Indiana State Department of Health
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Mitchell E. Daniels, Jr.
Governor

Gregory N. Larkin, M.D., F.A.A.F.P.
State Health Commissioner

DATE: November 1, 2010

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

SUGGESTED ACTION: **Unclassified Recall; Heparin Sodium USP due a trace amount of oversulfated chondroitin sulfate (OSCS) contaminant; Information provided in case of consumer inquiry.**

From the information provided by FDA, the products being recalled may be distributed in the State of Indiana. B. Braun is initiating a voluntary recall of seven lots of heparin injection products to the healthcare provider level. Detail information is not available at this time. In addition, if any recalled products are found, please notify this office at 317-233-7360.

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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 Voluntarily Recalls Seven Lots of Heparin Manufactured in 2008 Due to Supplier-Initiated Recall of Heparin Active Pharmaceutical Ingredient (API)

No adverse events reported and no detectable contaminate found in testing of API or finished product

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Corporate Contact:
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Customer Support:
800.227.2862

FOR IMMEDIATE RELEASE - OCT. 27, 2010 - Irvine, CA - B. Braun Medical Inc. (B. Braun) was recently notified by its supplier, Scientific Protein Laboratories LLC (SPL), of a nationwide recall of a lot of Heparin Sodium USP Active Pharmaceutical Ingredient (API) sold to B. Braun because additional testing of retained crude heparin samples used by SPL to manufacture this single API lot indicated a trace amount of oversulfated chondroitin sulfate (OSCS) contaminant. As a result, B. Braun is initiating a voluntary recall of seven lots of heparin injection products to the healthcare provider level. These lots were manufactured in 2008 and will be expiring on October 31, 2010 and November 30, 2010.

B. Braun has not received any reports of adverse events regarding the B. Braun finished products manufactured using this API.

Based on current information, the recalled lots do not pose a significant health risk; however, B. Braun is performing this voluntary recall as a precautionary measure with the support of the U.S. Food and Drug Administration (FDA).

Heparin is a blood thinner used to treat and prevent blood clots. The voluntary recall affects the following seven Finished Product (FP) lots manufactured in 2008 by B. Braun Medical Inc. and distributed nationwide to distributors and direct healthcare provider customers.

Product Name	B. Braun Catalog Number	B. Braun Lot Number	B. Braun Manufacture Date	Expiration Date
25,000 Units Heparin in 5% Dextrose Injection, 50 Units/mL	P5771	J8D674	4/15/2008	10/31/2010
1,000 Units Heparin in 0.9% Sodium Chloride Injection, 2 Units/mL	P8721	J8D676	4/17/2008	10/31/2010
1,000 Units Heparin in 0.9% Sodium Chloride Injection, 2 Units/mL	P8721	J8D677	4/17/2008	10/31/2010
1,000 Units Heparin in 0.9% Sodium Chloride Injection, 2 Units/mL	P8721	J8D702	4/30/2008	10/31/2010
1,000 Units Heparin in 0.9% Sodium Chloride Injection, 2 Units/mL	P8721	J8D703	4/30/2008 – 5/1/2008	10/31/2010
25,000 Units Heparin in 5% Dextrose Injection, 50 Units/mL	P5771	J8E462	5/8/2008	11/30/2010
1,000 Units Heparin in 0.9% Sodium Chloride Injection, 2 Units/mL	P8721	J8E539	5/15/2008	11/30/2010

B. Braun is notifying its distributors and customers by certified mail and is arranging for return of all recalled product. Customers who have product from the recalled product lots in their possession should discontinue use immediately. Patients reporting any problems that may be

related to the use of this product should be advised to contact a physician. Customers may contact B. Braun Medical Inc. Customer Support Department at 800-227-2862 Monday through Friday, 8 a.m. to 7 p.m. ET for instructions for handling the affected product and to arrange for replacement product.

Adverse reactions or quality problems experienced in the U.S. 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[9]
- **Regular Mail:** Use postage-paid, pre-addressed Form FDA 3500 available at: www.fda.gov/MedWatch/getforms.htm[10]. Mail to address on the pre-addressed form.
- **Fax:** 1-800-FDA-0178