Indiana State Department of Health
An Equal Opportunity Employer

Michael R. Pence
Governor

Jerome M. Adams, MD, MPH
State Health Commissioner

DATE: July 20, 2015

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: 0.9 % Sodium Chloride Injection, USP, 50 mL VIAFLEX Plastic Container

SUMMARY: Unclassified Recall; The recall is due to the potential presence of particulate matter.

This recall affects the following lots:

Product Code	Product Description	Lot Number	Expiration Date	NDC
2B1301	0.9 % Sodium Chloride Injection, USP, 50 mL VIAFLEX Plastic Container	P319921	12/31/2015	0338-0049-11
2B0043	0.9% Sodium Chloride Injection, USP, 100 mL MINI-BAG Plus Container	P327635	12/30/2015	0338-0553-18

The recalled lot was distributed to distributors/wholesalers, hospitals, and pharmacies nationwide and more specifically I

The lots being recalled were distributed to customers and distributors in the United States between October 7, 2014 and July 14, 2015.

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 Recall Of Two Lots Of IV Solutions Due To The Potential Presence Of Particulate Matter

Contact:
Consumer:
1-800-422-9837

onebaxter@baxter.com

Media:
John O'Malley
1-224-948-5353
media@baxter.com

FOR IMMEDIATE RELEASE – July 17, 2015 – Baxter International Inc. announced today it is voluntarily recalling two lots of intravenous (IV) solutions to the hospital/user level due to the potential presence of particulate matter. The particulate matter in each case was determined to be an insect and was identified as a result of a customer complaint. The matter was identified prior to patient administration and there have been no adverse events associated with this issue reported to Baxter.

Injecting a product containing particulate matter, in the absence of in-line filtration, may result in blockage 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.

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0.9 % Sodium Chloride Injection, USP, 50 mL VIAFLEX Plastic Container is intended for intravenous use as a source of water and electrolytes. 0.9% Sodium Chloride Injection, USP, 100 mL MINI-BAG Plus Container is indicated as a source of water and electrolytes, and may also be used as a diluent for reconstitution of a powdered drug product packaged in a vial with a 20 mm closure.

The lots being recalled were distributed to customers and distributors in the United States between October 7, 2014 and July 14, 2015. Baxter is directing customers not to use product from the recalled lots. Recalled 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 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. provides a broad portfolio of essential renal and hospital products, including home, acute and in-center dialysis; sterile IV solutions; infusion systems and devices; parenteral nutrition; biosurgery

products and anesthetics; and pharmacy automation, software and services. The company's global footprint and the critical nature of its products and services play a key role in expanding access to healthcare in emerging and developed countries. Baxter's 50,000 employees worldwide are building upon the company's rich heritage of medical breakthroughs to advance the next generation of healthcare innovations that enable patient care.

Baxter Initiates Voluntary Recall Of Two Lots Of IV Solutions Due To The Potential Presence Of Particulate Matter
Photo

LOT **EXP**

2B0043 NDC 0338-0553-18

0.9% Sodium Chloride Injection USP

MINI-BAG Plus Container

100 mL 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 INTRAVENOUSLY AS DIRECTED BY A PHYSICIAN CAUTIONS MUST NOT BE USED IN SERIES CONNECTIONS DO NOT USE UNLESS SOLUTION IS CLEAR **RX ONLY**

VIAFLEX SINGLE DOSE CONTAINER PL 146 PLASTIC

Baxter

BAXTER HEALTHCARE CORPORATION
DEERFIELD IL 60015 USA
MADE IN USA

0.9% Sodium Chloride Injection USP

2B1301
NDC 0338-0049-11

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 INTRAVENOUSLY AS DIRECTED BY A PHYSICIAN CAUTIONS MUST NOT BE USED IN SERIES CONNECTIONS DO NOT USE UNLESS SOLUTION IS CLEAR **Rx ONLY**

VIAFLEX CONTAINER PL 146 PLASTIC

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BAXTER HEALTHCARE CORPORATION
DEERFIELD IL 60015 USA
MADE IN USA