Indiana State Department of Health
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Michael R. Pence
Governor

William C. VanNess II, MD
State Health Commissioner

DATE: October 17, 2013

TO: All Local Health Departments
Attn: Chief Food Inspection Officer

FROM: A. Scott Gilliam, MBA, CP-FS
Director, Food Protection Program

SUBJECT: B. Braun Medical Inc. Recall [Drug]

AFFECTED PRODUCT(S): **1g Cefepime for Injection USP/Dextrose Injection USP (Lot H3A744, catalog 3193-11)**

SUMMARY: **Voluntary Recall; B. Braun Medical Inc. (B.Braun) is voluntarily recalling one lot of 1g Cefepime for Injection USP and Dextrose Injection USP (Lot H3A744, catalog 3193-11) to the consumer level. The 1g Cefepime for Injection USP and Dextrose Injection USP lot has been found to contain visible organic particulate matter in a reserve sample unit. B.Braun has not received any reports of adverse events related to this lot to date. The affected lot H3A744, expiring January 2015, was distributed nationwide to Distributors, Hospitals, Pharmacies, and customers from February 4, 2013 to March 1, 2013.**

SUGGESTED ACTION: **Recommend notification of affected parties via phone, fax, or e-mail. B.Braun is notifying its distributors and customers by written, return receipt letters and is arranging for return of all recalled product. Distributors and customers that have inventory of the 1g Cefepime for Injection USP and Dextrose Injection USP of lot H3A744 should discontinue use immediately and contact B.Braun's Customer Support Department at 1-800-227-2862, Monday through Friday, 8 a.m. to 7 p.m. EST for instructions for returning the affected product and to arrange for replacement product.**

Refer patients reporting any problems that may be related to the use of this product to their physician and report all issues to B.Braun at 1-800-854-6851. 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.

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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.

B. Braun Medical Inc. Issues Voluntary Nationwide Recall of Lot H3A744, 1 gram Cefepime for Injection USP and Dextrose Injection USP Due to Visible Particulate Matter

Contact
Consumer:
Larry Lavi, Quality Director
949-660-2651
Larry.lavi@bbraun.com

Media:
Jason Ford
610-997-4722
Jason.ford@bbraun.com

FOR IMMEDIATE RELEASE - October 15, 2013 - B. Braun Medical Inc. (B.Braun) is voluntarily recalling one lot of 1g Cefepime for Injection USP and Dextrose Injection USP (Lot H3A744, catalog 3193-11) to the consumer level. The 1g Cefepime for Injection USP and Dextrose Injection USP lot has been found to contain visible organic particulate matter in a reserve sample unit. B.Braun has not received any reports of adverse events related to this lot to date.

Visible particulate matter, including metals, and organic material such as cotton fibers or hair, may also illicit inflammatory responses, both chronic and acute, and may be life threatening (e.g. systemic inflammatory response syndrome (SIRS and / or anaphylaxis). If a right to left cardiac shunt is present, the particulate may lead to arterial emboli and result in stroke, myocardial infarction, respiratory failure, and loss of renal and hepatic function or tissue necrosis. Other adverse effects associated with intravenous injection of particulate matter include foreign body granulomata, particularly in the lungs, and local irritation of blood vessels.

The product is used as a cephalosporin antibacterial indicated in the treatment of infections caused by susceptible strains of designated microorganisms. The product is packaged in a DUPLEX® single dose intravenous, plastic container with 24 units per case. The affected lot H3A744, which expires January 2015, was distributed nationwide to licensed Distributors, Hospitals and Pharmacies, and distributed to customers between the dates of February 4, 2013 and March 1, 2013.

B.Braun is notifying its distributors and customers by written, return receipt letters and is arranging for return of all recalled product. Distributors and customers that have inventory of the 1g Cefepime for Injection USP and Dextrose Injection USP of lot H3A744 should discontinue use immediately and contact B.Braun's Customer Support Department at 1-800-227-2862, Monday through Friday, 8 a.m. to 7 p.m. EST for instructions for returning the affected product and to arrange for replacement product.

Patients reporting any problems that may be related to the use of this product should be advised to contact a physician and report all issues to B.Braun at 1-800-854-6851. 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[1]
- Regular Mail: use postage-paid, pre-addressed Form FDA 3500 available at: www.fda.gov/MedWatch/getforms.htm[2]. 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.

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