Indiana State Department of Health
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Michael R. Pence
Governor

Jerome M. Adams, MD, MPH
State Health Commissioner

DATE: April 13, 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: Sodium Chloride, Dextrose, and Lactated Ringer's Injections

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

Products affected by this recall are listed in the following table:

Product Code	NDC Number	Product Name	Lot Number	Manufacturing Date	Expiration Date
2B1322Q	0338-0049-02	0.9% Sodium Chloride Injection, USP (250mL)	C965038	01/20/2015	07/31/2016
2B1322Q	0338-0049-02	0.9% Sodium Chloride Injection, USP (250mL)	C965293	1/22/2015	07/31/2016
2B1322Q	0338-0049-02	0.9% Sodium Chloride Injection, USP (250mL)	C963785	01/09/2015	07/31/2016
2B1322Q	0338-0049-02	0.9% Sodium Chloride Injection, USP (250mL)	C963884	01/10/2015	07/31/2016
2B1322Q	0338-0049-02	0.9% Sodium Chloride Injection, USP (250mL)	C963660	01/08/2015	07/31/2016
2B1322Q	0338-0049-02	0.9% Sodium Chloride Injection, USP (250mL)	C964320	01/14/2015	07/31/2016
2B1322Q	0338-0049-02	0.9% Sodium Chloride Injection, USP (250mL)	C964486	01/15/2015	07/31/2016
2B1322Q	0338-0049-02	0.9% Sodium Chloride Injection, USP (250mL)	C964890	01/19/2015	07/31/2016
2B0162Q	0338-0023-02	10% Dextrose Injection, USP (250mL)	C965558	01/24/2015	07/31/2016
2B0162Q	0338-0023-02	10% Dextrose Injection, USP (250mL)	C963520	01/07/2015	07/31/2016
2B0062Q	0338-0017-02	5% Dextrose Injection, USP (250mL)	C963413	01/06/2015	07/31/2016
2B0062Q	0338-0017-02	5% Dextrose Injection, USP (250mL)	C963413A	01/06/2015	07/31/2016
2B2322Q	0338-0117-02	Lactated Ringer's Injection, USP (250mL)	C964619	01/16/2015	07/31/2016
2B2322Q	0338-0117-02	Lactated Ringer's Injection, USP (250mL)	C964056	01/12/2015	07/31/2016
2B2322Q	0338-0117-02	Lactated Ringer's Injection, USP (250mL)	C964163	01/13/2015	07/31/2016

The lots being recalled were distributed to customers and distributors in the United States between January 14, 2015 and March 5, 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 Select Lots of IV Solutions Due to the Potential Presence of Particulate Matter

Contact:
Consumer:
888-229-0001

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

Investors:
Mary Kay Ladone
224-948-3371
Clare Trachtman
224-948-3085

FOR IMMEDIATE RELEASE — April 9, 2015 — Deerfield, IL — Baxter International Inc. announced today it is voluntarily recalling select lots of intravenous (IV) solutions to the hospital/user level due to the potential presence of particulate matter. Intravenous administration of a solution containing sterile particulate matter may lead to adverse health consequences. The extent and severity of harm depends on the size, number, and composition of the foreign material, and patient's underlying medical condition. In the absence of in-line filtration, these particles may cause: local vein irritation, inflammatory reaction, aggravation of preexisting infections, allergic reactions, and systemic embolization. In high-risk patients this may lead to serious adverse health consequences.

While Baxter manufacturing personnel were performing routine maintenance, particulate matter was detected and identified as material from a solution transmission system pump. There have been no adverse events or product complaints associated with this issue reported to Baxter.

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2B0062Q	0338-0017-	5% Dextrose Injection, USP (250mL)	C963413A	01/06/2015	07/31/2016

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2B2322Q	0338-0117-02	Lactated Ringer's Injection, USP (250mL)	C964619	01/16/2015	07/31/2016
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Sodium Chloride Injection, USP is indicated as a source of water and electrolytes and for use as a priming solution in hemodialysis procedures. Dextrose Injection, USP is indicated as a source of water and calories. Lactated Ringer's Injection, USP is indicated as a source of water and electrolytes, or as an alkalinizing agent. The lots being recalled were distributed to customers and distributors in the United States and Bermuda between January 14, 2015 and March 5, 2015.

Baxter began the customer notification process on March 24, 2015. Customers have been 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.

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