Indiana State Department of Health
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Michael R. Pence
Governor

William C. VanNess II, MD
State Health Commissioner

DATE: July 17, 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: **Four lots of Intravenous (IV) solutions**

SUMMARY: **Unclassified Recall; These products have been found to contain particulate matter identified as cellulosic fibers and/or plastics.**

Products affected by this recall are found in the table below:

Product Code	Description	Lot #	Expiry Date	NDC
2B1302	0.9% Sodium Chloride 100 mL (Quad Pack)	P298190	Aug 2014	0338-0049-18
2B0043	0.9% Sodium Chloride 100 mL MINI-BAG Plus	P308650	Oct 2014	0338-0553-18
2B1306	0.9% Sodium Chloride, 50 mL (Single Pack)	P309187	Oct 2014	0338-0049-41
2B0822	Highly Concentrated Potassium Chloride Injection, 20 mEq/50 mL, VIAFLEX Plus Container	P309476	Oct 2014	0338-0703-41

These products were distributed nationwide.

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 Voluntary Worldwide Recall Of Four Lots Of IV Solutions Due To The Presence Of Particulate Matter

Contact:
Consumer:
1-800-422-9837
onebaxter@baxter.com

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

FOR IMMEDIATE RELEASE - July 14, 2014 – Baxter International Inc. announced today it is voluntarily recalling four lots of intravenous (IV) solutions to the hospital/user level. These products have been found to contain particulate matter identified as cellulosic fibers and/or plastics. Baxter received four complaints over a period of six months from customers whose visual inspection identified the appearance of visible particulate matter prior to administration to a patient.

If infused, adverse health consequences of particulate matter could vary depending on the amount of particulate matter injected into the patient, the size of the particles, the patient's underlying medical condition and the presence of a right-to-left cardiac shunt. The presence of particulate foreign matter may elicit inflammatory and allergic responses, both chronic and acute, and may be life threatening. There have been no reported adverse events associated with this issue to date, and an investigation is underway to determine root cause.

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Product Code	Description	Lot #	Expiry Date	NDC
2B1306	0.9% Sodium Chloride, 50 mL (Single Pack)	P309187	Oct 2014	0338-0049-41
2B0822	Highly Concentrated Potassium Chloride Injection, 20 mEq/50 mL, VIAFLEX Plus Container	P309476	Oct 2014	0338-0703-41

Sodium Chloride Injection, USP is an intravenously administered injectable indicated as a source of water and electrolytes, for use as a priming solution in hemodialysis procedures, and may be used as a diluent for reconstitution of a powdered drug product. Potassium Chloride Injection is an intravenously administered injectable indicated as a potassium replacement to support nerve conduction, muscle contraction and prevention of cardiac arrhythmias. The lots being recalled were distributed worldwide to customers and distributors between February 2013 and June 2014.

Baxter has notified customers, who are being directed not to use products from the recalled lots. Recalled products 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 these drug products.

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.

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 Voluntary Worldwide Recall Of Four Lots Of IV Solutions Due To The Presence Of Particulate Matter
Photos

LOT EXP

0.9% Sodium Chloride Injection USP

2B1306
NDC 0338-0049-41

50 mL

SINGLE DOSE CONTAINER
EACH 50 mL CONTAINS 450 mg SODIUM CHLORIDE USP pH 5 0 (4 5 TO 7 0) mEq/50 mL SODIUM 8 CHLORIDE 8 OSMOLARITY 308 mOsmol/L (CALC) STERILE NONPYROGENIC READ PACKAGE INSERT FOR FULL INFORMATION ADDITIVES MAY BE INCOMPATIBLE DOSAGE NTRAVENOUSLY AS DIRECTED BY A PHYSICIAN CAUTIONS MUST NOT BE USED IN SERIES CONNECTIONS DO NOT USE UNLESS SOLUTION IS CLEAR Rx ONLY
V AFLEX CONTAINER PL 146 PLASTIC

Baxter
BAXTER HEALTHCARE CORPORATION
DEERFIELD L 60015 USA
MADE IN USA

LOT EXP

0.9% Sodium Chloride Injection USP

2B1302
NDC 0338 0049 18

100mL SINGLE DOSE CONTAINER
EACH 100 mL CONTAINS
900 mg SODIUM CHLORIDE USP
pH 5 0 (4 5 TO 7 0) mEq/100 mL
SODIUM 15 CHLORIDE 15 OSMOLARITY
308 mOsmol/L (CALC) STERILE
NONPYROGENIC READ PACKAGE INSERT
FOR FULL INFORMATION ADDITIVES MAY
BE INCOMPATIBLE DOSAGE
NTRAVENOUSLY AS DIRECTED BY A
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UNLESS SOLUTION IS CLEAR **RX ONLY**

V AFLEX CONTAINER PL 146 PLASTIC

Baxter

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DEERFIELD L 60015 USA
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