



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 19-952/S-012

B. Braun Medical Inc.
Attention: Quansy Salako, Ph.D.
Director, Regulatory Affairs
2525 McGaw Avenue
Irvine, CA 92614

Dear Dr. Salako:

Please refer to your supplemental new drug application dated April 7, 2003, received April 9, 2003, submitted pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act for Heparin Sodium in 5% Dextrose Injection in EXCEL[®] Plastic Container.

We acknowledge receipt of your submissions dated October 10, 2003, and March 5 and April 6, 2004.

Your submission of October 10, 2003, received October 14, 2003, constituted a complete response to our September 29, 2003, action letter.

This "Changes Being Effected" supplemental new drug application provides for revisions in the package insert to strengthen the PRECAUTIONS section for geriatric age group patients and to add a statement that the EXCEL container is latex-free, polyvinyl chloride (PVC)-free and Di (2-ethylhexyl) phthalate (DEHP)-free.

We completed our review of this application, as amended. This application is approved, effective on the date of this letter, for use as recommended in the final printed labeling (FPL) (text for the package insert submitted on April 7, 2003 and immediate container and carton labels submitted on April 7, 2003).

If you issue a letter communicating important information about this drug product (i.e., a "Dear Health Care Professional" letter), we request that you submit a copy of the letter to this NDA and a copy to the following address:

MEDWATCH, HFD-410
FDA
5600 Fishers Lane
Rockville, MD 20857

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 Diane Moore, Regulatory Project Manager, at (301) 827-7476.

Sincerely,

{See appended electronic signature page}

Robert L. Justice, M.D., M.S.
Director
Division of Gastrointestinal & Coagulation Drug Products
Office of Drug Evaluation III
Center for Drug Evaluation and Research

**This is a representation of an electronic record that was signed electronically and
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/s/

Robert Justice
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