DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 50-780/S-008

B. Braun Medical, Inc.
Attention: Susan Olinger
Corporate Vice President, Regulatory Affairs
901 Marcon Boulevard
Allentown, PA 18109

Dear Ms. Olinger:

Please refer to your supplemental new drug application dated November 5, 2004, received Novemeber 8, 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, 1.5 gram cefuroxime, 740 mg cefuroxime. 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 "Changes Being Effected in 30 days" supplemental new drug application provides for revisions to the package insert to conform to the labeling of the reference listed drug (RLD). The labeling revisions also include minor administrative/editorial changes.

We completed our review of this application and it is approved, effective on the date of this letter, for use as recommended in the agreed-upon labeling text and with the minor editorial revisions listed below:

- Under the DIRECTIONS section, the acronym DEHP should be spelled out as "Di (2-ethylhexyl) phthalate." This change can be made at the next printing.

The final printed labeling (FPL) must be identical to the labeling (package insert) submitted November 5, 2004, and include the minor editorial revisions indicated above. These revisions are terms of the approval of this application.

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 paper or similar material. For administrative purposes, designate this submission "**FPL for approved supplement NDA 50-780/S-008**." 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 J. Christopher Davi, Regulatory Project Manager, at (301) 827-2217.

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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