DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 50-780/S-005

B. Braun Medical Inc.
Attention: Monica M. Tinio
Senior Regulatory Specialist
2525 McGaw Avenue
P.O. Box 19791
Irvine, CA 92623-9791

Dear Ms. Tinio:

Please refer to your supplemental new drug application dated March 28, 2003, received March 31, 2003, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Cefuroxime for Injection USP and Dextrose Injection USP in the Duplex® Container. We note that this application is subject to the exemption provisions contained in section 125(d)(2) of Title I of the FDA Modernization Act of 1997.

This supplemental new drug application provide for the labeling revision for the referenced subject product following the recommendation of the Office of Drug Safety relative to medication errors resulting from look-alike drug product labeling.

We have completed the review of this supplemental new drug application, and have concluded that adequate information has been presented to demonstrate that the drug is safe and effective for use as recommended in the final printed labeling received on March 31, 2003. Accordingly, the supplemental new drug application is approved effective on the date of this letter.

If a letter communicating important information about this drug product (i.e., a "Dear Health Care Professional" letter) is issued to physicians and others responsible for patient care, we request that you submit a copy of the letter to this NDA and a copy to the following address:

MEDWATCH, HF-2
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 LTJG Raquel Peat, Regulatory Health Project Manager, at (301) 827-2125.

Sincerely yours,

{See appended electronic signature page}

James Vidra, Ph.D.
Chemistry Team Leader for the
Division of Anti-Infective Drug Products, (HFD-520)
DNDC III, Office of New Drug Chemistry
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/

Jim Vidra

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