DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 19-708/S-016
NDA 19-630/S-026

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

Attention: Susan Olinger
Corporate Vice President, Regulatory Affairs

Dear Ms. Olinger:

Please refer to your supplemental new drug applications dated March 2, 2005, received March 4 and 7, 2005, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for the following:

sNDA Number:	**Name of Drug Product:**
N 19-630/S-026	Potassium Chloride in Dextrose and Sodium Chloride Injection, in EXCEL plastic containers
N 19-708/S-016	Potassium Chloride in Sodium Chloride Injection, in EXCEL plastic containers Injection

These "Changes Being Effected" supplemental new drug applications provide for changes to the labeling to incorporate information about approved, but not previously marketed strengths of your products.

We have completed our review of these supplemental new drug applications, and they are approved, effective on the date of this letter, for use as recommended in the agreed-upon labeling.

The final printed labeling (FPL) must be identical to the submitted labeling (package insert and immediate container label submitted March 2, 2005).

Please submit an electronic version of the FPL 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 but no more than 30 days after it is printed. Individually mount 15 of the copies on heavy-weight pape or similar material. For administrative purposes, designate these submissions "**FPL for approved supplemental NDA 19-708/S-016 and NDA 19-630/S-026**." Approval of these submissions 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 the requirements for an approved NDA set forth under 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 Anesthesia, Analgesia and
Rheumatology Products
Office of Drug Evaluation II
Center for Drug Evaluation and Research

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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