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 6, 2012

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

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

ASG

SUBJECT: Bedford Laboratories Recall

SUGGESTED ACTION: **Unclassified Recall; Bedford Laboratories issued a voluntary recall of Leucovorin Calcium Injection due to the discovery of visible crystalline particulate matter ina small number of vials; Information provided in case of consumer inquiry.**

From the information provided by FDA, the products being recalled may have been distributed in the State of Indiana. The recalled products were directly distributed to the healthcare marketplace. Detail information is not available at this time. In addition, if any recalled products are found, please notify this office at 317-351-7190-x255.

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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.

Bedford Laboratories Issues Nationwide Voluntary Hospital/User-Level Recall Of Leucovorin Calcium Injection

Contact:
Consumer:
For Information: 1-800-562-4797
Adverse Reactions: 1-800-521-5169
Media:
Marjorie Moeling, 440-703-7525
marjorie.moeling@boehringer-ingelheim.com

FOR IMMEDIATE RELEASE - July 3, 2012 -Bedford Laboratories™ today announced a nationwide voluntary hospital/user-level recall for:

Product Description	NDC	Package Size	Lot#/ Expiration Date	First Ship Date	Last Ship Date
Leucovorin Calcium Injection, 500mg SDV Bedford Label	55390-009-01	1 pack	2017620-1/31/2013 2038374-2/28/2013	1/31/2011 5/17/2011	2/24/2011 6/15/2011
Leucovorin Calcium Injection, 500mg SDV NOVA PLUS® Label	55390-826-01	1 pack	2038374A – 2/28/2013	5/16/2011	6/29/2011

Please note: This recall is for lots listed in the above table only. No other lots of Leucovorin Calcium Injection are subject to this voluntary recall.

This voluntary recall is being conducted due to the discovery of visible crystalline particulate matter in a small number of vials within the lots listed above. The particulate matter has been identified as active drug substance and not foreign material or contamination. Particulate matter has been recognized as a potential health hazard. Adverse reactions may include vein irritation and phlebitis, clinically occult pulmonary granulomas detected at routine autopsy examination, local tissue infarction, severe pulmonary dysfunction, occlusion of capillaries and arteries, anaphylactic shock and death.

Leucovorin Calcium rescue is indicated after high-dose methotrexate therapy in osteosarcoma. Leucovorin Calcium is also indicated to diminish the toxicity and counteract the effects of impaired methotrexate elimination and of inadvertent overdosages of folic acid antagonists; the treatment of megaloblastic anemias due to folic acid deficiency when oral therapy is not feasible; and for use in combination with 5-fluorouracil to prolong survival in the palliative treatment of patients with advanced colorectal cancer.

Notification of the Leucovorin Calcium lots listed above is being sent to customers who have received product from the identified lots. Healthcare practitioners who had received the lot were instructed not to use the product and immediately quarantine it for return. Anyone with questions can contact Bedford Laboratories Client Services at 800-562-4797 between 8 a.m. and 5 p.m. Eastern time, Monday through Friday.

Any adverse reactions experienced with the lot reported in this release should be reported to Bedford Laboratories at 800-521-5169. Adverse reactions or quality problems experienced with the use of this product may also be

reported to the
FDA's MedWatch Adverse Event Reporting program:

□ 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.
Bedford Laboratories, a division of Ben Venue Laboratories, Inc. 300 Northfield Road, Bedford, OH 44146 • U.S.A. •Phone: 440.232.3320 • Fax: 440.232.6264 www.bedfordlabs.com[3]

□ Fax: 1-800-FDA-0178

Bedford Laboratories has informed the U.S. Food and Drug Administration (FDA) of its actions and is maintaining ongoing
discussions with the agency. This voluntary recall is being conducted with the knowledge of the U.S. FDA.

The discovery was made due to a field product complaint for visible crystalline particulate and discovery of crystalline
particulate in a retained sample. To date, there have been no reports of any adverse events for the lots being recalled. Our
highest priority is the delivery of safe and effective medicines for the patients who need them.

As is standard practice, and as stated in the Product Package Insert, "Parenteral drug products should be inspected visually
for particulate matter and discoloration prior to administration whenever solution and container permit."

About Bedford Laboratories
Bedford Laboratories, located in Bedford, Ohio, is a division of Ben Venue Laboratories. Bedford Laboratories supplies a
selection of critical-care and medically necessary multisource and specialty injectable products to the healthcare
marketplace. For more information, please visit http://www.BedfordLabs.com[4].

About Ben Venue Laboratories, Inc.
Ben Venue Laboratories, Inc. was founded in 1938 and is a leading manufacturer of highly complex, sterile injectable drug
products for the global pharmaceutical industry. Ben Venue is located in Bedford, Ohio, where the company employs more
than 1,300 people. For more information, visit www.benvenue.com[5].

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RSS Feed for FDA Recalls Information[6] [what's this?[7]]

Photo: Product Labels[8]

Recalled Product Photos Are Also Available on FDA's Flickr Photostream.[9]

Bedford Laboratories Issues Nationwide Voluntary Hospital/User-Level Recall Of Leucovorin Calcium Injection
Photos