DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring, MD 20993

NDA 019952/S-038

SUPPLEMENT APPROVAL

B. Braun Medical Inc.
Attention: Cindy Katsempris
Director, Regulatory Affairs
901 Marcon Blvd.
Allentown, PA 18109

Dear Ms. Katsempris:

Please refer to your Supplemental New Drug Application (sNDA) dated May 3, 2018, received May 4, 2018, and your amendments, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Heparin Sodium in 5% Dextrose injection in EXCEL Plastic Container.

This "Changes Being Effected in 30 days" supplemental new drug application provides for reformatting container labels for Heparin Sodium in 5% Dextrose injection, 25,000 USP units per 500 mL (Catalogue P5771), and 25,000 USP units per 250 mL(Catalogue P5872) EXCEL plastic containers and the corresponding over-wrap labels.

APPROVAL & LABELING

We have completed our review of this supplemental application, as amended. It is approved, effective on the date of this letter, for use as recommended in the enclosed agreed-upon labeling text.

CARTON AND IMMEDIATE CONTAINER LABELS

Submit final printed carton and immediate container labels that are identical to enclosed carton and immediate container labels, as soon as they are available, but no more than 30 days after they are printed. Please submit these labels electronically according to the guidance for industry *Providing Regulatory Submissions in Electronic Format – Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications (May 2015, Revision 3)*. For administrative purposes, designate this submission "**Product Correspondence – Final Printed Carton and Container Labels for approved NDA 019952/S-038.**" Approval of this submission by FDA is not required before the labeling is used.

REPORTING REQUIREMENTS

We remind you that you must comply with reporting requirements for an approved NDA (21 CFR 314.80 and 314.81).

If you have any questions, call Adijat Abass-Fasuyi, Regulatory Business Process Manager, at (301) 796 - 3609.

Sincerely,

{See appended electronic signature page}

Ramesh Raghavachari, Ph.D.
Chief, Branch I
Division of Post-Marketing Activities I
Office of Lifecycle Drug Products
Office of Pharmaceutical Quality
Center for Drug Evaluation and Research

Enclosure:
Carton and Container Labeling

Ramesh Raghavachari

Digitally signed by Ramesh Raghavachari
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