information is not available at this time. In addition, if any recalled products are found, please notify this office at 317-233-7360.

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Recall -- Firm Press Release

FDA posts press releases and other notices of recalls and market withdrawals from the firms involved as a service to consumers, the media, and other interested parties. FDA does not endorse either the product or the company.

American Regent Initiates Voluntary Nationwide Recall of Calcium Gluconate Injection, USP, 10%, 100 mL Pharmacy Bulk Package Due to Particulates

Contact:
Consumer:
877-788-3232 (Customer Service)
800-734-9236 (American Regent, Inc.)
pv@luitpold.com

Media:
Walter Tozzi, R.Ph., M.S., M.B.A.
Sr. Director of Professional Services
1-631-924-4000

FOR IMMEDIATE RELEASE - July 18, 2011 - American Regent is conducting a voluntary nationwide recall to the user and consumer level of the following product:

Calcium Gluconate Injection, USP, 10%, 100 mL Pharmacy Bulk Package, Lot # 1006, Expiration Date: January 2013, NDC # 0517-3900-25

***PLEASE NOTE*: This voluntary nationwide recall, initiated on July 18, 2011 to the user and consumer level is for lot # 1006 only. No other sizes or lots of Calcium Gluconate Injection, USP, are subject to this voluntary recall.**

This voluntary recall was initiated because some of the vials of this lot may contain silicone particles. 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. American Regent is undertaking this voluntary recall in consideration of the potential for safety issues if this lot of product is administered to patients.

Calcium gluconate is used to treat conditions arising from calcium deficiencies such as hypocalcemic tetany, hypocalcemia related to hypoparathyroidism and hypocalcemia due to rapid growth or pregnancy. It is also used in the treatment of black widow spider bites to relieve muscle cramping and as an adjunct in the treatment of rickets, osteomalacia, lead colic and magnesium sulfate overdosage.

Calcium gluconate has also been employed to decrease capillary permeability in allergic conditions, non-thrombocytopenic purpura and exudative dermatoses such as dermatitis herpetiformis and for pruritus of eruptions caused by certain drugs. In hyperkalemia, calcium gluconate may aid in antagonizing the cardiac toxicity provided the patient is not receiving digitalis therapy.

The product was distributed to wholesalers and distributors nationwide.

Hospitals, infusion centers, clinics and other healthcare facilities should not use American Regent Inc., Calcium Gluconate Injection, USP, 10%, Lot # 1006 for patient care, and should immediately quarantine any product for return to American Regent, Inc.

Please Note: Calcium Gluconate Injection, USP, 10% is a supersaturated solution and is prone to precipitation. Other lots and sizes may contain a precipitate that should dissolve upon warming. The Product Package Insert contains directions on dissolving this precipitate should it occur. However, the injection must be clear at the time of use. As stated in the 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 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, infusion centers, clinics and other healthcare facilities, 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 EDT.

Any adverse reactions experienced with the use of this product should be reported to American Regent, Inc. via e-mail at pv@luitpold.com, 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 EDT. 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 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[1]
- **Regular Mail:** use postage-paid, pre-addressed Form FDA 3500 available at: www.fda.gov/MedWatch/getforms.htm[2]. Mail to address on the pre-addressed form.
- **Fax:** 1-800-FDA-0178.

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

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

Source: Luitpold Pharmaceuticals, Inc.

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RSS Feed for FDA Recalls Information[3] [what's this?[4]]

Photo: Product Labels[5]