DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 16-822/S-065

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

Attention: Pushpa Mehta, RAC
Regulatory Affairs Specialist

Dear Ms. Mehta:

Please refer to your supplemental new drug application dated January 22, 2004, received January 28, 2004, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for 3% FreAmine III with Electrolytes, 6.9% FreAmine HBC, 8.5% FreAmine III, 8.5% FreAmine III with Electrolytes, and 10% FreAmine III (amino acid injections.)

This supplemental new drug application provides for revised **PRECAUTIONS** and **WARNINGS** sections of the package insert, and revised release specification and stability protocol containing a test for aluminum determination with a validated analytical method and an acceptance criterion of NMT 25 mcg/L of aluminum in accordance with the requirements of 21 CFR 201.323.

Also, revisions are made to the other sections of the package insert to be consistent with the approved labeling of other amino acid products.

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

The final printed labeling (FPL) must be identical to the draft labeling for each product submitted January 22, 2004.

Please submit the copies of final printed labeling (FPL) electronically according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format - NDA* (January 1999). 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. Please individually mount ten of the copies on heavy-weight paper or similar material. For administrative purposes, this submission should be designated "FPL for approved supplement NDA 16-822/S-065." 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 Kim Compton, Regulatory Project Manager, at (301) 827-7410.

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

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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