DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 50-780/S-006

B. Braun Medical Inc.
Attention: Qansy Salako, PhD
Director, Regulatory Affairs
2525 McGaw Avenue
Irvine, CA 92614-5895

Dear Dr. Salako:

Please refer to your supplemental new drug application dated January 26, 2004, received January 28, 2004, 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.

We acknowledge receipt of your submission dated April 20, 2004.

This supplemental application, submitted as a "Supplement - Changes Being Effected in 0 days" supplement, proposes the following change to be in compliance with the systemic antibacterial drug products labeling regulations as found in 21 CFR 201.24.

We have completed our review of this application, as amended. It is approved, effective on the date of this letter, for use as recommended in the final printed labeling (FPL) dated April 20, 2004.

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 LT Raquel Peat, Regulatory Health Project Manager, at (301) 827-2125.

Sincerely,

{See appended electronic signature page}

Janice M. Soreth, M.D.
Director
Division of Anti-Infective Drug Products
Office of Drug Evaluation IV
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/

Janice Soreth

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