610-727-3625

B BRAUN

B. Braun Medical Inc.
2525 McGaw Ave
PO Box 19791
Irvine, CA 92623

Telephone: (949) 660-2000
Fax: (949) 660-2730

March 20, 2008

AmerisourceBergen Drug Corp
9900 Jeb Stuart Pkwy
Glen Allen, VA 23060

URGENT – DRUG RECALL

Dear Distributor:

B. Braun was recently notified by our supplier, Scientific Protein Laboratories LLC (SPL), of a nationwide recall of two lots of Heparin Sodium USP. A copy of the SPL recall letter is attached. The SPL recall is due to the presence of a heparin-like contaminant, a large molecule similar to Heparin. As a result of the SPL recall, a total of six B. Braun product catalog codes (23 lots) are affected and are being removed from the market. To date, B. Braun Medical Inc. has not observed any adverse event reports related to Heparin products manufactured by B. Braun Medical Inc.

In compliance with the U.S. Food and Drug Administration (FDA) regulations, B. Braun's own high quality standards, and B. Braun's commitment to maintaining the utmost safety of our customers. B. Braun is voluntarily recalling these lots of product. The FDA has been informed of this product recall.

Table 1 provides a list of the affected lots along with the product catalog numbers, lot numbers, date of manufacture, and labeled expiration date.

Our records indicate that you received one or more of these lots. **Further distribution or use of these lots should be discontinued immediately.**

Please immediately contact your customers who have received these lots and inform them of this product recall. Under the FDA recall enforcement policy, you are legally obligated to notify your customers of drug recalls such as this one. It is highly recommended that you determine your customers' inventory levels and request the return of these lots to you. Please combine your customers' inventory with your own inventory and return all affected product at one time.

Please use the attached form (Attachment 1) to document the number of individual units (that have been taken out of their shipping cases) and the number of full, unopened cases. Return the completed form in the enclosed self-addressed envelope, ***within two (2) weeks.*** Even if you do not have any of the affected lots in your inventory, please complete this form and return it to B. Braun Medical Inc., as required by the FDA.

Please return all full, unopened cases to B. Braun Medical Inc. For individual units, from opened cases, you may either destroy the units at your facility or return the units to B. Braun Medical Inc. Regardless of the option you choose, you must complete and return the form in Attachment 1. Your account will be credited based upon the amounts documented in the completed form returned to B. Braun Medical Inc.

United States Customers: For product return, shipping instructions, product developments, or additional information, please contact the B. Braun customer support at **(800) 227-2862**

Canada Customers: For product return, shipping instructions, product development, or additional information, please contact the B.Braun customer support at **(800) 624-2920**

We apologize for any inconvenience this may have caused and we appreciate your cooperation and patience.

Sincerely,

Kikoo Tejwani
Corporate Vice President, Quality/Regulatory Compliance

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Table 1 - 23 Lots for Immediate Recall

Product Catalog Number	Lot Number	Date Manufactured	Labeled Exp. Date
P5872	J7C470	03/08/07	03/31/09
	J7E494	05/12/07	05/31/09
	J7N556	05/10/07	10/31/09
	J7P476	11/08/07	11/30/09
	J7D490	04/11/07	04/30/09
P5771	J7C684	03/29/07	09/30/09
	J7D496	04/12/07	10/31/09
	J7P404	11/02/07	5/31/2010
	J7E500	05/11/07	11/30/09
	J7N604	10/19/07	04/30/10
P5671-00	J7D580	04/20/07	10/31/09
P5872-00	J7E420	05/05/07	05/31/09
P8721	J7E489	05/10/07	11/30/09
	J7C611	03/22/07	09/30/09
	J7C557	03/16/07	09/30/09
	J7C477	03/08/07	09/30/09
	J7N519	10/18/07	04/30/10
	J7N676	10/25/07	04/30/10
	J7C705	3/31/07	09/30/09
	J7D485	04/11/07	10/31/09
	J7E415	05/02/07	11/30/09
	J7E416	05/03/07	11/30/09
P5771-00	J7E577	05/30/07	11/30/09

700 E. Main Street, P.O. Box 158
Waunakee, WI 53597-0158
(608) 849-5944 Fax (608) 849-4053

Scientific Protein Laboratories LLC

URGENT Drug Recall

Voluntary Recall of two lots of **Heparin Sodium USP**
Lot Numbers: 1035-0772 & 1035-0773
Scientific Protein Laboratories LLC

March 17, 2008

Marty Gahman
B. Braun Medical, Inc.
901 Marcon Boulevard
Allentown, PA 18109

Re: Scientific Protein Laboratories LLC

Dear Mr. Gahman:

This letter serves as notification of Scientific Protein Laboratories LLC's (SPL) voluntary recall of two lots of Heparin Sodium USP (SPL Code 1035) Active Pharmaceutical Ingredient (API). The specific lots and shipping dates are listed below.

Lot numbers	Shipping Dates
1035-0772	12/4/06, 2/28/07, 9/17/07

This recall has been initiated due to the presence of a contaminant in these specific lots of heparin API. The Food and Drug Administration has received reports of serious injuries and/or deaths in patients administered finished heparin injectable products manufactured from heparin API containing this contaminant. Typical symptoms include anaphylactic-like reactions such as; low blood pressure, shortness of breath, nausea, vomiting, abdominal pain.

This recall is an expansion of our earlier recall dated March 6, 2008 that consisted of 37 lots.

Our records indicate that you have received these lot(s). Please confirm if you have received these lots and place them under quarantine. **Stop using these lots Immediately!** Please contact us to arrange for the product to be returned to Scientific Protein Laboratories, 700 E. Main Street, Waunakee, Wisconsin, 53597. Attached to this letter is a response form. Please sign and return the form to me as soon as possible.

If you have incorporated this material into a product and/or distributed this material to a contractor or to a consignee for further manufacturing, you must take immediate action to recover the material.

The recall is being conducted with the knowledge of the Food and Drug Administration.

Your assistance is appreciated. If you have any questions concerning this recall, please call me at 608-849-1601. {7:45 am – 4:30 pm} {Monday - Friday}

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
- 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

Sincerely,

David G. Strunce
President and CEO