DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 19-708/S-013

B. Braun Medical Inc.
2525 McGaw Ave.
P.O. Box 19791
Irvine, CA 92623-9791

Attention: Qansy Salako, Ph.D.
Director, Regulatory Affairs

Dear Dr. Salako:

Please refer to your supplemental new drug application dated March 3, 2004, received March 5, 2004, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Potassium Chloride in Sodium Chloride Injection, USP in EXCEL plastic containers.

We acknowledge receipt of your submission dated September 2, 2004.

This "Changes Being Effected in 30 days" supplemental new drug application provides for a revised package insert and immediate container labels. In accordance with the requirements of 21 CFR 201.57, subsections **Laboratory Tests, Carcinogenesis, Mutagenesis and Impairment of Fertility, Labor and Delivery, Nursing Mothers, Pediatric Use and Geriatric Use** are added to the **PRECAUTIONS** section of the package insert.

We have completed our review of this application, as amended, and it is approved, effective on the date of this letter.

As agreed to by you in your September 2, 2004 submission, the final printed labeling (FPL) will be identical to the enclosed labeling text for the package insert, and to the packaging labels submitted on March 3, 2004. These revisions are terms of the approval of this application.

Please submit the FPL electronically according to the guidance for industry titled Providing Regulatory Submissions in Electronic Format – NDA. Alternatively, you may submit 20 paper copies of the FPL as soon as it is available, in no case more than 30 days after it is printed. Please individually mount 15 of the copies on heavy-weight paper or similar material. For administrative purposes, these submissions should be designated "FPL for approved supplement NDA 19-708/S-013. Approval of this submission by FDA is not required before the labeling is used.

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 Kimberly Compton, Regulatory Project Manager, at (301) 827-7432.

Sincerely,

{See appended electronic signature page}

Bob Rappaport, M.D.
Director
Division of Anesthetic, Critical Care and
Addiction Drug Products
Office of Drug Evaluation II
Center for Drug Evaluation and Research

Enclosure

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

Bob Rappaport

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