Indiana State Department of Health
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Michael R. Pence
Governor

William C. VanNess II, MD
State Health Commissioner

DATE: December 27, 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: **One lot of 5% Dextrose Injection, USP and four lots of 0.9% Sodium Chloride Injection.**

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

Products affected by this recall were packaged in flexible plastic containers with 96 containers per carton. Affected product was distributed to healthcare centers and distributors in the *United States* including *Indiana*.

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 Worldwide Voluntary Recall Of Select Lots Of 5% Dextrose Injection, USP And 0.9% Sodium Chloride Injection, USP Intravenous (IV) Solutions

Contact
Consumer:

Baxter Healthcare Center for Service
1-888-229-0001

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

FOR IMMEDIATE RELEASE – December 23, 2013 – Baxter International Inc. announced today it has initiated a voluntary recall to the hospital/user level of one lot of 5% Dextrose Injection, USP and four lots of 0.9% Sodium Chloride Injection, USP due to particulate matter found in the solutions.

Injecting a product containing 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 recall has been identified and resolved.

Dextrose Injection, USP is an intravenously administered injectable indicated as a source of water and calories. Sodium Chloride Injection, USP is an intravenously administered injectable indicated as a source of water and electrolytes and for use as a priming solution in hemodialysis procedures. These 50 mL and 100 mL containers are primarily used for admixture of medication and as priming solutions. The product codes affected by this recall are found in the table below:

Product Name	Product Code	NDC	Container Size	Lot #	Exp.
5% Dextrose Injection, USP	2B0089	0338-0017-38	100 mL	P285288	Nov-13
0.9% Sodium Chloride Injection, USP	2B1308	0338-0049-31	50 mL	P297283	Aug-14
0.9% Sodium Chloride Injection, USP	2B1302	0338-0049-18	100 mL	P292326	Apr-14
				P293993	May-14
0.9% Sodium Chloride Injection, USP	2B1309	0338-0049-38	100 mL	P293514	Apr-14

Products affected by this recall were packaged in flexible plastic containers with 96 containers per carton. Affected product was distributed to healthcare centers and

distributors in Saudi Arabia, Singapore, United Arab Emirates, and the United States and Puerto Rico.

Baxter has notified customers, who are being directed not to use product from the recalled lots. Customers that have product affected by this recall should stop use and arrange for return. 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.

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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