Indiana State Department of Health
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Michael R. Pence
Governor

Jerome M. Adams, MD, MPH
State Health Commissioner

DATE: December 16, 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: **0.9% Sodium Chloride Injection USP**

SUMMARY: **Unclassified Recall; The recall is being initiated as a result of two complaints (one per lot) of particulate matter that was identified as a fragment of the frangible from the vial adapter.**

0.9% Sodium Chloride Injection USP in 100 mL MINI-BAG PLUS Container is a sterile, nonpyrogenic solution for intravenous administration after admixture with a single dose powdered drug. This recall affects the following lots of 0.9% Sodium Chloride Injection USP in 100 mL MINI-BAG PLUS Container:

Product Code	NDC Number	Lot #	Expiration Date
2B0043	0338-0553-18	P317842	May 2015
2B0043	0338-0553-18	P317891	May 2015

The product was distributed throughout the U.S.

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 Voluntarily Initiates U.S. Recall of Two Lots of Sodium Chloride Injection, USP Due to the Presence of Particulate Matter

Contact:
Consumer:
1-800-422-9837

FOR IMMEDIATE RELEASE – December 11, 2014 – DEERFIELD, Ill. – Baxter International Inc. announced today it voluntarily initiated a recall in the United States of two lots of 0.9% Sodium Chloride Injection USP in 100 mL MINI-BAG PLUS Container to the hospital/user level. The recall is being initiated as a result of two complaints (one per lot) of particulate matter that was identified as a fragment of the frangible from the vial adapter. The issue was identified upon standard visual inspection prior to patient administration.

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 the patient's underlying medical condition. In the absence of in-line filtration, particles may cause: local vein irritation, inflammatory reaction, aggravation of preexisting infections, allergic reactions, and systemic embolization (blockage of blood vessels, which can result in stroke, heart attack, or damage to other organs such as the kidney or liver). There have been no reported adverse events for the affected lots.

0.9% Sodium Chloride Injection USP in 100 mL MINI-BAG PLUS Container is a sterile, nonpyrogenic solution for intravenous administration after admixture with a single dose powdered drug. This recall affects the following lots of 0.9% Sodium Chloride Injection USP in 100 mL MINI-BAG PLUS Container:

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Unaffected lot numbers can continue to be used according to the instructions for use.

According to the 0.9% Sodium Chloride Injection USP in 100 mL MINI-BAG PLUS Container product labeling, the product should be inspected visually for particulate matter and discoloration whenever solution and container permit.

Baxter has notified customers, who are being directed 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 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.

- 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.

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