Indiana State Department of Health
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Michael R. Pence
Governor

William C. VanNess II, MD
State Health Commissioner

DATE: January 7, 2013

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

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

SUBJECT: Baxter International, Inc. [Drug]

AFFECTED PRODUCT: **CLINIMIX and one lot of CLINIMIX E Injection parenteral nutrition.**

SUMMARY: **Unclassified Recall; The recall is due to complaints of particulate matter found in the products.**

The affected product codes are 2B7729 (lot P287045, exp 06/14), 2B7717 (lot P275883, exp 10/13) and 2B7709 (lot P285122, exp 05/14). The affected lots were distributed to customers between May 2012 and October 2013. The products were distributed to healthcare centers and distributors in the United Sates.

SUGGESTED ACTION: **For consumer inquiry only. Consumers with questions regarding this recall can call Baxter at 1-800-422-9837, Monday through Friday, between the hours of 8:00 a.m. and 5:00 p.m. Central Time, or e-mail Baxter at onebaxter@baxter.com.**

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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.

Baxter Initiates Nationwide Voluntary Recall of Select Lots of Premix Parenteral Nutrition

Contact
Consumer:
(800) 422-9837

Media:
Deborah Spak
John O'Malley
(224) 948-5353
Email: media@baxter.com

FOR IMMEDIATE RELEASE - January 3, 2014 - Baxter International Inc. announced today it has initiated a voluntary recall in the United States of two lots of CLINIMIX and one lot of CLINIMIX E Injection parenteral nutrition products to the user level due to complaints of particulate matter found in the products. If infused, particulate matter may result in blockages of blood vessels, which can result in stroke, heart attack, or damage to other organs such as the kidney or liver. There is also the possibility of allergic reactions, local irritation, and inflammation in tissues and organs. There have been no reported adverse events associated with this issue to date, and the root cause of this voluntary recall has been identified and resolved.

CLINIMIX (Amino Acid in Dextrose) Injection and CLINIMIX E (Amino Acid with Electrolytes in Dextrose with Calcium) Injections are premixed sterile intravenous (IV) parenteral nutrition products that come in multi-chambered containers and are used as a caloric component and as a protein source in a parenteral nutrition program. The affected product codes are 2B7729 (lot P287045, exp 06/14), 2B7717 (lot P275883, exp 10/13) and 2B7709 (lot P285122, exp 05/14). Affected products were distributed to healthcare centers and distributors in the United Sates.

Baxter has notified customers, who are being directed not to use product from the recalled lots. Customers should locate and remove all affected product from their facility. The affected lots were distributed to customers between May 2012 and October 2013. Unaffected lot numbers can continue to be used according to the instructions for use. Affected product should be returned to Baxter for credit by contacting Baxter Healthcare Center for Service at 1-888-229-0001, Monday through Friday, between the hours of 7:00 a.m. and 6:00 p.m., Central Time. Unaffected lots of product are available for replacement.

Consumers with questions regarding this recall can call Baxter at 1-800-422-9837, Monday through Friday, between the hours of 8:00 a.m. and 5:00 p.m. Central Time, or e-mail Baxter at onebaxter@baxter.com. Consumers should contact their physician or healthcare provider if they have experienced any problems that may be related to using this drug product.

Adverse reactions or quality problems experienced with the use of this product may be reported to the FDA's MedWatch Adverse Event Reporting program either 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

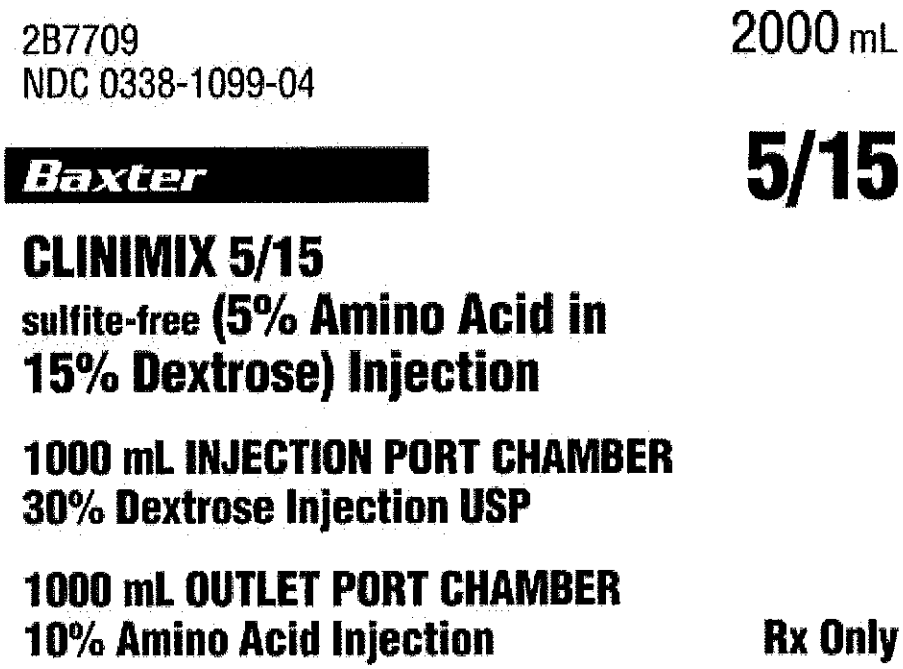
This recall is being conducted with the knowledge of the U.S. Food and Drug Administration.

According to the CLINIMIX and CLINIMIX E product labeling, parenteral drug products should be inspected visually for particulate matter and discoloration whenever solution and container permit. The use of a final filter is recommended during administration of all parenteral solutions where possible.

About Baxter

Baxter International Inc., through its subsidiaries, develops, manufactures and markets products that save and sustain the lives of people with hemophilia, immune disorders, cancer, infectious diseases, kidney disease, trauma and other chronic and acute medical conditions. As a global, diversified healthcare company, Baxter applies a unique combination of expertise in medical devices, pharmaceuticals and biotechnology to create products that advance patient care worldwide.

Baxter Initiates Nationwide Voluntary Recall of Select Lots of Premix Parenteral Nutrition
Photos



2B7729
NDC 0338-1136-03

1000 mL

Baxter

4.25/25

CLINIMIX 4.25/25
sulfite-free (4.25% Amino Acid in 25% Dextrose) Injection

500 mL INJECTION PORT CHAMBER
50% Dextrose Injection USP

500 mL OUTLET PORT CHAMBER
8.5% Amino Acid Injection

Rx Only

2B7717
NDC 0338-1115-04

2000 mL

Baxter

E 4.25/10

CLINIMIX E 4.25/10
sulfite-free (4.25% Amino Acid with Electrolytes in 10% Dextrose with Calcium) Injection

1000 mL INJECTION PORT CHAMBER
20% Dextrose Injection with Calcium

1000 mL OUTLET PORT CHAMBER
8.5% Amino Acid Injection with Electrolytes

Rx Only