Recall -- Firm Press Release

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B. Braun's Supplier Recall of Heparin API Prompts Voluntary Recall of Heparin Solutions

Scientific Protein Laboratories LLC (SPL) manufactures Heparin Sodium USP active pharmaceutical ingredient that is used by B. Braun Medical Inc. to produce Heparin Sodium in 5% Dextrose and 0.9% Sodium Chloride injection solution

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FOR IMMEDIATE RELEASE --Irvine, CA -- March 21, 2008 --- B. Braun Medical Inc. was recently notified by its supplier, Scientific Protein Laboratories LLC (SPL) of a nationwide recall of Heparin Sodium USP active pharmaceutical ingredient (API). The voluntary recall affects the following 23 Finished Product (FP) lots manufactured and distributed by B. Braun Medical Inc. nationwide and to Canada.

B. Braun FP Lot #	B. Braun FP Material	Description	NDC Numbers	CAN DIN
J7D490	P5872	Heparin Sodium 25,000 Units in 5% Dextrose Injection (250mL)	0264-9587-20	N/A
J7C684	P5771	Heparin Sodium 25,000 Units in 5% Dextrose Injection (500mL)	0264-9577-10	N/A
J7D496	P5771	Heparin Sodium 25,000 Units in 5% Dextrose Injection (500mL)	0264-9577-10	N/A
J7C470	P5872	Heparin Sodium 25,000 Units in 5% Dextrose Injection (250mL)	0264-9587-20	N/A
J7D580	P5671-00	Heparin Sodium 20,000 Units in 5% Dextrose Injection (500mL)	N/A	02209713
J7E420	P5872-00	Heparin Sodium 25,000 Units in 5% Dextrose Injection (250mL)	N/A	02209721
J7C611	P8721	Heparin Sodium 1000 Units in 0.9% Sodium Chloride Injection (500mL)	0264-9872-10	01935933

J7C557	P8721	Heparin Sodium 1000 Units in 0.9% Sodium Chloride Injection (500mL)	0264-9872-10	01935933
J7C477	P8721	Heparin Sodium 1000 Units in 0.9% Sodium Chloride Injection (500mL)	0264-9872-10	01935933
J7C705	P8721	Heparin Sodium 1000 Units in 0.9% Sodium Chloride Injection (500mL)	0264-9872-10	01935933
J7D485	P8721	Heparin Sodium 1000 Units in 0.9% Sodium Chloride Injection (500mL)	0264-9872-10	01935933
J7E415	P8721	Heparin Sodium 1000 Units in 0.9% Sodium Chloride Injection (500mL)	0264-9872-10	01935933
J7E416	P8721	Heparin Sodium 1000 Units in 0.9% Sodium Chloride Injection (500mL)	0264-9872-10	01935933
J7E494	P5872	Heparin Sodium 25,000 Units in 5% Dextrose Injection (250mL)	0264-9587-20	N/A
J7E500	P5771	Heparin Sodium 25,000 Units in 5% Dextrose Injection (500mL)	0264-9577-10	N/A
J7E577	P5771-00	Heparin Sodium 25,000 Units in 5% Dextrose Injection (500mL)	N/A	01935941
J7E489	P8721	Heparin Sodium 1000 Units in 0.9% Sodium Chloride Injection (500mL)	0264-9872-10	01935933
J7N556	P5872	Heparin Sodium 25,000 Units in 5% Dextrose Injection (250mL)	0264-9587-20	N/A
J7P404	P5771	Heparin Sodium 25,000 Units in 5% Dextrose Injection (500mL)	0264-9577-10	N/A
J7N604	P5771	Heparin Sodium 25,000 Units in 5% Dextrose Injection (500mL)	0264-9577-10	N/A
J7P476	P5872	Heparin Sodium 25,000 Units in 5% Dextrose Injection (250mL)	0264-9587-20	N/A
J7N519	P8721	Heparin Sodium 1000 Units in 0.9% Sodium Chloride Injection (500mL)	0264-9872-10	01935933
J7N676	P8721	Heparin Sodium 1000 Units in 0.9% Sodium Chloride Injection (500mL)	0264-9872-10	01935933

B. Braun Medical Inc. began recalling the lots on March 21, 2008 as a precautionary measure. This product recall was initiated due to a notification received from the supplier, Scientific Protein Laboratories (SPL), disclosing that one lot of Heparin Sodium, USP Active

Pharmaceutical Ingredient acquired by B. Braun Medical Inc. has a heparin-like contaminant. To date, B. Braun Medical Inc. has not received any adverse event reports related to this issue.

The Food and Drug Administration has received reports of serious injuries and/or deaths in patients who have been administered Heparin injectable products of other companies containing this contaminant. As indicated in the notification issued by the supplier SPL, typical symptoms include anaphylactic-like reactions such as low blood pressure, shortness of breath, nausea, vomiting, diarrhea and abdominal pain.

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
- **Regular Mail:** use postage-paid FDA form 3500 available at: www.fda.gov/MedWatch/getforms.htm.
  Mail to MedWatch 5600 Fishers Lane, Rockville, MD 20852-9787
- **Fax:** 1-800-FDA-0178

Adverse reactions or quality problems experienced in Canada with use of this product may be reported to Health Canada. For details on how to report these reactions please refer to the following website:

- **Online:** http://www.hc-sc.gc.ca/dhp-mps/medeff/report-declaration/index_e.html

Customers who have product in their possession from the recalled product lots 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 for U.S. and (800) 624-2920 for Canada, Monday through Friday, 8 AM to 7 PM EST for instructions for handling the affected product and to arrange for replacement product.

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