Indiana State Department of Health
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Michael R. Pence
Governor

William C. VanNess II, MD
State Health Commissioner

DATE: August 15, 2014

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

FROM: Laurie Kidwell, RRT Supervisor
Food Protection Program

SUBJECT: Baxter International Inc. – RECALL [Drug]

AFFECTED PRODUCT: **DIANEAL Low Calcium (2.5mEq/L) Peritoneal Dialysis Solution**

SUMMARY: **Unclassified Recall; The recall is being initiated due to the presence of oxidized stainless steel, garment fiber, and PVC particulate matter identified during the manufacturing process.**

This recall affects the following lots of DIANEAL Low Calcium (2.5 mEq/L) Peritoneal Dialysis Solution with 2.5% Dextrose 5000 mL (Ambu-Flex II container):

Product Code	NDC Number	Lot #	Expiration Date
L5B5202	0941-0457-05	C940700	May 31, 2016
L5B5202	0941-0457-05	C940841	May 31, 2016

The recalled product was distributed nationwide.

SUGGESTED ACTION: **For consumer inquiry only. Consumers with questions regarding this recall or requiring replacement product can call Baxter Home Care Services at 1-800-284-4060, Monday through Friday, between the hours of 7:00 a.m. and 6:00 p.m. Central Time.**

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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 Voluntarily Initiates U.S. Recall of Two Lots of Peritoneal Dialysis Solution Due to Presence of Particulate Matter

Contact:
Consumer:
1-800-284-4060

Media Contacts:
Deborah Spak
(224) 948-5353
Email: media@baxter.com

FOR IMMEDIATE RELEASE - DEERFIELD, Ill., - August 13, 2014 – Baxter International Inc. announced today it is voluntarily initiating a recall in the United States of two lots of DIANEAL Low Calcium (2.5mEq/L) Peritoneal Dialysis Solution with 2.5% Dextrose 5000mL (Ambu-Flex II) to the hospital/user level. The recall is being initiated due to the presence of oxidized stainless steel, garment fiber, and PVC particulate matter identified during the manufacturing process.

To date, no adverse events or related product complaints have been associated with the recalled products, which were distributed to dialysis centers, facilities, distributors, and patients in the United States.

Intraperitoneal administration of a product with particulate matter may cause local inflammation with foreign body reaction or result in adhesion formation. The particulate matter could potentially serve as a focal point for infection should any pre-existing peritonitis exist, and may lead to a fatal outcome.

DIANEAL is a peritoneal dialysis (PD) solution for use in chronic renal failure patients being maintained on peritoneal dialysis therapy. PD therapy is performed by using the body's peritoneal membrane as a filter, while special solution and osmotic pressure help remove extra fluids and clean the blood. This process takes the place of what healthy kidneys do for the body.

This recall affects the following lots of DIANEAL Low Calcium (2.5 mEq/L) Peritoneal Dialysis Solution with 2.5% Dextrose 5000 mL (Ambu-Flex II container):

The number of individual units within these two lots represents less than one percent of Baxter's average annual units produced globally. Unaffected lot numbers can continue to be used according to the instructions for use.

Baxter notified customers by recall letter to instruct them to locate and remove any affected product from their facility. All patients who received product from the affected lots also were contacted by recall letter and provided instructions to arrange for product return. Dialysis centers, facilities, distributors, and patients should stop use and return to place of purchase. The affected lots were distributed to customers between May 30, 2014 and July 9, 2014.

Healthcare providers who received affected product should return it 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 or requiring replacement product can call Baxter Home Care Services at 1-800-284-4060, Monday through Friday, between the hours of 7:00 a.m. and 6:00 p.m. Central Time. Patients should contact their physician or PD nurse if they have experienced any problems that may be related to taking or using this drug product.

Any adverse reactions or quality problems experienced with the use of these products may be reported to the FDA's MedWatch Adverse Event Reporting program either online, by regular mail, or by fax.

- Complete and submit the report Online: www.fda.gov/medwatch/report.htm.
- Regular Mail or Fax: Download form www.fda.gov/MedWatch/getforms.htm or call 1-800-332-1088 to request a reporting form, then complete and return to the address on the pre-addressed form, or submit by fax to 1-800-FDA-0178.

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

According to the DIANEAL PD Solution product labeling, the container should be inspected visually for signs of leakage prior to use. Solutions that are cloudy, discolored, contain visible particulate matter, or show evidence of leakage should not be used.

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.

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