Indiana State Department of Health
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Michael R. Pence
Governor

William C. VanNess II, MD
State Health Commissioner

DATE: March 6, 2014

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. – RECALL [Drug]

AFFECTED PRODUCT: **DIANEAL PD-2 Peritoneal Dialysis Solution with 1.5% Dextrose 6000mL (Ambu-Flex II)**

SUMMARY: **Unclassified Recall; The recall is due to complaints of particulate matter, identified as mold, resulting from a leak in the container. The one affected lot is C903799, expiration 05/15 (product code L5B9710), NDC 00941-0411-11. Product affected by this recall was packaged in flexible plastic containers.**

This product was distributed to dialysis centers, facilities, distributors and patients in the United States.

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 Initiates U.S. Voluntary Recall of One Lot of Peritoneal Dialysis Solution Due to Container-Closure Non-Integrity

Contact:
Consumer:

(888) 229-0001

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

Investor:
Mary Kay Ladone
(224) 948-3371

FOR IMMEDIATE RELEASE - March 5, 2014 – DEERFIELD, Ill.,– Baxter International Inc. announced today it has initiated a voluntary recall in the United States of a single lot of DIANEAL PD-2 Peritoneal Dialysis Solution with 1.5% Dextrose 6000mL (Ambu-Flex II) to the hospital/user level. The recall is being initiated as a result of complaints of particulate matter, identified as mold, resulting from a leak in the container.

Intraperitoneal administration of a product contaminated with mold could result in life-threatening fungal peritoneal infection or sepsis. Baxter has received reports of adverse events for this lot of DIANEAL PD Solution; no causal relationship has been established between the events and this recall to date.

DIANEAL is a peritoneal dialysis (PD) solution for use in chronic renal failure patients being maintained on PD therapy. The one affected lot is C903799, expiration 05/15 (product code L5B9710), NDC 00941-0411-11. Product affected by this recall was packaged in flexible plastic containers and distributed to dialysis centers, facilities, distributors and patients in the United States.

Baxter notified customers by recall letter to instruct customers to locate and remove any affected product from their facility. All patients who received product from the affected lot 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 lot was distributed to customers between May 2013 and January 2014. Unaffected lot numbers can continue to be used according to the instructions for use. 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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