Indiana State Department of Health
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Michael R. Pence
Governor

William C. VanNess II, MD
State Health Commissioner

DATE: September 20, 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., Recall [Medical Device]

AFFECTED PRODUCT: **Luer Lock Caps, Product Code 2C6250, Lots 10043 and 10044**

SUMMARY: **Class I Recall; Baxter International Inc. announced that they have initiated a voluntary recall of two lots of its Dual Luer Lock Caps (Product Code 2C6250, Lots 10043 and 10044) because of the presence of loose particulate matter found in the packaging. Particulate matter entering the fluid path from the Luer Lock Caps may result in thrombotic and embolic events, including: pulmonary embolism, myocardial infarction and stroke. There have been no reported complaints associated with this issue, however embolic events may not be easily attributed to such particulate matter. The root cause has been identified and resolved.**

SUGGESTED ACTION: **Recommend notification of affected parties via phone, fax, or e-mail. Customers should not use product from the two recalled lots and should locate and remove all affected product from their facility. Affected lots were distributed to customers between June 19, 2013, and August 20, 2013. Non-affected lot numbers can continue to be used according to the instructions for use. Affected lots should be returned to Baxter for credit by contacting Baxter Healthcare Center for Service at 1-888-229-0001 between the hours of 7:00 a.m. and 6:00 p.m., Central Time. Unaffected lots of product code 2C6250 are available for replacement. Adverse reactions or quality problems can be reported to the FDA at http://www.fda.gov/Safety/medwatch/howtoreport/default.htm[1].**

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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 Dual Luer Lock Caps

Contact:
Consumer:
(888) 229-0001

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

FOR IMMEDIATE RELEASE - September 19, 2013 - Baxter International Inc. announced today it has initiated a voluntary recall of two lots of its Dual Luer Lock Caps (Product Code 2C6250, Lots 10043 and 10044) because of the presence of loose particulate matter found in the packaging. Particulate matter entering the fluid path from the Luer Lock Caps may result in thrombotic and embolic events, including: pulmonary embolism, myocardial infarction and stroke. There have been no reported complaints associated with this issue, however embolic events may not be easily attributed to such particulate matter. The root cause has been identified and resolved. The U.S. Food and Drug Administration (FDA) has designated this as a Class I recall.

Baxter's Dual Luer Lock Cap is used as a protective cap on access ports on medical devices such as stopcocks or IV sets when not in use.

Customers should not use product from the two recalled lots and should locate and remove all affected product from their facility. Affected lots were distributed to customers between June 19, 2013, and August 20, 2013. Non-affected lot numbers can continue to be used according to the instructions for use. Affected lots should be returned to Baxter for credit by contacting Baxter Healthcare Center for Service at 1-888-229-0001 between the hours of 7:00 a.m. and 6:00 p.m., Central Time. Unaffected lots of product code 2C6250 are available for replacement. Adverse reactions or quality problems can be reported to the FDA at http://www.fda.gov/Safety/medwatch/howtoreport/default.htm[1].

The financial impact of the recall is not material.

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.

This release includes forward-looking statements concerning Baxter's voluntary recall of two lots of its Dual Luer Lock Caps, including with respect to its financial impact on the company. The statements are based on assumptions about many important factors, including the following, which could cause actual results to differ materially from those in the forward-looking statements:

future actions of the FDA or any other regulatory body or government authority; product quality or patient safety issues; and other risks identified in Baxter's most recent filing on Form 10-K and other SEC filings, all of which are available on Baxter's website. Baxter does not undertake to update its forward-looking statements.

Contacts

Baxter International Inc.
Media Contacts:
Bill Rader
Deborah Spak
John O'Malley
(224) 948-5353
media@baxter.com
or
Investor Contact:
Mary Kay Ladone
(224) 948-3371

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