



Michael R. Pence  
Governor

William C. VanNess II, MD  
State Health Commissioner

**DATE:** May 10, 2013  
**TO:** All Local Health Departments  
Attn: Chief Food Inspection Officer  
**FROM:** A. Scott Gilliam, MBA, CP-FS  
Director, Food Protection Program  
**SUBJECT:** Bimeda Inc. Recall

**SUGGESTED ACTION:**

Unclassified Recall; One lot of Calcium Gluconate, one lot of Dextrose 50%, and one lot of Hypertonic Saline, all of which are in the form of injectable fluids, to the user level because of departures from customary sterility procedures, sterility cannot be entirely assured; Recommend notification of affected stores via phone, fax or e-mail.

From the information provided by FDA, the recalled products may have been distributed in the State of Indiana. The recalled products were distributed nationwide to veterinary product wholesalers and retailers. Detail store information is not available at this time. In addition, if any recalled products are found, please notify this office at 317-233-8475.

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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.

**Bimeda Inc. on Behalf of Manufacturer Bimeda-MTC Animal Health Inc. Issues Voluntary Nationwide Recall of Sterile Solutions Due to Concerns Regarding Sterility and Possible Health Risk**

**Contact:**  
Consumer:  
888-524-6332

Media:  
416-863-2130

866-805-9530  
[cnwtor@newswire.ca](mailto:cnwtor@newswire.ca)

**FOR IMMEDIATE RELEASE** - May 2, 2013 - Bimeda Inc., on behalf of the manufacturer, Bimeda-MTC Animal Health Inc. is voluntarily recalling one lot of Calcium Gluconate, one lot of Dextrose 50%, and one lot of Hypertonic Saline, all of which are in the form of injectable fluids, to the user level. These injectable fluids are being recalled as a precautionary measure; because of departures from customary sterility procedures, sterility cannot be entirely assured.

The products potentially could result in a reaction in animals administered the products listed in the table below. There have been no adverse events reported to date with respect to the above-noted products, and although no product contamination has been identified in the lots that have been tested for sterility; because of departures from our customary protocol, sterility cannot be entirely assured.

The products are used as fluid therapies and packaged in plastic serum 500 mL or 1000 mL bottles. Following are the affected lot numbers, expiration dates, and label identifiers:

<b>Product Name</b>	<b>Product Number</b>	<b>Lot Number</b>	<b>Label</b>	<b>Shipment Date</b>	<b>Quantity</b>	<b>Expiry Date</b>
<b>Calcium Glucium</b>	1CAL028	2J029A	Bimeda	11/01/12	20,064	09/14
<b>Dextrose 50%</b>	1DEX005	2J028	Bimeda	10/26/12	6702	09/15
<b>Hypertonic Saline</b>	1HYP009	2J041	MWI	11/01/12	8975	09/14

These products were distributed nationwide to veterinary product wholesalers and retailers.

Bimeda Inc., on behalf of manufacturer Bimeda-MTC Animal Health Inc., is notifying its distributors and customers by press release and is arranging for return of all recalled products. Users, distributors or retailers that have any of these products should stop using the product and return to place of purchase.

Customers with questions regarding this recall can contact Bimeda Inc. by phone 888-524-6332, Option or extension #2, Monday to Friday from 9 AM to 5 PM CST. Customers should contact their veterinarian if animals owned by them have experienced any problems that may be related to using these products.

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[RSS Feed for FDA Recalls Information](#)<sup>1</sup> [[what's this?](#)<sup>2</sup>]

Photo: [Product Labels](#)<sup>3</sup>